Non-Medicare Injectable Drugs Requiring Prior Authorization (April 11, 2024)

KAISER PERMANENTE®

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
Alpha 1-proteinase inhibitor	Aralast† Aralast NP† Glassia Prolastin† Prolastin C† Zemaira	J0257, 10 mg J0256, 10 mg	N/A	• Covered for alpha-1-antitrypsin deficiency. Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts. †Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change.
Abatacept intravenous	Orencia	J0129, 10 mg	1500	• Covered for patients with rheumatoid arthritis with failure, contraindication, or intolerance to methotrexate and one anti-TNF inhibitor (e.g., adalimumab [Amjevita] or infliximab [Inflectra]). • Covered for patients ≥ 6 years old with juvenile idiopathic arthritis with failure, contraindication, or intolerance to methotrexate. • For psoriatic arthritis in patients with failure, contraindication, or intolerance to: ○ At least one conventional synthetic disease modifying anti-rheumatic drug (csDMARD) (methotrexate preferred), and ○ Two of the following biologics (one of which must be adalimumab or infliximab) AND: ▪ adalimumab (e.g., Amjevita) ▪ infliximab (e.g., Inflectra) ▪ secukinumab ▪ etanercept ○ Guselkumab Note: csDMARD not required for patients with axial disease or severe (rapidly progressive, erosive) disease Not covered for use in combination with disease modifying or other biologic therapies including (but not limited to): ○ infliximab, adalimumab, etanercept, vedolizumab, rituximab, certolizumab, tocilizumab golimumab, ustekinumab, natalizumab, tofacitinib, upadacitinib, ozanimod, apremilast **Quantity Limits (all indications):** • Induction: 1000 mg at weeks 0, 2, and 4 • Maintenance: 1000 mg every 4 weeks

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts. Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change. **Applicable codes:** *ICD-10 codes covered if selection criteria or medical necessity is met. Listing of code does not guarantee coverage or reimbursement. The following list is provided for reference purposes only and may not be all inclusive.* M05 - M05.9, M06 - M06.09, M06.1, M06.80 - M06.9, M08 - M08.9, M08.20 - M08.3, M08.80 - M08.99, L40.5 - L40.59

Abatacept subcutaneous	Orencia	J0129,
		10 mg
			N/A	Subcutaneous formulations not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit.
				• Exception criteria may be considered for the following:
				  ○ Patients with impaired manual dexterity, impaired vision, or patients who are unable to use prefilled syringe safely
				  AND
				  ○ Who have poor venous access that would make IV administration burdensome
				  AND
				  ○ Patient meets clinical criteria
				
				• Covered for patients with rheumatoid arthritis with failure, contraindication, or intolerance to methotrexate and one anti-TNF inhibitor (e.g., adalimumab [Amjevita] or infliximab [Inflectra]).
				• Covered for patients ≥ 6 years old with juvenile idiopathic arthritis with failure, contraindication, or intolerance to methotrexate.
				• For psoriatic arthritis in patients with failure, contraindication, or intolerance to:
				  ○ At least one conventional synthetic disease modifying anti-rheumatic drug (csDMARD) (methotrexate preferred), and
				  ○ Two of the following biologics (one of which must be adalimumab or infliximab) AND:
				  ▪ adalimumab (e.g., Amjevita)
				  ▪ infliximab (e.g., Inflectra)
				  ▪ secukinumab
				  ▪ etanercept
				  ○ Guselkumab

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				Note: csDMARD not required for patients with axial disease or severe (rapidly progressive, erosive) disease Not covered for use in combination with disease modifying or other biologic therapies including (but not limited to): ○ infliximab, adalimumab, etanercept, vedolizumab, rituximab, certolizumab, tocilizumab golimumab, ustekinumab, natalizumab, tofacitinib, upadacitinib, ozanimod, apremilast **Quantity Limits (all indications):** • Subcutaneous formulation limited to 4 injections for 28 days Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts. Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change. **Applicable codes:** *ICD-10 codes covered if selection criteria or medical necessity is met. Listing of code does not guarantee coverage or reimbursement. The following list is provided for reference purposes only and may not be all inclusive.* M05 - M05.9, M06 - M06.09, M06.1, M06.80 - M06.9, M08 - M08.9, M08.20 - M08.3, M08.80 - M08.99, L40.5 - L40.59
Adalimumab	Humira	J0135, 20 mg	62	Covered for new starts who have had a failure, contraindication, or intolerance to the preferred biosimilar adalimumab-atto (Amjevita) AND one of the following below: • For patients with rheumatoid arthritis with failure, contraindication, or intolerance to methotrexate • Covered for patients ≥ 2 years old with juvenile idiopathic arthritis with failure, contraindication, or intolerance to methotrexate. • For psoriatic arthritis in patients with failure, contraindication, or intolerance to at least one conventional synthetic disease modifying anti-rheumatic drug (csDMARD) (methotrexate preferred) Note: csDMARD not required for patients with axial disease or severe (rapidly progressive, erosive) disease • For adult patients with moderate to severe psoriasis with an inadequate response, contraindication, or intolerance to topical psoriasis treatments and at least two of the following*: ○ 12-week trial of phototherapy ○ acitretin

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				○ methotrexate *Note: cyclosporine may also be counted towards 1 of the required therapies, but should not be required. • For patients with active ankylosing spondylitis. • For adult patients with moderately to severely active ulcerative colitis or Crohn's disease. It is recommended that adalimumab (e.g., Amjevita) is used in combination with azathioprine, 6-mercaptopurine, or methotrexate. It is recommended that only responders to induction therapy continue with longer term maintenance therapy. • For pediatric patients (5 to 17 years old) with moderately to severely active UC or pediatric patients (6 to 17 years) with moderately to severely active Crohn's disease. It is recommended only responders to induction therapy continue with longer term maintenance therapy. • For patients with moderate to severe Hidradenitis Suppurativa (HS) who meet all the following criteria: ○ Contraindication, intolerance, or failure of 12 weeks total of at least one systemic antibiotic (doxycycline, minocycline, or clindamycin/rifampin) Established patients on Humira must have a documented inadequate response or intolerance to an adalimumab biosimilar (e.g., Amjevita). Not covered for use in combination with disease modifying or other biologic therapies including (but not limited to): • infliximab, etanercept, vedolizumab, rituximab, certolizumab, tocilizumab, golimumab, ustekinumab, natalizumab, tofacitinib, upadacitinib, ozanimod, apremilast **Quantity Limits**: • Rheumatoid arthritis: Limit dosing to 40 mg every 2 weeks. • Juvenile idiopathic arthritis: Limit dosing to 40 mg every 2 weeks. • Psoriatic arthritis: Limit dosing to 40 mg every 2 weeks. • Psoriasis: Limit dosing to 80 mg at week 1, then 40mg every 2 weeks beginning 1 week after initial dose. • Ankylosing spondylitis: Limit dosing to 40 mg every 2 weeks. • Crohn's disease: Limit dosing to induction dosing of 160 mg week 0, 80 mg week 2, then 40 mg every 2 weeks. ○ If patient has inadequate response or flare after 12 weeks of initiation of therapy, may request authorization for 40 mg every week for 12 weeks. ○ Reauthorization would require reassessment for reduction in signs and symptoms of disease. • Moderate to severe Crohn's disease in pediatric patients

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				○ Patients 17 < 40 kg ▪ Day 1: 80 mg ▪ Days 15: 40 mg ▪ Starting on day 29: 20 mg every other week ○ Patients ≥ 40 kg ▪ Day 1: 160 mg ▪ Days 15: 80 mg ▪ Starting on day 29: 40 mg every other week • Ulcerative Colitis: Limit dosing to induction dosing of 160 mg week 0, 80 mg week 2, then 40 mg every other week. ○ If patient has inadequate response or flare after 12 weeks of initiation of therapy, may request authorization for 40 mg every week for 12 weeks. ○ Reauthorization would require reassessment for reduction in signs and symptoms of disease. • Moderate to severe ulcerative colitis in pediatric patients: ○ Patients 20 to < 40 kg ▪ Day 1: 80 mg ▪ Days 8 & 15: 40 mg ▪ Starting on day 29: 40 mg every other week or 20 mg every week ○ Patients ≥ 40 kg ▪ Day 1: 160 mg ▪ Days 8 & 15: 80 mg Starting on day 29: 80 mg every other week or 40 mg every week • Hidradenitis suppurativa: ○ For adults and adolescents ≥12 years with body weight ≥60 kg, limit dosing to induction dosing of 160mg week 0, 80 mg week 2, then 40 mg every week. ○ For adolescents ≥12 years with body weight between 30 to <60 kg, limit dosing to induction dosing of 80 mg week 0, 40 mg week 2, then 40 mg every other week.
Adalimumab-aacf Adalimumab-aaty Adalimumab-adaz	Idacio Yuflyma Hyrimoz, adalimumab-adaz	Q5131 Unspecified J3490, J3590 Unspecified J3490, J3590	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria below Failure, contraindication, intolerance to the preferred biosimilar adalimumab-atto (Amjevita) AND one of the following below:

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
Adalimumab-adbm Adalimumab-aqvh Adalimumab-bwwd Adalimumab-fkjp Adalimumab-afzb	Cyltezo Yusimry Hadlima Hulio, adalimumab-fkjp Abrilada	Unspecified J3490, J3590 Unspecified J3490, J3590 Unspecified J3490, J3590 Unspecified J3490, J3590 Q5132		• For patients with rheumatoid arthritis with failure, contraindication, or intolerance to methotrexate • Covered for patients ≥ 2 years old with juvenile idiopathic arthritis with failure, contraindication, or intolerance to methotrexate. • For psoriatic arthritis in patients with failure, contraindication, or intolerance to at least one conventional synthetic disease modifying anti-rheumatic drug (csDMARD) (methotrexate preferred) Note: csDMARD not required for patients with axial disease or severe (rapidly progressive, erosive) disease • For adult patients with moderate to severe psoriasis with an inadequate response, contraindication, or intolerance to topical psoriasis treatments and at least two of the following*: o 12-week trial of phototherapy o acitretin o methotrexate *Note: cyclosporine may also be counted towards 1 of the required therapies, but should not be required. • For patients with active ankylosing spondylitis. • For adult patients with moderately to severely active ulcerative colitis or Crohn's disease. It is recommended that adalimumab (e.g., Amjevita) is used in combination with azathioprine, 6-mercaptopurine, or methotrexate. It is recommended that only responders to induction therapy continue with longer term maintenance therapy. • For pediatric patients (5 to 17 years old) with moderately to severely active UC or pediatric patients (6 to 17 years) with moderately to severely active Crohn's disease. It is recommended only responders to induction therapy continue with longer term maintenance therapy. • For patients with moderate to severe Hidradenitis Suppurativa (HS) who meet all the following criteria: o Contraindication, intolerance, or failure of 12 weeks total of at least one systemic antibiotic (doxycycline, minocycline, or clindamycin/rifampin) Not covered for use in combination with disease modifying or other biologic therapies including (but not limited to): • infliximab, etanercept, vedolizumab, rituximab, certolizumab, tocilizumab, golimumab, ustekinumab, natalizumab, tofacitinib, upadacitinib, ozanimod, apremilast **Quantity Limits**: • Rheumatoid arthritis: Limit dosing to 40 mg every 2 weeks. • Juvenile idiopathic arthritis: Limit dosing to 40 mg every 2 weeks. • Psoriatic arthritis: Limit dosing to 40 mg every 2 weeks.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• Psoriasis: Limit dosing to 80 mg at week 1, then 40mg every 2 weeks beginning 1 week after initial dose. • Ankylosing spondylitis: Limit dosing to 40 mg every 2 weeks. • Crohn's disease: Limit dosing to induction dosing of 160 mg week 0, 80 mg week 2, then 40 mg every 2 weeks. o If patient has inadequate response or flare after 12 weeks of initiation of therapy, may request authorization for 40 mg every week for 12 weeks. o Reauthorization would require reassessment for reduction in signs and symptoms of disease. • Moderate to severe Crohn's disease in pediatric patients o Patients 17 < 40 kg ▪ Day 1: 80 mg ▪ Days 15: 40 mg ▪ Starting on day 29: 20 mg every other week o Patients ≥ 40 kg ▪ Day 1: 160 mg ▪ Days 15: 80 mg ▪ Starting on day 29: 40 mg every other week • Ulcerative Colitis: Limit dosing to induction dosing of 160 mg week 0, 80 mg week 2, then 40 mg every other week. o If patient has inadequate response or flare after 12 weeks of initiation of therapy, may request authorization for 40 mg every week for 12 weeks. o Reauthorization would require reassessment for reduction in signs and symptoms of disease. • Moderate to severe ulcerative colitis in pediatric patients: o Patients 20 to < 40 kg ▪ Day 1: 80 mg ▪ Days 8 & 15: 40 mg ▪ Starting on day 29: 40 mg every other week or 20 mg every week o Patients ≥ 40 kg ▪ Day 1: 160 mg ▪ Days 8 & 15: 80 mg Starting on day 29: 80 mg every other week or 40 mg every week • Hidradenitis suppurativa: o For adults and adolescents ≥12 years with body weight ≥60 kg, limit dosing to induction dosing of 160mg week 0, 80 mg week 2, then 40 mg every week. o For adolescents ≥12 years with body weight between 30 to <60 kg, limit dosing to induction dosing of 80 mg week 0, 40 mg week 2, then

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				40 mg every other week.
Adalimumab-atto	Amjevita	Unspecified J3490, J3590	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria below • For patients with rheumatoid arthritis with failure, contraindication, or intolerance to methotrexate • Covered for patients ≥ 2 years old with juvenile idiopathic arthritis with failure, contraindication, or intolerance to methotrexate. • For psoriatic arthritis in patients with failure, contraindication, or intolerance to at least one conventional synthetic disease modifying anti-rheumatic drug (csDMARD) (methotrexate preferred) Note: csDMARD not required for patients with axial disease or severe (rapidly progressive, erosive) disease • For adult patients with moderate to severe psoriasis who have not had an adequate response to topical psoriasis treatments and at least two of the following*: ○ 12-week trial of phototherapy ○ acitretin ○ methotrexate *Note: cyclosporine may also be counted towards 1 of the required therapies, but should not be required. • For patients with active ankylosing spondylitis. • For adult patients with moderately to severely active ulcerative colitis or Crohn's disease. It is recommended that adalimumab is used in combination with azathioprine, 6-mercaptopurine, or methotrexate. It is recommended that only responders to induction therapy continue with longer term maintenance therapy. • For pediatric patients (5 to 17 years old) with moderately to severely active UC or pediatric patients (6 to 17 years) with moderately to severely active Crohn's disease. It is recommended only responders to induction therapy continue with longer term maintenance therapy. • For patients with moderate to severe Hidradenitis Suppurativa (HS) who meet all the following criteria:

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				○ Contraindication, intolerance, or failure of 12 weeks total of at least one systemic antibiotic (doxycycline, minocycline, or clindamycin/rifampin) **Quantity Limits:** • Rheumatoid arthritis: Limit dosing to 40mg every 2 weeks. • Juvenile idiopathic arthritis: Limit dosing to 40mg every 2 weeks. • Psoriatic arthritis: Limit dosing to 40mg every 2 weeks. • Psoriasis: Limit dosing to 80mg at week 1, then 40mg every 2 weeks beginning 1 week after initial dose. • Ankylosing spondylitis: Limit dosing to 40mg every 2 weeks. • Crohn's disease: Limit dosing to induction dosing of 160mg week 0, 80mg week 2, then 40mg every 2 weeks. ○ If patient has inadequate response or flare after 12 weeks of initiation of therapy, may request authorization for 40mg every week for 12 weeks. ○ Reauthorization would require reassessment demonstrating reduction in signs and symptoms of disease. • Moderate to severe Crohn's disease in pediatric patients: ○ Patients 17 < 40 kg ▪ Day 1: 80 mg ▪ Days 15: 40 mg ▪ Starting on day 29: 20 mg every other week ○ Patients > 40 kg ▪ Day 1: 160 mg ▪ Days 15: 80 mg ▪ Starting on day 29: 40 mg every other week • Ulcerative Colitis: Limit dosing to induction dosing of 160mg week 0, 80mg week 2, then 40mg every other week. ○ If patient has inadequate response or flare after 12 weeks of initiation of therapy, may request authorization for 40mg every week for 12 weeks. ○ Reauthorization would require reassessment demonstrating reduction in signs and symptoms of disease. • Moderate to severe ulcerative colitis in pediatric patients: ○ Patients 20 to < 40 kg ▪ Day 1: 80 mg ▪ Days 8 & 15: 40 mg ▪ Starting on day 29: 40 mg every other week or 20 mg every week ○ Patients > 40 kg ▪ Day 1: 160 mg ▪ Days 8 & 15: 80 mg ▪ Starting on day 29: 80 mg every other week or 40 mg every week • Hidradenitis suppurativa:

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				○ For adults and adolescents ≥12 years with body weight ≥60 kg, limit dosing to induction dosing of 160mg week 0, 80 mg week 2, then 40 mg every week. ○ For adolescents ≥12 years with body weight between 30 to <60 kg, limit dosing to induction dosing of 80mg week 0, 40 mg week 2, then 40 mg every other week.
Adalimumab-rysk	Simlandi	Unspecified J3490, J3590	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria (refer to pharmacy benefit)
Ado-trastuzumab emtansine	Kadcyla	J9354, 1 mg	N/A	Covered for use as a single-agent in patients with a documented diagnosis of recurrent, unresectable, or metastatic HER2+ breast cancer who: • Have received prior therapy for advanced disease including a trial and failure of at least one trastuzumab + taxane-containing chemotherapy regimen. Covered for use as adjuvant therapy in patients with a documented diagnosis of HER2-positive early breast cancer who: • Have residual invasive disease in the breast or axilla at surgery after receiving neoadjuvant therapy containing a taxane and trastuzumab (e.g., Kanjinti) Covered for the treatment of patients with Salivary Gland Cancer if all the following apply: • Adenocarcinomas NOS, Mucoepidermoid or Salivary Duct Carcinoma • Recurrent Metastatic disease • Not a candidate for surgery or radiation • HER2 positive ○ If HER2 positive and AR positive (immunostain) covered in the 2nd line setting
Aducanumab	Aduhelm*	J0172	N/A	• Not covered, not medically necessary
Afamelanotide acetate	Scenesse	J7352	N/A	• Not covered, not medically necessary
Aflibercept	Eylea	J0178	24	• Covered for wet age-related macular degeneration if the patient has failed or is intolerant to bevacizumab.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• Covered for central retinal vein occlusion (CVRO) and branch retinal vein occlusion (BRVO). • Covered for diabetic eye disease if the patient has failed or is intolerant to bevacizumab, or if patient has lower visual acuity (defined by visual-acuity letter score <69 or equivalent to 20/50 or worse).
Aflibercept	Eylea HD	C9161, J0177	N/A	Medical necessity review required.
Agalsidase	Fabrazyme	J0180	N/A	Covered for patients with a confirmed diagnosis of Fabry disease Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts. Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change.
Alemtuzumab	Lemtrada	J0202	N/A	Covered for patients who: • Are diagnosed with a relapsing form of MS based on McDonald criteria AND • Have failure or intolerance to ≥2 disease modifying therapies, including natalizumab OR rituximab (e.g., Riabni) (unless the patient is not a candidate for both). • Note: Must be prescribed by or in consultation with a neurology specialist • Not covered for oncology diagnoses Not covered for use in combination with other disease-modifying multiple sclerosis therapies including (but not limited to): • Cladribine (Mavenclad), Dimethyl fumarate, Diroximel fumarate (Vumerity), Fingolimod (Gilenya), Glatiramer acetate, Interferon beta-1a (Avonex, Rebif), Interferon beta-1b (Betaseron, Extavia), Mitoxantrone (Novantrone), Natalizumab (Tysabri), Ocrelizumab (Ocrevus), Peginterferon beta-1a (Plegridy), Siponimod (Mayzent), Teriflunomide (Aubagio), Ofatumumab (Kesimpta) **Quantity Limit:** 12 mg daily for 5 days (once per year) Reauthorization: reassessment every 12 months to confirm clinical benefit including disease stability or improvement in symptoms.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts. **Applicable codes:** *ICD-10 codes covered if selection criteria or medical necessity is met. Listing of code does not guarantee coverage or reimbursement. The following list is provided for reference purposes only and may not be all inclusive.* G35
Alglucosidase	Lumizyme*†	J0221	N/A	Covered for patients with a confirmed diagnosis of Pompe Disease. Reauthorization: reassessment every 12 months to confirm clinical benefit including disease stability or improvement in symptoms and a current weight **Quantity Limit:** Up to 26 infusions per year; ≤ 20 mg/kg every 2 weeks Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts. †Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change.
Alglucosidase	Myozyme	J0220	N/A	• Covered for FDA approved indications Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.

Alirocumab	Praluent	Unspecified J3490, J3590	N/A	Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit.
				• Exception criteria may be considered for the following:
				  ○ Patients with impaired manual dexterity, impaired vision, or patients who are unable to use prefilled syringe safely
				  AND
				• Patient meets clinical criteria below
				
				Primary hyperlipidemia including heterozygous familial hypercholesterolemia (HeFH):
				• The patient is at least 18 years of age
				• The patient has at least a probable diagnosis of HeFH based on a validated diagnostic tool (Simon Broome, Dutch Lipid Clinic Network, MEDPED)
				•

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria

				• The patient failed to achieve an LDL-C<100 mg/dL and meets one of the following:
				  ○ Currently 90% adherent to maximally tolerated high-intensity statin therapy (i.e., atorvastatin 80 mg or rosuvastatin 40 mg) in combination with ezetimibe for at least 8 weeks.
				  ○ The patient has a documented contraindication to statin and ezetimibe therapy
				  ○ The patient has a documented intolerance to statin therapy, as defined by the National Lipid Association (NLA)
				• Maximally tolerated statin therapy is continued while receiving alirocumab therapy (unless not tolerated or contraindicated)
				• Failure or intolerance to evolocumab
				
				Clinical atherosclerotic cardiovascular disease (ASCVD):
				• The patient is at least 18 years of age
				• The patient has a diagnosis of clinical ASCVD evidenced of at least one of the following conditions:
				  ○ Coronary heart disease (CHD), such as myocardial infarction (MI), angina, or prior CABG or PCI
				  ○ Cerebrovascular disease, such as transient ischemic attack (TIA), ischemic stroke, or prior CEA or carotid stenting
				  ○ Peripheral artery disease, such as claudication
				• The patient failed to achieve an LDL-C <70 mg/dL and meets one of the following:
				  ○ Currently 90% adherent to maximally tolerated high-intensity statin therapy (i.e., atorvastatin 80 mg or rosuvastatin 40 mg) in combination with ezetimibe for at least 8 weeks.
				  ○ The patient has a documented contraindication to statin and ezetimibe therapy
				  ○ The patient has a documented intolerance to statin therapy, as defined by the National Lipid Association (NLA)
				• Maximally tolerated statin therapy is continued while receiving alirocumab therapy (unless not tolerated or contraindicated)
				• Failure or intolerance to evolocumab
				
				Authorization will be reviewed after 6 and 12 months of therapy to confirm demonstration of continued clinical benefit, as demonstrated by LDL reduction since initiation of therapy with alirocumab.

Amivantamab-vmjw	Rybrevant	C9083, J9061	N/A	Covered for the treatment of metastatic NSCLC that is EGFR mutated with Exon 20 insertion in the second line setting for diffuse progression
Anakinra	Kineret	Unspecified C9399,	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
		J3490, J3590		pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria (refer to pharmacy benefit)
Anifrolumab-fnia	Saphnelo	C9086, J0491	N/A	Covered for patients who meet all of the following: • Diagnosis of active systemic lupus erythematosus (SLE) • Documented failure, inadequate response, or intolerance to: o Methotrexate OR azathioprine OR mycophenolate AND o Hydroxychloroquine AND o Belimumab • Prescribed by or in consultation with a Rheumatologist • Patient is not using concurrently with belimumab • Patient does not have active central nervous system (CNS) lupus or active lupus nephritis. **Quantity Limit:** 300 mg every 4 weeks Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.
Apomorphine	Apokyn	J0364	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer • Plans with reduction rider AND • Must meet clinical criteria (refer to pharmacy benefit)
Asfotase alfa	Strensiq	Unspecified C9399, J3490, J3590	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria (refer to pharmacy benefit)

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
Asparaginase Erwinia Recombinant	Rylaze	J9021	N/A	Medical necessity review required.
Atezolizumab	Tecentriq	J9022	N/A	1. Covered for metastatic or unresectable melanoma: o BRAF V600 mutation positive disease AND o In combination with cobimetinib and vemurafenib o Covered up to 2 years 2. Covered for treatment of advanced HCC: o If combined with bevacizumab, AND o Child Pugh A 3. First line treatment of extensive stage small cell lung cancer in combination with carboplatin and etoposide for Stage IIB-IV or Stage I-IIA medically inoperable. 4. First line treatment of any high grade NET. Note: SCLC = High grade NET. 5. First line treatment of stage IV Large cell NET cancer of the lung. 6. Covered for: o First line metastatic non-squamous NSCLC o NSCLC without disease progression during or following platinum chemotherapy 7. Not covered, not medically necessary for the treatment of patients with metastatic urothelial carcinoma who are platinum ineligible in the first-line setting 8. Not covered, not medically necessary for metastatic urothelial carcinoma in the second-line setting
Avacincaptad pegol	Izervay	C9162, J2782	N/A	Medical necessity review required.
Avalglucosidase alfa-ngpt	Nexviazyme	C9085, J0219	N/A	Covered for patients who meet the following criteria: • Diagnosis of Late-onset Pompe disease in patients 1 year of age and older. • For patients < 30 kg, must have documentation that treatment with alglucosidase (Lumizyme) is ineffective, contraindicated, or not tolerated. Reauthorization: reassessment every 12 months to confirm clinical benefit including disease stability or improvement in symptoms and a current weight **Quantity Limit:** • Patients weighing 30 kg or more o Up to 26 infusions per year; ≤ 20 mg/kg every 2 weeks • Patients weighing less than 30 kg o Up to 26 infusions per year; ≤ 40 mg/kg every 2 weeks

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.
Avelumab	Bavencio	J9023	N/A	• Covered for treatment of metastatic Merkel cell carcinoma • Covered for treatment of metastatic urothelial carcinoma as maintenance with stable disease after first line platinum therapy
Axicabtagene ciloleucel	Yescarta	Q2041	N/A	Covered for patients with DLBCL or Follicular Lymphoma that has transformed to DLBCL, who have primary refractory or relapse disease within one year. Covered for patients with relapsed or refractory Follicular lymphoma with all the following conditions: • No histologic transformation • Either late relapse or early relapse for patients who are considered transplant ineligible. • Have good performance status ECOG 0-1 Covered for patients with primary mediastinal large B-cell lymphoma (PMBCL) that meet all of the following: • Prescribed by an oncologist with expertise in malignant hematology • Age 18 years or older • Chemotherapy-refractory disease, defined as one or more of the following: o Refractory to two or more lines of chemotherapy with less than partial response to last line of therapy OR o Refractory post-autologous hematopoietic stem cell transplantation (HSCT) • Required documentation: o Adequate prior therapy including at a minimum: ▪ anti-CD20 monoclonal antibody unless tumor is CD20-negative and an anthracycline containing chemotherapy regimen • Not covered for patients with: o Prior CAR-T therapy or other genetically modified T cell therapy Authorization duration: limited to a one-time (single infusion) treatment
Belatacept	Nulojix	J0485	N/A	For patients who are post-renal transplant, Epstein-Barr Virus (EBV) seropositive. Note: Must be administered in a non-hospital setting for kidney diagnosis. Allow for 5 dose exceptions. See site of care policy for criteria, reauthorization, and exceptions for new starts. Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change.
Belantamab mafodotin-blmf	Blenrep	J9037	N/A	Medical necessity review required for multiple myeloma.
Belimumab intravenous	Benlysta	J0490, 10 mg	N/A	• For patients with autoantibody positive active SLE who have documented failure, inadequate response, or intolerance to: ○ methotrexate OR azathioprine OR mycophenolate AND ○ hydroxychloroquine • For patients with histologically active lupus nephritis who meet all of the following: ○ Biopsy-proven class III or IV with or without coexisting class V or pure class V ○ Currently receiving standard immunosuppressive therapy (e.g., cyclophosphamide-azathioprine or mycophenolate mofetil), and belimumab will be used concurrently with the standard immunosuppressive therapy ○ eGFR > 30 mL/min • Prescribed by or in consultation with a nephrologist or rheumatologist • Not covered for patients with severe active CNS lupus. Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts. Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change.
Belimumab subcutaneous	Benlysta	J0490, 10 mg	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer OR • Plans with reduction rider AND • Meet clinical criteria below

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria

				• For patients with autoantibody positive active SLE who have documented failure, inadequate response, or intolerance to:
				  ○ methotrexate OR azathioprine OR mycophenolate
				  AND
				  ○ hydroxychloroquine
				• For patients with histologically active lupus nephritis who meet all of the following:
				  ○ Biopsy-proven class III or IV with or without coexisting class V or pure class V
				  ○ Currently receiving standard immunosuppressive therapy (e.g., cyclophosphamide-azathioprine or mycophenolate mofetil), and belimumab will be used concurrently with the standard immunosuppressive therapy
				  ○ eGFR > 30 mL/min
				• Prescribed by or in consultation with a nephrologist or rheumatologist
				• Not covered for patients with severe active CNS lupus.
				
				Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.
				
				Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change.

Belinostat	Beleodaq	J9032	N/A	For the treatment of relapsed or refractory peripheral T-cell lymphoma.
Bendamustine	Treanda Bendeka	J9033 J9034	N/A	When used to treat CLL, the following criteria apply: • As first line therapy in patients without deletion 17P who are ≥65 years old or for patients less than 65 years old who are IGHV unmutated • For the treatment of patients relapsed or refractory to one first-line therapy recommended by the NCCN guidelines (e.g., fludarabine-based therapy, obintuzumab+chlorambucil, rituximab+chlorambucil). • NOT covered for use in patients with del(17p). Covered for relapsed refractory multiple myeloma after progression with an immunomodulatory agent (e.g., thalidomide, lenalidomide, pomalidomide) and proteasome inhibitor (e.g., bortezomib, ixazomib) as a third line or greater treatment option. For other FDA-approved indications (e.g., other lymphomas), no restrictions apply.

Benralizumab	Fasenra	J0517	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer OR • Plans with reduction rider AND • Meet clinical criteria below For patients with severe eosinophilic asthma who meet the following criteria: • Prescribed by an Allergist or Pulmonologist. • Patient is at least 12 years of age. • Documented severe persistent asthma (see Table 1) • Reversible airway obstruction as documented by the following: o Response to inhaled short-acting beta agonists (e.g., FEV_1 reversibility of >12% with at least a 200 mL increase in FEV_1) within 30 minutes after administration of albuterol (90-180 mcg) OR o Positive exercise or methacholine challenge OR o Positive response (at least a 15% increase in FEV_1 with at least a 200 mL increase in FEV_1) after a course of treatment with inhaled or systemic corticosteroids. • Documentation of eosinophilic phenotype indicated by one of the following: o Non-oral corticosteroid (OCS) dependent: serum eosinophil count of ≥300 cells/mcL within the past 12 months o OCS dependent: serum eosinophil count of ≥ 150 cells/mcL within the previous 12 months. • Patient has uncontrolled asthma (see Table 1) despite all the following: o Trigger avoidance measures o Comorbidities that can cause asthma exacerbations (e.g., gastroesophageal reflux disease [GERD], allergic rhinitis) and non-asthma diagnoses (e.g., laryngeal dysfunction, panic disorder) have been evaluated and treated. o Aggressive drug therapy regimen for at least 6 months (see Table 2). **Exclusion criteria:** If ONE or more of the following criteria is met, patient is NOT eligible: • Current smoker who is not currently enrolled in a smoking cessation program (e.g., Quit for Life) • Non adherence to pre-requisite asthma drug therapies. o Non adherence is defined as less than 75% of proportion of days covered (calculated by day supply dispensed over the total number of days since treatment was initiated). • Concomitant use with omalizumab, mepolizumab, reslizumab, or dupilumab **Evaluation for Continuation of Therapy:** • Evaluate response after 6 months and then annually thereafter. • Clinical improvement must be demonstrated by at least one of the following: o Decreased use of rescue medications

- Decreased frequency of exacerbations (defined as worsening of asthma that requires increase in ICS dose or treatment with systemic corticosteroids)
- Improvement in lung function (e.g., FEV1) from pretreatment baseline
- Objective improvement in quality of life: minimally important difference of 3 points on the Asthma Control Test
- Improvement in asthma symptoms (such as asthmatic symptoms upon wakening, coughing, fatigue, shortness of breath, sleep disturbance, wheezing, or reduced missed days from work or school).
- Decreased corticosteroid requirement if on OCS.

Table 1. Evidence for severe refractory asthma and indicators of uncontrolled asthma

Evidence for severe refractory asthma
• Asthma meets criteria for moderate-to-severe asthma as defined by the NHLBI's EPR-3 and the patient has uncontrolled asthma which should be noted both subjectively and with objective evidence of asthma, despite the following: o Ruling out comorbid factors (e.g., allergy, sinusitis, GERD, anxiety disorder, panic disorder, vocal cord dysfunction) to determine if these measures can decrease the need to initiate biologic therapy. o Address and manage all triggers from the home (e.g., animal dander if allergic, dust mites, foods, pollen, smoke exposure). o Aggressive trials of therapy (refer to Table 2)
Indicators of uncontrolled asthma
• Any one of the following criteria qualifies the patient as having uncontrolled asthma: o Two or more asthma exacerbations requiring systemic corticosteroids (≥3 days each) in the past 12 months o Serious exacerbations: at least one hospitalization, intensive care unit (ICU) stay or mechanical ventilation in the previous year o Asthma Control Test (ACT) is consistently <20

Table 2. Aggressive drug therapy regimens for asthma

A. Triple drug therapy with high-dose ICS plus LABA combination* plus tiotropium (Spiriva Respimat) (unless contraindications or intolerance) and on oral corticosteroid (OCS) for most days during the previous 6 months (e.g., ≥50% of days) **OR** **B.** Triple drug therapy with high-dose ICS plus LABA combination* plus tiotropium (Spiriva Respimat) (unless contraindications or intolerance) who are not on daily OCS, but who otherwise meet other inclusion criteria and have had frequent severe exacerbations (≥2) in the past 12 months requiring systemic corticosteroids for ≥3 days and/or a history of a serious exacerbation requiring at least one hospitalization, ICU stay, or

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				mechanical ventilation in the previous year. **OR** **C.** Corticosteroid adverse effects: If a patient has been poorly controlled over at least one year and is experiencing corticosteroid adverse effects while on aggressive drug therapy (A or B) then treatment with a biologic drug may be considered. **High-dose ICS plus LABA combinations include: fluticasone/salmeterol 500/50 mcg, 1 inh twice daily or fluticasone salmeterol 230/21 mcg, 2 puffs twice daily*. **Quantity Limit:** Loading dose: 1 autoinjector (30 mg) every 28 days for dose 1 and 2 Maintenance: 1 autoinjector (30 mg) every 56 days for dose 3 and beyond Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.
Beremagene geperpavec-svdt	Vyjuvek*	J3401	N/A	Covered for patients 6 months of age and older who meet ALL of the following: • Prescribed by or in consultation with a Dermatologist • Confirmed diagnosis of dystrophic epidermolysis bullosa (DEB) • Documentation showing mutation in the collagen type VII alpha 1 chain (*COL7A1)* gene • Presence of wounds that have not healed despite 2 months of standard wound care OR have recurrent ulceration of wound • Confirmed negative pregnancy status (if applicable) • Individual does not have current evidence or history of squamous cell carcinoma in the wound • Individual is not actively receiving chemotherapy or immunotherapy • Maximum weekly dose prescribed is based on the age of the individual: o 1.6×10^9 PFU (0.8 mL) for individuals 6 months to < 3 years old o 3.2×10^9 PFU (1.6 mL) for individuals 3 years and older Initial authorization: 3 months Reauthorization: reassessment required every 3 months to evaluate need for continued therapy as determined by clinically significant signs of improvement.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
Betibeglogene autotemcel	Zynteglo*	Unspecified J3490, J3590	N/A	Covered for the treatment of adult and pediatric patients with β-thalassemia who require regular RBC transfusions when all of the following are met: • Prescribed by or in consultation with Pediatric or Adult Hematology/Oncology Specialists • Patient is 50 years or younger • Confirmed diagnosis of β-thalassemia through genetic testing • Diagnosis of transfusion dependent β-thalassemia (TDT) by hematology specialist with a history of at least 100 mL/kg/year or 10 units/year of packed red blood cells (pRBCs) in prior 2 years: • Karnofsky performance status of ≥80% or Lansky performance status ≥80 (if <16 years old) • Clinically stable and eligible to undergo hematopoietic stem cell therapy (HSCT) Exclusion criteria: • Positive for presence of human immunodeficiency virus type 1 or 2 (HIV-1 and HIV-2), hepatitis B virus (HBV), or hepatitis C (HCV); or • Any prior or current malignancy (other than nonmelanoma skin cancer); or • Prior HSCT; or • Prior receipt of gene therapy; or • Evidence of cardiac or hepatic dysfunction due to iron overload; or • White blood cell (WBC) count $<3\times10^9$/L, and/or platelet count $<100\times10^9$/L not related to hypersplenism; or • Uncorrected bleeding disorder; or • Immediate family member with a known Familial Cancer Syndrome Required baseline labs: • Echocardiogram • Electrocardiogram • T2* weighted MRI for liver and heart Authorization duration: limited to a one-time single infusion therapy **Note: Prior to treatment with betibeglogene autotemcel, review by an Inter-regional Consultative Physician Panel is required.**
Bevacizumab	Avastin	C9257 (0.25 mg) J9035 (10 mg)	N/A	• Criteria review not required for ophthalmic diagnoses. • New starts must have had an inadequate response or intolerance to a bevacizumab biosimilar declared equivalent by KPWA P&T Committee. KPWA equivalent bevacizumab products include: bevacizumab-awwb (Mvasi). • Established patients on Avastin must have a documented inadequate response or intolerance to a bevacizumab biosimilar Note: Must be administered in a non-hospital setting when used as monotherapy. See site of care policy for criteria, reauthorization, and exceptions for new starts.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
Bevacizumab-adcd	Vegzelma	Q5129	N/A	Medical necessity review required. Note: Must be administered in a non-hospital setting when used as monotherapy. See site of care policy for criteria, reauthorization, and exceptions for new starts.
Bevacizumab-awwb	Mvasi	Q5107	N/A	Note: Must be administered in a non-hospital setting when used as monotherapy. See site of care policy for criteria, reauthorization, and exceptions for new starts.
Bevacizumab-bvzr	Zirabev	Q5118	N/A	Covered for patients who have an inadequate response or intolerance to the preferred biosimilar, bevacizumab-awwb (Mvasi). Note: Must be administered in a non-hospital setting when used as monotherapy. See site of care policy for criteria, reauthorization, and exceptions for new starts.
Bevacizumab-maly	Alymsys	C9142, Q5126	N/A	Medical necessity review required. Note: Must be administered in a non-hospital setting when used as monotherapy. See site of care policy for criteria, reauthorization, and exceptions for new starts.
Bezlotoxumab	Zinplava	J0565	N/A	Covered for patients who meet all of the following: • Diagnosis of recurrent *Clostridioides difficile* infection (CDI) confirmed by documentation of positive test. • Completed a 6-month trial of a vancomycin taper (a short and extended course) • Completed a 10-day course of fidaxomicin or rifaximin (a short and extended course) *Please note: fecal microbiome transplant (FMT) is a preferred alternative but is not required due to highly variable access. Approved duration is initial one-time dose
Bimatoprost intracameral	Durysta	J7351	N/A	Medical necessity review required.
Blinatumomab	Blincyto	J9039	N/A	Covered for patients with Philadelphia Chromosome positive Acute Lymphoblastic Leukemia Ph(+) ALL: • In combination with either ponatinib or dasatinib for patients who are not candidates for intensive chemotherapy. • Or as monotherapy for patients who have less than CR after first line therapy.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
Blood Factors: Antihemophilic factor	Advate, Helixate, Kogenate FS, Kovaltry, Recominate, Xyntha, Obizur, Afstyla, Novoeight, Nuwiq, Adynovate, Koate, Alphanate, Humate-P, Wilate, Hemofil-M, Monarc-M, Monoclate, Jivi,	J7182, J7183, J7185, J7186, J7187, J7188, J7190, J7192, J7198, J7199, J7207, J7208, J7209, J7211, J7210	N/A	Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Pharmacy Network. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
Anti-inhibitor coagulant	Feiba	J7198		
Coagulation factor IX	Rixubis, Benefix, Ixinity	J7200, J7195, J7213		
Factor VIIa	Novoseven Eptacog alfa	J7189		
Factor IX	Idelvion, Bebulin, Profilnine, Alphanine-SD, Mononine, Rebinyn	J7202, J7194, J7193, J7203		
Factor X	Coagadex	J7175		
Factor XIII	Corifact, Tretten	J7180, J7181		
Von Willebrand factor	Vonvendi	J7179		
Antihemophilic factor recomb glycopeg-exei	Esperoct	J7204		
Factor viia (antihemophilic factor, recombinant)-jncw	Sevenfact	J7212		
Antihemophilic factor recombinant fc-vwf-xten-ehtl	Altuviiio	J7214		

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
Bortezomib	Velcade	J9041, J9046, J9048, J9049	N/A	Note: Must be administered in a non-hospital setting when used as monotherapy. See site of care policy for criteria, reauthorization, and exceptions for new starts. Site of Care Exceptions: 2 doses within 2 months.
Brexanolone	Zulresso*	J1632	N/A	Covered for patients with postpartum depression (PPD) who meet ALL of the following: • Prescribed by psychiatrist or an OB/GYN or Pediatric specialist in consultation with a psychiatrist. • Age ≥15 to 45 years and diagnosis of PPD (onset no earlier than third trimester of pregnancy or no later than 4 weeks postpartum) • Patient is ≤6 months postpartum • Active suicidal or homicidal ideation and/or severe functional impairment • Patient Health Questionnaire-9 (PHQ-9) score ≥20 within 2 weeks prior to treatment initiation. • Patient has tried or declined trial of an antidepressant medication, or other somatic treatments such as electroconvulsive therapy (ECT) and/or repetitive transcranial magnetic stimulus (rTMS), if patient is a candidate • Psychosocial and environmental factors (e.g., sleep, household support) have been assessed and addressed appropriately in the treatment plan Not covered for patients with: • Active psychosis • Diagnosis of bipolar disorder, schizophrenia, or schizoaffective disorder • Active alcohol or drug abuse (within prior 30 days) • End-stage renal disease (eGFR <15 mL/min/1.73 m^2)

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
Brentuximab vedotin	Adcetris	J9042	N/A	• For the treatment of previously untreated stage III or IV Hodgkin lymphoma • For the treatment of relapsed refractory Hodgkin lymphoma after multi-agent chemotherapy • For the treatment of patients with systemic anaplastic large cell lymphoma and other CD-30 expressing peripheral T-cell lymphomas (PTCL) • For the treatment of patients with diffuse large B-cell lymphoma (DLBC) as 3rd line or greater therapy if CD30+ • For treatment of Mycosis Fungoides as first line therapy if CD30+ ≥5% for: o Stage IIB Large cell Transformation o Stage IV Nodal or Visceral disease o Covered for treatment of Mycosis Fungoides as second line therapy following skin directed topical or phototherapy if ≥5% CD30 positive • For the treatment of Sezary Syndrome without nodal or visceral disease in the second line setting if CD30+ ≥5% * Duration of therapy not to exceed 1 yr (or 16 cycles)
Brexucabtagene autoleucel	Tecartus	Q2053	N/A	Covered for patients with Philadelphia Chromosome negative Acute Lymphoblastic Leukemia Ph(-) ALL: • Who have less than CR after extended remission induction who are 25 yrs old and younger. • Who are 40 years old and greater who not a candidate for intensive chemotherapy. Covered for patients with Philadelphia Chromosome positive Acute Lymphoblastic Leukemia Ph(+) ALL: • Who have received intensive chemotherapy with TKI therapy o AND who are not MRD negative at 3 months Covered for the treatment of Relapsed or Refractory Mantle Cell Lymphoma: • Stage I, II disease post prior chemotherapy +RT followed by BTK inhibitor or additional novel chemotherapy resulting in partial response or refractory disease • Relapse after Stem cell transplant • Stage II (bulky), III, IV for patients with partial response to initial treatment of refractory disease • Not covered for patient with: o Burkitt's lymphoma/leukemia o Active hepatitis B, C, or any uncontrolled infection o Active Grade 2 to 4 Graft versus Host Disease (GVHD) o Central Nervous System (CNS) 3 disease (white blood cell count ≥ 5/mL with blasts on cytocentrifuge and/or signs of CNS leukemia (e.g., cranial nerve palsy). Authorization duration: limited to a one-time (single infusion) treatment

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
Brivaracetam	Briviact	Unspecified J3490, J3590	N/A	Covered for patients 16 years or older who have been taking oral brivaracetam.
Brodalumab	Siliq	Unspecified C9399, J3490, J3590	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria (refer to pharmacy benefit)
Brolucizumab-dbll	Beovu	J0179	N/A	Covered for the treatment of neovascular (wet) age-related macular degeneration (AMD) if the patient has failed or is intolerant to: • Bevacizumab, and • Ranibizumab (Lucentis) OR aflibercept (Eylea)
Buprenorphine extended release	Brixadi	C9154, J0576, J0577, J0578	N/A	Patient has a diagnosis of moderate to severe opioid use disorder and meets all of the following: • Patient has initiated treatment with a buprenorphine dose prior to initiation of Brixadi. • In the past year, the patient has had one or more of the following related to opioid use: ○ Emergency room visit ○ Hospital admission ○ Opioid overdose reversal intervention Not covered for treatment of chronic pain Reauthorization required 3 months after initiation: • Documentation that patient is stabilized & benefiting from weekly or monthly injections. • Rationale for inability to safely transition to sublingual buprenorphine including attestation that patient will not receive supplemental doses of sublingual or transmucosal buprenorphine.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria

Buprenorphine extended release	Sublocade	Q9991, Q9992	N/A	Patient has a diagnosis of moderate to severe opioid use disorder or opioid dependence and meets all of the following:
				• Patient is currently maintained on a transmucosal or sublingual buprenorphine dose for at least 7 days prior to initiation of Sublocade.
				• In the past year, the patient has had one or more of the following related to opioid use:
				  ○ Emergency room visit
				  ○ Hospital admission
				  ○ Opioid overdose reversal intervention
				• Not covered for treatment of chronic pain
				• Reauthorization required 3 months after initiation:
				  ○ Documentation that patient is stabilized & benefiting from monthly injections.
				  ○ Rationale for inability to safely transition to sublingual buprenorphine including attestation that patient will not receive supplemental doses of sublingual or transmucosal buprenorphine.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria

Buprenorphine implant	Probuphine	J0570	N/A	• Not covered for treatment of chronic pain.
				• Covered for patients who has a diagnosis of opioid dependence or opioid use disorder and meets all of the following:
				  ○ Patient is currently on 8 mg per day or less of oral, sublingual, or transmucosal buprenorphine equivalent [e.g., Subutex 8 mg or less, Suboxone (or generic) 8 mg/2 mg or less, Zubsolv 5.7 mg/1.4 mg or less, or Bunavail 4.2 mg/0.7 mg)].
				  ○ Patient is stable on transmucosal buprenorphine dose listed above for six months or longer without any need for supplemental dosing or dose adjustments.
				  ○ Patient has not had an opioid-positive drug screening (apart from buprenorphine) in the past 90 days*.
				  ○ Prescriber meets DATA 2000 requirements and has been assigned a unique identification number specific to the prescription of medication assisted therapy (DEA-X).
				  ○ Prescriber and/or healthcare professional performing the insertion are certified by the Probuphine REMS program.
				
				Initial authorization is for 6 months in one upper arm with subsequent **one-time reauthorization** for 6 months in the other upper arm (maximum cumulative therapy is two 6-month cycles). Reauthorization required after 6 months of initiation with all of the following:
				• Documentation that patient has appropriate morphology for implantation with no history of prior medication implantation into upper medial aspect of at least one arm and adequate physical characteristics for successful implantation.
				• Documentation that patient has received no more than 1 cycle of Probuphine.
				• Urine and other body fluid testing from the past six months are consistent with abstinence from unprescribed opioids and adherence to treatment with buprenorphine.
				• Patient has not, nor will receive supplemental doses of sublingual or transmucosal buprenorphine.
				• Prescriber meets DATA 2000 requirements and has been assigned a unique identification number specific to the prescription of medication assisted therapy (DEA-X).
				• Prescriber and/or healthcare professional performing the insertion are certified by the Probuphine REMS program.
				
				*Patients screening positive for opioid use outside of the opioid dependence treatment regimen (i.e. other than buprenorphine) is evidence that the patient has not achieved sustained, prolonged, clinical stability and Probuphine is not indicated for this population.

Burosumab-twza	Crysvita*	J0584	N/A	Coverage Criteria: Covered for patients with X-linked hypophosphatemia who meet all of the following criteria: • Prescribed by an endocrinologist or nephrologist • Age 6 months and older • Diagnosis of X-linked hypophosphatemia supported by one of the following: o Genetic testing (PHEX mutation) of patient o Family member with X-linked inheritance o Serum FGF23 level >30 pg/mL • Required documentation: o The following labs prior to treatment initiation, after discontinuation of any oral phosphate and active vitamin D analogs ▪ Fasting serum phosphorus (must be below the reference range for age at treatment initiation) ▪ Renal function ▪ Parathyroid hormone (PTH), alkaline phosphatase (ALP), calcium, vitamin D, and urine calcium/creatinine (Ca/Cr) ratio o Renal ultrasound within 6 months o Adults and adolescent patients who have reached final adult height (e.g., epiphyseal growth plates are closed): ▪ Radiographic evidence of non-healing fractures (defined as a visible fracture line) OR ▪ Persistent symptoms (e.g., limited mobility, musculoskeletal pain) of XLH and inadequate response, contraindication, or intolerance to standard treatment with oral phosphate and active vitamin D analogs. o Pediatric patients: ▪ Radiographic evidence of active bone disease (e.g., rickets in wrists/knees, femoral/tibial bowing) OR abnormal growth velocity (if open epiphyseal growth plates) OR ▪ Patients < 2 years without radiographic evidence but with confirmed genetic testing or family history, strong clinical suspicion, and low fasting serum phosphorous. • Not covered for patients with: o eGFR<30 mL/min/1.73 m^2 o Evidence of tertiary hyperparathyroidism • Reassess every 12 months to evaluate need for continued treatment. Therapy should be discontinued if: o Member non-adherent to medication or follow-up assessments, o There is lack of normalization of serum phosphorous, o Or there is lack of positive clinical response (defined as an improvement in growth velocity, deformities, fractures, or bone pain).

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				Note: Prior to treatment initiation, patients should be reviewed by an Interregional Consultative Physician Panel. Covered for patients with FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) who meet all of the following criteria: • Prescribed by an endocrinologist or nephrologist • Age 2 years and older • Diagnosis of TIO not amenable to surgical excision of the offending tumor/lesion • Fasting serum phosphorus <2.5 mg/dL in adults or below normal reference range for pediatric patients • Elevated serum FGF23 level (assay specific) • Ratio of renal tubular maximum phosphate reabsorption rate to glomerular filtration rate (TmP/GFR) less than 2.5 mg/dL for adults or below normal reference range for pediatric patients • Corrected serum calcium <10.8 mg/dL for adults or below normal reference range for pediatric patients • Required documentation: o The following labs prior to treatment initiation, after discontinuation of any oral phosphate and active vitamin D analogs ▪ Fasting serum phosphorus (must be below the reference range for age at treatment initiation) ▪ Renal function ▪ Parathyroid hormone (PTH), alkaline phosphatase (ALP), calcium, vitamin D, 24 hour and urine calcium/creatinine (Ca/Cr) ratio o Renal ultrasound within 6 months • Not covered for patients with: o eGFR<30 mL/min/1.73 m2 o Evidence of tertiary hyperparathyroidism • Reassess every 12 months to evaluate need for continued treatment. Therapy should be discontinued if: o Member non-adherent to medication or follow-up assessments, o There is lack of normalization of serum phosphorous, o Initiating chemotherapy or have planned surgical excision of tumor/lesion. **Note: Prior to treatment initiation, patients should be reviewed by an Interregional Consultative Physician Panel.** Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
onabotulinumtoxinA rimabotulinumtoxinB abobotulinumtoxinA incobotulinumtoxinA	Botox Myobloc Dysport Xeomin	J0585, Type A per unit J0587, Type B per 100 units J0586, per 5 units J0588, Per 1 unit	All indications: Max of 1 treatment every 12 weeks See next column for max units per treatment	Covered for the following indications: 1) Hyperhidrosis. 2) Anal fissures not responding to treatment with topical nitroglycerin ointment. 3) Achalasia in patients who are not candidates for pneumatic dilation. 4) Torticollis (cervical dystonia), other focal dystonia, hemifacial spasms, dysphonia, strabismus, or blepharospasm. 5) Vocal cord granuloma. 6) Cerebral palsy. 7) Limb spasticity due to multiple sclerosis, spinal cord injury or after stroke with documented functional impairment, hygiene complications or infection due to spasticity. 8) For prevention of migraine in adult patients, must meet all the following criteria: a) Meet diagnostic criteria for migraine or migraine with muscle tension headache. b) Documented assessment to exclude medication-overuse headaches based on International Headache Society Classification ICHD-3 (use of triptans, ergotamine, opioids or any combination of these agents for 10 or more days/month for more than 3 months; non-opioid analgesic use for 15 or more days/month for more than 3 months). c) Documentation of an adequate trial of 3 formulary preventative agents, 2 of which must be from the following list (minimum of 2 classes required): • tricyclic antidepressants (e.g., nortriptyline, amitriptyline) • beta blockers (e.g., propranolol, metoprolol) • topiramate • divalproex or valproate i) An adequate trial is defined as at least 2 months of a maximally tolerated dose, or documented intolerance or contraindication d) Patient has been seen by a neurology specialist who recommends the trial of botulinum toxin. e) Not covered for concomitant use with CGRP monoclonal antibodies or small molecule CGRP receptor antagonists used for migraine prophylaxis (e.g., galcanezumab-gnlm, erenumab-aooe, fremanezumab-vfrm, eptinezumab-jjmr, rimegepant, atogepant) 9) Treatment of urinary incontinence due to detrusor over activity associated with a neurologic condition (e.g., spinal cord injury (SCI), multiple sclerosis (MS)) who have an inadequate response to or are intolerant of at least 2 formulary-preferred anticholinergic medications (i.e. oxybutynin, trospium, solifenacin, etc.). 10) Treatment of urinary incontinence due to idiopathic OAB in adults who have an inadequate response, contraindication or intolerance to at least 2 formulary anticholinergic chemical entities (i.e. oxybutynin, trospium, or solifenacin.). 11) Medical necessity review required for sialorrhea in bulbar motor neuron disease and Parkinson's Disease.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				BotulinumtoxinA (Botox, Xeomin, Dysport) will be approved if the patient meets any of the above criteria. Myobloc will be approved if clinical failure of Botox, Dysport, or Xeomin in above circumstances. Botulinum toxin products not covered for use in combination with other botulinum products for the same treated condition (same diagnosis code). **Max Units per Treatment:** Overactive Bladder: Botox 200 units, Xeomin 200 units, Dysport 240 units Urinary Incontinence: Botox 100 units, Xeomin 200 units, Dysport 120 units Chronic Migraine: Botox 200 units **Max Cumulative Units across all covered indications per treatment period (12 weeks):** • Botox: 400 units (adults); 340 units (pediatrics) • Dysport: 1,500 units (adults); 1,000 units (pediatrics) • Xeomin: 400 units (adults and pediatrics) • Myobloc: 5,000 units (adults) **ICD-10 code needed to auto-auth with specific code** ***(corresponds with numbered criteria above)*** *1) R61, L74.510, L74.511, L74.512, L74.513, L74.519, L74.52* *4) G24.1, G24.3, G24.4, G24.5, G24.8, G24.9, G25.89, G51.2, G51.4, G51.8, H50.00-H51.9, M43.6, R49.8* *5) J38.3* *6) G80.0, G80.1, G80.2, G80.3, G80.8, G80.9* Note: Myobloc will only be approved if clinical failure of Botox, Dysport, or Xeomin in above circumstances. **Applicable codes:** *ICD-10 codes covered if selection criteria or medical necessity is met. Listing of code does not guarantee coverage or reimbursement. The following list is provided for reference purposes only and may not be all inclusive.* G11.4, G24.5, G24.3, G24.01, G24.02, G24.09, G24.1, G24.2, G24.4, G24.8, G24.9, G25.0-G25.3, G25.89, G35, G36.0-G37.9, G51.0-G80.9, G81.10-G81.14, G82.20-G83.34, J38.5, L74.510-L74.519, L74.52, G43.001-G43.919, M43.6-M43.9, N31.0-N31.9, N32.81, N39.3-N39.498, N36.44, H49.0-H49.9, H50.0-H50.9, H51.0-H51.9, H52.531-H52.539, R25.2, R49.0, R49.8, K11.1, K11.7, K22.0, F45.8, I69.051-I69.059, I69.061-I69.069, I69.098, I69.151-I69.159, I69.251-I69.259, I69.351 - I69.359, I69.851 - I69.859, I69.951 - I69.959, K22.5, K44.9, K59.4, K60.0 - K60.5, Q43.1 - Q43.2, R32, S04.01 - S04.049S, S04.10 - S04.12XS, S04.20 - S04.22XS, S04.30 - S04.32XS, S04.40 - S04.42XS, S04.50 - S04.52XS, S04.60 -

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				S04.62XS, S04.70 - S04.72XS, S04.81 - S04.899S, S04.9XXA - S04.9XXS, R61, J38.3. M62.40, M62.838- only with 2nd dx below: I69.931, I69.932, I69.933, I69.934, I69.941, I69.942, I69.943, I69.944, I60.9, I61.9, I62.1, I62.01, I62.02, I62.03, I62.9, I62.00, I63.22, I63.139
C1 esterase inhibitor	Berinert	J0597, 10 units	N/A	• For acute treatment of patients with an established diagnosis of type 1 or type 2 hereditary angioedema (HAE); AND • Prescribed by an allergy specialist or emergency medicine provider Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.
C1 esterase inhibitor	Cinryze	J0598, 10 units	N/A	• Chronic prophylaxis of hereditary angioedema (HAE) for patients age 6 years and older with failure, contraindication, or intolerance to lanadelumab-flyo • Routine (short-term procedural) prophylaxis of HAE for patients age 6 years of age and older • Must be prescribed by an Allergy specialist. Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.
C1 esterase inhibitor	Haegarda	J0599	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria (refer to pharmacy benefit)
C1 esterase inhibitor	Ruconest	J0596, 10 units	N/A	• For acute treatment of patients with an established diagnosis of type 1 or type 2 hereditary angioedema (HAE); AND • Prescribed by an allergy specialist or emergency medicine provider Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.
Cabazitaxel	Jevtana	J9043, 1 mg	N/A	For use in treatment of patients with hormone-refractory metastatic prostate (HRMP) cancer previously treated with a docetaxel-containing treatment regimen, or if history of peripheral neuropathy.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
Cabotegravir extended release	Apretude	J0739	N/A	Covered for patients who meet the following criteria: • Patient is 13 years of age or older and weighs ≥ 35 kg AND • Use is for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection. AND 1 of the following: • Patient has an allergy or intolerance* to oral PrEP treatment (emtricitabine/tenofovir disoproxil fumarate [generic Truvada] AND emtricitabine/tenofovir alafenamide [Descovy]) after an adequate trial^ • Patient is unable to use generic Truvada and Descovy due to moderate or severe renal impairment (CrCl <30 mL/min) • Patients with persistent increased serum creatinine from baseline defined as 2 or more labs with an increase of 0.4 mg/dL change or sustained proteinuria/glycosuria while using generic Truvada and Descovy • Patients who have needed more than 2 nPEP (non-occupational post-exposure prophylaxis) courses over 12 months due to poor adherence to oral PrEP treatment • Patients experiencing structural or individual level barriers to oral PrEP use • Patients who have evidence of malabsorption from GI conditions (e.g., sleeve gastrectomy, gastric bypass, terminal ileitis, celiac disease, severe chronic diarrhea) * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation ^ Adequate trial is defined as 21-day treatment duration
Cabotegravir/rilpivirine	Cabenuva	J0741	N/A	Covered for patients who meet the following criteria: • Diagnosis of HIV-1 • Antiretroviral therapy experienced with virologic suppression for at least 3 months prior to therapy (HIV-1 RNA < 50 copies/mL) • Prescribed by or in consultation with an HIV specialist or Infectious Diseases specialist. • No known or suspected resistance to rilpivirine or cabotegravir Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
Casimersen	Amondys 45*	J1426	N/A	Covered for patients with Duchenne muscular dystrophy who meet ALL of the following: • Prescribed by or in consultation with pediatric neurology, adult neurology or Physical Medicine & Rehabilitation • Documented deletion/mutation amenable to exon 45 skipping (must be confirmed by a geneticist) • At least 4 years old • Ambulatory without wheelchair dependency (cane or walker use acceptable) • Documented minimum distance for unassisted 6-minute walk test (6MWT) of 180 meters at baseline • Must be on a stable dose of glucocorticoid for at least 6 months • Forced Vital Capacity % (FVC%) greater than or equal to 50% predicted Not covered for patients who: • Are non-ambulatory. • Are ambulatory with some level of wheelchair dependency. • Require nocturnal ventilation (including BiPAP), but excluding CPAP. • Prior or planned treatment with gene therapy for Duchenne muscular dystrophy. Reassessment every 12 months to determine need for continued therapy. Patient must meet ALL of the following functional criteria for continued coverage: • Ambulation test: Greater than limited home level (e.g., home, limited community, or community independent) • Sit to stand test: Moderate assist or Independent • No ventilator support (excluding use of nocturnal CPAP) Note: Prior to treatment initiation, all patients should be reviewed by an Interregional Consultative Physician Panel. Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts. Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change.
CGRP inhibitors:				
Fremanezumab-vfrm	Ajovy	J3031	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the
Erenumab-aooe	Aimovig			

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
Galcanezumab-gnlm	Emgality	J3490, J3590		pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria (refer to pharmacy benefit)
Calaspargase pegol-mknl	Asparlas	J9118	N/A	Medical necessity review required.
Canakinumab	Ilaris	J0638, 1 mg	300mg for 13 weeks of treatment (can dose every 4 weeks)	Covered for patients 2 years or older with systemic juvenile idiopathic arthritis (sJIA) with active systemic features who have failure, contraindication, or intolerance to NSAIDs, glucocorticoids, anakinra, AND tocilizumab. Max 300 mg per dose. **Note:** Active systemic features include fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, or serositis. Covered for patients 4 years or older with a diagnosis of familial cold auto-inflammatory syndrome (FCAS) or Muckle-Wells syndrome (MWS) who have a confirmed NLRP3 (or CIAS1) mutation. Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.
Caplacizumab-yhdp	Cablivi	C9047	N/A	Treatment of confirmed high risk TTP in conjunction with therapeutic plasma exchange and rituximab.
Capsaicin	Qutenza	J7336	N/A	Medical necessity review required.
Carbidopa and levodopa enteral suspension	Duopa	J7340, 5mg/20mg	N/A	• For patients with a diagnosis of advanced Parkinson's disease AND • Presence of motor fluctuations after trial and failure of oral carbidopa/levodopa in combination with at least two of the following agents from different classes: o Dopamine agonist (e.g., ropinirole, pramipexole) o COMT inhibitor (e.g., entacapone) o MAO inhibitor (e.g., selegiline, rasagiline) o Amantadine • Prescribed by or in consultation with a movement disorders specialist Note: Medication will initially be authorized for 12 weeks. Continuous coverage will be contingent provider or patient attestation of a response to treatment demonstrated by clinical improvement in off time by one hour.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
Carfilzomib	Kyprolis	J9047	N/A	Covered for the treatment of patients with multiple myeloma who have received at least 1 prior therapy including a proteasome inhibitor (e.g., bortezomib, ixazomib) or an immunomodulatory agent (e.g., thalidomide, lenalidomide, pomalidomide) and have demonstrated disease progression according to International Myeloma Working Group (IMWG) criteria. • Must be in combination with dexamethasone
Cemiplimab-rwlc	Libtayo	J9119	N/A	Covered for treatment of patients with metastatic cutaneous squamous cell carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation
Cerliponase alfa	Brineura*	J0567	N/A	Covered for patients with late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), also known as tripeptidyl peptidase 1 (TPP1 deficiency) who meet all of the following: • Prescribed by or in consultation with Pediatric Neurology or Neurology • Documented diagnosis of symptomatic CLN2 with confirmation via either TPP1 deficiency or the detection of pathogenic mutations in each allele of the TPP1 gene (also known as the CLN2 gene) • Age 3 years or older • Ability to walk unassisted for at least 10 steps (may have obvious instability/intermittent falls) Required documentation: • Confirmation that sample CSF was obtained for bacteria culture to detect subclinical device-related infections. Signs and symptoms of infection may not be apparent. Not covered for patients with: • Contraindications to neurosurgery (e.g., congenital heart disease or severe respiratory impairment) • Underlying condition that would make patient prone to complications from using an intraventricular shunt (e.g., hydrocephalus or ventricular shunts) Reassess ambulation every 6 months to determine need for continued therapy. Therapy should be discontinued if member has loss of independent ambulation (defined as unable to ambulate 10 steps or more, with or without use of a walker)
Certolizumab	Cimzia	J0717	6000	• For patients with moderate to severe psoriasis with an inadequate response, contraindication, or intolerance to topical psoriasis treatments AND o at least one formulary anti-TNF agent (e.g., adalimumab [Amjevita], infliximab [Inflectra]), AND o secukinumab AND o two preferred IL-23 or IL-12/IL-23 inhibitors (guselkumab, ustekinumab, risankizumab), AND o at least two of the following*: ▪ 12-week trial of phototherapy ▪ acitretin

<table>
<tr><th>Generic Name</th><th>Brand Name</th><th>J Codes</th><th>Max J code unit per year</th><th>Coverage Criteria</th></tr>
<tr><td></td><td></td><td></td><td></td><td>
methotrexate
*Note: cyclosporine may also be counted towards 1 of the required therapies, but should not be required.

• Patients with moderately to severely active Crohn’s disease with contraindication, intolerance, or loss of response to at least one TNF-inhibitor (infliximab [e.g., Inflectra], adalimumab [e.g., Amjevita]). It is recommended that TNF-inhibitors are used in combination with azathioprine, 6-mercaptopurine, or methotrexate.
• For rheumatoid arthritis patients with failure, contraindication, or intolerance to two formulary anti-TNFs (e.g., adalimumab [Amjevita], infliximab [Inflectra]), abatacept, and one other biologic DMARD.
• For psoriatic arthritis in patients with failure, contraindication, or intolerance to:
o At least one conventional synthetic disease modifying anti-rheumatic drug (csDMARD) (methotrexate preferred), and
o Two of the following biologics (one of which must be adalimumab or infliximab) and:
o adalimumab (e.g., Amjevita)
o infliximab (e.g., Inflectra)
o secukinumab
o etanercept
o Guselkumab, and
o At least one of the following biologic DMARDs (ustekinumab, risankizumab, abatacept)

Note: csDMARD not required for patients with axial disease or severe (rapidly progressive, erosive) disease

• For patients with active ankylosing spondylitis who have failure, contraindication, or intolerance to two formulary anti-TNF agents, and secukinumab.

Not covered for use in combination with disease modifying or other biologic therapies including (but not limited to):
• Infliximab, adalimumab, etanercept, vedolizumab, rituximab, tocilizumab, golimumab, ustekinumab, natalizumab, tofacitinib, upadacitinib, ozanimod, apremilast

Quantity Limits:
<table>
<tr><th>Indication</th><th>Quantity Limit</th></tr>
<tr><td>Psoriasis</td><td>Patients ≤90 kg:
<u>Induction:</u> 400 mg at weeks 0, 2, and 4.
<u>Maintenance:</u> 200 mg every 2 weeks. 400 mg every 2 weeks may be considered after failure</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><th>Generic Name</th><th>Brand Name</th><th>J Codes</th><th>Max J code unit per year</th><th>Coverage Criteria</th></tr>
<tr><td></td><td></td><td></td><td></td><td>
<table>
<tr><td></td><td>of an adherent 3-month trial of 200 mg every 2 weeks.
Patients >90 kg:
<u>Induction and maintenance:</u> 400 mg every 2 weeks.</td></tr>
<tr><td>Crohn’s disease,
Rheumatoid arthritis,
Psoriatic arthritis, and
Ankylosing spondylitis</td><td><u>Induction:</u>
400 mg at weeks 0, 2, and 4.
<u>Maintenance:</u>
400 mg every 4 weeks (400 mg per 28 days).</td></tr>
</table>
</td></tr>
<tr><td>Ciltacabtagene autoleucel</td><td>Carvykti</td><td>C9098,
Q2056</td><td>N/A</td><td>Covered for the treatment of multiple myeloma if used as 4th line and beyond.
• Progression on, or intolerant to, at least 5 drugs with at least 1 from each of the following 3 drug classes, with or without prior transplant.
o Immunomodulatory agents (lenalidomide, pomalidomide)
o Proteasome inhibitors (carfilzomib, bortezomib, ixazomib)
o Anti-CD38 monoclonal antibodies (isatuximab, daratumumab)
• Other regimens, including alkylators and anthracyclines, have been considered.

Not covered for patients with:
• Prior CAR-T therapy or other genetically modified T cell therapy</td></tr>
<tr><td>Cipaglucosidase alfa-atga</td><td>Pombiliti</td><td>J1203</td><td>N/A</td><td>Medical necessity review required.</td></tr>
<tr><td>Collagenase clostridium histolyticum</td><td>Xiaflex</td><td>J0775,
0.01 mg</td><td>N/A</td><td><u>For Dupuytren’s contracture</u>:
• Dupuytren’s contracture with palpable cord with finger flexion contracture of 20° to 100° in a metacarpophalangeal (MP) joint or 20° to 80° in a proximal interphalangeal (PIP) joint, AND
• Administering physician is a member of the American Society for Surgery of the Hand (ASSH) OR administering physician has successfully completed the Subspecialty Certificate in Surgery of the Hand (formerly CAQ Hand) as administered by the American Board of Orthopaedic Surgery (ABOS), the American Board of Plastic Surgery (ABPS), the American Board of Surgery (ABS), or the American Osteopathic Board of Orthopedic Surgery (AOBOS).

<u>For Peyronie’s disease</u>:
• Diagnosis of Peyronie’s disease for greater than or equal to 12 months in patients with stable disease, AND
• Penile curvature of ≥30° and <90°</td></tr>
<tr><td>Copanlisib</td><td>Aliqopa</td><td>J9057</td><td>N/A</td><td>Not covered not medically necessary, due to availability of treatment alternatives</td></tr>
<tr><td>Crizanlizumab-tmca</td><td>Adakveo*</td><td>J0791</td><td>N/A</td><td>Covered for patients with sickle cell anemia or sickle beta thalassemia who meet all of the following:
• Prescribed by or in consultation with a hematology-oncology specialist
• Age ≥16 years old</td></tr>
</table>

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• Diagnosed with sickle cell anemia or sickle beta thalassemia (documented by hemoglobin electrophoresis) • Currently taking maximum tolerated dose of hydroxyurea (35 mg/kg or dose limited by absolute neutrophil count [ANC] ≤1,000/uL or platelets ≤100,000/uL) for at least 3 months, unless history of intolerance or patient declines use due to potential adverse effects • Prior trial of L-glutamine for at least 3 months • Two or more sickle cell pain crises within prior 12 months requiring intervention (hospitalizations, emergency department or urgent care visits) Required documentation: • Number of hospitalizations, emergency department visits, and urgent care visits for vaso-occlusive events (VOE) in the previous 12 months. • Complete blood count (CBC) • PT/INR • ALT and bilirubin • Estimated glomerular filtration rate (eGFR) Reassessment every 12 months to determine need for continued therapy. Therapy should be discontinued if patient meets any one of the following criteria: • No clinically meaningful reduction in frequency of VOEs. • Non-adherence to medication Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.
Cytomegalovirus	Cytogam	J0850	N/A	Covered for prophylaxis of cytomegalovirus (CMV) disease in lung, liver, kidney, pancreas, or heart transplant Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.

Daratumumab	Darzalex	J9145	N/A	Treatment of patients with multiple myeloma who:
				• Have demonstrated disease progression according to International Myeloma Working Group (IMWG) criteria and have received 1 or more prior lines of therapy including either bortezomib or lenalidomide with dexamethasone.
				  ○ Must be in combination with bortezomib or lenalidomide with dexamethasone
				  ○ For patients with contraindication or intolerance to bortezomib or lenalidomide, must be in combination with dexamethasone AND:
				  ▪ An alternate proteasome inhibitor (e.g., carfilzomib, ixazomib) OR
				  ▪ An immunomodulatory agent (e.g., thalidomide, lenalidomide, pomalidomide)
				• Are newly diagnosed and ineligible for autologous stem cell transplant

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				○ Must be used with bortezomib combination or lenalidomide combination therapy
Daratumumab/hyaluronidase-fihj	Darzalex Faspro	J9144	N/A	Covered for patients with Multiple Myeloma if all the following apply: • Given as monthly maintenance therapy. • After completion of 6-month titration with a CD38 IV drug. (Proactive authorization can be given after at least 3 months demonstration of IV titration therapy).
Darbepoetin	Aranesp	J0881, J0882, 1 mcg	N/A	**Epoetin alpha is the preferred agent.** Darbepoetin will be covered when a clinical rationale is provided describing why epoetin alfa cannot be used OR patient is on hemodialysis **Covered for patients on hemodialysis** **End stage renal disease (ESRD) or chronic kidney disease of at least stage 3 (eGFR < 60 mL/min) not on hemodialysis** • Hb ≤ 10g/dL within 30 days • TSAT ≥ 20%, unless ferritin >500, then may be approved with TSAT <20%*. • B12 and folate not deficient. • Patient does not have ongoing bleeding disorders or hemolysis. **Chemotherapy-induced anemia. Patients currently receiving a course of chemotherapy or have received a course within the past 2 months for non-myeloid, non-erythroid cancer (e.g., solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia).** • Hb ≤ 10g/dL or Hb 10-11 within 7 days and clinical risk of anemia warrants earlier initiation. • TSAT ≥ 20%, unless ferritin >500, then may be approved with TSAT <20%*. • B12 and folate not deficient. • Patient does not have ongoing bleeding disorders or hemolysis. • Patient does not have metastatic breast cancer or head and neck cancer. **Myelodysplastic syndrome (MDS); chronic hepatitis C (under treatment with ribavirin and either interferon alfa or peginterferon alfa); systemic lupus erythematosus; or patient taking chemotherapeutic medications when medically necessary for non-cancer diagnosis or following stem cell transplantation and associated immunosuppression.** • Hb < 10g/dL within 7 days. • TSAT ≥ 20%, unless ferritin >500, then may be approved with TSAT <20%*. • B12 and folate not deficient. • Patient does not have ongoing bleeding disorders or hemolysis. • Symptomatic anemia (fatigue, SOB). *TSAT (Transferrin saturation) measured as a percentage, is the ratio of serum iron and total iron-binding capacity, multiplied by 100.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				*CMS regulations allow for measurement of either hemoglobin or hematocrit using the conversion of hematocrit = 3x hemoglobin (e.g., Hct 30% = Hb 10).
Daunorubicin/cytarabine	Vyxeos	J9153	N/A	Medical necessity review required.
DaxibotulinumtoxinA-lanm	Daxxify	C9160, J0589	N/A	Medical necessity review required.
Degarelix	Firmagon	J9155, 1 mg	1280	Covered for the maintenance treatment of advanced prostate cancer in patients who have an intolerance to leuprolide.* Covered for a single dose to prevent clinical flare associated with initiation of hormone therapy in patients with advanced prostate cancer. *Hot flashes and local injection site reactions are not considered an intolerance to leuprolide
Delandistrogene moxeparvovec-rokl	Elevidys*	J1413	N/A	Covered for patients with Duchenne muscular dystrophy (DMD) who meet ALL of the following: • Prescribed by or in consultation with pediatric neurology, neurology, physical medicine & rehabilitation, or genetics • Diagnosis of DMD is based on clinical findings and prior genetic testing • Patient is a male and aged 4 through 5 years old • Anti-AAVrh74 total binding antibody titers are less than 1:400 (within 1 month prior to gene therapy administration) • If patient is currently receiving exon skipping medication, must discontinue exon skipping therapy before receiving gene therapy one week before initiation Baseline required assessment and labs: • Echocardiogram • Hepatitis B, Hepatitis C • Human immunodeficiency virus (HIV) antibody • CBC with differential • GGT, ALT, AST • Total bilirubin • Troponin-I Not covered for patients who are/have: • Non-ambulatory; or • Any deletion in exon 8 and/or exon 9 in the DMD gene; or • Active viral infection based on clinical observations; or • Severe infection (e.g., pneumonia, pyelonephritis, or meningitis) within 4 weeks before gene transfer date; or

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• Signs of cardiomyopathy; or • Serological evidence of HIV, Hepatitis B, or Hepatitis C infection • Abnormal laboratory values considered clinically significant (GGT >3 times upper limit of normal [ULN], bilirubin ≥3 mg/dL, creatinine ≥1.8 mg/dL, Hgb <8 or >18 g/dL; WBC >18,500/μL); or • Exposure to other DMD gene therapy; or • Unwilling to be on a steroid regimen Authorization duration: limited to a one-time (single infusion) treatment Note: Prior to treatment initiation, all patients should be reviewed by an Interregional Consultative Physician Panel.
Denosumab	Prolia	J0897, 1 mg	120	For the treatment of osteoporosis*: 1) Patient has a contraindication to bisphosphonate; **or** 2) In patients who: a) Experienced non-GI intolerance to oral bisphosphonate; *Note: if there is malabsorption or non-compliance with the medication consider switching to IV bisphosphonate* **or** b) Experienced significant decrease in DEXA bone density after 5 years of treatment on oral bisphosphonate; **or** c) Had an osteoporotic fracture (other than atypical femur fracture) and fracture resulting from a low degree of trauma (e.g., from sitting or standing height) and decrease in DEXA bone density after having been on oral bisphosphonate for at least 2 years OR 3) In patients who: a) Experienced intolerance to the IV bisphosphonate; **or** b) Experienced significant decrease in DEXA bone density after 5 years of treatment on IV bisphosphonate; **or** c) Had an osteoporotic fracture (fracture resulting from a low degree of trauma, e.g., from sitting or standing height) and decrease in DEXA bone density after having been on IV bisphosphonate for at least 2 years. 4) For osteoporosis* in patients who have completed a full bisphosphonate therapy (IV and oral) and deemed inappropriate to use more of this class in their lifetime. **Note: Osteoporosis is defined as:* *a) History of fracture from low impact injury (including any vertebral compression fracture which reduces vertebra height by 20% compared to neighboring vertebrae, but excluding finger, toe, or head)* ***or*** *b) Femoral neck, total hip, or lumbar spine BMD T score of -2.5 or lower.*

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				For treatment of patients receiving Androgen Deprivation Therapy (ADT) for prostate cancer **or** receiving adjuvant aromatase inhibitor (AI) therapy for non-metastatic breast cancer who a) Have a T-score < -1.0 in the lumbar spine, total hip or femoral neck or a history of osteoporotic fracture. AND b) Experienced non-GI intolerance to oral bisphosphonate or intolerance to IV bisphosphonate; **or** c) Experienced significant decrease in DEXA bone density after 5 years of treatment on oral or IV bisphosphonate; **or** d) Had an osteoporotic fracture (fracture resulting from a low degree of trauma, e.g., from sitting or standing height) and decrease in DEXA bone density after having been on oral or IV bisphosphonate for at least 2 years. Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change. Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.
Denosumab	Xgeva	J0897, 1 mg	1560 mg	• Prevention of skeletal-related events (SREs) in patients with metastatic solid tumors who are intolerant to IV bisphosphonate. ○ Not covered for patients who have osteonecrosis of the jaw or who have renal dysfunction (CrCl < 30 ml/min). • Adults and skeletally mature adolescents with giant cell tumor of the bone that is unresectable or where surgical resection is likely to result in severe morbidity. • Prevention of SREs in patients with bone related disease of multiple myeloma with intolerance to IV bisphosphonate. Note: Must be administered in a non-hospital setting when used as monotherapy. See site of care policy for criteria, reauthorization, and exceptions for new starts. Site of Care Exceptions: 2 doses within 2 months.
Difelikefalin acetate	Korsuva	J0879	N/A	Covered for the treatment of moderate-to-severe pruritus associated with chronic kidney disease (CKD) in adults undergoing hemodialysis who have symptoms despite trials of all below: • Optimization of dialysis regimen (frequency and/or duration) for at least 3 months • Correction of parathyroid, calcium, and phosphate abnormalities for at least 3 months

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• Trial of topical emollients/analgesics (e.g., topical capsaicin) for at least 1 month • Trial of non-sedating oral antihistamines for at least 1 month, AND • Trial of oral gabapentin or pregabalin for at least 1 month Exclusion criteria: • Hyperkalemia • Missing 2 or more dialysis treatments per month • Opioid allergy Must be prescribed by a Nephrology specialist Initial authorization: 3 months Reauthorization: reassessment every 3 months to confirm clinical benefit including disease stability or improvement in symptoms.
Dostarlimab-gxly	Jemperli	C9082, J9272	N/A	Covered for the treatment of patients with locally advanced rectal cancer who are dMMR. **Quantity limit:** Limit to 9 cycles
Dupilumab	Dupixent	Unspecified C9399, J3490, J3590	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria (refer to pharmacy benefit)
Durvalumab	Imfinzi	J9173	N/A	Not covered not medically necessary for urothelial carcinoma Covered for the treatment of Unresectable or Metastatic Biliary Tract Cancer in the first line setting, if combined with Cisplatin and Gemcitabine, AND contraindicated or intolerant to Pembrolizumab. Covered for treatment of advanced HCC: • If combined with Tremelimumab, AND • Child Pugh A AND • Immunotherapy naïve Treatment of patients with NSCLC if all the following apply: • If EGFR/ALK negative

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• Consolidation therapy for patients with unresectable stage III disease, ECOG performance status of 0-1 • Treatment not to exceed 12 months • Start of durvalumab consolidation therapy must not exceed 42 days after completing chemo radiotherapy
Ecallantide	Kalbitor	J1290, 1 mg	N/A	• For acute treatment of patients with an established diagnosis of type 1 or type 2 hereditary angioedema (HAE); AND • Prescribed by an allergy specialist or emergency medicine provider Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.
Eculizumab	Soliris	J1300	N/A	Covered for patients with neuromyelitis optica spectrum disorder (NMOSD) who meet the following criteria: • Prescribed by or in consultation with a Multiple sclerosis specialist or Neurologist • Age ≥18 years • AQP4 antibody seropositive • Either of the following: o Severe breakthrough relapse while on rituximab (e.g., Riabni) for at least 6 months not attributed to rapid steroid discontinuation. Examples of severe breakthrough relapse include: ▪ hospitalization for neurological deficits from NMOSD relapse (e.g., quadriparesis or paraparesis) ▪ optic neuritis severity (hand motion only or worse) confirmed by an ophthalmologist o Recurrent moderate breakthrough relapses after 6 month trial of rituximab (e.g., Riabni) in combination with maximum tolerated doses of either mycophenolate mofetil or azathioprine. • Required documentation: o Complete blood count with differential o Meningococcal vaccination status o AQP4 antibody test • Initial authorization: 6 months • Reauthorization: reassessment every 12 months to confirm clinical benefit including disease stability or improvement in symptoms. Note: may consider treatment with tocilizumab prior to eculizumab. Covered for patients with atypical hemolytic uremic syndrome (aHUS) who meet all of the following: • Diagnoses confirmed by or in consultation with a nephrologist or hematologist. • Causes of typical hemolytic uremic syndrome (HUS) have been ruled out including:

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				○ Infectious causes including Shiga toxin-related HUS AND ○ Thrombotic thrombocytopenic purpura (TTP) [confirmed by a disintegrin and metalloprotease with thrombospondin type 1 motif, 13 (ADAMTS13) activity ≥10%]. • Initial authorization: 6 months • Reauthorization: reassessment every 12 months to confirm clinical benefit including disease stability or improvement in symptoms. Covered for patients with paroxysmal nocturnal hemoglobinuria (PNH) who meet all of the following: • Diagnoses confirmed by high sensitivity flow cytometry and established by or in consultation with a hematology specialist. • Failure, intolerance, or contraindication to ravulizumab-cwvz (Ultomiris) • Patient meets one of the following: ○ Transfusion-dependent** OR ○ History of major adverse vascular event from thromboembolism. • Initial authorization: 6 months • Reauthorization: reassessment every 12 months to confirm clinical benefit including disease stability or improvement in symptoms. ***Transfusion-dependence defined as hemoglobin less than 7 g/dL OR hemoglobin less than or equal to 9 g/dL and patients is experiencing symptoms from anemia requiring transfusion.* Covered for adult patients with generalized myasthenia gravis (MG) who meet all of the following: • Positive serologic test for anti-acetylcholine receptor (AChR) antibodies • Myasthenia Gravis Activities of Daily Living (MG-ADL) score ≥5 • Adequate trial of a corticosteroid • Inadequate response to at least two of the following medications ○ azathioprine, 2 mg/kg daily, for at least 9-12 months ○ rituximab, for at least 12 months ○ other disease modifying therapy (e.g., cyclophosphamide, mycophenolate mofetil, cyclosporine, methotrexate), for at least 9-12 months. • Dependent on chronic intravenous immunoglobulin (IVIG) or chronic plasma exchange (PLEX) • Prescribed by or in consultation with a neurology specialist Not covered for patients who have:

<table>
<tr><th>Generic Name</th><th>Brand Name</th><th>J Codes</th><th>Max J code unit per year</th><th>Coverage Criteria</th></tr>
<tr><td></td><td></td><td></td><td></td><td>
Anti-muscle-specific receptor tyrosine kinase (MuSK) or anti-low-density lipoprotein receptor related protein (LRP4) antibody positive MG, seronegative MG, or ocular MG (seropositive or seronegative)
Initial authorization: 12 months

Reauthorization: reassessment every 12 months to confirm clinical benefit including disease stability (e.g., documentation of no disease progression).

Other indications:
Medical necessity review required
Initial authorization: 6 months
Reauthorization: reassessment every 12 months to confirm clinical benefit including disease stability or improvement in symptoms.
<table>
<tr><th>Indication</th><th>Max Dose and Frequency</th></tr>
<tr><td>PNH</td><td>Induction: 600 mg weekly for first 4 weeks, then 900 mg for fifth dose 1 week later
Maintenance dose: 900 mg every 2 weeks</td></tr>
<tr><td>aHUS</td><td rowspan="3">Induction: 900 mg weekly for first 4 weeks, then 1200 mg for fifth dose 1 week later
Maintenance dose: 1200 mg every 2 weeks</td></tr>
<tr><td>Myasthenia Gravis</td></tr>
<tr><td>NMOSD</td></tr>
</table>
Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.

Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change.
</td></tr>
<tr><td>Edaravone</td><td>Radicava*</td><td>J1301</td><td>N/A</td><td>
Covered for patients with Amyotrophic lateral sclerosis (ALS) who meet the following:
Clinical ALS diagnosed by a neurologist
ALS Functional Rating Scale–Revised (ALSFRS-R) score of 2 points or better on each of the 12 items within past two months
Duration of 2 years or less from onset of first symptom
Forced vital capacity (%FVC) ≥ 80% within past two months
Exclusion criteria:
Score of ≤ 3 on ALSFRS-R for dyspnea, orthopnea, or respiratory insufficiency
</td></tr>
</table>

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				Reauthorization required every 6 months. Coverage will not continue to be authorized if patient meets any of the following criteria: • Non-adherence to follow-up assessments • Patient is requiring a tracheotomy or non-invasive ventilation all day • %FVC ≤50% and blood gas PaCO2 >45 mmHg • Significant clinical decline based on ALSFRS-R and/or %FVC status • Patient is requiring hospice care Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.

Efgartigimod alfa-fcab	Vyvgart	J9332	N/A	Covered for adult patients with generalized myasthenia gravis (MG) who meet all of the following:
				• Positive serologic test for anti-acetylcholine receptor (AChR) antibodies
				• Myasthenia Gravis Activities of Daily Living (MG-ADL) score ≥5
				• Adequate trial of a corticosteroid
				• Inadequate response to at least two of the following medications
				  ○ azathioprine, 2 mg/kg daily, for at least 9-12 months
				  ○ rituximab, for at least 12 months
				  ○ other disease modifying therapy (e.g., cyclophosphamide, mycophenolate mofetil, cyclosporine, methotrexate), for at least 9-12 months.
				• Dependent on chronic intravenous immunoglobulin (IVIG) or chronic plasma exchange (PLEX)
				• Prescribed by or in consultation with a neurology specialist
				
				Not covered for patients who have:
				• Anti-muscle-specific receptor tyrosine kinase (MuSK) or anti-low-density lipoprotein receptor related protein (LRP4) antibody positive MG, seronegative MG, or ocular MG (seropositive or seronegative)
				• Low immunoglobulin G (IgG) serum levels < 6 g/L
				
				Initial authorization: 12 months
				
				Reauthorization: reassessment every 12 months to confirm clinical benefit including disease stability (e.g., documentation of no disease progression).

Efgartigimod alfa-hyaluronidase-qvfc	Vyvgart Hytrulo	J9334	N/A	Medical necessity review required.
Eflapegrastim-xnst	Rolvedon	J1449	N/A	Medical necessity review required.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
Elapegademase-lvlr	Revcovi	Unspecified J3490, J3590	N/A	Medical necessity review required. Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.

Elivaldogene autotemcel	Skysona*	Unspecified J3490, J3590	N/A	Covered for the treatment of early, active cerebral adrenoleukodystrophy (CALD) when all of the following are met:
				• Prescribed by or in consultation with Pediatric Neurology or Pediatric Hematology/Oncology Specialists
				• Patient is a male aged 4 to 17 years old
				• Diagnosis of active CALD as defined by:
				  ○ Elevated very long chain fatty acids (VLCFA) values; and
				  ○ Active central nervous system (CNS) disease established by central radiographic review of brain MRI demonstrating:
				  ▪ Loes score between 0.5 and 9 (inclusive) on the 34-point scale; and
				  ▪ Gadolinium enhancement on MRI of demyelinating lesions
				• Neurologic function score (NFS) less than or equal to 1
				
				Exclusion criteria:
				• Advanced disease (as evidenced by rapidly changing Loes score and/or NFS greater than 1)
				• Previous recipient of BMT
				• Patient is not able to tolerate BMT (or has any condition that disqualifies them from BMT)
				
				Required baseline assessment and labs:
				• Confirmed adrenal function with stress dose of steroids
				• Human leukocyte antigen (HLA) typing
				• Neuropsychological evaluation to assess neurocognitive function, neuropsychiatric function, and/or intelligence quotient (IQ)
				• Baseline organ function per BMT
				• Endocrine testing: morning (AM) cortisol, adrenocorticotropic hormone (ACTH), ACTH stimulation test.
				
				Authorization duration: limited to a one-time single infusion therapy
				
				Note: Prior to treatment with elivaldogene autotemcel, review by an Inter-regional Consultative Physician Panel is required.

Elosulfase Alfa	Vimizim	J1322	N/A	Not covered due to lack of evidence for sustained improvement of endurance and safety concerns. Medical necessity review required. Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
Elotuzumab	Empliciti	J9176	N/A	Covered in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received 2 prior therapies and have demonstrated disease progression according to International Myeloma Working Group (IMWG) criteria.
Elranatamab-bcmm	Elrexfio	C9165, J1323	N/A	Medical necessity review required.
Emapalumab-lzsg	Gamifant	J9210	N/A	Medical necessity review required.
Emicizumab-kxwh	Hemlibra*	J7170	N/A	Covered for patients with hemophilia A (congenital factor VIII deficiency) who meet all of the following: • Prescribed by a hematology-oncology specialist (consultation with a regional hemophilia expert is recommended) • Documentation of severe hemophilia A requiring prophylaxis (frequent bleeding or higher risk for frequent bleeding, regardless of FVIII level) with or without factor VIII inhibitors ○ For patients with documented history of clinically significant factor VIII inhibitors: ▪ Documentation that member is nonresponsive to prior trial with first-line therapy of immune tolerance induction (ITI), or is not a candidate for ITI (e.g., cannot undergo central line placement), or requires prophylaxis while on ITI therapy Reassessment every 12 months to confirm clinical benefit (e.g., decrease in bleed rates from baseline) Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Pharmacy Network. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change.
Enfortumab vedotin-ejfv	Padcev	J9177	N/A	Covered for treatment of Metastatic urothelial carcinoma: • As fist line therapy if combined with pembrolizumab OR • As monotherapy after progression on platinum or immunotherapy.
Epcoritamab-bysp	Epkinly	C9155, J9321	N/A	Medical necessity review required.
Eplontersen sodium	Wainua*	Unspecified J3490, J3590	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria (refer to pharmacy benefit)
Epoetin alfa	Epogen, Procrit	J0885, 1000 Units Q4081	N/A	Covered for patients on hemodialysis End-stage renal disease (ESRD) or chronic kidney disease of at least stage 3 (eGFR < 60 mL/min) not on hemodialysis • Hb ≤ 10 g/dL within 30 days • TSAT ≥ 20%, unless ferritin >500, then may be approved with TSAT <20%*. • B12 and folate not deficient. • Patient does not have ongoing bleeding disorders or hemolysis. Chemotherapy-induced anemia. Patients currently receiving a course of chemotherapy or have received a course within the past 2 months for non-myeloid, non-erythroid cancer (e.g., solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia). • Hb ≤ 10g/dL or Hb 10-11 within 7 days and clinical risk of anemia warrants earlier initiation. • TSAT ≥ 20%, unless ferritin >500, then may be approved with TSAT <20%*. • B12 and folate not deficient. • Patient does not have ongoing bleeding disorders or hemolysis. • Patient does not have metastatic breast cancer or head and neck cancer. Myelodysplastic syndrome (MDS); chronic hepatitis C (under treatment with ribavirin and either interferon alfa or peginterferon alfa); systemic lupus erythematosus; or patient taking chemotherapeutic medications when medically necessary for non-cancer diagnosis or following stem cell transplantation and associated immunosuppression. • Hb < 10 g/dL within 7 days. • TSAT ≥ 20%, unless ferritin >500, then may be approved with TSAT <20%*. • B12 and folate not deficient. • Patient does not have ongoing bleeding disorders or hemolysis. • Symptomatic anemia (fatigue, SOB). *TSAT (Transferrin saturation) measured as a percentage, is the ratio of serum iron and total iron-binding capacity, multiplied by 100. *CMS regulations allow for measurement of either hemoglobin or hematocrit using the conversion of hematocrit = 3x hemoglobin (e.g., Hct 30% = Hb 10).

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				Covered for patients with myeloproliferative disorders (e.g., primary myelofibrosis (MF), post-polycythemia vera myelofibrosis (PPV-MF) or post-essential thrombocythemia myelofibrosis (PET-MF) who have symptomatic disease related Anemia, AND Serum EPO < 500 mU/mL
Epoetin alfa-epbx	Retacrit	Q5105, Q5106	N/A	Covered for patients on hemodialysis End-stage renal disease (ESRD) or chronic kidney disease of at least stage 3 (eGFR < 60 mL/min) not on hemodialysis • Hb ≤ 10 g/dL within 30 days • TSAT ≥ 20%, unless ferritin >500, then may be approved with TSAT <20%*. • B12 and folate not deficient. • Patient does not have ongoing bleeding disorders or hemolysis. Chemotherapy-induced anemia. Patients currently receiving a course of chemotherapy or have received a course within the past 2 months for non-myeloid, non-erythroid cancer (e.g., solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia). • Hb ≤ 10 g/dL or Hb 10-11 within 7 days and clinical risk of anemia warrants earlier initiation. • TSAT ≥ 20%, unless ferritin >500, then may be approved with TSAT <20%*. • B12 and folate not deficient. • Patient does not have ongoing bleeding disorders or hemolysis. • Patient does not have metastatic breast cancer or head and neck cancer. Myelodysplastic syndrome (MDS); chronic hepatitis C (under treatment with ribavirin and either interferon alfa or peginterferon alfa); systemic lupus erythematosus; or patient taking chemotherapeutic medications when medically necessary for non-cancer diagnosis or following stem cell transplantation and associated immunosuppression. • Hb < 10 g/dL within 7 days. • TSAT ≥ 20%, unless ferritin >500, then may be approved with TSAT <20%*. • B12 and folate not deficient. • Patient does not have ongoing bleeding disorders or hemolysis. • Symptomatic anemia (fatigue, SOB). *TSAT (Transferrin saturation) measured as a percentage, is the ratio of serum iron and total iron-binding capacity, multiplied by 100. *CMS regulations allow for measurement of either hemoglobin or hematocrit using the conversion of hematocrit = 3x hemoglobin (e.g., Hct 30% = Hb 10). Covered for patients with myeloproliferative disorders (e.g., primary myelofibrosis (MF), post-polycythemia vera myelofibrosis (PPV-MF) or post-essential thrombocythemia myelofibrosis (PET-MF) who have symptomatic disease related Anemia, AND Serum EPO < 500 mU/mL

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
Epoprostenol	Flolan, Veletri	J1325, 0.5 mg	N/A	Covered for patients: • With pulmonary arterial hypertension (WHO Group 1) as confirmed by right heart catheterization in WHO functional class III and IV; **and** • When prescribed by or in consultation with a cardiologist or pulmonologist
Eptinezumab-jjmr	Vyepti	J3032	N/A	Covered for patients with chronic migraine or episodic migraines who meet all of the following: • Prescribed by or in consultation with a neurology specialist • Adult patients (at least 18 years old) • Failure, contraindication, or intolerance to fremanezumab-vfrm (Ajovy) and galcanezumab-gnlm (Emgality). • Documentation of an adequate trial of 3 formulary preferred preventative agents, 2 of which must be from the following list (minimum of 2 classes required): ▪ tricyclic antidepressants (e.g., nortriptyline, amitriptyline) ▪ beta blockers (e.g., propranolol, metoprolol) ▪ topiramate, ▪ divalproex or valproate. ○ An adequate trial is defined as at least 2 months of a maximally tolerated dose, or documented intolerance or contraindication. • Chart notes documenting migraine frequency, severity, and characteristics (e.g., headache diary, Migraine Disability Assessment [MIDAS] score) • Documented assessment to exclude medication-overuse headaches based on International Headache Society Classification ICHD-3 (use of triptans, ergotamine, opioids or any combination of these agents for 10 or more days/month for more than 3 months; non-opioid analgesic use for 15 or more days/month for more than 3 months) Not covered for patients with: • Concomitant use with botulinum toxin for the treatment of migraine or small molecule CGRP receptor antagonists (e.g., ubrogepant, or rimegepant). • Concomitant use with other monoclonal CGRP inhibitors (e.g., fremanezumab-vfrm [Ajovy], galcanezumab-gnlm [Emgality], or erenumab-aooe [Aimovig]). Initial authorization: 6 months. Reauthorization contingent upon documented response to therapy defined as 30% or more reduction in headache days per month OR 50% or more improvement in MIDAS score Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
Eribulin	Halaven	J9179, 0.1 mg	N/A	• For the treatment of metastatic or recurrent breast cancer in patients who have previously received at least 3 chemotherapy regimens, including an anthracycline and a taxane containing regimen. • Treatment of patients with unresectable or metastatic liposarcoma and ECOG 0-1, as subsequent therapy after a prior anthracycline-containing regimen.
Esketamine	Spravato*	J3490, S0013, G2082, G2083	N/A	Covered for adult patients with treatment-resistant depression, in conjunction with an oral antidepressant, who meet all of the following: • Prescribed by or in consultation with a psychiatrist. • Age ≥18 years old • Diagnosis of major depressive disorder (MDD), severe, without psychotic features • Inadequate response to at least 2 antidepressant medications in at least 2 different classes including: SSRIs, SNRIs, atypical antidepressants, MAOIs and/or TCAs at adequate dose and duration for treatment of MDD • Patient did not respond to, inappropriate for, or declined a trial of repetitive transcranial magnetic stimulation (rTMS) and electroconvulsive therapy (ECT) Required documentation: • Patient Health Questionnaire-9 (PHQ-9) score of 20 or greater • Negative urine drug screen prior to treatment initiation Not covered for patients with: • History of psychosis • History of dissociation • Unstable angina or history of myocardial infarction • Uncontrolled hypertension • Increased intracranial pressure • Increased intraocular pressure • Active substance or alcohol abuse • Use of cannabinoids, cannabis, or cannabis derivatives • Positive test result(s) for drugs of abuse • Severe hepatic impairment (Child-Pugh Class C) or on renal dialysis • Women who are pregnant or breast-feeding • Contraindication to esketamine use (aneurysmal vascular disease, arteriovenous malformation, history of intracerebral hemorrhage, or hypersensitivity to esketamine, ketamine, or any of the excipients) Reauthorization required every 6 months. Coverage will not continue to be authorized if patient meets any of the following criteria: • Worsening depression or poor response to esketamine treatment (e.g., unsustained response) • Non-adherence or intolerance to esketamine • Non-adherence to medical treatment plan and/or follow-up assessments • Positive urine drug screen, if ordered by prescriber

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• Pregnancy is diagnosed or patient is breastfeeding **Quantity Limits:** • Induction: Up to 12 dose kits (56 mg or 84 mg per dose kit) for first 8 weeks • Maintenance: Up to 4 dose kits (56 mg or 84 mg per dose kit) every 28 days.
Etanercept	Enbrel, Enbrel Mini	J1438, 25 mg	128	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria below 1) For patients with rheumatoid arthritis with failure, contraindication, or intolerance to methotrexate. 2) For patients ≥ 2 years old with juvenile idiopathic arthritis who have failure, contraindication, or intolerance to methotrexate. 3) For psoriatic arthritis patients with failure, contraindication, or intolerance to: a) at least one conventional synthetic disease modifying anti-rheumatic drug (csDMARD) (methotrexate preferred) AND b) adalimumab (e.g., Amjevita) OR infliximab (e.g., Inflectra) Note: csDMARD not required for patients with axial disease or severe (rapidly progressive, erosive) disease 4) For treatment of active ankylosing spondylitis. 5) For adult patients with moderate to severe psoriasis with an inadequate response, contraindication, or intolerance to topical psoriasis treatments AND a) adalimumab (e.g., Amjevita) OR infliximab (e.g., Inflectra) AND b) secukinumab AND c) at least two of the following*: i) 12-week trial of phototherapy ii) acitretin iii) methotrexate *Note: cyclosporine may also be counted towards 1 of the required therapies, but should not be required.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				6) For treatment of moderate to severe psoriasis in pediatric patients 17 years of age or younger who have contraindication or inadequate response to the following: a) topical psoriasis treatment and b) methotrexate or a 12-week trial of phototherapy Not covered for use in combination with disease modifying or other biologic therapies including (but not limited to): • infliximab, adalimumab, vedolizumab, rituximab, certolizumab, tocilizumab, golimumab, ustekinumab, natalizumab, tofacitinib, upadacitinib, ozanimod, apremilast **Quantity Limits:** • RA/AS/PsA—50 mg every week **or** 2 x 25 mg given the same day or 3-4 days apart every week. • Psoriasis—50 mg twice weekly x 3 months, then 50 mg per week. • JIA—0.8 mg/kg per week (max 50 mg/week).
Etelcalcetide	Parsabiv	J0606	N/A	Chronic kidney disease (CKD) patients with secondary hyperparathyroidism must meet the following criteria: • 18 years or older • Moderate-to-severe hyperparathyroidism with PTH ≥400 pg/mL despite use of a vitamin D analog and a phosphate binder • Receiving hemodialysis at least three times weekly • Trial and failure or intolerance, or non-adherence of cinacalcet with discontinuation of cinacalcet at least 7 days prior to starting etelcalcetide
Eteplirsen	Exondys 51*	J1428	N/A	Covered for patients with Duchenne muscular dystrophy who meet ALL of the following: • Prescribed by or in consultation with pediatric neurology, adult neurology or Physical Medicine & Rehabilitation • Documented deletion/mutation amenable to exon 51 skipping (must be confirmed by a geneticist) • At least 4 years old • Ambulatory without wheelchair dependency (cane or walker use acceptable) • Documented minimum distance for unassisted 6-minute walk test (6MWT) of 180 meters at baseline • Must be on a stable dose of glucocorticoid for at least 6 months • Forced Vital Capacity % (FVC%) greater than or equal to 50% predicted Not covered for patients who:

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• Are non-ambulatory • Are ambulatory with some level of wheelchair dependency • Require nocturnal ventilation (including BiPAP), but excluding CPAP • Prior or planned treatment with gene therapy for Duchenne muscular dystrophy Reassessment every 12 months to determine need for continued therapy. Patient must meet ALL of the following functional criteria for continued coverage: • Ambulation test: Greater than limited home level (e.g., home, limited community, or community independent) • Sit to stand test: Moderate assist or Independent • No ventilator support (excluding use of nocturnal CPAP) **Note:** Prior to treatment initiation, all patients should be reviewed by an Interregional Consultative Physician Panel. Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts. Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change.
Etranacogene dezaparvovec-drlb	Hemgenix*	J1411	N/A	Covered for the treatment of adults with hemophilia B who meet all of the following: • Prescribed by a hematologist • Patient is male aged 18 years or older • Diagnosis of congenital Hemophilia B classified as severe or moderately severe • Currently on factor IX prophylaxis • Documentation of more than 150 previous exposure days of treatment with factor IX protein • Documentation of current or historical life-threatening hemorrhage • Documentation of repeated, serious spontaneous bleeding episodes • Documentation of negative factor IX inhibitor test Not covered if patient meets any of the following: • History of inhibitors to factor IX therapy or positive factor IX inhibitor test • Prior treatment with any gene therapy for hemophilia B • CKD Stage 3 or greater Authorization duration: limited to a one-time singe infusion therapy

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				Note: Prior to treatment with Etranacogene dezaparvovec-drlb, review by an Inter-regional Consultative Physician Panel is required.

Evinacumab-dgnb	Evkeeza	J1305		Covered for patients who meet all of the following:
				• Documented diagnosis of homozygous familial hypercholesterolemia (HoFH)
				• Prescribed by or in consultation with a lipid specialist with experience in treating HoFH
				• Patient is ≥ 12 years old
				• Patient has failed to meet LDL target despite 80% adherence or intolerance to all of the following:
				  ○ Maximally tolerated statin
				  ○ Ezetimibe
				  ○ PCSK9 inhibitor
				
				Note: adherence defined as greater than 80% of proportion of days covered (calculated by day supply dispensed over the total number of days since treatment was initiated).
				
				Initial authorization: 12 months
				
				Reauthorization:
				• Patient is currently receiving concomitant antihyperlipidemic agents
				• Patient has achieved and maintained an LDL-C reduction
				
				Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.

Evolocumab	Repatha	Unspecified J3490, J3590	N/A	Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit.
				• Exception criteria may be considered for the following:
				  ○ Patients with impaired manual dexterity, impaired vision, or patients who are unable to use prefilled syringe safely
				  AND
				• Patient meets clinical criteria below
				
				Primary hyperlipidemia including heterozygous familial hypercholesterolemia (HeFH):
				• The patient is at least 10 years of age.
				• The patient has at least a probable diagnosis of HeFH based on a validated diagnostic tool (Simon Broome, Dutch Lipid Clinic Network, MEDPED)
				• The patient failed to achieve an LDL-C<100 mg/dL and meets one of the following:

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				○ Currently 90% adherent to maximally tolerated high-intensity statin therapy (i.e., atorvastatin 80 mg/20 mg in children or rosuvastatin 40/20 mg in children mg) in combination with ezetimibe for at least 8 weeks ○ The patient has a documented contraindication to statin and ezetimibe therapy ○ The patient has a documented intolerance to statin therapy, as defined by the National Lipid Association (NLA) • Maximally tolerated statin therapy is continued while receiving evolocumab therapy (unless not tolerated or contraindicated) Homozygous familial hypercholesterolemia (HoFH): • The patient is at least 10 years of age • The patient has a diagnosis of HoFH based on genetic testing or untreated LDL-C >300 mg/dL with documentation of cutaneous or tendon xanthomas before age 10 or evidence of HeFH in both parents • The patient failed to achieve an LDL-C<100 mg/dL or less than 50% reduction in LDL and meets one of the following: ○ Currently 90% adherent to maximally tolerated high-intensity statin therapy (i.e., atorvastatin 80 mg or rosuvastatin 40 mg) in combination with ezetimibe for at least 8 weeks. ○ The patient has a documented contraindication to statin and ezetimibe therapy ○ The patient has a documented intolerance to statin therapy, as defined by the National Lipid Association (NLA) • Maximally tolerated statin therapy is continued while receiving evolocumab therapy (unless not tolerated or contraindicated) Clinical atherosclerotic cardiovascular disease (ASCVD): • The patient is at least 18 years of age • The patient has a diagnosis of clinical ASCVD evidenced of at least one of the following conditions: ○ Coronary heart disease (CHD), such as myocardial infarction (MI), angina, or prior CABG or PCI ○ Cerebrovascular disease, such as transient ischemic attack (TIA), ischemic stroke, or prior CEA or carotid stenting ○ Peripheral artery disease, such as claudication • The patient failed to achieve an LDL-C<70 mg/dL and meets one of the following: ○ Currently 90% adherent to maximally tolerated high-intensity statin therapy (i.e., atorvastatin 80 mg or rosuvastatin 40 mg) in combination with ezetimibe for at least 8 weeks. ○ The patient has a documented contraindication to statin and ezetimibe therapy ○ The patient has a documented intolerance to statin therapy, as defined by the National Lipid Association (NLA)

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• Maximally tolerated statin therapy is continued while receiving evolocumab therapy (unless not tolerated or contraindicated)
Exagamglogene autotemcel	Casgevy*	Unspecified C9399, J3490, J3590	N/A	**Sickle Cell Disease:** Covered for the treatment of patients with Sickle Cell Disease (SCD) when all of the following are met: • Prescribed by or in consultation with Hematology or Sickle Cell Disease Specialists • Patient is between 12 and 25 years old • Patient has severe SCD (defined as ≥2 of the following events per year during the two year period before treatment initiation): o Acute pain requiring medical facility visit and administration of pain medications (opioids or IV non-steroidal anti-inflammatory drugs [NSAIDs]) or RBC transfusions o Acute chest syndrome, as indicated by the presence of a new pulmonary infiltrate associated with pneumonia-like symptoms, pain, or fever o Priapism lasting >2 hours o Splenic sequestration • Karnofsky performance status of ≥80% or Lansky performance status ≥80 (if <16 years old) • Medically eligible to undergo hematopoietic stem cell therapy (HSCT) • Experienced hydroxyurea failure at any point in the past (defined as >1 VOC or ≥1 acute coronary syndromes [ACS] after taking hydroxyurea for at least three months) or must have intolerance to hydroxyurea (defined as inability to be maintained on an adequate dose of hydroxyurea due to marrow suppression or severe drug-induced toxicity [e.g. gastrointestinal distress, fatigue]) Exclusion criteria: • Positive for presence of human immunodeficiency virus type 1 or 2 (HIV-1 and HIV-2), hepatitis B virus (HBV), or hepatitis C (HCV); or • Clinically significant or active bacterial, viral, fungal, or parasitic infection; or • Inadequate bone marrow function (defined as an absolute neutrophil count [ANC] of <1000/μL or 500/μL for patients on hydroxyurea treatment, or a platelet count <50,000/μL); or • Baseline estimated glomerular filtration rate (eGFR) <60 mL/min/1.73m^2; or • Prior HSC transplant or receipt of gene therapy; or • Baseline left ventricular ejection fraction (LVEF) <40%; or • Prior or current malignancy or myeloproliferative disorder, or a significant immunodeficiency disorder; or

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• fetal hemoglobin (HbF) level >15%, irrespective of concomitant treatment with HbF-inducing treatments such as hydroxyurea Authorization duration: limited to a one-time single infusion therapy Note: Prior to treatment with exagamglogene autotemcel, review by an Inter-regional Consultative Physician Panel is required. **Transfusion dependent beta-thallassemia:** Covered for the treatment of adult and pediatric patients with β-thalassemia who require regular RBC transfusions when all of the following are met: • Prescribed by or in consultation with Pediatric or Adult Hematology/Oncology Specialists • Patient is 12 years old or older • Confirmed diagnosis of β-thalassemia through genetic testing • Diagnosis of transfusion dependent β-thalassemia (TDT) by hematology specialist with a history of at least 100 mL/kg/year or 10 units/year of packed red blood cells (pRBCs) in prior 2 years • Karnofsky performance status of ≥80% or Lansky performance status ≥80 (if <16 years old) • Clinically stable and eligible to undergo hematopoietic stem cell therapy (HSCT) Exclusion criteria: • Positive for presence of human immunodeficiency virus type 1 or 2 (HIV-1 and HIV-2), hepatitis B virus (HBV), or hepatitis C (HCV); or • Any prior or current malignancy or myeloproliferative disorder; or • Prior HSCT; or • Prior receipt of gene therapy; or • Evidence of cardiac dysfunction due to iron overload; or • White blood cell (WBC) count <3×10^9/L, and/or platelet count <50×10^9/L not related to hypersplenism; or • History of significant bleeding disorder Authorization duration: limited to a one-time single infusion therapy Note: Prior to treatment with exagamglogene autotemcel, review by an Inter-regional Consultative Physician Panel is required.
Exenatide	Bydureon Bcise, Byetta	Unspecified C9399, J3490, J3590	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following:

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria (refer to pharmacy benefit)
Factor VIII, Fc fusion protein, (recombinant)	Eloctate	J7205	N/A	Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change.
Factor IX antihemophilic factor, (recombinant)	Alprolix	J7201	N/A	Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change.
Fam-trastuzumab deruxtecan-nxki	Enhertu	J9358	N/A	Covered for advanced or metastatic HER2 positive breast cancer after HER 2 directed therapy (i.e., trastuzumab [e.g., Kanjinti], pertuzumab, TDM-1) Covered for the treatment of Recurrent, Unresectable or Metastatic Breast Cancer that is ER/PR positive, HER2 negative or HER2 low after treatment with a CDK4/6 inhibitor. Covered for the treatment of HER-2 positive metastatic or advanced GEJ, esophageal, gastric cancer in the second-line setting after previous treatment with trastuzumab (e.g., Kanjinti) Covered for the treatment of patients with HER2 (ErbB2), NSCLC after initial treatment with chemotherapy +/- immunotherapy as detected by NGS. Covered for the treatment of stage IV Colorectal Cancer in the third line setting if all the following apply: • HER 2 amplification
Faricimab-svoa	Vabysmo	C9097, J2777	N/A	• Covered for neovascular (wet) age-related macular degeneration in patients who have failed or are intolerant to bevacizumab. • Covered for diabetic macular edema in patients who have failed or are intolerant to bevacizumab.
Fecal microbiota live-jslm	Rebyota	J1440	N/A	Covered for patients who meet all of the following:* • Diagnosis of recurrent *Clostridioides difficile* infection (CDI) confirmed by documentation of positive test

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• Completed a 6-month trial of a vancomycin taper (a short and extended course) • Completed a 10-day course of fidaxomicin or rifaximin and an extended course (a short and extended course) • Completed 1 unsuccessful treatment with bezlotoxumab *Please note: fecal microbiota transplant (FMT) is a preferred alternative but is not required due to highly variable access.
Ferric carboxymaltose	Injectafer	J1439	N/A	For adult patients with failure or intolerance of two of the following: • Iron dextran (Infed) • Iron sucrose (Venofer) • Ferric gluconate (Ferrlecit) Covered for pediatric patients < 18 years old.
Ferric derisomaltose	Monoferric	J1437	N/A	Medical necessity review required.
Ferumoxytol	Feraheme	Q0138 Q0139	N/A	For patients with failure or intolerance of one of the following: • Iron sucrose (Venofer) • Ferric gluconate (Ferrlecit)
Filgrastim	Neupogen	J1442	N/A	Not covered under the medical benefit. May be covered under pharmacy benefit. • Exceptions: ○ First 3 doses within 5 days may be given under medical benefit ○ Plans with reduction rider ○ Patients and donors planned to undergo bone marrow transplant
Filgrastim-aafi	Nivestym	Q5110	N/A	Not covered under the medical benefit. May be covered under pharmacy benefit. • Exceptions: ○ First 3 doses within 5 days may be given under medical benefit ○ Plans with reduction rider ○ Patients and donors planned to undergo bone marrow transplant
Filgrastim-ayow	Releuko	C9096, Q5125	N/A	Not covered under the medical benefit. May be covered under pharmacy benefit. • Exceptions: ○ First 3 doses within 5 days may be given under medical benefit ○ Plans with reduction rider ○ Patients and donors planned to undergo bone marrow transplant
Filgrastim-sndz	Zarxio	Q5101	N/A	Not covered under the medical benefit. May be covered under pharmacy benefit. • Exceptions: ○ First 3 doses within 5 days may be given under medical benefit ○ Plans with reduction rider

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				○ Patients and donors planned to undergo bone marrow transplant
Fosdenopterin hydrobromide	Nulibry	Unclassified J3490, J3590	N/A	Covered for patients who meet the following criteria: • Diagnosis of molybdenum cofactor deficiency (MoCD) type A confirmed by genetic testing documenting mutations in the molybdenum cofactor synthesis 1 gene (MOCS1) • Prescribed by or in consultation with a geneticist, neonatologist, or pediatric specialist. • Dosing does not exceed 0.9 mg/kg once daily Reauthorization: reassessment every 12 months to confirm clinical benefit including disease stability or improvement in symptoms and a current weight
Furosemide	Furoscix	J1941	N/A	Medical necessity review required.
Galsulfase	Naglazyme	J1458	N/A	Covered for patients with a confirmed diagnosis of MPS VI (Maroteaux-Lamy syndrome). Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts. Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change.
Gemcitabine	Infugem	J9199, J9198	N/A	Not covered, not medically necessary
Gemtuzumab/ozogamicin	Mylotarg	J9203	N/A	Covered for acute promyelocytic leukemia if WBC ≥10,000 Covered for the treatment AML in intensive remission induction therapy eligible patients who are CD33 positive and core binding protein positive.
Givosiran	Givlaari*	J0223	N/A	Covered for adult patients with acute hepatic porphyria who meet all of the following: • Prescribed by or in consultation with a hematology specialist • Age ≥18 years old • Clinical symptoms consistent with active AHP (e.g., neurovisceral attacks, abdominal pain, central nervous system symptoms such as paralysis or psychosis)

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• Documentation of ≥ 2 porphyria attacks within the last 6 months leading to hospitalization, emergency department (ED) visit, or intravenous hemin administration • Elevated urinary (24-urine collection) porphobilinogen (PBG) or aminolevulinic acid (ALA) within the past year Not covered for patients with: • Active HIV, hepatitis C virus, or hepatitis B virus infection(s) • Planned liver transplantation • History of recurrent pancreatitis Required documentation: • Number of attacks leading to hospitalizations, emergency department visits, and clinic visits. • Number of attacks requiring hemin. • Number of days receiving heme • 24-urine collection for PBG or ALA within past year. • Baseline LFTs, SCr, and eGFR Reassessment every 6 months to determine need for continued therapy. Therapy should be discontinued if patient meets any one of the following criteria: • No improvement in the number of attacks leading to hospitalizations, ED visits, clinic visits, or hemin requirement after 6 months of treatment (i.e., status stable or worse from baseline) • Clinically significant changes in LFTs, SCr, or eGFR • Non-adherence to medication Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.
Glatiramer acetate	Glatopa, Copaxone	J1595	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria (refer to pharmacy benefit)
Glofitamab-gxbm	Columvi	J9286	N/A	For the treatment of patients with Relapsed/ Refractory DLBCL in the 3rd line setting.

Golimumab intravenous injection	Simponi Aria	J1602, 1 mg	N/A	1. Patients with rheumatoid arthritis (RA) who have failure, contraindication, or intolerance to methotrexate, two formulary anti-TNFs (e.g., adalimumab [e.g., Amjevita], infliximab [e.g., Inflectra]), abatacept, and one other biologic DMARD. 2. For psoriatic arthritis in patients with failure, contraindication, or intolerance to: ○ At least one conventional synthetic disease modifying anti-rheumatic drug (csDMARD) (methotrexate preferred), and ○ Two of the following biologics (one of which must be adalimumab or infliximab) and ○ adalimumab (e.g., Amjevita) ○ infliximab (e.g., Inflectra) ○ secukinumab ○ etanercept ○ Guselkumab, and ○ at least one of the following biologic DMARDs (ustekinumab, risankizumab, abatacept) Note: csDMARD not required for patients with axial disease or severe (rapidly progressive, erosive) disease 3. Patients with active ankylosing spondylitis (AS) who have failure, contraindication, or intolerance to two formulary anti-TNFs (e.g., adalimumab [Amjevita] or infliximab [Inflectra]), and secukinumab Not covered for use in combination with other biologic therapies including (but not limited to): • Infliximab, adalimumab, etanercept, vedolizumab, rituximab, abatacept, tocilizumab, certolizumab, ustekinumab, canakinumab Quantity Limit for RA: • Induction: 2 mg/kg at weeks 0 and 4 • Maintenance: 2 mg/kg every 8 weeks Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts. Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change. Applicable codes: *ICD-10 codes covered if selection criteria or medical necessity is met. Listing of code does not guarantee coverage or reimbursement. The following list is provided for reference purposes only and may not be all inclusive.*

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				M05 - M05.9, M06 - M06.09, M06.1, M06.80 - M06.9, M08 - M08.9, M08.20 - M08.3, M08.80 - M08.99, L40.5 - L40.59
Golimumab subcutaneous injection	Simponi	Unclassified J3590	N/A	1. Patients with rheumatoid arthritis (RA) who have failure, contraindication, or intolerance to methotrexate, two formulary anti-TNFs (e.g., adalimumab [Amjevita] or infliximab [Inflectra]), abatacept, and one other biologic DMARD. 2. For psoriatic arthritis in patients with failure, contraindication, or intolerance to: o At least one conventional synthetic disease modifying anti-rheumatic drug (csDMARD) (methotrexate preferred), and o Two of the following biologics (one of which must be adalimumab or infliximab) and o adalimumab (e.g., Amjevita) o infliximab (e.g., Inflectra) o secukinumab o etanercept o Guselkumab, and o at least one of the following biologic DMARDs (ustekinumab, risankizumab, abatacept) Note: csDMARD not required for patients with axial disease or severe (rapidly progressive, erosive) disease 3. Patients with active ankylosing spondylitis (AS) who have failure, contraindication, or intolerance to two formulary anti-TNFs (e.g., adalimumab [Amjevita] or infliximab [Inflectra]), and secukinumab 4. Patients with moderately to severely ulcerative colitis (UC) with contraindication, intolerance, or loss of response to at least two TNF-inhibitors (e.g., adalimumab [Amjevita] or infliximab [Inflectra]). It is recommended that TNF-inhibitors are used in combination with azathioprine, 6-mercaptopurine or methotrexate. a. Only responders to induction therapy may continue with longer term maintenance therapy. Not covered for use in combination with other biologic therapies including (but not limited to): • infliximab, adalimumab, etanercept, vedolizumab, rituximab, abatacept, tocilizumab, certolizumab, ustekinumab, canakinumab **Quantity Limits:** • RA/PsA/AS: 50 mg every month • UC: 200 mg at week 0, 100 mg at week 2, and then 100 mg every 4 weeks. **Applicable codes**: *ICD-10 codes covered if selection criteria or medical necessity is met. Listing of code does not guarantee coverage or reimbursement. The following list is provided for reference purposes only and may not be all inclusive.*

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				M05 - M05.9, M06 - M06.09, M06.1, M06.80 - M06.9, M08 - M08.9, M08.20 - M08.3, M08.80 - M08.99, L40.5 - L40.59
Golodirsen	Vyondys 53*	J1429	N/A	Covered for patients with Duchenne muscular dystrophy (DMD) who meet ALL of the following: • Prescribed by or in consultation with Pediatric Neurology, Adult Neurology, or Physical Medicine & Rehabilitation • Documented deletion/mutation amenable to exon 53 skipping (must be confirmed by a geneticist) • At least 4 years old • Ambulatory without wheelchair dependency (cane or walker use acceptable) • Documented minimum distance for unassisted 6-minute walk test (6MWT) of 180 meters at baseline • Must be on a stable dose of glucocorticoid for at least 6 months • Forced Vital Capacity % (FVC%) greater than or equal to 50% predicted Not covered for patients who: • Are non-ambulatory • Are ambulatory with some level of wheelchair dependency • Require nocturnal ventilation (including BiPAP), but excluding CPAP • Prior or planned treatment with gene therapy for Duchenne muscular dystrophy Reassessment every 12 months to determine need for continued therapy. Patient must meet ALL of the following functional criteria for continued coverage: • Ambulation test: Greater than limited home level (e.g., home, limited community, or community independent) • Sit to stand test: Moderate assist or Independent • No ventilator support (excluding use of nocturnal CPAP) Note: Prior to treatment initiation, all patients should be reviewed by an Interregional Consultative Physician Panel. Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts. Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
Goserelin	Zoladex	J9202, 3.6 mg	N/A	Covered for the treatment of: • Prostate cancer in patients that do not tolerate or respond to leuprolide • Diagnosis of gender identity/gender dysphoria in patients who have failure, intolerance, or contraindication to leuprolide or are unable to safely administer leuprolide. Medical necessity review required for other types of cancer.
Growth hormone Somatropin	Genotropin; Humatrope; Norditropin NordiFlex; Nutropin; Nutropin AQ; Omnitrope; Saizen; Serostim; Tev-Tropin; Zorbtive	J2941	N/A	Children with one of the following: 1) Prader-Willi syndrome. 2) Idiopathic or secondary growth hormone deficiency. 3) End-stage renal disease (on or off dialysis) for whom growth hormone is expected to produce the necessary weight gain in order to qualify patients for graft procedure. 4) Turner syndrome. Not covered in the children with idiopathic short stature in the absence of growth hormone deficiency. Not covered for adult patients with growth hormone deficiency due to insufficient evidence to demonstrate long term benefit and safety. Only short term intermediate outcomes data are available showing small improvements in body composition (e.g., lean body mass, abdominal fat). Observational studies with long-term follow-up have not demonstrated improved health outcomes and indicate that the benefit of GH replacement on body composition is attenuated over time. Potential risks of long-term treatment with GH in adults include increased risk of diabetes mellitus, retinopathy, benign intracranial hypertension, and increased risk for neoplasm. **Omnitrope is the preferred agent.**
Guselkumab	Tremfya	J1628	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria below Guselkumab may be considered for adult patients (18 years or older) with moderate to severe psoriasis with an inadequate response, contraindication, or intolerance to topical psoriasis treatments AND,

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria

				• at least one formulary anti-TNF agent (e.g., adalimumab [Amjevita], infliximab [Inflectra]), AND
				• secukinumab AND
				• at least two of the following*:
				  ○ 12-week trial of phototherapy
				  ○ acitretin
				  ○ methotrexate
				
				*Note: cyclosporine may also be counted towards 1 of the required therapies, but should not be required.
				
				For psoriatic arthritis in patients with failure, contraindication, or intolerance to:
				• At least one conventional synthetic disease modifying anti-rheumatic drug (csDMARD) (methotrexate preferred), and
				• Two of the following biologics (one of which must be adalimumab or infliximab):
				  ○ adalimumab (e.g., Amjevita)
				  ○ infliximab (e.g., Inflectra)
				  ○ secukinumab
				  ○ etanercept
				
				Note: csDMARD not required for patients with axial disease or severe (rapidly progressive, erosive) disease
				
				Not covered for use in combination with disease modifying or other biologic therapies including (but not limited to):
				• infliximab, adalimumab, etanercept, vedolizumab, rituximab, certolizumab, tocilizumab, golimumab, ustekinumab, natalizumab, tofacitinib, upadacitinib, ozanimod, apremilast
				
				Quantity Limits:
				• Induction: 100 mg at week 0, 4, and 8
				• Maintenance: 100 mg every 8 weeks

Histrelin	Supprelin LA	J9226, 50 mg		Covered for the treatment of: • Central precocious puberty in patients who have failure, intolerance, or contraindication to leuprolide and are less than 13 years old. Supprelin LA is NOT covered for other forms of precocious puberty. • Gender identity/gender dysphoria in patients who have failure, intolerance, or contraindication to leuprolide or are unable to safely administer leuprolide.
Histrelin	Vantas	J9225, 50 mg		Histrelin (Vantas) is covered for the treatment of advanced prostate cancer in patients who require continuous chemical castration (i.e. advanced disease with rapid PSA recurrence or currently receiving combination radiation) AND have

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				intolerance or contraindication to leuprolide. NOTE that local injection site reactions are not considered an intolerance or contraindication.
Hyaluronic acid, intra-articular	Supartz/Hyalgan Euflexxa Orthovisc Synvisc/Synvisc One Gel-One Monovisc Gel-Syn Durolane Trivisc Visco-3 Synojoynt Triluron Genvisc 850 Totalvisc	J7321 J7323 J7324 J7325 J7326 J7327 J7328 J7329 J7322 J7320 J7318 J7331 J7332 J3490 J3590	N/A	Not covered. *Intra-articular hyaluronic acid injections are not medically necessary for osteoarthritis of the knee or osteoarthritis of any joints. In 2021, the American Academy of Orthopedic Surgeons (AAOS) published evidence-based treatment guidelines in which they concluded hyaluronic acid supplements (HAS) could not be recommended for routine use in patients with symptomatic osteoarthritis of the knee. This conclusion is based on moderate evidence from a meta-analysis of clinical trials that intra-articular hyaluronic acid injections fail to provide clinically significant benefit.*

Ibalizumab-uiyk	Trogarzo	J1746	N/A	Covered for patients who meet the following criteria:
				• Diagnosis of HIV-1 with documented failure or resistance to at least 1 drug in each of at least 2 of the following classes of antiretrovirals (ARV):
				  ○ Nucleoside reverse-transcriptase inhibitors
				  ○ Non-nucleoside reverse-transcriptase inhibitors
				  ○ Protease inhibitors
				• Currently on ARV regimen for at least 6 months and viral load is > 1000 copies/mL
				• Patient is currently taking or will be prescribed an optimized background antiretroviral regimen.
				• Prescribed by or in consultation with an HIV specialist or Infectious Diseases specialist.
				• Trial and failure, intolerance or contraindication to lenacapavir
				
				Initial authorization: 12 months
				
				Reauthorization required every 12 months to confirm decreasing trend in viral load or continued viral load suppression.
				
				Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
Ibandronate	Boniva	J1740, 1 mg	12	Medical necessity review required.
Icatibant	Firazyr	J1744	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria below 1. For acute treatment in patients with an established diagnosis of type 1 or type 2 hereditary angioedema (HAE). 2. Prescribed by an allergy or emergency medicine provider.
Idecabtagene vicleucel	Abecma	C9081, Q2055	N/A	Covered for the treatment of multiple myeloma if used as 4th line and beyond. • Progression on, or intolerant to, at least 5 drugs with at least 1 from each of the following 3 drug classes, with or without prior transplant. ○ Immunomodulatory agents (lenalidomide, pomalidomide) ○ Proteasome inhibitors (carfilzomib, bortezomib, ixazomib) ○ Anti-CD38 monoclonal antibodies (isatuximab, daratumumab) • Other regimens, including alkylators and anthracyclines, have been considered. Not covered for patients with: • Prior CAR-T therapy or other genetically modified T cell therapy Authorization duration: limited to a one-time (single infusion) treatment
Idursulfase	Elaprase	J1743	N/A	Covered for patients with a confirmed diagnosis of MPS II (Hunter syndrome). Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts. Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change.
Imiglucerase	Cerezyme	J1786	N/A	Covered for patients with a confirmed diagnosis of Type 1 or Type 3 Gaucher disease.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
		10 units		Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts. Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change.
Immune globulin	Cutaquig	J1551	N/A	Medical necessity review required.
Immune globulin human-stwk	Alyglo	J1599	N/A	Medical necessity review required.
Immunoglobulin subcutaneous	Hizentra	J1559	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria below ○ For patients with primary immunodeficiency. ○ For patients with chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy to prevent relapse of neuromuscular disability and impairment Note: Please submit a referral to KPWASP and a sample request form to 1-800-340-4230 for pharmacy coverage and training for new start patients.
Immunoglobulin subcutaneous	Cuvitru	J1555	N/A	Medical necessity review required. For patients with primary immunodeficiency. Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.
Immune globulin infusion 10% with recombinant hyaluronidase subcutaneous	Hyqvia	J1575, 100 mg	N/A	Medical necessity review required. For patients with primary immunodeficiency.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.
Inclisiran sodium	Leqvio	J1306	N/A	Primary hyperlipidemia including heterozygous familial hypercholesterolemia (HeFH): • The patient is at least 18 years of age • The patient has at least a probable diagnosis of HeFH based on a validated diagnostic tool (Simon Broome, Dutch Lipid Clinic Network, MEDPED) • The patient failed to achieve an LDL-C<100 mg/dL and meets one of the following: o Currently 90% adherent to maximally tolerated high-intensity statin therapy (i.e., atorvastatin 80 mg or rosuvastatin 40 mg) in combination with ezetimibe for at least 8 weeks. o The patient has a documented contraindication to statin and ezetimibe therapy o The patient has a documented intolerance to statin therapy, as defined by the National Lipid Association (NLA) • Maximally tolerated statin therapy is continued while receiving inclisiran therapy (unless not tolerated or contraindicated) • Failure or intolerance to evolocumab and alirocumab Clinical atherosclerotic cardiovascular disease (ASCVD): • The patient is at least 18 years of age • The patient has a diagnosis of clinical ASCVD evidenced of at least one of the following conditions: o Coronary heart disease (CHD), such as myocardial infarction (MI), angina, or prior CABG or PCI o Cerebrovascular disease, such as transient ischemic attack (TIA), ischemic stroke, or prior CEA or carotid stenting o Peripheral artery disease, such as claudication • The patient failed to achieve an LDL-C <70 mg/dL and meets one of the following: o Currently 90% adherent to maximally tolerated high-intensity statin therapy (i.e., atorvastatin 80 mg or rosuvastatin 40 mg) in combination with ezetimibe for at least 8 weeks. o The patient has a documented contraindication to statin and ezetimibe therapy

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				○ The patient has a documented intolerance to statin therapy, as defined by the National Lipid Association (NLA) • Maximally tolerated statin therapy is continued while receiving inclisiran therapy (unless not tolerated or contraindicated) • Failure or intolerance to evolocumab and alirocumab Authorization will be reviewed after 6 months of therapy to confirm demonstration of continued clinical benefit, as demonstrated by LDL reduction since initiation of therapy with inclisiran.
Inebilizumab-cdon	Uplizna*	J1823	N/A	Covered for patients with neuromyelitis optica spectrum disorder (NMOSD) who meet the following criteria: • Prescribed by or in consultation with a Multiple sclerosis specialist or Neurologist • Age ≥18 years • AQP4 antibody seropositive • Either of the following: ○ Severe breakthrough relapse while on rituximab (e.g., Riabni) for at least 6 months not attributed to rapid steroid discontinuation. Examples of severe breakthrough relapse include: ▪ hospitalization for neurological deficits from NMOSD relapse (e.g., quadriparesis or paraparesis) ▪ optic neuritis severity (hand motion only or worse) confirmed by an ophthalmologist ○ Recurrent moderate breakthrough relapses after 6 month trial of rituximab (e.g., Riabni) in combination with maximum tolerated doses of either mycophenolate mofetil or azathioprine. • Required documentation: ○ Complete blood count with differential ○ Tuberculosis screening ○ Hepatitis B virus screening ○ AQP4 antibody test ○ Quantitative serum immunoglobulins • Initial authorization: 6 months • Reauthorization: reassessment every 12 months to confirm clinical benefit including disease stability or improvement in symptoms. Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.
Infliximab	Remicade	J1745, 10 mg	varies by indication – see next column	1) Covered for new starts who have had an inadequate response or intolerance to an infliximab (e.g., Inflectra) biosimilar declared equivalent by KPWA P&T Committee* for the following diagnoses: rheumatoid arthritis, ankylosing spondylitis, sarcoidosis, ulcerative colitis, Crohn's disease, psoriatic arthritis, and psoriasis.

<table>
<tr><th>Generic Name</th><th>Brand Name</th><th>J Codes</th><th>Max J code unit per year</th><th>Coverage Criteria</th></tr>
<tr><td></td><td></td><td></td><td></td><td>2) Established patients on Remicade must have a documented inadequate response or intolerance to an infliximab (e.g., Inflectra) biosimilar

Not covered for use in combination with disease modifying or other biologic therapies including (but not limited to):
○ adalimumab, etanercept, vedolizumab, rituximab, abatacept, tocilizumab, certolizumab, golimumab, ustekinumab, natalizumab, canakinumab, tofacitinib, upadacitinib, ozanimod

*KPWA equivalent infliximab products include: infliximab (e.g., Inflectra).

Limit dosing as follows:
Induction dosing for all indications as follows: Infusion at 0, 2, and 6 weeks followed by maintenance dose:
<table><tr><th>Indication</th><th>Max Dose</th><th>Max Frequency</th></tr><tr><td>Rheumatoid Arthritis</td><td rowspan="8">1000mg</td><td>4 weeks</td></tr><tr><td>Crohn’s and Ulcerative Colitis</td><td>6 weeks</td></tr><tr><td>Psoriatic arthritis</td><td>8 weeks</td></tr><tr><td>Ankylosing spondylitis</td><td>6 weeks</td></tr><tr><td>Psoriasis</td><td>8 weeks</td></tr><tr><td>Sarcoidosis</td><td>8 weeks</td></tr><tr><td>Other</td><td>8 weeks</td></tr></table>
Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.

Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington’s Specialty Pharmacy Network for medications impacted by this change.

Applicable codes:
ICD-10 codes covered if selection criteria or medical necessity is met. Listing of code does not guarantee coverage or reimbursement. The following list is provided for reference purposes only and may not be all inclusive.
K50 - K50.919, K51 - K51.919, L40 - L40.4, L40.5 - L40.59, L40.8 - L40.9, M05 - M05.9, M06 - M06.9, M08 - M08.99, M45 - M45.9, M35.2, L88, M30.3, D86.0-D86.9, K60.3 - K60.5, K63.2, M02.30 - M02.39, M14 - M14.89, L73.2</td></tr>
<tr><td>Infliximab-abda</td><td>Renflexis</td><td>Q5104</td><td>N/A</td><td>Covered for patients who have an inadequate response or intolerance to the preferred biosimilar, infliximab-dyyb (Inflectra), for the following diagnoses:</td></tr>
</table>

<table>
<tr><th>Generic Name</th><th>Brand Name</th><th>J Codes</th><th>Max J code unit per year</th><th>Coverage Criteria</th></tr>
<tr><td>Infliximab-axxq

Infliximab-qbtx</td><td>Avsola

Ixifi</td><td>Q5121

Q5109</td><td></td><td>rheumatoid arthritis, ankylosing spondylitis, sarcoidosis, ulcerative colitis, Crohn’s disease, psoriatic arthritis, and psoriasis.

Not covered for use in combination with disease modifying or other biologic therapies including (but not limited to):
○ adalimumab, etanercept, vedolizumab, rituximab, abatacept, tocilizumab, certolizumab, golimumab, ustekinumab, natalizumab, canakinumab, tofacitinib, upadacitinib, ozanimod

Limit dosing as follows:
Induction dosing for all indications as follows: Infusion at 0, 2, and 6 weeks followed by maintenance dose:
<table>
<tr><th>Indication</th><th>Max Dose</th><th>Max Frequency</th></tr>
<tr><td>Rheumatoid Arthritis</td><td rowspan="8">1000mg</td><td>4 weeks</td></tr>
<tr><td>Crohn’s and Ulcerative Colitis</td><td>6 weeks</td></tr>
<tr><td>Psoriatic arthritis</td><td>8 weeks</td></tr>
<tr><td>Ankylosing spondylitis</td><td>6 weeks</td></tr>
<tr><td>Psoriasis</td><td>8 weeks</td></tr>
<tr><td>Sarcoidosis</td><td>8 weeks</td></tr>
<tr><td>Other</td><td>8 weeks</td></tr>
</table>
Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.

Applicable codes:
ICD-10 codes covered if selection criteria or medical necessity is met. Listing of code does not guarantee coverage or reimbursement. The following list is provided for reference purposes only and may not be all inclusive.
K50 - K50.919, K51 - K51.919, L40 - L40.4, L40.5 - L40.59, L40.8 - L40.9, M05 - M05.9, M06 - M06.9, M08 - M08.99, M45 - M45.9, M35.2, L88, M30.3, D86.0-D86.9, K60.3 - K60.5, K63.2, M02.30 - M02.39, M14 - M14.89, L73.2</td></tr>
<tr><td>Infliximab-dyyb</td><td>Inflectra</td><td>Q5103</td><td>varies by indication – see next column</td><td>1. Criteria review not required for the following diagnoses: rheumatoid arthritis, ankylosing spondylitis, sarcoidosis, ulcerative colitis, Crohn’s disease, psoriatic arthritis, and psoriasis.*
2. Medical necessity review required for other diagnoses.

Not covered for use in combination with disease modifying or other biologic therapies including (but not limited to):
○ adalimumab, etanercept, vedolizumab, rituximab, abatacept, tocilizumab, certolizumab, golimumab, ustekinumab, natalizumab, canakinumab, tofacitinib, upadacitinib, ozanimod

Limit dosing as follows:</td></tr>
</table>

<table>
<tr><th>Generic Name</th><th>Brand Name</th><th>J Codes</th><th>Max J code unit per year</th><th>Coverage Criteria</th></tr>
<tr><td></td><td></td><td></td><td></td><td>Induction dosing for all indications as follows: Infusion at 0, 2, and 6 weeks followed by maintenance dose:
<table>
<tr><th>Indication</th><th>Max Dose</th><th>Max Frequency</th></tr>
<tr><td>Rheumatoid Arthritis</td><td rowspan="8">1000 mg</td><td>4 weeks</td></tr>
<tr><td>Crohn’s and Ulcerative Colitis</td><td>6 weeks</td></tr>
<tr><td>Psoriatic arthritis</td><td>8 weeks</td></tr>
<tr><td>Ankylosing spondylitis</td><td>6 weeks</td></tr>
<tr><td>Psoriasis</td><td>8 weeks</td></tr>
<tr><td>Sarcoidosis</td><td>8 weeks</td></tr>
<tr><td>Others</td><td>8 weeks</td></tr>
</table>

*Note: Must be administered in a non-hospital setting for all diagnoses. See site of care policy for criteria, reauthorization, and exceptions for new starts.

Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington’s Specialty Pharmacy Network for medications impacted by this change.

Applicable codes:
ICD-10 codes covered if selection criteria or medical necessity is met. Listing of code does not guarantee coverage or reimbursement. The following list is provided for reference purposes only and may not be all inclusive.
K50 - K50.919, K51 - K51.919, L40 - L40.4, L40.5 - L40.59, L40.8 - L40.9, M05 - M05.9, M06 - M06.9, M08 - M08.99, M45 - M45.9, M35.2, L88, M30.3, D86.0-D86.9, K60.3 - K60.5, K63.2, M02.30 - M02.39, M14 - M14.89, L73.2</td></tr>
<tr><td>Infliximab-dyyb</td><td>Zymfentra</td><td>Unspecified
C9399,
J3490,
J3590</td><td>N/A</td><td>Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following:
• First dose for new starts to allow for self-administration training OR
• Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer
AND
• Must meet clinical criteria (refer to pharmacy benefit)</td></tr>
<tr><td>Inotersen</td><td>Tegsedi</td><td>Unspecified
C9399,
J3490,
J3590</td><td>N/A</td><td>Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following:
• First dose for new starts to allow for self-administration training OR
• Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer</td></tr>
</table>

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				AND • Must meet clinical criteria (refer to pharmacy benefit)
Inotuzumab ozogamicin	Besponsa	J9229	N/A	Covered for R/R B cell ALL who failed to achieve CR after initial induction therapy. Covered in combination with mini-Hyper CVD for newly diagnosed ALL if age is ≥40 years old.
Interferon beta-1a	Avonex, Rebif	J1826	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria (refer to pharmacy benefit)
Interferon beta-1b	Betaseron, Extavia	J1830	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria (refer to pharmacy benefit)
Ipilimumab	Yervoy	J9228, 1 mg	N/A	1. Melanoma: • Patients with unresectable or metastatic melanoma. ○ Cover for a max of 4 doses at 3 mg/kg. ○ Do not cover 10 mg/kg dose or maintenance therapy. • Treatment of patients with stage IIB, IIC or III in the adjuvant setting, after previous PD-1 inhibitor. ○ Cover for a max of 4 doses at 3 mg/kg. ○ Do not cover 10 mg/kg dose or maintenance therapy • Covered for neoadjuvant treatment of stage IIIB- IV Melanoma if all the following apply: ○ BRAF+ ○ PS 0-1 ○ Combined with Nivolumab 2. Covered for the treatment of patients with uveal melanoma: • For localized or symptomatic disease palliation after radiation therapy or clinical trial when combined with nivolumab. • For metastatic disease,

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				○ If combined with nivolumab AND ○ If patient is tebentafusp ineligible 3. NSCLC: • Treatment of patients with advanced stage NSCLC who: ○ Exhibit PD-L1 expression AND ○ Combine treatment with Nivolumab AND ○ Have not been previously been treated with PD-1 immunotherapy agents. 4. Renal Cell Carcinoma: • In combination with nivolumab for advanced clear-cell renal cell carcinoma • In combination with nivolumab for previously untreated metastatic non clear cell, sarcomatoid renal cell carcinoma. 5. Covered for locally advanced unresectable mesothelioma if combined with nivolumab. 6. Treatment of hepatocellular carcinoma if ALL the following apply: • Second line treatment option if combined with nivolumab • Child Pugh A • Immunotherapy naïve 7. Treatment of stage IV colorectal cancer that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) • Patients who are immunotherapy naïve • Combined with nivolumab • Note: If progression noted off immuno-oncology (IO) therapy after completion of 2 years of therapy, may restart utilizing first line IO therapy options. 8. For patients with locoregionally advanced colorectal cancer as neoadjuvant treatment if: • Microsatellite instability-high (MSIH) or mismatch repair deficient (dMMR) • Patients who are immunotherapy naïve • Combined with nivolumab • Limited to one year total therapy. 9. Covered as peri-operative/neoadjuvant treatment of Gastric Cancer/GEJ Siewert III: • If planned Lymphadenectomy AND • If combined with Nivolumab AND • dMMR/MSI-H tumor
Irinotecan liposome	Onivyde	J9205	N/A	Covered for metastatic adenocarcinoma of the pancreas progression as a second line or beyond setting in combination with 5FU and leucovorin

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
Isatuximab-irfc	Sarclisa	J9227	N/A	Treatment of patients with multiple myeloma who: • Have demonstrated disease progression according to International Myeloma Working Group (IMWG) criteria and have received 1 or more prior lines of therapy including either bortezomib or lenalidomide with dexamethasone. • Must be in combination with bortezomib or lenalidomide with dexamethasone o For patients with contraindication or intolerance to bortezomib or lenalidomide, must be in combination with dexamethasone AND: o An alternate proteasome inhibitor (e.g., carfilzomib, ixazomib) OR o An immunomodulatory agent (e.g., thalidomide, lenalidomide, pomalidomide) • Are newly diagnosed and ineligible for autologous stem cell transplant or transplant eligible with high-risk cytogenetics (as defined by IMWG or mSMART) o Must be used with bortezomib combination and/or lenalidomide combination therapy
IVIG	Privigen† Bivigam Gammaplex Gamunex-C† Gammaked Other IVIG Octagam† Gammagard liquid† Flebogamma/ Flebogamma Dif Other immune globulins IV Panzyga Asceniv	J1459 J1556 J1557 J1561 J1566 J1568 J1569 J1572 J1599 J1576 J1554	N/A	1) Immune thrombocytopenic purpura. 2) Primary humoral immunodeficiency. 3) Kawasaki syndrome. 4) Guillian-Barre syndrome (polyradiculoneuropathy). 5) Myasthenia gravis: approved for patients who are in myasthenic crisis and unresponsive to other immunosuppressive therapy (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate mofetil, cyclophosphamide) and high dose steroids. 6) Chronic inflammatory demyelinating polyneuropathy (CIDP). 7) Mulitfocal motor neuropathy (MMN). 8) B-cell chronic lymphocytic leukemia or multiple myeloma patients who have had 3 life-threatening infections within 1 year. **Quantity Limit:** • 150,000 mg maximum daily dose **ICD-10 code needed to auto-auth with specific code** 1) D69.3 2) D80.1, D80.2, D80.3, D80.4, D80.0, D80.5, D83.0, D83.2, D83.8, D83.9, D80.7 3) M30.3 4) G61.0 5) G70.00, G70.01 6) G61.81 7) C91.10, C91.90, C91.11, C91.Z2 8) C90.00, C90.01, C90.02

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts. †Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change. **Applicable codes:** *ICD-10 codes covered if selection criteria or medical necessity is met. Listing of code does not guarantee coverage or reimbursement. The following list is provided for reference purposes only and may not be all inclusive.* D80.0, D80.1, D80.5, D81.0, D81.1, D81.2, D81.89, D81.9, D83.0, D83.8, D83.9, D82.0, D80.3, D83.2, D69.3, D69.59, C91.10, C91.11, C91.12, G61.81, G61.82, G61.9, M30.3, T86.00, T86.01, T86.02, T86.03, T86.09, B20, B05.0, B05.1, B05.2, B05.3, B05.4, B05.81, B05.89, B05.9, G61.81, D69.3, M33.00, M33.10, M33.11, M33.12, M33.13, M33.19, M33.90, M33.91, M33.92, M33.93, M33.99, G61.0, G70.01, P55.0, P55.1, P55.8, P55.9, D69.51, L10.0-L10.9, L12.0, L12.1, L12.8, L12.9, L13.8, B15.0, B15.9, B06.00, B06.01, B06.02, B06.09, B06.81, B06.82, B06.89, B06.9, P61.0, P55.0-P55.9, B16.0, B16.1, B16.2, B16.9, B18.0, B18.0, P36.0-P36.9
Ixabepilone	Ixempra	J9207	N/A	Covered as monotherapy for the treatment of relapsed or refractory triple negative breast cancer in patients who have been previously treated with at least three prior lines of therapy including an anthracycline, taxane and capecitabine in the advanced setting.

Ixekizumab	Taltz	Unspecified J3490, J3590	N/A	For psoriatic arthritis in patients with contraindication, intolerance, or failure to:
				• At least one conventional synthetic disease modifying anti-rheumatic drug (csDMARD) (methotrexate preferred), and
				• Two of the following biologics (one of which must be adalimumab or infliximab) AND:
				  ○ adalimumab (e.g., Amjevita)
				  ○ infliximab (e.g., Inflectra)
				  ○ secukinumab
				  ○ etanercept
				• AND Guselkumab
				• AND at least one of the following biologic DMARDs (i.e., ustekinumab, risankizumab, abatacept)

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria

				Note: csDMARD not required for patients with axial disease or severe (rapidly progressive, erosive) disease
				
				Ixekizumab may be considered for adult patients (18 years or older) with moderate to severe psoriasis, including psoriasis involving the genital area, with an inadequate response, contraindication, or intolerance to topical psoriasis treatments AND
				• at least one formulary anti-TNF agent (e.g., adalimumab [Amjevita], infliximab [Inflectra]), AND
				• secukinumab AND
				• two preferred IL-23 or IL-12/IL-23 inhibitors (guselkumab, ustekinumab, risankizumab) AND
				• at least two of the following*:
				  • 12-week trial of phototherapy
				  • acitretin
				  • methotrexate
				
				*Note: cyclosporine may also be counted towards 1 of the required therapies, but should not be required.
				
				Ixekizumab may be considered for adult patients (18 years or older) with active ankylosing spondylitis who have not had an adequate response to two formulary anti-TNF agent (e.g., adalimumab [Amjevita], infliximab [Inflectra]) and secukinumab.
				• For Ankylosing Spondylitis, reauthorization required after 16 weeks for prescriber attestation of reduction in signs and symptoms of disease.
				
				Not covered for use in combination with disease modifying or other biologic therapies including (but not limited to):
				• infliximab, adalimumab, etanercept, vedolizumab, rituximab, certolizumab, tocilizumab, golimumab, ustekinumab, natalizumab, tofacitinib, upadacitinib, ozanimod, apremilast
				
				Quantity limit:
				Induction phase (psoriasis): 2 syringes/pens (160 mg) at week 0 and 1 syringe/pen (80 mg) at week 2, 4, 6, 8, 10, 12
				Induction phase (psoriatic arthritis and active ankylosing spondylitis): 2 syringes/pens (160 mg) at week 0
				Maintenance phase: 1 syringe/pen (80 mg) per 28 days

Ketamine	Ketalar	Unspecified J3490, J3590	N/A	Not covered for non-FDA approved indications.
Lanreotide	Somatuline Depot	J1930	N/A	Covered for the treatment of acromegaly or gastroenteropancreatic neuroendocrine tumors (GEP-NETs) in patients with intolerance of maximum doses of octreotide.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
Lanadelumab-flyo	Takhzyro	J0593	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria (refer to pharmacy benefit)
Laronidase	Aldurazyme	J1931	N/A	Covered for patients with a confirmed diagnosis of MPS I (Hurler, Scheie, and Scheie forms) Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.

Lenacapavir sodium	Sunlenca	J1961	N/A	Covered for patients who meet the following criteria:
				• Diagnosis of HIV-1 with documented failure or resistance to at least 2 drugs in each of at least 3 of the following classes of antiretrovirals (ARV):
				  ○ Nucleoside reverse-transcriptase inhibitors
				  ○ Non-nucleoside reverse-transcriptase inhibitors
				  ○ Protease inhibitors
				  ○ Integrase strand transfer inhibitors
				• Current ARV regimen has been stable for at least 2 months and viral load is ≥ 400 copies/mL
				• Patient is currently taking or will be prescribed an optimized background antiretroviral regimen.
				• Prescribed by or in consultation with an HIV specialist or Infectious Diseases specialist.

Lecanemab-irmb	Leqembi*	J0174	N/A	Not covered, not medically necessary
Leuprolide mesylate 6 month emulsion	Camcevi	J1952	N/A	Medical necessity review required.
Levoleucovorin	Khapzory	J0642, J0641	N/A	Medical necessity review required.
Liraglutide	Victoza	Unspecified C9399, J3490, J3590	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria (refer to pharmacy benefit)
Lisocabtagene maraleucel	Breyanzi	Q2054	N/A	Covered for patients with DLBCL who have primary refractory or relapse disease within one year. Covered for patients with relapsed or refractory follicular lymphoma with all the following conditions: • No histologic transformation • Either late relapse or early relapse for patients who are considered transplant ineligible. • Have good performance status ECOG 0-1 Covered for patients with Primary Mediastinal Large B-Cell Lymphoma (PMBCL) that meet all of the following: • Prescribed by an oncologist with expertise in malignant hematology • Age 18 years or older • Chemotherapy-refractory disease, defined as one or more of the following: o Refractory to two or more lines of chemotherapy with less than partial response to last line of therapy OR o Refractory post-autologous hematopoietic stem cell transplantation (HSCT) • Required documentation: o Adequate prior therapy including at a minimum: ▪ anti-CD20 monoclonal antibody unless tumor is CD20-negative and an anthracycline containing chemotherapy regimen Authorization duration: limited to a one-time (single infusion) treatment
Lonacastuximab tesirine-lpyl	Zynlonta	C9084, J9359	N/A	Covered for the treatment of DLBCL in the third line setting or beyond for CD19 positive disease.
Lovotibeglogene autotemcel	Lyfgenia*	Unspecified C9399, J3490, J3590	N/A	Covered for the treatment of patients with Sickle Cell Disease (SCD) when all of the following are met: • Prescribed by or in consultation with Hematology or Sickle Cell Disease Specialists • Patient is between 12 and 40 years old • Patient has severe SCD (defined as ≥2 of the following events per year during the two year period before treatment initiation): o Acute pain requiring medical facility visit and administration of pain medications (opioids or IV non-steroidal anti-inflammatory drugs [NSAIDs]) or RBC transfusions

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				○ Acute chest syndrome, as indicated by the presence of a new pulmonary infiltrate associated with pneumonia-like symptoms, pain, or fever ○ Priapism lasting >2 hours ○ Splenic sequestration • Karnofsky performance status of ≥80% or Lansky performance status ≥80 (if <16 years old) • Medically eligible to undergo hematopoietic stem cell therapy (HSCT) • Experienced hydroxyurea failure at any point in the past (defined as >1 VOC or ≥1 acute coronary syndromes [ACS] after taking hydroxyurea for at least three months) or must have intolerance to hydroxyurea (defined as inability to be maintained on an adequate dose of hydroxyurea due to marrow suppression or severe drug-induced toxicity [e.g. gastrointestinal distress, fatigue]) Exclusion criteria: • Positive for presence of human immunodeficiency virus type 1 or 2 (HIV-1 and HIV-2), hepatitis B virus (HBV), or hepatitis C (HCV); or • Clinically significant or active bacterial, viral, fungal, or parasitic infection; or • Inadequate bone marrow function (defined as an absolute neutrophil count [ANC] of <1000/μL or 500/μL for patients on hydroxyurea treatment, or a platelet count <50,000/μL); or • Baseline estimated glomerular filtration rate (eGFR) <60 mL/min/1.73m^2; or • Prior HSC transplant or receipt of gene therapy; or • Baseline left ventricular ejection fraction (LVEF) <40%; or • Prior or current malignancy or myeloproliferative disorder, or a significant immunodeficiency disorder; or Authorization duration: limited to a one-time single infusion therapy Note: Prior to treatment with lovotibeglogene autotemcel, review by an Inter-regional Consultative Physician Panel is required.
Lumasiran	Oxlumo*	J0224	N/A	Covered for patients who meet all of the following: • Diagnosis of Primary hyperoxaluria type 1 (PH1) with documented genetic testing confirming *AGXT* mutation. • Prescribed by or in consultation with a Nephrologist, Pediatric Nephrologist, Urologist, or Pediatric Urologist. • Elevated 24-hour urine oxalate level or elevated spot urine oxalate/creatinine ratio consistent with diagnosis of PH1. • Documentation of maintaining appropriate fluid intake as advised by prescriber. • Required baseline labs:

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				○ 24-hour urine oxalate within 3 months prior to treatment initiation (for pediatric patients unable to complete 24-hour urine oxalate, spot urine oxalate/creatinine ratio is sufficient) ○ spot urine oxalate/creatinine ratio just prior to treatment initiation ○ estimated glomerular filtration rate (eGFR) Not covered for patients with: • history of liver or kidney transplant • Diagnosis of primary hyperoxaluria type 2 (PH2) or type 3 (PH3) Reassessment every 6 months must include clinical documentation to confirm improvement in symptoms and confirm that patient is not post liver transplant. Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.
Lurbinectedin	Zepzelca	J9223	N/A	Medical necessity review required for metastatic small cell lung cancer (NSCLC). Covered for subsequent treatment of SCLC with relapse less than or equal to 6 months after platinum based chemotherapy.
Luspatercept-aamt	Reblozyl*	J0896	N/A	**Myelodysplastic syndrome:** Covered for the treatment of lower risk symptomatic MDS that is: • Without del(5q) AND • With ring sideroblasts greater or equal to 15% or greater or equal to 5% if SF3B1 mutation) AND • Serum epo greater or equal to than 500mU/ml. • Or if less than 500mU/ml and after inadequate response to epoetin alfa therapy. Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts. **Beta thalassemia:** Covered for adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions who meet all of the following: • Prescribed by or in consultation with a hematologist • Age ≥18 years old • Documented diagnosis of beta thalassemia or hemoglobin E/beta thalassemia • Documentation of receiving regular transfusions (defined as 6 to 20 RBC units in the 24 weeks prior to treatment initiation and no transfusion-free period for ≥ 35 days during that period)

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				Required documentation: • Number of RBC transfusions within prior 6 months • Baseline Hemoglobin Not covered for patients with: • Diagnosis of hemoglobin S/β-thalassemia or alpha (α)-thalassemia (e.g., Hemoglobin H) Reassessment every 6 months to determine need for continued therapy. Therapy should be discontinued if patient meets any one of the following criteria: • No clinically meaningful decrease in transfusions on maximum recommended dose • Non-adherence to medication Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.
Margetuximab-cmkb	Margenza	J9353	N/A	Medical necessity review required.
Melphalan flufenamide	Pepaxto	C9080, J9247	N/A	Medical necessity review required.

Mepolizumab	Nucala	J2182	N/A	Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit.
				• Exception criteria may be considered for the following:
				  ○ Patients with impaired manual dexterity, impaired vision, or patients who are unable to use prefilled syringe safely
				  AND
				• Patient meets clinical criteria below
				
				For patients with chronic rhinosinusitis with nasal polyps (CRSwNP) who meet the following criteria:
				• Prescribed by an Allergist or Otolaryngologist.
				• Patient is at least 18 years of age.
				• Persistent rhinosinusitis symptoms that include 2 or more of the following for at least 12 weeks (1 of which is nasal obstruction):
				  ○ Severe nasal obstruction AND
				  ○ Rhinorrhea (anterior/posterior) OR
				  ○ Reduction or loss of smell
				• Failure, contraindication, or intolerance to dupilumab

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• Bilateral nasal polyps with polyps filling the middle meatuses and obstructing the ostia OR failure of normalization of the mucosa after a full sinus surgery despite maximal post-operative medical management. • Prior treatment with the following: o Nasal corticosteroids o Oral corticosteroids (OCS) for the treatment of nasal polyps within the past year (unless contraindication or intolerance to OCS) AND o A prior full endoscopic sinus surgery (ESS) or contraindication to full ESS. • Elevated serum eosinophils (≥300 cells/mcL) within the prior 12 months OR moderate or severe eosinophil-predominant inflammatory infiltrate in surgical tissue. Evaluation for Continuation of Therapy: • Evaluate response after 6 months and then annually thereafter. • Clinical improvement must be demonstrated by one or more of the following: • Reduction in size of nasal polyps • Improvement in patient symptoms (e.g., congestion, smell test) • Decreased need for oral corticosteroids and nasal polyp surgery • Improvement in health-related quality of life and/or the 22-item Sino-Nasal Outcomes Test (SNOT-22) score **Quantity Limit for CRSwNP**: 100 mg administered subcutaneously once every 28 days **For patients with severe eosinophilic asthma who meet the following criteria:** • Prescribed by an Allergist or Pulmonologist. • Patient is at least 6 years of age. • Failure, contraindication, or intolerance to benralizumab (applicable to patients 12 years old or greater) • Documented severe persistent asthma (**Table 1**) • Reversible airway obstruction as documented by the following: o Response to inhaled short-acting beta agonists (e.g., FEV_1 reversibility of >12% with at least a 200 mL increase in FEV1) within 30 minutes after administration of albuterol (90-180 mcg) OR o Positive exercise or methacholine challenge OR o Positive response (at least a 15% increase in FEV_1 with at least a 200 mL increase in FEV_1) after a course of treatment with inhaled or systemic corticosteroids. • Documentation of eosinophilic phenotype indicated by one of the following: o Non-oral corticosteroid (OCS) dependent: serum eosinophil count of ≥300 cells/mcL within the past 12 months

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				○ OCS dependent: serum eosinophil count of ≥ 150 cells/mcL within the previous 12 months. • Patient has uncontrolled asthma (see **Table 1**) despite all the following: ○ Trigger avoidance measures ○ Comorbidities that can cause asthma exacerbations (e.g., gastroesophageal reflux disease [GERD], allergic rhinitis) and non-asthma diagnoses (e.g., laryngeal dysfunction, panic disorder) have been evaluated and treated. ○ Aggressive drug therapy regimen for at least 6 months (see **Table 2**) Exclusion criteria: If ONE or more of the following criteria is met, patient is NOT eligible: • Current smoker who is not currently enrolled in a smoking cessation program (e.g., Quit for Life) • Non adherence to pre-requisite asthma drug therapies. ○ Non adherence is defined as less than 75% of proportion of days covered (calculated by day supply dispensed over the total number of days since treatment was initiated). • Concomitant use with omalizumab, benralizumab, reslizumab, or dupilumab. Evaluation for continuation of therapy: • Evaluate response 6 months and then annually thereafter. • Clinical improvement must be demonstrated by at least one of the following: ○ Decreased use of rescue medications ○ Decreased frequency of exacerbations (defined as worsening of asthma that requires increase in ICS dose or treatment with systemic corticosteroids) ○ Improvement in lung function (e.g., FEV1) from pretreatment baseline ○ Objective improvement in quality of life: minimally important difference of 3 points on the Asthma Control Test ○ Improvement in asthma symptoms (such as asthmatic symptoms upon wakening, coughing, fatigue, shortness of breath, sleep disturbance, wheezing, or reduced missed days from work or school). ○ Decreased corticosteroid requirement if on OCS. **Table 1. Evidence for severe refractory asthma and indicators of uncontrolled asthma** **Evidence for severe refractory asthma** • Asthma meets criteria for moderate-to-severe asthma as defined by the NHLBI's EPR-3 and the patient has uncontrolled asthma which should be noted both subjectively and with objective evidence of asthma, despite the following: ○ Ruling out comorbid factors (e.g., allergy, sinusitis, GERD, anxiety disorder, panic disorder, vocal cord dysfunction) to determine if

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				these measures can decrease the need to initiate biologic therapy. o Address and manage all triggers from the home (e.g., animal dander if allergic, dust mites, foods, pollen, smoke exposure). o Aggressive trials of therapy (refer to Table 2) **Indicators of uncontrolled asthma** • Any one of the following criteria qualifies the patient as having uncontrolled asthma: o Two or more asthma exacerbations requiring systemic corticosteroids (≥3 days each) in the past 12 months o Serious exacerbations: at least one hospitalization, intensive care unit (ICU) stay or mechanical ventilation in the previous year o Asthma Control Test (ACT) is consistently <20 **Table 2. Aggressive drug therapy regimens for asthma** *Patients 12 years and older* **A.** Triple drug therapy with high-dose ICS plus LABA combination* plus tiotropium (Spiriva Respimat) (unless contraindications or intolerance) and on oral corticosteroid (OCS) for most days during the previous 6 months (e.g., ≥50% of days) **OR** **B.** Triple drug therapy with high-dose ICS plus LABA combination* plus tiotropium (Spiriva Respimat) (unless contraindications or intolerance) who are not on daily OCS, but who otherwise meet other inclusion criteria and have had frequent severe exacerbations (≥2) in the past 12 months requiring systemic corticosteroids for ≥3 days and/or a history of a serious exacerbation requiring at least one hospitalization, ICU stay, or mechanical ventilation in the previous year. **OR** **C.** Corticosteroid adverse effects: If a patient has been poorly controlled over at least one year and is experiencing corticosteroid adverse effects while on aggressive drug therapy (A or B) then treatment with a biologic drug may be considered. **High-dose ICS plus LABA combinations include: fluticasone/salmeterol 500/50 mcg, 1 inh twice daily or fluticasone salmeterol 230/21 mcg, 2 puffs twice daily*. *Children 6 to 11 years of age* **A.** High-dose ICS** plus LABA combination plus montelukast **OR** **B.** Children on high-dose** ICS plus LABA combination who have had a prior trial of a leukotriene modifier may also be considered

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				High-dose ICS includes ciclesonide 160 mcg, 1 puff twice daily* **For patients with eosinophilic granulomatosis with polyangiitis (EGPA) who meet the following criteria: • Prescribing by an Allergist, Pulmonologist, or Rheumatologist. • Patient is at least 18 years of age. • Documented severe disease (e.g., vasculitis with cerebral, cardiac, renal, or gastrointestinal involvement) or disease flares with tapering of corticosteroid therapy. • Documented trial and failure of, contraindication to, or clinical inappropriateness of treatment with at least one of the following immunosuppressants: azathioprine, cyclophosphamide, or methotrexate. **Exclusion criteria:** If ONE or more of the following criteria is met, patient is NOT eligible: • Severe or clinically significant cardiovascular disease uncontrolled with standard treatment. • Patients with known evidence of lack of adherence to controller medications and/or ability to follow providers recommendations. **Evaluation for Continuation of Therapy:** • Evaluate response after 6 months and then annually thereafter. • Consider discontinuation if there is not a significant decrease in utilization of systemic corticosteroids. Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.
Mirvetuximab soravtansine-gynx	Elahere	C9146, J9063	N/A	Covered for the treatment of patients with Recurrent Ovarian Cancer after primary treatment who are ALL of the following: • Relapse less than 6 months after platinum treatment. • FOLR1 Positive disease (≥75%)
Mitomycin	Jelmyto	J9281	N/A	Covered for the treatment of non-metastatic low-grade upper tract urothelial cancer (LG-UTUC) if all of the following are met: • Patient has a solitary, residual, low-grade, UTUC tumor that is low volume (5-15 mm) • Complete or near complete endoscopic resection or ablation is intended prior to instillation of mitomycin gel
Mirikizumab-mrkz	Omvoh	C9168	N/A	Medical necessity review required.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria

Mogamulizumab-kpkc	Poteligeo	J9204	N/A	Covered in the treatment of Mycosis Fungoides as:
				• 3rd line therapy if:
				  ○ Stage IIB disease.
				  ○ Stage IV disease with nodal or visceral involvement.
				• 2nd line therapy if:
				  ○ Stage III disease following skin directed therapy or Total Electron Beam therapy.

Mometasone furoate implant	Sinuva	J7401, J7402	N/A	Covered for otolaryngology patients with refractory chronic rhinosinusitis with nasal polyps (CRSwNP) with previous bilateral total ethmoidectomy who are candidates for revision sinus surgery due to recurrent symptoms and bilateral polyposis with failure of other corticosteroid treatment including ALL of the following: • Nasal corticosteroids • Corticosteroid nasal rinse/irrigation • Oral corticosteroids Note: Request approved for one administration
Motixafortide acetate	Aphexda	J2277	N/A	Medical necessity review required.
Moxetumomab pasudotox-tdfk	Lumoxiti	J9313	N/A	Covered for treatment of patients with relapsed or refractory hairy cell leukemia (HCL) who received at least two prior systemic therapies, including treatment with a purine nucleoside analog (PNA).

Nadofaragene firadenovec-vncg	Adstiladrin*	J9029	N/A	Covered for adult patients (≥18 years old) who meet all of the following:
				• Confirmed biopsy pathology of either carcinoma in situ (CIS) with or without Ta/T1 papillary tumors; and
				• Non-responsive to BCG defined as having an adequate induction treatment with BCG, (e.g., received at least two previous courses of BCG within a 12-month period, defined as at least five of six induction BCG instillations and at least two out of three instillations of maintenance BCG, or at least two of six instillations of a second induction course, where maintenance BCG is not given); and
				• High-grade BCG-unresponsive NMIBC which includes patients who have:
				  ○ Recurrence despite adequate BCG treatment and have a persistent high-grade recurrence within 12 months after BCG was initiated
				  ○ Relapse with high-grade CIS within 12 months of last intravesical BCG treatment despite an initial complete response to BCG
				  ○ Relapse with high-grade Ta/T1 NMIBC within six months of last intravesical BCG treatment
				and
				• All visible papillary tumors are resected and those with persistent T1 disease on transurethral resection of bladder tumor (TURBT) should undergo an additional re-TURBT within approximately four to six weeks prior to beginning treatment; and

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• Life expectancy >2 years; and • No concomitant upper tract urothelial carcinoma or urothelial carcinoma within the prostatic urethra Initial authorization: 3 months Reauthorization every 12 months to confirm no recurrence of high-grade disease.
Natalizumab	Tysabri	J2323, 1 mg	3900	Approved for patients with the following: • Diagnosis of a relapsing form of MS based on the McDonald criteria AND • Failure or intolerance to either beta-interferon or glatiramer. Minor injection site reactions are not considered medication failure. OR • Diagnosis of a relapsing form of MS based on the McDonald criteria AND • Evidence of highly active disease. Note: Must be prescribed by or in consultation with a neurology specialist. Not covered for other types of MS or for Crohn's disease. Not covered for use in combination with other disease-modifying multiple sclerosis therapies OR other biologics including (but not limited to): • Alemtuzumab (Lemtrada), Cladribine (Mavenclad), Dimethyl fumarate, Diroximel fumarate (Vumerity), Fingolimod (Gilenya), Glatiramer acetate, Interferon beta-1a (Avonex, Rebif), Interferon beta-1b (Betaseron, Extavia), Mitoxantrone (Novantrone), Ocrelizumab (Ocrevus), Peginterferon beta-1a (Plegridy), Siponimod (Mayzent), Teriflunomide (Aubagio), ofatumumab (Kesimpta) • Adalimumab (e.g., Amjevita), certolizumab, etanercept, golimumab, infliximab (e.g., Inflectra) **Quantity Limit:** 300 mg every 4 weeks Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts. **Applicable codes:** *ICD-10 codes covered if selection criteria or medical necessity is met. Listing of code does not guarantee coverage or reimbursement. The following list is provided for reference purposes only and may not be all inclusive.* K50.K50.919, G35
Naxitamab-gqgk	Danyelza	J9348	N/A	Medical necessity review required.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
Necitumumab	Portrazza	J9295, 1 mg	N/A	Not covered, not medically necessary Approval of necitumumab was based on the randomized, open-label, controlled Phase 3 SQUIRE trial evaluating necitumumab as part of combination therapy for patients with previously untreated stage IV squamous non-small cell lung cancer (NSCLC). A modest 1.6 month improvement in median OS was observed with the addition of necitumumab to gemcitabine and cisplatin over gemcitabine and cisplatin alone, which is not considered clinically significant per the American Society of Clinical Oncology (ASCO) Clinical Research Committee. Necitumumab has two Boxed Warnings regarding the risk for cardiopulmonary arrest and/or sudden death, and hypomagnesemia. Cardiopulmonary arrest and/or sudden death occurred in 3% of patients treated with necitumumab with gemcitabine and cisplatin versus 0.6% in patients treated with gemcitabine and cisplatin. The most common adverse drug events (ADEs) observed in patients receiving necitumumab with gemcitabine and cisplatin therapy were: rash, hypomagnesemia, nausea, vomiting, neutropenia, and anemia. Due to toxicity, cost, and limited efficacy when compared to gemcitabine and cisplatin therapy, necitumumab with gemcitabine and cisplatin first-line regimen for metastatic, squamous NSCLC is currently considered a category 3 recommendation by the NCCN Panel.
Nivolumab	Opdivo	J9299, 1mg	N/A	Covered for: 1. Treatment of stage IV colorectal cancer that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) • Patients who are immunotherapy naïve • Combined with ipilimumab • Note: If progression noted off immuno-oncology (IO) therapy after completion of 2 years of therapy, may restart utilizing first line IO therapy options. 2. For patients with locoregionally advanced colorectal cancer as neoadjuvant treatment if: • Microsatellite instability-high (MSIH) or mismatch repair deficient (dMMR) • Patients who are immunotherapy naïve • Combined with ipilimumab. • Limited to one year total therapy. 3. Treatment of patients with metastatic urothelial carcinoma as second line therapy after platinum-based therapy 4. Treatment of metastatic esophageal squamous cell carcinoma as monotherapy if ALL the following apply: • Immunotherapy naïve • Progression following platinum-based chemotherapy 5. Treatment of Nasopharyngeal Metastatic, recurrent, or unresectable squamous-cell carcinoma of the head and neck as second line therapy.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• Not covered for failure or progression on or after an alternative PD-L1 agent. 6. Treatment of patients with Hodgkin lymphoma: • Diagnosis of relapsed or refractory Hodgkin Lymphoma AND • Progression of disease on or after one or more lines of therapy and no prior I/O therapy. 7. Treatment of primary central nervous system lymphoma (PCNSL) after first progression or lack of response to first line therapeutic options 8. Treatment of patients with melanoma: • Covered for unresectable or metastatic disease for up to 2 years either: o As monotherapy, except following progression on an alternative PD-1 agent such as pembrolizumab. o In combination with CTLA-4 agents such as ipilimumab in patients with ECOG score of 0 or 1 • Covered for adjuvant treatment of resected stage III disease for up to 1 year. • Covered for neoadjuvant treatment of stage IIIB- IV Melanoma if all the following apply: o BRAF+ o PS 0-1 o Combined with Ipilimumab 8. Treatment of patients with uveal melanoma: • For localized or symptomatic disease palliation after radiation therapy or clinical trial when combined with ipilimumab. • For metastatic disease, o If combined with ipilimumab AND o If patient is tebentafusp ineligible. 9. Covered for locally advanced unresectable mesothelioma 10. Treatment of patients with advanced stage non-small cell lung cancer (NSCLC): • Covered as single agent for patients who have progressed on or after chemotherapy, have no EGFR or ALK mutations, and have not previously been treated with PD-1 immunotherapy agents. • Patients with ROS-1 gene aberrations must have progressed on approved applicable agents. • In combination with ipilimumab for patients with PD-L1 expression who have not been previously been treated with PD-1 immunotherapy agents.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				11. Treatment of patients with stage II-III non-small cell lung cancer (NSCLC), ALL of the following must apply: • Candidate for neoadjuvant therapy. • If EGFR/ALK negative. • Combined with platinum-based chemotherapy. 12. Treatment of small cell lung cancer (SCLC): • Covered as subsequent therapy if PS 0-2, relapse less than 6 months, and have not previously been treated with PD-1 immunotherapy agents 13. Treatment of patients with metastatic non papillary renal cell carcinoma (RCC) if combined with either ipilimumab OR cabozantinib OR as monotherapy if used in the second line setting and patient is immunotherapy naïve. 14. Treatment of patients with recurrent or metastatic non-nasopharyngeal squamous-cell carcinoma of the head and neck (SCCHN): • If not eligible for chemotherapy • Not covered for patients who progressed on or after an alternative PD-1 agent. 15. Treatment of metastatic GEJ, esophageal, gastric cancer in the first line setting 16. Covered for locally advanced esophageal, GEJ or gastric cancer after neo-adjuvant chemotherapy with residual disease at surgery. Coverage not to exceed 1 year. 17. Treatment of Siewert type I and II Esophageal, GEJ for up to 1 year in patients who received neoadjuvant chemoradiation and have residual disease at surgery. 18. Covered as adjuvant therapy for patients with completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease, who have received neoadjuvant chemoradiotherapy for a total treatment duration of one year. 19. Covered for the treatment of Hepatocellular Carcinoma if ALL the following apply: • Second line treatment option if combined with ipilimumab • Child Pugh A • Immunotherapy naïve 20. Covered as combination therapy as first line treatment of Esophageal Squamous cell Metastatic Carcinoma. 21. Covered as peri-operative/neoadjuvant treatment of Gastric Cancer/GEJ Siewert III:

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• If planned Lymphadenectomy AND • If combined with Ipilimumab. AND • dMMR/MSI-H tumor 22. Treatment of metastatic esophageal squamous cell carcinoma: • In the first line setting if combined with platinum-based chemotherapy or ipilimumab and Immunotherapy naïve 23. Neo-adjuvant treatment of non-metastatic Merkel cell carcinoma. Note: Must be administered in a non-hospital setting when used as monotherapy (new starts and maintenance monotherapy). Dose exceptions for new starts: 2 doses within 3 months. See site of care policy for criteria, reauthorization, and exceptions for new starts.
Nivolumab/relatlimab-rmbw	Opdualag	J9298	N/A	Covered for the treatment of unresectable or metastatic melanoma in the first line setting for patients: • Who have PD-L1 less than 1%
Nusinersen	Spinraza*	J2326	N/A	Covered for patients with spinal muscular atrophy (SMA) who meet all of the following: • Prescribed by or in consultation with Pediatric Neurology, Neurology or other specialist with expertise in managing SMA. • Documented diagnosis of 5q-autosomal recessive SMA (biallelic deletions or mutations in the *SMN1* gene). • Two to four copies of the *SMN2* gene. • If patient is 22 to 65 years old, patient is ambulatory with baseline Hammersmith Functional Motor Scale-Expanded Exam (HFMSE) score ≥35 and documented disease progression. • Required documentation: ○ Baseline labs (CBC, PT/PTT, urinalysis) ○ Baseline functional motor assessment ▪ Infants: • Hammersmith Infant Neurological Examination Section 2 (HINE-2) OR Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) ▪ Children (age > 24 months), adolescents, adults: • HFMSE AND Revised Upper Limb Module (RULM) ▪ All ambulatory: 6-minute walk test (6MWT) ○ Spine evaluation to assess ease of lumbar puncture entry ○ Risk assessment for procedure: objective respiratory testing ▪ Age ≥ 6 years: pulmonary function tests (PFTs) ▪ Age < 6 years: pulse oximetry and End-Tidal CO2 (ETCO2) measurements; Also consider screening sleep studies in non-ambulatory, hypotonic infants and young children

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				Not covered for patients: • Age > 65 years at time of treatment initiation • Permanent invasive ventilation or tracheostomy • Dependent on invasive or non-invasive ventilation during waking hours each day to control hypercarbia, or development of hypercarbia without ventilatory support • Contraindication to lumbar puncture • Concurrent treatment with risdiplam (Evrysdi) • Prior or planned treatment with gene therapy for SMA Reassessment every 12 months to determine need for continued therapy. Therapy should be discontinued if patient meets at least one of the discontinuation criteria: • Non-adherence to follow-up assessment including medical treatment plan (e.g., nutrition, pulmonary, physical therapy). • Permanent invasive ventilation or tracheostomy • Dependent on invasive or non-invasive ventilation during waking hours each day to control hypercarbia, or development of hypercarbia without ventilatory support • Loss of function or progressive weakness (physical and/or pulmonary) • Risdiplam or other therapy for SMA is initiated
Obinutuzumab	Gazyva	J9301, 10 mg	N/A	• For the treatment of treatment-naive patients with chronic lymphocytic leukemia (CLL). Obinutuzumab must be used with venetoclax. ○ Not covered for treatment-naive CLL or small lymphocytic lymphoma (SLL) as combination therapy with ibrutinib, acalabrutinib or zanubrutinib
Ocrelizumab	Ocrevus	J2350	N/A	Covered for patients who: • Have primary progressive multiple sclerosis as confirmed by a neurologist and are ≤55 years old OR • Have a relapsing form of MS based on McDonald criteria AND have failure or intolerance to ≥2 disease modifying therapies (e.g., glatiramer, interferon beta, rituximab (e.g., Riabni), natalizumab) Note: Must be prescribed by or in consultation with a neurology specialist Not covered for use in combination with other disease-modifying multiple sclerosis therapies including (but not limited to): • Alemtuzumab (Lemtrada), Cladribine (Mavenclad), Dimethyl fumarate, Diroximel fumarate (Vumerity), Fingolimod (Gilenya), Glatiramer acetate, Interferon beta-1a (Avonex, Rebif), Interferon beta-1b (Betaseron, Extavia), Mitoxantrone (Novantrone), Natalizumab (Tysabri), Peginterferon beta-1a (Plegridy), Siponimod (Mayzent), Teriflunomide (Aubagio), Ofatumumab (Kesimpta) **Quantity Limit:**

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• Induction: 300 mg on day 1 and day 15 • Maintenance dose: 600 mg every 24 weeks Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts. Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change. **Applicable codes:** *ICD-10 codes covered if selection criteria or medical necessity is met. Listing of code does not guarantee coverage or reimbursement. The following list is provided for reference purposes only and may not be all inclusive.* (G35)
Ocriplasmin	Jetrea	J7316	N/A	Covered for patients with moderate to severe symptomatic vitreomacular adhesion who: • Do not have cataracts OR have contraindications to vitrectomy; AND • Do not have the following co-morbid conditions: high myopia, diabetic retinopathy, macular hold >400 µm, history of retinal detachment, or any proliferative retinopathy; AND • Have not previously been treated with ocriplasmin (i.e., only 1 injection per eye will be allowed).
Ofatumumab	Arzerra	J9302, 10 mg	N/A	• For the treatment of patients with CLL that is refractory to prior therapy • NOT covered for use as first line therapy (i.e. treatment naïve) in CLL.
Ofatumumab	Kesimpta	Unspecified J3490, J3590	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria (refer to pharmacy benefit)
Olaratumab	Lartruvo	J9285	N/A	Covered in combination with doxorubicin, for adult patients with soft tissue sarcoma (STS) with a histologic subtype for which an anthracycline-containing regimen is

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				appropriate and which is not amenable to curative treatment with radiotherapy or surgery
Olipudase alfa-rpcp	Xenpozyme	J0218	N/A	Covered for patients with non-central nervous system (non-CNS) manifestations of acid sphingomyelinase deficiency (ASMD) who meet the following: • Documentation of genetic presence of SMPD1 mutation and/or enzymatic confirmation (acid sphingomyelin deficiency) • Documentation of non-CNS manifestations of ASMD • Dose prescribed is no more than 3 mg/kg administered every 2 weeks. Reauthorization: reassessment every 12 months to confirm clinical benefit including disease stability or improvement in symptoms and a current weight **Quantity limit:** Up to 26 infusions per year; ≤ 3 mg/kg every 2 weeks
Omacetaxine	Synribo	J9262	N/A	For patients with chronic myelogenous leukemia (CML) who had: 1. Failure, contraindication or intolerance to three or more tyrosine kinase inhibitors including imatinib and a second generation agent (dasatinib or nilotinib) OR 2. A susceptible T315I mutation
Omalizumab	Xolair	J2357	N/A	Not covered under the medical benefit (hospital, clinic, or home infusion) after initial 3 doses. May be covered under the pharmacy benefit. • Exceptions may be considered for the following: ○ Patients with impaired manual dexterity, impaired vision, or patients who are unable to safely self-administer (e.g., documented history of anaphylaxis [such as bronchospasm, hypotension, syncope, urticaria, angioedema] to medications or foods) AND who meet clinical criteria ○ NOTE: plans with reduction rider must meet clinical criteria for exceptions. **1. Moderate-to-severe persistent allergic asthma who meet the following criteria**: • Prescribing physician is an Allergist or Pulmonologist • Patient age 6 years or older • Documented moderate-to-severe persistent asthma **(see Table 1)** • Documented atopic asthma by the following methods ○ Specific IgE by skin PRICK test OR CAP “RAST” AND ○ Determination of atopic status by an Allergist • Documented baseline total IgE serum level between 30 and 700 international units/mL for patients ≥ 12 years OR between 30 and 1300 international units/mL for children 6 to 11 years AND total serum IgE and weight are within dosage range. • Reversible airway obstruction as documented by the following

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				○ Response to inhaled short-acting beta agonists (e.g., FEV_1 reversibility of >12% with at least a 200 mL increase in FEV_1) within 30 minutes after administration of albuterol (90-180 mcg) OR ○ Positive exercise or methacholine challenge OR ○ Positive response (at least a 15% increase in FEV_1 with at least a 200 mL increase in FEV_1) after a course of treatment with inhaled or systemic corticosteroids • Patient has uncontrolled asthma **(see Table 1)** despite all the following: ○ Trigger avoidance measures ○ Comorbidities that can cause asthma exacerbations (e.g., gastroesophageal reflux disease [GERD], allergic rhinitis) and non-asthma diagnoses (e.g., laryngeal dysfunction, panic disorder) have been evaluated and treated. ○ Aggressive drug therapy regimen for at least 6 months **(see Table 2).** **Exclusion criteria: If ONE or more of the following criteria is met, patient is NOT eligible:** • Current smoker who is not currently enrolled in a smoking cessation program (e.g., Quit for Life) • Non adherence to pre-requisite asthma drug therapies. ○ Non adherence is defined as less than 75% of proportion of days covered (calculated by day supply dispensed over the total number of days since treatment was initiated). • Concomitant use with mepolizumab, benralizumab, reslizumab, or dupilumab **Reauthorization Criteria:** • Evaluate response after 6 months and then annually thereafter. • Clinical improvement must be demonstrated by at least one of the following: ○ Decreased use of rescue medications ○ Decreased frequency of exacerbations (defined as worsening of asthma that requires increase in ICS dose or treatment with systemic corticosteroids) ○ Improvement in lung function (e.g., FEV1) from pretreatment baseline ○ Objective improvement in quality of life: minimally important difference of 3 points on the Asthma Control Test ○ Improvement in asthma symptoms (such as asthmatic symptoms upon wakening, coughing, fatigue, shortness of breath, sleep disturbance, wheezing, or reduced missed days from work or school). ○ Decreased corticosteroid requirement if on OCS. **Table 1. Evidence for severe refractory asthma and indicators of uncontrolled asthma** **Evidence for severe refractory asthma**

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• Asthma meets criteria for moderate-to-severe asthma as defined by the NHLBI's EPR-3 and the patient has uncontrolled asthma which should be noted both subjectively and with objective evidence of asthma, despite the following: o Ruling out comorbid factors (e.g., allergy, sinusitis, GERD, anxiety disorder, panic disorder, vocal cord dysfunction) to determine if these measures can decrease the need to initiate biologic therapy. o Address and manage all triggers from the home (e.g., animal dander if allergic, dust mites, foods, pollen, smoke exposure). o Aggressive trials of therapy (refer to Table 2) **Indicators of uncontrolled asthma** • Any one of the following criteria qualifies the patient as having uncontrolled asthma: o Two or more asthma exacerbations requiring systemic corticosteroids (≥3 days each) in the past 12 months o Serious exacerbations: at least one hospitalization, intensive care unit (ICU) stay or mechanical ventilation in the previous year o Asthma Control Test (ACT) is consistently <20 **Table 2. Aggressive drug therapy regimens for asthma** *Patients 12 years and older* **D.** Triple drug therapy with high-dose ICS plus LABA combination* plus tiotropium (Spiriva Respimat) (unless contraindications or intolerance) and on oral corticosteroid (OCS) for most days during the previous 6 months (e.g., ≥50% of days) **OR** **E.** Triple drug therapy with high-dose ICS plus LABA combination* plus tiotropium (Spiriva Respimat) (unless contraindications or intolerance) who are not on daily OCS, but who otherwise meet other inclusion criteria and have had frequent severe exacerbations (≥2) in the past 12 months requiring systemic corticosteroids for ≥3 days and/or a history of a serious exacerbation requiring at least one hospitalization, ICU stay, or mechanical ventilation in the previous year. **OR** **F.** Corticosteroid adverse effects: If a patient has been poorly controlled over at least one year and is experiencing corticosteroid adverse effects while on aggressive drug therapy (A or B) then treatment with a biologic drug may be considered.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				High-dose ICS plus LABA combinations include: fluticasone/salmeterol 500/50 mcg, 1 inh twice daily or fluticasone salmeterol 230/21 mcg, 2 puffs twice daily*. *Children 6 to 11 years of age* **C. High-dose ICS** plus LABA combination plus montelukast **OR** **D.** Children on high-dose** ICS plus LABA combination who have had a prior trial of a leukotriene modifier may also be considered **High-dose ICS includes ciclesonide 160 mcg, 1 puff twice daily* Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts. **2. Chronic idiopathic urticaria (CIU) who meet the following criteria**: • 12 years of age or older, and • urticaria (hives) on most days of the week for ≥6 weeks, and • no external allergic cause or contributing disease can be identified, and • prescribed by or in consultation with an allergist, and • Have failed, are intolerant to, or have a contraindication to an adequate duration of all of the following: o Histamine-1 receptor antagonist at four times the FDA-approved dose, and o Leukotriene receptor antagonist (4 weeks minimum) Reauthorization criteria: • Initial authorization period: 6 months. Afterwards, annual re-authorization is required • Reauthorization requires documentation of continued patient benefit on therapy. **3. For patients with chronic rhinosinusitis with nasal polyps (CRSwNP) who meet the following criteria:** • Prescribed by an Allergist or Otolaryngologist. • Patient is at least 18 years of age. • Persistent rhinosinusitis symptoms that include 2 or more of the following for at least 12 weeks (1 of which is nasal obstruction): o Severe nasal obstruction AND o Rhinorrhea (anterior/posterior) OR o Reduction or loss of smell

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria

				• Bilateral nasal polyps with polyps filling the middle meatuses and obstructing the ostia OR failure of normalization of the mucosa after a full sinus surgery despite maximal post-operative medical management.
				• Prior treatment with the following:
				  ○ Nasal corticosteroids
				  ○ Oral corticosteroids (OCS) for the treatment of nasal polyps within the past year (unless contraindication or intolerance to OCS) AND
				  ○ A prior full endoscopic sinus surgery (ESS) or contraindication to full ESS.
				• Failure, contraindication, or intolerance to dupilumab (Dupixent)
				• Elevated serum eosinophils (≥300 cells/mcL) within the prior 12 months OR moderate or severe eosinophil-predominant inflammatory infiltrate in surgical tissue.
				
				Evaluation for Continuation of Therapy:
				• Evaluate response after 6 months and then annually thereafter.
				• Clinical improvement must be demonstrated by one or more of the following:
				  ○ Reduction in size of nasal polyps
				  ○ Improvement in patient symptoms (e.g., congestion, smell test)
				  ○ Decreased need for oral corticosteroids and nasal polyp surgery
				  ○ Improvement in health-related quality of life and/or the 22-item Sino-Nasal Outcomes Test (SNOT-22) score
				
				Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.

Onasemnogene abeparvovec-xioi	Zolgensma*	J3399		Covered for pediatric patients with spinal muscular atrophy (SMA) who meet all of the following:
				• Prescribed by or in consultation with Pediatric Neurology, Neurology, or other specialist with expertise in managing infantile SMA
				• Documented bi-allelic SMN1 mutation (deletion or point mutations)
				• Documentation of 1, 2, or 3 copies of SMN2 gene
				• Treatment must be administered no later than age 6 months
				• Required documentation:
				  ○ Gene mutation analysis and confirmatory testing for bi-allelic SMN1 mutations (deletions or point mutation)
				  ○ Baseline labs (CBC, serum creatinine, liver function tests [ALT, AST, GGT, total bilirubin] PT/PTT, Troponin-I)
				  ○ Baseline labs negative for active viral infection (HIV, Hep B and Hep C)
				  ○ Anti-AAV9 antibody titer ≤1:50 within 14 days prior to onasemnogene abeparvovec-xioi infusion

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				○ Baseline functional motor assessment (CHOP-INTEND) performed by a physical therapist as soon as possible after diagnosis (2 to 4 weeks post-diagnosis is optimal) Not covered for: • Patients with zero or ≥4 copies of *SMN2* gene • Patients with other types of SMA that do not involve SMN1 mutation • Patients requiring use of invasive ventilation (tracheotomy with positive pressure)* or pulse oximetry <95% saturation. *Exception: non-invasive ventilator support (BiPAP) for less than 10 hours a day. • Prior or planned treatment with gene therapy for SMA **Note: Prior to treatment with onasemnogene abeparvovec, review by an Inter-regional Consultative Physician Panel is required.**
Paclitaxel protein-bound	Abraxane	J9264, J9258	N/A	• Covered for advanced breast cancer for patients who are allergic to the paclitaxel solvent (polyoxyethylated caster oil) and cannot be re-challenged with a taxane due to a hypersensitivity to the solvent base. • Covered for treatment of unresectable, locally advanced, or metastatic triple-negative breast cancer in combination with pembrolizumab in patients with: ○ Demonstrated PD-L1 expression ≥ 1% on tumor-infiltrating immune cell (IC) via SP142 immunohistochemical assay • Covered in pancreatic adenocarcinoma if combined with gemcitabine. • Covered for previously treated Unresectable or Metastatic Biliary Tract Cancer if combined with gemcitabine. • Covered for other indications based on medical necessity review.
Palivizumab	Synagis	S9562, 90378	N/A	The American Academy of Pediatrics recommends immunoprophylaxis with intramuscular palivizumab (Synagis) during the RSV season for children who meet one or more of the criteria listed below. Palivizumab (Synagis) Preauthorization Criteria 2023-2024 • Children younger than 12 months at the start of RSV season (i.e., born after 10/1/22) AND one or more of the following: ○ Children born before 29 weeks 0 days OR ○ Born before 32 weeks 0 days and have Chronic Lung Disease AND had a requirement for > 21% oxygen for at least the first 28 days after birth OR ○ Hemodynamically significant heart disease OR ○ Pulmonary abnormalities or neuromuscular disease that impairs the ability to clear secretions

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria

				• Children between 12 and 24 months of age at the start of RSV season (e.g., born between 10/1/2021 and 12/1/2021) AND:
				  ○ Born before 32 weeks 0 days and have Chronic Lung Disease and had a requirement for >21% oxygen for at least the first 28 days after birth and continue to require medical intervention for lung disease (supplemental oxygen, chronic corticosteroids, or diuretic therapy)
				• Children younger than 24 months of age at the start of RSV season (e.g., born after 10/1/2021) AND:
				  ○ Profound immunocompromised status
				• Additional information:
				  ○ There is insufficient data to recommend palivizumab for patients with Down Syndrome or cystic fibrosis who would not otherwise meet criteria.
				  ○ Qualifying infants will need a maximum of 5 monthly doses in a season. Qualifying infants born during RSV season may require fewer doses
				  ○ Monthly prophylaxis should be discontinued in any child who experiences a breakthrough RSV hospitalization.
				
				Note: updates to align with National AAP recommendations including effective dates are updated as appropriate on an ongoing basis.
				
				**Infants with hemodynamically significant congenital heart disease that are most likely to benefit include infants with acyanotic heart disease who are receiving medication to control CHF and will require cardiac surgical procedures and infants with moderate to severe pulmonary hypertension. NOTE: Infants NOT at increased risk include hemodynamically insignificant heart disease (such as secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosis), infants with lesions corrected by surgery unless they continue to require medications for CHF, and infants with mild cardiomyopathy who are not receiving medical therapy. The benefit of prophylaxis in cyanotic heart defects is unknown – decision should be discussed with the infant's pediatric cardiologist.*
				
				***Palivizumab prophylaxis is <u>not</u> recommended in the second year of life <u>except</u> for children who require at least 28 days of supplemental oxygen after birth and who continue to require medical intervention as defined by needing supplemental oxygen, chronic corticosteroid, or diuretic therapy.*

Panitumumab	Vectibix	J9303, 10 mg	N/A	For use in combination with chemotherapy or as monotherapy in patients with wildtype KRAS / NRAS metastatic left sided, colorectal cancer who cannot tolerate cetuximab. Not covered for use as a second-line therapy in patients who progress on cetuximab therapy.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
Pasireotide	Signifor	Unspecified C9399, J3490, J3590	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria (refer to pharmacy benefit)
Pasireotide	Signifor LAR	J2502	N/A	Initial Authorization: For the treatment of Cushing's Disease in patients who: • Have failure, contraindication or intolerance to ketoconazole • Initial Authorization: 90 days Reauthorization Criteria: • Patient has experienced a significant reduction in 24-hour urinary free cortisol (UFC) defined as ≥50% reduction in UFC from baseline.
Patisiran	Onpattro*	J0222	N/A	Covered for patients who meet all of the following criteria: • Prescribed by a Neurologist or Neuromuscular specialist • Age 18 years or older • Diagnosis of hereditary transthyretin mediated amyloidosis (hATTR) with polyneuropathy that is thought to be primarily due to amyloidosis. • Documentation of genetic testing to confirm transthyretin (TTR) mutation • Karnofsky performance status score ≥50 • Objective weakness in motor strength exam consistent with diagnosis and with confirmation via electrodiagnostic studies (i.e., electromyogram, nerve conduction study) • Signs of large fiber neuropathy on exam and/or clinically significant autonomic findings (e.g., orthostatic hypotension, tachycardia, bradycardia, etc.) • Required baseline documentation: o Medical Research Council (MRC) strength testing scale (0-5) o electromyography (EMG)/nerve conduction studies (NCS) Exclusion criteria: • Concomitant use with tafamidis/tafamidis meglumine Reassess every 6 months to evaluate need for continued treatment. Therapy should be discontinued if: • Member non-adherent to medication or follow-up assessments, • Significant clinical decline with life expectancy of less than one year • Karnofsky performance status score of less than 30

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• Patient requiring hospice care **Note: Prior to treatment initiation, patients should be reviewed by an Interregional Consultative Physician Panel.** Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.
Peanut allergen powder	Palforzia	J8499	N/A	**Initial Authorization:** Approved for patients with a peanut allergy diagnosis who meet all of the following criteria: • Prescribed by or in consultation with an allergist/immunologist • Age 4-17 years old when starting Initial Dose Escalation (IDE) phase • Patient is not on concurrent peanut-specific immunotherapy (e.g., Viaskin Peanut) • To be used in conjunction with a peanut-avoidant diet • Confirmation of diagnosis of allergy to peanuts or peanut-containing foods as determined one of the criteria below: ○ Clinical history consistent with IgE-mediated food allergy to peanut and meets the following criteria: ▪ Positive skin prick test (wheal diameter ≥ 3 mm) **OR** ▪ Peanut-specific IgE ≥ 0.35 kUA/L ○ No clear clinical history of food allergy to peanut but meets the following criteria: ▪ Positive skin prick test (wheal diameter ≥ 8 mm) **OR** ▪ Peanut-specific IgE ≥ 14 kUA/L ○ No clear clinical history of food allergy to peanut but meets the following criteria: ▪ Documented reaction to peanut protein upon a supervised oral food challenge (OFC) **AND** ▪ Positive skin prick test (wheal diameter 3-8 mm) **OR** ▪ Peanut-specific IgE 0.35-14 kUA/L **Reauthorization Criteria:** Physician attestation of persistent peanut allergy **Initial authorization duration:** 12 months **Reauthorization duration:** every 24 months
Pegcetacoplan intravitreal	Syfovre	J2781	N/A	Covered for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD) in patients who meet all of the following:

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• Age 60 years or older • No diagnosis of GA secondary to other disease (e.g., Stargardt disease, cone rod dystrophy, or toxic maculopathies) • Administered by a retina specialist. **Quantity limit:** 15 mg every 25 days per affected eye
Pegfilgrastim	Neulasta	J2505, J2506	N/A	Covered only for patients who cannot physically self-administer filgrastim (e.g., Nivestym [preferred], Zarxio) via a prefilled syringe AND who have demonstrated an inadequate response or intolerance to a pegfilgrastim biosimilar (e.g., Fulphila). **Quantity Limit:** 6 mg every week **Applicable codes:** *ICD-10 codes covered if selection criteria or medical necessity is met. Listing of code does not guarantee coverage or reimbursement. The following list is provided for reference purposes only and may not be all inclusive.* (C00.0-C96.Z, D40.1)
Pegfilgrastim	Neulasta Onpro	J2505, J2506	N/A	Coverage Restriction: Not covered, not medically necessary due to the availability of treatment alternatives
Pegfilgrastim-apgf	Nyvepria	Q5122	N/A	Covered only for patients who cannot physically self-administer filgrastim (e.g., Nivestym [preferred], Zarxio) via a prefilled syringe **Quantity Limit:** 6 mg every week **Applicable codes:** *ICD-10 codes covered if selection criteria or medical necessity is met. Listing of code does not guarantee coverage or reimbursement. The following list is provided for reference purposes only and may not be all inclusive.* (C00.0-C96.Z, D40.1)
Pegfilgrastim-fpgk	Stimufend	Q5127	N/A	Covered only for patients who cannot physically self-administer filgrastim (e.g., Nivestym [preferred], Zarxio) via a prefilled syringe. **Quantity Limit:** 6 mg every week **Applicable codes:** *ICD-10 codes covered if selection criteria or medical necessity is met. Listing of code does not guarantee coverage or reimbursement. The following list is provided for reference purposes only and may not be all inclusive.* (C00.0-C96.Z, D40.1)

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
Pegfilgrastim-jmdb	Fulphila	Q5108	N/A	Covered only for patients who cannot physically self-administer filgrastim (e.g., Nivestym [preferred], Zarxio) via a prefilled syringe. **Quantity Limit:** 6 mg every week **Applicable codes:** *ICD-10 codes covered if selection criteria or medical necessity is met. Listing of code does not guarantee coverage or reimbursement. The following list is provided for reference purposes only and may not be all inclusive.* (C00.0-C96.Z, D40.1)
Pegfilgrastim-bmez	Ziextenzo	Q5120	N/A	Covered only for patients who cannot physically self-administer filgrastim (e.g., Nivestym [preferred], Zarxio) via a prefilled syringe **Quantity Limit:** 6 mg every week **Applicable codes:** *ICD-10 codes covered if selection criteria or medical necessity is met. Listing of code does not guarantee coverage or reimbursement. The following list is provided for reference purposes only and may not be all inclusive.* (C00.0-C96.Z, D40.1)
Pegfilgrastim-cbqv	Udenyca	Q5111	N/A	Covered only for patients who cannot physically self-administer filgrastim (e.g., Nivestym [preferred], Zarxio) via a prefilled syringe **Quantity Limit:** 6 mg every week **Applicable codes:** *ICD-10 codes covered if selection criteria or medical necessity is met. Listing of code does not guarantee coverage or reimbursement. The following list is provided for reference purposes only and may not be all inclusive.* (C00.0-C96.Z, D40.1)
Pegfilgrastim-pbbk	Fylnetra	Q5130	N/A	Covered only for patients who cannot physically self-administer filgrastim (e.g., Nivestym [preferred], Zarxio) via a prefilled syringe. **Quantity Limit:** 6 mg every week **Applicable codes:** *ICD-10 codes covered if selection criteria or medical necessity is met. Listing of code does not guarantee coverage or reimbursement. The following list is provided for reference purposes only and may not be all inclusive.*

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				(C00.0-C96.Z, D40.1)
Peginterferon beta-1a	Plegridy	Unspecified C9399, J3490, J3590	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria (refer to pharmacy benefit)
Pegloticase	Krystexxa	J2507, 1 mg	208 mg	Pegloticase is not covered due to insufficient evidence to show that it provides better long-term outcomes or better long-term safety than current standard therapies. While more pegloticase treated patients were able to achieve a plasma UA level <6 mg/dL than placebo treated patients in two randomized clinical trials, there are no comparative data against alternatives such as febuxostat. There was a higher rate of cardiac events (e.g., arrhythmia, tachycardia, CHF, etc.) associated with pegloticase leading to uncertainty in long term safety. Pegloticase is also significantly less affordable than other alternatives. Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.
Pegunigalsidase alfa-iwxj	Elfabrio	J2508	N/A	Covered for adult patients with a confirmed diagnosis of Fabry disease Reauthorization: reassessment every 12 months to confirm clinical benefit including disease stability or improvement in symptoms and a current weight
Pegvisomant	Somavert	Unspecified C9399, J3490, J3590	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria (refer to pharmacy benefit)
Pembrolizumab	Keytruda	J9271, 1 mg	N/A	Covered for: 1. Treatment of patients with metastatic urothelial carcinoma • As first line therapy if combined with enfortumab or • Second line monotherapy after platinum-based therapy 2. Treatment of patients with melanoma:

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria

				• Covered for treatment of patients with unresectable or metastatic melanoma as a single agent
				  ○ Covered in combination with CTLA-4
				  ○ Not covered as monotherapy following progression on checkpoint inhibitor.
				• Covered for adjuvant treatment of resected stage IIB, IIC melanoma.
				• Covered for neoadjuvant treatment of Stage IIIB-IV
				
				3. Treatment of patients with stage II-III non-small cell lung cancer (NSCLC), ALL of the following must apply:
				• Candidate for neoadjuvant therapy.
				• If EGFR/ALK negative.
				• Combined with platinum-based chemotherapy
				
				4. Treatment of metastatic NSCLC if ALL of the following apply:
				• Without progression on immunotherapy.
				• PD-L1 positive
				• No EGFR/ALK mutations.
				• As a single agent if PS>2
				• Patients with ROS-1 gene aberrations must have progressed on approved applicable agents (e.g., ceritinib, alectinib, lorlatinib, entrectinib) and have not previously progressed on with PD-1 immunotherapy agents.
				
				5. Treatment of stage IV Thymic Carcinoma as subsequent therapy after chemotherapy.
				
				6. Treatment of metastatic pancreatic adenocarcinoma:
				• Covered as second line therapy if MSI-H or dMMR tumor status.
				• Covered as third line therapy if TMB is at least 10.
				
				7. Treatment of hepatocellular carcinoma if ALL the following apply:
				• Second line treatment option
				• Child Pugh A
				• Immunotherapy Naïve
				
				8. Treatment of neoadjuvant triple negative breast cancer in patients with high risk disease (High Tumor Burden or ≥T1c and LN + or ≥T2) when combined with paclitaxel, carboplatin or doxorubicin and cytoxan.
				
				9. Adjuvant treatment of TNBC after neoadjuvant pembrolizumab treatment.
				
				10. First line therapy for metastatic, unresectable, or recurrent PDL1 (CPS ≥10) positive, triple negative breast cancer, or after 1st line therapy if no prior immunotherapy in the following conditions:

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• ER/PR negative and HER2 Low in the first line setting OR • In combination with carboplatin and gemcitabine OR • In combination with paclitaxel 11. Treatment of Endometrial Cancer if: • First Line (systemic treatment naïve) o dMMR/MSI-H & Stage III disease. o Stage IV • Recurrent Endometrial Cancer o Platinum free interval > 6months or No prior systemic treatment. o Platinum free interval ≤ 6months, dMMR/MSI-H, or pMMR/MSS if combined with Lenvatinib. 12. Treatment of recurrent or metastatic cervical cancer when ALL of the following apply: • Not a surgical candidate • PDL1 Positive (CPS ≥ 1) • Immunotherapy naïve 13. For patients with locoregionally advanced colorectal cancer as neoadjuvant treatment if: • Microsatellite instability-high (MSIH) or mismatch repair deficient (dMMR) • Patients who are immunotherapy naïve 14. Locally advanced or metastatic Basal Cell carcinoma • If not amenable to RT or surgery as first line therapy. • If used as second line therapy. 15. Treatment of metastatic or advanced GEJ, esophageal, gastric cancer: • In the first line setting: o as monotherapy o OR in combination with platinum-based chemotherapy o OR in combination with trastuzumab for Her2 over expression and with CPS greater or equal to 1. • In the second line setting: o if immunotherapy naïve o PD-L1 greater or equal to 1 or dMMR/MSI-H • In the 3rd line setting and beyond if TMB high (greater or equal to 10 mut/MB) 16. Treatment of metastatic esophageal squamous cell carcinoma: • In the first line setting if combined with platinum-based chemotherapy • As monotherapy if ALL of the following are met: o Immunotherapy naïve o Progression following platinum-based chemotherapy

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				17. Treatment of Nasopharyngeal Metastatic, recurrent, or unresectable squamous-cell carcinoma of the head and neck. • As first line treatment if combined with chemotherapy • As second line treatment • In patients who are MSI-H or TMB-H • Not covered for failure or progression on or after an alternative PD-L1 agent. 18. Treatment of Unresectable or Metastatic Biliary Tract Cancer: • In the first line setting if combined with Cisplatin and gemcitabine. • In the second line setting, as monotherapy if MSI-H /dMMR AND if patient is pembrolizumab naïve. • In the third line setting if TMB- High (greater or equal to 10mut/MB) AND patient is pembrolizumab naïve. 19. Treatment of metastatic Merkel cell carcinoma. 20. Relapsed/Refractory classical Hodgkin Lymphoma (cHL) after at least one prior line of therapy and no prior I/O therapy. 21. Treatment of patients with metastatic or unresectable squamous-cell carcinoma of the head and neck (SCCHN): • Covered as first line a single agent if CPS ≥1. o in combination with platinum chemotherapy for first line treatment (regardless of CPS). • Not covered for failure or progression on or after an alternative PD-L1 agent 22. Treatment of mesothelioma after first line therapy for patients who are immunotherapy naïve 23. Treatment of stage IV Colorectal Cancer that is • Microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) OR • Non-oligometastatic for second-line or greater therapy with tumor mutational burden (TMB) ≥10 • Note: If progression noted off immuno-oncology (IO) therapy after completion of 2 years of therapy, may restart utilizing first line IO therapy options. 24. Treatment of renal cell carcinoma (RCC): • In combination with axitinib or Lenvatinib for patients with metastatic renal clear cell carcinoma (RCC) who are not surgical candidates OR • As adjuvant therapy if given as monotherapy for up to one year

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				25. Treatment of patients with metastatic, or locally advanced, cutaneous squamous cell carcinoma 26. Covered for the treatment of metastatic castration resistant prostate cancer if: • MSI-H, dMMR • TMB at least 10 mut/Mb 27. Covered for the treatment of patients with metastatic perianal/anal cancer: • Following platinum-based therapy if no prior immunotherapy used AND: ○ No molecular findings to guide treatment OR ○ MSI-H/dMMR or TMB-H (greater or equal to 10 mut/MB) 28. Covered for the treatment of patients with Salivary Gland Cancer if all the following apply: • Adenocarcinomas NOS, Mucoepidermoid or Salivary Duct Carcinoma • Recurrent Metastatic disease • Not a candidate for surgery or radiation • TMB greater or equal to 10 Mutations/Mb 29. Covered for patients with Anaplastic Thyroid Carcinoma (ATC) if no actionable mutation present or as subsequent line of therapy AND in combination with Lenvatinib. • Patient must be intolerant or contraindicated to chemotherapy. **Quantity Limit**: Pembrolizumab authorizations for all indications, will be limited to 1 year. Requests for an additional year of therapy will require documentation of disease stability (lack of progression). Note: Must be administered in a non-hospital setting when used as monotherapy (new starts and maintenance monotherapy). Dose exceptions for new starts: 2 doses within 3 months. See site of care policy for criteria, reauthorization, and exceptions for new starts.
Pertuzumab	Perjeta	J9306, 1mg	N/A	Covered for: 1. Use in combination with trastuzumab (e.g., Kanjinti) and a taxane in patients who: • Have a documented diagnosis of recurrent, unresectable, or metastatic (stage 4) HER2+ breast cancer. ○ Not to be combined with T-DM1 or T-DXd 2. Neoadjuvant use in combination with trastuzumab (e.g., Kanjinti) and a taxane in patients with confirmed HER2+, locally advanced, inflammatory, or early stage (either greater than 2 cm in diameter or lymph node positive) breast cancer. 3. Adjuvant use in patients with HER2-positive early breast cancer who:

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• Have residual invasive disease in the breast or axilla at surgery after receiving neoadjuvant therapy containing a taxane and trastuzumab (e.g., Kanjinti) and who were LN positive at diagnosis. 4. Treatment of HER 2 positive metastatic colorectal cancer: • Must be combined with trastuzumab (e.g., Kanjinti) • After treatment with 5FU/ leucovorin, oxaliplatin, and irinotecan 5. Treatment of patients with Salivary Gland Cancer if all the following apply: • Adenocarcinomas NOS, Mucoepidermoid or Salivary Duct Carcinoma • Recurrent Metastatic disease • Not a candidate for surgery or radiation • In combination with trastuzumab • HER2+ positive Note: Must be administered in a non-hospital setting when used in combination with trastuzumab products. Site of Care does not apply if administered in combination with cytotoxic chemotherapy. See site of care policy for criteria, reauthorization, and exceptions for new starts. Site of Care Exceptions: 2 doses within 2 months.
Pertuzumab/trastuzumab/hyaluronidase-zzxf	Phesgo	J9316	N/A	Medical necessity review required.
Plasminogen, human-tvmh	Ryplazim	C9090, J2998	N/A	Medical necessity review required. Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change.
Plerixafor	Mozobil	J2562, 1 mg	N/A	• Covered for patients approved for autologous stem cell transplant.
Polatuzumab vedotin-piiq	Polivy	J9309	N/A	• For treatment of first line DLBCL if use with R-CHP only in patients who are > 60 years old, non-GCB, non-bulky disease, and higher IPI score (3-4 or high risk). • For treatment of diffuse large B-cell lymphoma (DLBCL) when combined with bendamustine as 3rd or 2nd line therapy, if not a candidate for CD-19 CAR-T.
Pozelimab-bbfg	Veopoz	J9376	N/A	Medical necessity review required.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
Pralatrexate	Folotyn	J9307	N/A	Covered for the treatment of patients with Relapsed/Refractory Peripheral T-Cell Lymphoma (R/R PTCL) in the 3rd line setting or beyond.
Radium-223 dichloride	Xofigo	A9606	N/A	Patients with metastatic, castration-resistant prostate cancer who: • Have symptomatic bone metastases, with or without lymph node metastases AND • Have no visceral metastases.
Ramucirumab	Cyramza	J9308	N/A	• Covered for the treatment of Hepatocellular Carcinoma if ALL the following apply: o Second line or Third line treatment option. o Child Pugh A. o Immunotherapy Naïve. o AFP greater or equal to 400ng/ml • Covered for the treatment of metastatic or advanced GEJ, esophageal, gastric cancer in the second- or third-line setting • Covered for subsequent line therapy of mesothelioma if combined with Gemcitabine in patients without prior history of thromboembolism. • Not covered for NSCLC or mCRC due to limited overall survival benefit compared to standard of care
Ranibizumab	Lucentis	J2778, 0.1 mg	60 (up to 24 injections annually)	Covered for patients who have an inadequate response or intolerance to the preferred biosimilar, ranibizumab-nuna (Byooviz) for the following diagnoses: • wet age-related macular degeneration if the patient has failed or is intolerant to bevacizumab. • central retinal vein occlusion (CVRO) and branch retinal vein occlusion (BRVO). • diabetic eye disease if the patient has failed or is intolerant to bevacizumab. • myopic choroidal neovascularization if the patient has failed or is intolerant to bevacizumab. Established patients on Lucentis must have a documented inadequate response or intolerance to a ranibizumab (e.g., Byooviz) biosimilar
Ranibizumab intravitreal implant	Susvimo	C9093, J2779	N/A	Medical necessity review required.
Ranibizumab-eqrn	Cimerli	Q5128	N/A	Covered for patients who have an inadequate response or intolerance to the preferred biosimilar, ranibizumab-nuna (Byooviz) for the following diagnoses: • Wet age-related macular degeneration if the patient has failed or is intolerant to bevacizumab. • Central retinal vein occlusion (CVRO) and branch retinal vein occlusion (BRVO). • Diabetic eye disease if the patient has failed or is intolerant to bevacizumab.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• Myopic choroidal neovascularization if the patient has failed or is intolerant to bevacizumab
Ranibizumab-nuna	Byooviz	Q5124	N/A	Covered for patients with the following diagnoses: • Wet age-related macular degeneration if the patient has failed or is intolerant to bevacizumab. • Central retinal vein occlusion (CVRO) and branch retinal vein occlusion (BRVO). • Diabetic eye disease if the patient has failed or is intolerant to bevacizumab. • Myopic choroidal neovascularization if the patient has failed or is intolerant to bevacizumab
Ravulizumab-cwvz	Ultomiris	J1303	N/A	Covered for patients with atypical hemolytic uremic syndrome (aHUS) who meet all of the following: • Diagnosis confirmed by or in consultation with a nephrologist or hematologist. • Initial authorization: 6 months • Reauthorization: reassessment every 12 months to confirm clinical benefit including disease stability or improvement in symptoms. Covered for patients with paroxysmal nocturnal hemoglobinuria (PNH) who meet all of the following: • Diagnosis confirmed by high sensitivity flow cytometry and established by or in consultation with a hematology specialist. • Patient meets one of the following: o Transfusion-dependent** OR o History of major adverse vascular event from thromboembolism. • Initial authorization: 6 months • Reauthorization: reassessment every 12 months to confirm clinical benefit including disease stability or improvement in symptoms. ***Transfusion-dependence defined as hemoglobin less than 7 g/dL OR hemoglobin less than or equal to 9 g/dL and patients is experiencing symptoms from anemia requiring transfusion.* Covered for adult patients with generalized myasthenia gravis (MG) who meet all of the following: • Positive serologic test for anti-acetylcholine receptor (AChR) antibodies • Myasthenia Gravis Activities of Daily Living (MG-ADL) score ≥5 • Adequate trial of a corticosteroid • Inadequate response to at least two of the following medications o azathioprine, 2 mg/kg daily, for at least 9-12 months o rituximab, for at least 12 months

<table>
<tr><th>Generic Name</th><th>Brand Name</th><th>J Codes</th><th>Max J code unit per year</th><th>Coverage Criteria</th></tr>
<tr><td></td><td></td><td></td><td></td><td>
other disease modifying therapy (e.g., cyclophosphamide, mycophenolate mofetil, cyclosporine, methotrexate), for at least 9-12 months.
Dependent on chronic intravenous immunoglobulin (IVIG) or chronic plasma exchange (PLEX)
Prescribed by or in consultation with a neurology specialist
Not covered for patients who have:
Anti-muscle-specific receptor tyrosine kinase (MuSK) or anti-low-density lipoprotein receptor related protein (LRP4) antibody positive MG, seronegative MG, or ocular MG (seropositive or seronegative)
Initial authorization: 12 months

Reauthorization: reassessment every 12 months to confirm clinical benefit including disease stability (e.g., documentation of no disease progression).

<table>
<tr><th>Indication</th><th>Max Dose and Frequency</th></tr>
<tr><td>PNH</td><td rowspan="3">Induction: 3000 mg x 1 dose, then maintenance dosing starting 2 weeks after loading dose
Maintenance dose: 3600 mg every 8 weeks</td></tr>
<tr><td>aHUS</td></tr>
<tr><td>gMG</td></tr>
</table>
Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.

Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change.
</td></tr>
<tr><td>Reslizumab</td><td>Cinqair</td><td>J2786</td><td>N/A</td><td>Not medically necessary, not covered

FDA approval of reslizumab for the treatment of severe asthma with elevated level of blood eosinophils was based on the results of four Phase 3 trials. The pivotal studies demonstrated an improvement in forced expiratory volume in one second (FEV1), except for in patients with baseline eosinophil <400 cells/µL. The primary endpoint of two of the trials was frequency of asthma exacerbations, which was significantly decreased with reslizumab therapy compared to placebo. The most common adverse effects seen in the clinical trials were asthmatic symptoms, headache, nasopharyngitis, upper respiratory tract infections, sinusitis, and influenza. There is a boxed warning of anaphylaxis for reslizumab. Additional warnings include malignancy and musculoskeletal pain.</td></tr>
</table>

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				Although the studies demonstrated reslizumab can improve FEV1 and reduce exacerbation rates, there is uncertainty about whether benefits will persist long-term. The risk of black box warning of anaphylaxis and concern with monitoring burden may make this a lower value than mepolizumab.
Retifanlimab-dlwr	Zynyz	J9345	N/A	Medical necessity review required.
Rilonacept	Arcalyst	J2793, 1 mg	8480	Covered for patients 12 years or older with a diagnosis of familial cold auto-inflammatory syndrome (FCAS) or Muckle-Wells syndrome (MWS) who have a confirmed NLRP3 (or CIAS1) mutation and failure, intolerance or contraindications to canakinumab.
Risankizumab-rzaa	Skyrizi	J2327	N/A	For adult patients with moderately to severely active Crohn's disease with: • Contraindication or intolerance to at least two TNF-inhibitors (infliximab-dyyb [e.g., Inflectra], adalimumab [e.g., Amjevita]) and ustekinumab, OR • Inadequate response or loss of response to at least one TNF-inhibitor and ustekinumab • It is recommended that TNF-inhibitors are used in combination with azathioprine, 6-mercaptopurine, or methotrexate. Not covered for use in combination with disease modifying or other biologic therapies including (but not limited to): • infliximab, adalimumab, etanercept, vedolizumab, rituximab, certolizumab, tocilizumab, golimumab, ustekinumab, natalizumab, tofacitinib, upadacitinib, ozanimod, apremilast Quantity Limit for Crohn’s disease: • Induction: 600 mg administered intravenously at week 0, 4, and 8 • Maintenance: 360 mg administered by subcutaneous injection at week 12, and every 8 weeks thereafter.
Rituximab	Rituxan	J9310, 100 mg J9312, 10 mg	N/A	Covered for new starts who have had an inadequate response or intolerance to the preferred rituximab biosimilar (e.g., Riabni) declared equivalent by KPWA P&T Committee* for the following diagnoses: • Any oncology diagnoses. • Rheumatoid arthritis patients who have failure, contraindication, or intolerance to methotrexate. • ITP patients who have clinically failed corticosteroid and IVIG. • Granulomatosis polyangiitis (GPA or Wegener’s) or microscopic polyangiitis (MPA) in patients who are antineutrophil cytoplasmic antibody (ANCA) positive • Multiple sclerosis (MS) • Myasthenia gravis • Covered for adult patients ≥ 18 years old with thyroid eye disease (TED) who meet the following criteria:

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				○ Confirmed diagnosis of active TED by an oculoplastic surgeon ○ Clinical Activity Score (CAS) ≥4 (on the 7-item scale) ○ Moderate-to-severe active TED (not sight-threatening but has appreciable impact on daily life), associated with at least one of the following: lid retraction ≥2 mm, moderate or severe soft tissue involvement, exophthalmos ≥3 mm above normal for race and gender, or intermittent or constant diplopia. ○ Inadequate response, intolerance, or contraindication to IV steroid therapy with or without radiation therapy. • Patients ≥18 years old with neuromyelitis optica spectrum disorder (NMOSD) when prescribed by or in consultation with a Multiple sclerosis specialist or Neurologist AND AQP4 antibody seropositive. • Established patients on Rituxan must have a documented inadequate response or intolerance to a rituximab (e.g., Riabni) biosimilar Not covered for use in combination with disease modifying or other biologic therapies including (but not limited to): • infliximab, adalimumab, etanercept, vedolizumab, abatacept, tocilizumab, certolizumab, golimumab, ustekinumab, canakinumab, ocrelizumab, natalizumab, tofacitinib, upadacitinib, ozanimod, apremilast *KPWA preferred equivalent rituximab products include: rituximab-arrx (Riabni). **Quantity Limits:** • Rheumatoid arthritis. ○ Induction: 1000 mg on day 1 and 15; Maintenance: 1000 mg every 16 weeks • Granulomatosis polyangiitis ○ Induction: 1000 mg once weekly for 4 weeks; Maintenance: 1000 mg every 16 weeks • Multiple Sclerosis ○ Induction: 1000 mg on day 1 and day 15; Maintenance 1000 mg every 24 weeks • *Note: Quantity limits do not apply to oncology diagnoses or other listed diagnoses* Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts. Note: any oncology indication would not require patients to meet site of care criteria. Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				Washington's Specialty Pharmacy Network for medications impacted by this change. **Applicable codes**: *ICD-10 codes covered if selection criteria or medical necessity is met. Listing of code does not guarantee coverage or reimbursement. The following list is provided for reference purposes only and may not be all inclusive.* C00 – C96.Z, C82.00 - C82.49, C82.60 - C82.99, C83.00 - C83.09, C83.30 - C83.39, M31.30 - M31.31, C85.10 - C85.99, C88.4, C91.10, C91.12, M05.00 - M05.9, M06.00 - M06.9, M31.7, L10.0, L10.2, L10.81, C83.10 - C83.19, C83.70 - C83.79, C91.00 - C91.02, D47.Z2, D59.0 - D59.1, D69.3, D69.41, D69.59, D89.811, G35, M31.1, M31.4, C88.0, L12.0, L12.1, C81.00 - C81.09, C81.40 - C81.49, C83.80 - C83.89, C83.90 - C83.99, C86.5, C91.40 - C91.42, D47.Z1, G36.0, M06.20 - M06.29, M35.00 - M35.09, T86.20 - T86.39, Z94.0, G70.00-G70.01

Rituximab-abbs
 	
Rituximab-pvvr
	Truxima
	
	Ruxience
		Q5115
		
		Q5119
			N/A
			
			N/A
				Covered for patients who have an inadequate response or intolerance to the preferred biosimilar, rituximab-arrx (Riabni) for the following diagnoses:
				• Any oncology diagnoses
				• Rheumatoid arthritis patients who have failure, contraindication, or intolerance to methotrexate.
				• ITP patients who have clinically failed corticosteroid and IVIG.
				• Granulomatosis polyangiitis (GPA or Wegener's) or microscopic polyangiitis (MPA) in patients who are antineutrophil cytoplasmic antibody (ANCA) positive
				• Multiple Sclerosis (MS)
				• Myasthenia Gravis
				• Adult patients ≥ 18 years old with thyroid eye disease (TED) who meet the following criteria:
				  ○ Confirmed diagnosis of active TED by an oculoplastic surgeon
				  ○ Clinical Activity Score (CAS) ≥4 (on the 7-item scale)
				  ○ Moderate-to-severe active TED (not sight-threatening but has appreciable impact on daily life), associated with at least one of the following: lid retraction ≥2 mm, moderate or severe soft tissue involvement, exophthalmos ≥3 mm above normal for race and gender, or intermittent or constant diplopia.
				  ○ Inadequate response, intolerance, or contraindication to IV steroid therapy with or without radiation therapy.
				• Covered for patients ≥18 years old with neuromyelitis optica spectrum disorder (NMOSD) when prescribed by or in consultation with a Multiple sclerosis specialist or Neurologist AND AQP4 antibody seropositive.
				
				Not covered for use in combination with disease modifying or other biologic therapies including (but not limited to):
				• Infliximab, adalimumab, etanercept, vedolizumab, abatacept, tocilizumab, certolizumab, golimumab, ustekinumab, canakinumab, ocrelizumab, natalizumab, tofacitinib, upadacitinib, ozanimod, apremilast

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria

				Quantity Limits:
				• Rheumatoid arthritis.
				  ○ Induction: 1000 mg on day 1 and 15; Maintenance: 1000 mg every 16 weeks
				• Granulomatosis polyangiitis
				  ○ Induction: 1000 mg once weekly for 4 weeks; Maintenance: 1000 mg every 16 weeks
				• Multiple Sclerosis
				  ○ Induction: 1000 mg on day 1; Maintenance 500 mg every 24 weeks
				• *Note: Quantity limits do not apply to oncology diagnoses or other listed diagnoses*
				
				*Note: Must be administered in a non-hospital setting for all diagnosis except oncology. See site of care policy for criteria, reauthorization, and exceptions for new starts.
				
				Note: any oncology indication would not require patients to meet site of care criteria.
				
				Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change.
				
				Applicable codes:
				ICD-10 codes covered if selection criteria or medical necessity is met. Listing of code does not guarantee coverage or reimbursement. The following list is provided for reference purposes only and may not be all inclusive.
				C00 – C96.Z, C82.00 - C82.49, C82.60 - C82.99, C83.00 - C83.09, C83.30 - C83.39, M31.30 - M31.31, C85.10 - C85.99, C88.4, C91.10, C91.12, M05.00 - M05.9, M06.00 - M06.9, M31.7, L10.0, L10.2, L10.81, C83.10 - C83.19, C83.70 - C83.79, C91.00 - C91.02, D47.Z2, D59.0 - D59.1, D69.3, D69.41, D69.59, D89.811, G35, M31.1, M31.4, C88.0, L12.0, L12.1, C81.00 - C81.09, C81.40 - C81.49, C83.80 - C83.89, C83.90 - C83.99, C86.5, C91.40 - C91.42, D47.Z1, G36.0, M06.20 - M06.29, M35.00 - M35.09, T86.20 - T86.39, Z94.0, G70.00-G70.01

Rituximab-arrx	Riabni	Q5123	N/A	Criteria review not required for the following diagnoses: any oncology indication, multiple sclerosis (MS), myasthenia gravis.* Covered for: • Rheumatoid arthritis patients who have failure, contraindication, intolerance to methotrexate.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria

				• ITP patients who have clinically failed corticosteroid and IVIG.
				• Granulomatosis polyangiitis (GPA or Wegener's) or microscopic polyangiitis (MPA) in patients who are antineutrophil cytoplasmic antibody (ANCA) positive
				• Adult patients ≥ 18 years old with thyroid eye disease (TED) who meet the following criteria:
				  ○ Confirmed diagnosis of active TED by an oculoplastic surgeon
				  ○ Clinical Activity Score (CAS) ≥4 (on the 7-item scale)
				  ○ Moderate-to-severe active TED (not sight-threatening but has appreciable impact on daily life), associated with at least one of the following: lid retraction ≥2 mm, moderate or severe soft tissue involvement, exophthalmos ≥3 mm above normal for race and gender, or intermittent or constant diplopia.
				  ○ Inadequate response, intolerance, or contraindication to IV steroid therapy with or without radiation therapy.
				• Patients ≥18 years old with neuromyelitis optica spectrum disorder (NMOSD) when prescribed by or in consultation with a Multiple sclerosis specialist or Neurologist AND AQP4 antibody seropositive.
				
				Not covered for use in combination with disease modifying or other biologic therapies including (but not limited to):
				• infliximab, adalimumab, etanercept, vedolizumab, abatacept, tocilizumab, certolizumab, golimumab, ustekinumab, canakinumab, ocrelizumab, natalizumab, tofacitinib, upadacitinib, ozanimod, apremilast
				
				Quantity Limits:
				• Rheumatoid arthritis.
				  ○ Induction: 1000 mg on day 1 and 15; Maintenance: 1000 mg every 16 weeks
				• Granulomatosis polyangiitis
				  ○ Induction: 1000 mg once weekly for 4 weeks; Maintenance: 1000 mg every 16 weeks
				• Multiple Sclerosis
				  ○ Induction: 1000 mg on day 1 and day 15; Maintenance 1000 mg every 24 weeks
				• *Note: Quantity limits do not apply to oncology diagnoses or other listed diagnoses*
				
				Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.
				
				Note: any oncology indication would not require patients to meet site of care criteria.
				
				Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change. **Applicable codes**: *ICD-10 codes covered if selection criteria or medical necessity is met. Listing of code does not guarantee coverage or reimbursement. The following list is provided for reference purposes only and may not be all inclusive.* C00 – C96.Z, C82.00 - C82.49, C82.60 - C82.99, C83.00 - C83.09, C83.30 - C83.39, M31.30 - M31.31, C85.10 - C85.99, C88.4, C91.10, C91.12, M05.00 - M05.9, M06.00 - M06.9, M31.7, L10.0, L10.2, L10.81, C83.10 - C83.19, C83.70 - C83.79, C91.00 - C91.02, D47.Z2, D59.0 - D59.1, D69.3, D69.41, D69.59, D89.811, G35, M31.1, M31.4, C88.0, L12.0, L12.1, C81.00 - C81.09, C81.40 - C81.49, C83.80 - C83.89, C83.90 - C83.99, C86.5, C91.40 - C91.42, D47.Z1, G36.0, M06.20 - M06.29, M35.00 - M35.09, T86.20 - T86.39, Z94.0, G70.00-G70.01
Rituximab hyaluronidase	Rituxan Hycela	J9311	N/A	Not covered not medically necessary, due to availability of treatment alternatives
Romidepsin	Istodax	J9315, J9318, J9319	N/A	Covered for treatment of CD 30 positive Mycosis Fungoides as second line therapy following skin directed topical or phototherapy. Covered for the treatment of Sezary Syndrome without nodal or visceral disease in the second line setting.
Romiplostim	Nplate	J2796, 10 mcg	N/A	For patients with idiopathic thrombocytopenia (ITP) who: • Have a platelet count of ≤30,000/µL ($30x10^9$/L) and • Patient has experienced an insufficient response, allergy or contraindication to: corticosteroids (e.g., prednisone, methylprednisolone, dexamethasone) Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.
Romosozumab-aqqg	Evenity	J3111	N/A	Coverage Restriction: Not covered, not medically necessary due to the availability of treatment alternatives
Ropeginterferon alfa-2b	Besremi	Unclassified J3590, J3490	N/A	Covered for patients with polycythemia vera (PV) with contraindication, intolerance, or inadequate response to: • Hydroxyurea* AND • Interferon therapy *Note: • Inadequate response to hydroxyurea is defined as a dose ≥ 2g/day or a maximum tolerated dose < 2 g/day resulting in need for phlebotomy to maintain hematocrit < 45% OR

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• Unacceptable side effects to hydroxyurea is defined as at least one of the following: ○ Absolute neutrophil count < 1.0 x 10^9/L at the lowest dose of hydroxyurea required to achieve a response ○ Platelet count < 100 x 10^9/L or hemoglobin < 10 g/dL at the lowest dose of hydroxyurea required to achieve a response ○ Unacceptable toxicity (e.g., poor healing ulcers or mouth sores)
Rozanolixizumab-noli	Rystiggo	J9333	N/A	Medical necessity review required.
Sacituzumab govitecan-hziy	Trodelvy	J9317	N/A	Covered as monotherapy for the treatment of relapsed, refractory, or metastatic triple negative breast cancer or ER/PR negative HER2 low in patients who have been previously treated with at least two prior lines of therapy including a taxane, in the advanced setting AND who are not candidates for trastuzumab deruxtecan.
Sarilumab	Kevzara	Unspecified C9399, J3490, J3590	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria (refer to pharmacy benefit)
Satralizumab	Enspryng	Unspecified C9399, J3490, J3590	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer OR • Plans with reduction rider AND • Meet clinical criteria (refer to pharmacy benefit)
Sebelipase alfa	Kanuma	J2840	N/A	Medical necessity review required. Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.
Secukinumab	Cosentyx	Unclassified J3590, J3490	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria (refer to pharmacy benefit)
Semaglutide	Ozempic	Unspecified C9399, J3490, J3590	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria (refer to pharmacy benefit)
Setmelanotide	Imcivree	Unspecified C9399, J3490, J3590	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer OR • Plans with reduction rider AND • Meet clinical criteria (refer to pharmacy benefit)
Siltuximab	Sylvant	J2860, 10 mg	N/A	Treatment of multicentric Castleman's disease (MCD) in patients who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative.
Sipuleucel-T	Provenge	Q2043 J3490 J9999		Medical necessity review required. (same criteria as Noridian criteria for Medicare patients) 1) A diagnosis of prostate cancer (ICD-10-CM) C61—Malignant neoplasm, prostate. Documentation must demonstrate the patient was asymptomatic or very minimally symptomatic and had metastatic castrate resistant (hormone refractory) disease. 2) Evidence of metastases to soft tissue or bone, without visceral metastases. 3) Testosterone levels < 50 ng/dL or below lowest level of normal. 4) Two sequential rising PSA levels obtained 2-3 weeks apart or other evidence of disease progression. 5) Restriction of cancer therapy to sipuleucel-T alone. Patient may not be receiving simultaneous chemotherapy or other immunosuppressive therapy. Allow a maximum of three infusions per lifetime. **Note:** This is a drug with extremely limited availability.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
Sirolimus protein-bound particles	Fyarro	C9091, J9331	N/A	Medical necessity review required.
Site of care prior authorization criteria	N/A	N/A	N/A	**Site of Care** refers to the generic type of site or type of setting where the infused drug is administered. Infusions can be given in different settings, including outpatient infusion center located in a hospital, an infusion center that's not in a hospital, a physician's office, or in a member's home. All drugs with site of care requirements must be pre-authorized and administered in a non-hospital setting, also referred to as an alternate site of care, such as a provider's office, an infusion center, or home infusion. See site of care policy for criteria, reauthorization, and exceptions for new starts.
Site of Service Prior Authorization Criteria	N/A	N/A	N/A	**Site of Service** refers to a specific provider or facility for the member's health plan, generally in-network contracted providers. Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change. Exceptions: Prior authorization for an alternative site of service may be obtained if a preferred site of service is not available within a reasonable travel distance or timeframe, as established by Kaiser Permanente and Washington State provider network adequacy requirements, or for safety concerns. Note: All new coverage requests for the select medicines will require a medical necessity, site of care, and site of service review. Site of Service criteria will be waived for the administration of the first dose for all drugs. Further dose exceptions may apply depending on the drug and/or to ensure continuity of care, with prior authorization.
Sodium thiosulfate 12.5%	Pedmark	J0208	N/A	Not covered, not medically necessary.
Sotatercept-csrk	Winrevair	Unspecified C9399, J3490, J3590	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria (refer to pharmacy benefit)

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
Spesolimab-sbzo intravenous	Spevigo	J1747	N/A	Medical necessity review required.
Spesolimab-sbzo subcutaneous	Spevigo	J1747	N/A	Considered a self-administered medication for outpatient use. Subcutaneous formulations not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria (refer to pharmacy benefit)
Sutimlimab-jome	Enjaymo*	C9094, J1302	N/A	Covered to decrease the need for red blood cell transfusions due to hemolysis in patients with cold agglutinin disease (CAD) who meet the following criteria: • Prescribed by or in consultation with a hematologist • Patient is greater than or equal to 18 years of age and weighs at least 39 kg • Diagnosis of CAD is confirmed based on the following: o chronic hemolysis; and o polyspecific direct antiglobulin test (DAT) positive; and o monospecific DAT strongly positive for C3d; and o cold agglutinin titer ≥64 at 4°C; and o immunoglobulin G DAT ≤1+; and o no overt malignant disease; and • Bilirubin level above the normal reference range • Either of the following: o If acute anemia from CAD: ▪ patient with symptomatic anemia or need for transfusion; and ▪ awaiting for rituximab ± bendamustine treatment to take effect o If chronic anemia from CAD: ▪ patient with symptomatic anemia or need for transfusion; and ▪ not responding adequately to treatment with rituximab ± bendamustine Baseline labs: • hepatitis B virus, hepatitis C virus, and HIV screening • complete blood count (CBC) • reticulocyte count • lactate dehydrogenase (LDH)

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• total bilirubin • cold agglutinin titer Initial authorization: 2 months Reauthorization contingent upon demonstrating reduction in transfusion requirement or at least 2 g/dL increase in Hgb in the absence of a transfusion. Reassessment every 12 months to confirm clinical benefit. NOTE: After two months of therapy, patients should be reviewed by Interregional Consultative Physician Panel to assess need for ongoing treatment.
Tafasitamab-cxix	Monjuvi	J9349	N/A	For treatment of relapsed refractory diffuse large B-cell lymphoma (DLBCL) as 2nd line or beyond with lenalidomide for patients who are ineligible for cytotoxic chemotherapy AND CD-19 CAR T therapy.
Tagraxofusp-erzs	Elzonris	J9269	N/A	Medical necessity review required.
Taliglucerase alfa	Elelyso	J3060 10 units	N/A	Covered for patients with a confirmed diagnosis of Type 1 Gaucher disease. Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts. Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change.
Talimogene laherparepvec intralesional	Imlygic	J9325	N/A	Melanoma: Covered for the treatment of patients with metastatic or unresectable disease AND without brain metastasis as a second line option. Covered for the treatment of patients with Stage III unresectable disease who: • Are unable to tolerate systemic treatment.
Talquetamab-tgvs	Talvey	C9163, J3055	N/A	Covered for the treatment of patients with relapse refractory multiple myeloma in the 5th line of therapy if progression after BCMA therapy.
Tbo-Filgrastim	Granix	J1447	N/A	Not covered under the medical benefit. May be covered under pharmacy benefit. • Exceptions:

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				○ First 2 doses within 5 days may be given under medical benefit ○ Plans with reduction rider ○ Patients and donors planned to undergo bone marrow transplant
Tebentafusp-tebn	Kimmtrak	C9095, J9274	N/A	Treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma as monotherapy
Teclistamab-cqyv	Tecvayli	C9148, J9380	N/A	Covered for the treatment of patients with relapsed refractory multiple myeloma in the 5th line of therapy: • Therapy must have included a proteosome inhibitor, immunomodulatory drug and an anti-CD 38 MAB.
Teduglutide	Gattex	Unspecified C9399, J3490, J3590	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer OR • Plans with reduction rider AND • Meet clinical criteria (refer to pharmacy benefit)
Teplizumab-mzwv	Tzield*	C9149, J9381	N/A	Covered for patients who meet all of the following: • Prescribed by or in consultation with a pediatric or adult endocrinologist. • Diagnosis of Stage 2 Type 1 diabetes as documented by presence of at least two diabetes autoantibodies: glutamic acid decarboxylase 65 (GAD) autoantibody, zinc transporter 8 (ZnT8) autoantibody, islet cell autoantibody (ICA), insulin autoantibody (IAA), or insulinoma-associated antigen-2 (IA-2) autoantibody • Patient is between 8 and 45 years old • Have a first or second degree relative with Type 1 Diabetes ○ If first degree, relative must be between 8 to 45 years old (e.g., sibling, parent, or offspring) ○ If second degree, relative must be between 8 to 20 years old (e.g., niece, nephew, aunt, uncle, grandchild, or cousin) • Abnormal glucose tolerance by oral glucose tolerance test (OGTT) defined as fasting blood glucose >110 mg/dL and <126 mg/dL OR 2-hour glucose ≥140 mg/dL and <200 mg/dL OR 30-, 60-, or 90-minute value on OGTT ≥200 mg/dL. • Documented rationale that 2-year delay in developing T1D is necessary Authorization duration: one-time 14-day treatment course **Note: Prior to treatment with Teplizumab-mzwv, review by an Inter-regional Consultative Physician Panel is required.**

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria

Teprotumumab-trbw	Tepezza*	J3241	N/A	Covered for adult patients ≥ 18 years old with thyroid eye disease (TED) who meet all of the following:
				• Confirmed diagnosis of active TED by an oculoplastic surgeon
				• Clinical Activity Score (CAS) ≥4 (on the 7-item scale)
				• Moderate-to-severe active TED (not sight-threatening but has appreciable impact on daily life), associated with at least one of the following:
				  ○ Lid retraction ≥2 mm
				  ○ Moderate or severe soft tissue involvement
				  ○ Exophthalmos ≥3 mm above normal for race and gender
				  ○ Intermittent or constant diplopia
				• Inadequate response, intolerance, or contraindication to either of the following, with or without radiation therapy.
				  ○ IV methylprednisolone plus oral mycophenolate mofetil OR
				  ○ High dose IV methylprednisolone
				• Confirmation that patient is euthyroid
				• Documentation of hemoglobin A1c <9%
				
				Required documentation
				• Hemoglobin A1c
				• Thyroid function tests and thyroid stimulating immunoglobulins
				• Screening for HIV, Hepatitis B, and Hepatitis C
				• Pregnancy test (if patient of childbearing potential)
				
				Not covered for patients who:
				• Actively smoke
				• Current drug or alcohol abuse (within 6 months prior to treatment)
				• Untreated or uncontrolled human immunodeficiency virus (HIV), Hepatitis C or Hepatitis B infection
				• Clinically inactive disease or mild disease (e.g., decrease in CAS ≥2 point or decrease in proptosis of ≥2 mm from baseline to treatment initiation)
				• Presence of sight-threatening complications
				• Pre-existing inflammatory bowel disease
				
				Note: If patient is steroid refractory, may consider treatment with at least one of the following: orbital decompression, tocilizumab, or rituximab (e.g., Riabni).
				
				Note: Prior to treatment initiation, patients should be reviewed by an Interregional Consultative Physician Panel.
				
				Quantity Limits:
				• Limited to one treatment course (8 infusions) per lifetime based on 20 mg/kg/dose every 3 weeks.
				• The safety and efficacy of re-treatment has not been established.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts. Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change.
Teriparatide	Forteo	J3110	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria (refer to pharmacy benefit)
Testosterone undecanoate Testosterone pellet	Aveed Testopel	J3145 S0189	N/A	• Diagnosis of gender identity/gender dysphoria or delayed male puberty OR • Diagnosis of male hypogonadism AND ○ Contraindication, intolerance, or failure to testosterone 1.62% gel pump, AND ○ Contraindication, intolerance, or failure to injectable testosterone cypionate or testosterone enanthate
Tezepelumab-ekko	Tezspire	J2356	N/A	For patients with asthma who meet the following criteria: • Prescribed by an Allergist or Pulmonologist • Patient is at least 12 years of age • Documented severe persistent asthma (see Table 1) • Reversible airway obstruction as documented by the following: ○ Response to inhaled short-acting beta agonists (e.g., FEV_1 reversibility of >12% with at least a 200 mL increase in FEV_1) within 30 minutes after administration of albuterol (90-180 mcg) OR ○ Positive exercise or methacholine challenge OR ○ Positive response (at least a 15% increase in FEV_1 with at least a 200 mL increase in FEV_1) after a course of treatment with inhaled or systemic corticosteroids. • Patient has one of the following:

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				○ Severe asthma with a non-eosinophilic and non-allergic phenotype and OCS dependent AND patient has had a trial of dupilumab with an inadequate response unless contraindications/intolerance. ○ Severe asthma with a non-eosinophilic and non-allergic phenotype and not OCS dependent. ○ Severe eosinophilic asthma AND patient has had a trial of benralizumab with an inadequate response unless contraindications or intolerance. ○ Severe allergic asthma AND patient has an inadequate response to both omalizumab and dupilumab unless contraindications or intolerance. • Patient has uncontrolled asthma (see Table 1) despite all of the following: ○ Trigger avoidance measures ○ Comorbidities that can cause asthma exacerbations (e.g., gastroesophageal reflux disease [GERD], allergic rhinitis) and non-asthma diagnoses (e.g., laryngeal dysfunction, panic disorder) have been evaluated and treated. ○ Aggressive drug therapy regimen for at least 6 months (see Table 2). • Exclusion criteria: If ONE or more of the following criteria is met, patient is NOT eligible: ○ Current smoker who is not currently enrolled in a smoking cessation program (e.g., Quit for Life) ○ Non adherence to pre-requisite asthma drug therapies. ○ Non adherence is defined as less than 75% of proportion of days covered (calculated by day supply dispensed over the total number of days since treatment was initiated). ○ Concomitant use with omalizumab, benralizumab, reslizumab, or mepolizumab. Evaluation for Continuation of Therapy: • Evaluate response after 6 months and then annually thereafter. • Clinical improvement must be demonstrated by one or more of the following: ○ Decreased use of rescue medications ○ Decreased frequency of exacerbations (defined as worsening of asthma that requires increase in ICS dose or treatment with systemic corticosteroids) ○ Improvement in lung function (e.g., FEV1) from pretreatment baseline ○ Objective improvement in quality of life: minimally important difference of 3 points on the Asthma Control Test ○ Improvement in asthma symptoms (such as asthmatic symptoms upon wakening, coughing, fatigue, shortness of breath, sleep disturbance, wheezing, or reduced missed days from work or school). ○ Decreased corticosteroid requirement if on OCS.

<table>
<tr><th>Generic Name</th><th>Brand Name</th><th>J Codes</th><th>Max J code unit per year</th><th>Coverage Criteria</th></tr>
<tr><td></td><td></td><td></td><td></td><td>
Quantity Limit: 210 mg once every 4 weeks

Table 1. Evidence for severe refractory asthma and indicators of uncontrolled asthma
<table>
<tr><th>Evidence for severe refractory asthma</th></tr>
<tr><td>
• Asthma meets criteria for moderate-to-severe asthma as defined by the NHLBI’s EPR-3 and the patient has uncontrolled asthma which should be noted both subjectively and with objective evidence of asthma, despite the following:
o Ruling out comorbid factors (e.g., allergy, sinusitis, GERD, anxiety disorder, panic disorder, vocal cord dysfunction) to determine if these measures can decrease the need to initiate biologic therapy.
o Address and manage all triggers from the home (e.g., animal dander if allergic, dust mites, foods, pollen, smoke exposure).
o Aggressive trials of therapy (refer to Table 2)
</td></tr>
<tr><th>Indicators of uncontrolled asthma</th></tr>
<tr><td>
• Any one of the following criteria qualifies the patient as having uncontrolled asthma:
o Two or more asthma exacerbations requiring systemic corticosteroids (≥3 days each) in the past 12 months
o Serious exacerbations: at least one hospitalization, intensive care unit (ICU) stay or mechanical ventilation in the previous year
o Asthma Control Test (ACT) is consistently <20
</td></tr>
</table>
Table 2. Aggressive drug therapy regimens for asthma
<table>
<tr><td>
A. Triple drug therapy with high-dose ICS plus LABA combination* plus tiotropium (Spiriva Respimat) (unless contraindications or intolerance) and on oral corticosteroid (OCS) for most days during the previous 6 months (e.g., ≥50% of days)
OR
B. Triple drug therapy with high-dose ICS plus LABA combination* plus tiotropium (Spiriva Respimat) (unless contraindications or intolerance) who are not on daily OCS, but who otherwise meet other inclusion criteria and have had frequent severe exacerbations (≥2) in the past 12 months requiring systemic corticosteroids for ≥3 days and/or a history of a serious exacerbation requiring at least one hospitalization, ICU stay, or mechanical ventilation in the previous year.
OR
C. Corticosteroid adverse effects: If a patient has been poorly controlled over at least one year and is experiencing corticosteroid adverse effects while on aggressive drug therapy (A or B) then treatment with a biologic drug may be considered.
</td></tr>
</table>
</td></tr>
</table>

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				**High-dose ICS plus LABA combinations include: fluticasone/salmeterol 500/50 mcg, 1 inh twice daily or fluticasone salmeterol 230/21 mcg, 2 puffs twice daily.*
Tildrakizumab-asmn	Ilumya	J3245	N/A	For adult patients (18 years or older) with moderate to severe psoriasis who have an inadequate response, contraindication, or intolerance to topical psoriasis treatments AND • at least one formulary anti-TNF agent (e.g., adalimumab [Amjevita], infliximab [Inflectra]), AND • secukinumab AND • two preferred IL-23 or IL-12/IL-23 inhibitors (guselkumab, ustekinumab, risankizumab) AND • at least two of the following*: o 12-week trial of phototherapy o acitretin o methotrexate *Note: cyclosporine may also be counted towards 1 of the required therapies, but should not be required. Not covered for use in combination with disease modifying or other biologic therapies including (but not limited to): • infliximab, adalimumab, etanercept, vedolizumab, rituximab, abatacept, certolizumab, tocilizumab, golimumab, canakinumab, natalizumab, tofacitinib, upadacitinib, ozanimod, apremilast Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.
Tirzepatide	Mounjaro	Unspecified C9399, J3490, J3590	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria (refer to pharmacy benefit)
Tisagenlecleucel	Kymriah	Q2042	N/A	Covered for patients with DLBCL who have primary refractory or relapse disease within one year. Covered for patients with Philadelphia Chromosome negative Acute Lymphoblastic Leukemia Ph(-) ALL: • Who have less than CR after extended remission induction who are 18- 25 yrs old

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• Who are 40 years old and greater who are not a candidate for intensive chemotherapy Covered for patients with Philadelphia Chromosome positive Acute Lymphoblastic Leukemia Ph(+) ALL: • Who are not candidates for intensive chemotherapy and who have received dasatinib with prednisone or blinatumomab and have less than CR. • Who have received intensive chemotherapy with TKI therapy o AND who are not MRD negative at 3 months o AND who are bridging to transplant. • Not covered for patients with: o Prior CAR-T therapy or other genetically modified T cell therapy Authorization duration: limited to a one-time (single infusion) treatment.
Tisotumab vedotin	Tivdak	J9273	N/A	Covered for metastatic or recurrent cervical cancer after first line therapy, in patients who are ineligible for surgery.
Tocilizumab intravenous	Actemra	J3262, 1 mg	See next column	• Covered for adult patients ≥ 18 years old with thyroid eye disease (TED) who meet the following criteria: o Confirmed diagnosis of active TED by an oculoplastic surgeon o Clinical Activity Score (CAS) ≥4 (on the 7-item scale) o Moderate-to-severe active TED (not sight-threatening but has appreciable impact on daily life), associated with at least one of the following: ▪ Lid retraction ≥2 mm ▪ Moderate or severe soft tissue involvement ▪ Exophthalmos ≥3 mm above normal for race and gender ▪ Intermittent or constant diplopia o Inadequate response, intolerance, or contraindication to IV steroid therapy with or without radiation therapy. • Covered for patients with neuromyelitis optica spectrum disorder (NMOSD) who meet the following criteria: o Prescribed by or in consultation with a Multiple sclerosis specialist or Neurologist o Age ≥18 years o AQP4 antibody seropositive • Covered for cytokine release syndrome due to chimeric antigen receptor-T (CAR-T) therapy. • Covered for patients ≥ 2 years old with systemic subtype juvenile idiopathic arthritis who have failure, contraindication, or intolerance to NSAIDs, glucocorticoids, and anakinra. • Covered for patients ≥ 2 years old with polyarticular juvenile idiopathic arthritis (JIA) who have had failure, contraindication, or intolerance to methotrexate.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				Not covered for use in combination with disease modifying or other biologic therapies including (but not limited to): • infliximab, adalimumab, etanercept, vedolizumab, rituximab, abatacept, certolizumab, golimumab, ustekinumab, canakinumab, tofacitinib, upadacitinib, ozanimod, apremilast Not covered under the medical benefit for other indications (hospital, clinic, or home infusion). • Note: may be covered under the pharmacy benefit **Quantity Limit:** • TED and NMOSD: 800 mg every 4 weeks • Cytokine release syndrome associated with CAR-T: 800 mg up to 4 doses 8 hours apart. • Polyarticular juvenile idiopathic arthritis: 800 mg every 4 weeks • Systemic subtype juvenile idiopathic arthritis: 800 mg every 2 weeks Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts. Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change. **Applicable codes:** *ICD-10 codes covered if selection criteria or medical necessity is met. Listing of code does not guarantee coverage or reimbursement. The following list is provided for reference purposes only and may not be all inclusive.* M05.00 - M05.09, M05.10 - M05.19, M05.20 - M05.29, M05.30 - M05.39, M05.40 - M05.49, M05.50 - M05.59, M05.60 - M05.69, M05.70 - M05.7A, M05.80 - M05.8A, M05.9, M06.00 - M06.0A, M06.1, M06.4, M06.80 - M06.8A, M06.9, M08.00 - M08.0A, M08.20 - M08.2A, M08.3, M08.80 - M08.89, M08.90 - M08.9A, M31.5, M31.6, M08.20 - M08.3, T45.1X5A-T45.1X5S, D76.1, R65.10, M31.4, M34.0 - M34.9
Tocilizumab subcutaneous	Actemra	J3262, 1 mg	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria (refer to pharmacy benefit) Not covered for use in combination with other biologic therapies including (but not limited to): • infliximab, adalimumab, etanercept, vedolizumab, rituximab, abatacept, certolizumab, golimumab, ustekinumab, canakinumab, tofacitinib, upadacitinib, ozanimod, apremilast
Tofersen	Qalsody	C9157, J1304	N/A	Medical necessity review required.
Trabectedin	Yondelis	J9352	N/A	Covered for adult patients with unresectable or metastatic leiomyosarcoma

Tralokinumab-ldrm	Adbry	Unspecified J3490, J3590	N/A	For patients ≥18 years of age with moderate or severe atopic dermatitis who meet all of the following criteria:
				• Prescribed by or in consultation with an Allergist or Dermatologist.
				• Trial and failure of a high potency topical corticosteroid
				• Trial and failure of at least 3 months of at least one of the following*:
				  • Narrow Band UVB (NBUVB) phototherapy (preferred)
				  • Mycophenolate
				  • Methotrexate
				  • Azathioprine
				
				*Note: cyclosporine may count as one of the requisite therapies, but should not be required.
				
				Not covered for use in combination with disease modifying or other biologic therapies including (but not limited to):
				• infliximab, adalimumab, etanercept, vedolizumab, rituximab, abatacept, certolizumab, tocilizumab, golimumab, canakinumab, natalizumab, tofacitinib, upadacitinib, ozanimod, apremilast
				
				Quantity Limit: Limited to 600 mg (four 150 mg injections), followed by 300 mg (two 150 mg subcutaneous injections) administered every other week

Trastuzumab	Herceptin	J9355	N/A	• New starts must have had an inadequate response or intolerance to a trastuzumab (e.g., Kanjinti) biosimilar declared equivalent by KPWA P&T Committee. KPWA equivalent trastuzumab products include: trastuzumab (e.g., Kanjinti). • Established patients on Herceptin must have a documented inadequate response or intolerance to a trastuzumab (e.g., Kanjinti) biosimilar

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				Note: Must be administered in a non-hospital setting when used as monotherapy or in combination with pertuzumab. See site of care policy for criteria, reauthorization, and exceptions for new starts. Site of Care Exceptions: 2 doses within 2 months. Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change.
Trastuzumab-anns	Kanjinti	Q5117	N/A	Note: Must be administered in a non-hospital setting when used as monotherapy or in combination with pertuzumab. See site of care policy for criteria, reauthorization, and exceptions for new starts. Site of Care Exceptions: 2 doses within 2 months. Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change.
Trastuzumab-dkst	Ogivri	Q5114	N/A	Covered for patients who have an inadequate response or intolerance to the preferred biosimilar, trastuzumab-anns (Kanjinti). Note: Must be administered in a non-hospital setting when used as monotherapy or in combination with pertuzumab. See site of care policy for criteria, reauthorization, and exceptions for new starts. Site of Care Exceptions: 2 doses within 2 months.
Trastuzumab-dttb	Ontruzant	Q5112	N/A	Covered for patients who have an inadequate response or intolerance to the preferred biosimilar, trastuzumab-anns (Kanjinti). Note: Must be administered in a non-hospital setting when used as monotherapy or in combination with pertuzumab. See site of care policy for criteria, reauthorization, and exceptions for new starts. Site of Care Exceptions: 2 doses within 2 months.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
Trastuzumab-qyyp	Trazimera	Q5116	N/A	Covered for patients who have an inadequate response or intolerance to the preferred biosimilar, trastuzumab-anns (Kanjinti). Note: Must be administered in a non-hospital setting when used as monotherapy or in combination with pertuzumab. See site of care policy for criteria, reauthorization, and exceptions for new starts. Site of Care Exceptions: 2 doses within 2 months.
Trastuzumab-pkrb	Herzuma	Q5113	N/A	Covered for patients who have an inadequate response or intolerance to the preferred biosimilar, trastuzumab-anns (Kanjinti). Note: Must be administered in a non-hospital setting when used as monotherapy or in combination with pertuzumab. See site of care policy for criteria, reauthorization, and exceptions for new starts. Site of Care Exceptions: 2 doses within 2 months.
Trastuzumab-hyaluronidase-oysk	Herceptin Hylecta	J9356	N/A	Not covered not medically necessary, due to availability of treatment alternatives
Tremelimumab-actl	Imjudo	C9147, J9347	N/A	Covered as first line treatment of Hepatocellular Carcinoma (HCC) If ALL the following apply: • Stage B/C • Child Pugh A • Used in combination with Durvalumab. • Not a candidate for bevacizumab (i.e., bleeding risk or pending surgery) Covered for treatment of advanced Hepatocellular Carcinoma (HCC): • If combined with Durvalumab, AND • Child Pugh A AND • Immunotherapy naïve
Treprostinil	Remodulin	J3285, 1 mg	N/A	Covered for patients: • With pulmonary arterial hypertension (WHO Group 1) as confirmed by right heart catheterization in WHO functional class III and IV; **and** • When prescribed by or in consultation with a cardiologist or pulmonologist.
Trilaciclib dihydrochloride	Cosela	J1448	N/A	Medical necessity review required.
Triptorelin ER	Triptodur	J3316	N/A	• Covered for diagnosis of gender identity/gender dysphoria in patients who have failure, intolerance, or contraindication to leuprolide or are unable to safely administer leuprolide. • Medical necessity review required for other indications.

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
Ublituximab-xiiy	Briumvi	J2329	N/A	Medical necessity review required.
Unspecified codes: Pegcetacoplan Selexipag intravenous Terlipressin acetate Mosunetuzumab-axgb Omidubicel-onlv Leuprolide acetate 6 month for IM injection pediatric kit 45 mg Botulism immune globulin human Toripalimab-tpzi ADAMTS13 recombinant-krhn Donislecel-jujn Travoprost intracameral implant Nedosiran sodium Pegfilgrastim-cbqv Lifileucel Atidarsagene autotemcel	 Empaveli Uptravi Terlivaz Lunsumio Omisirge Lupron Depot Inj Ped 6 Mon Babybig Loqtorzi Adzynma Lantidra iDose TR Rivfloza Udenyca Onbody Amtagvi Lenmeldy*	Unspecified codes (J3490, J3590, J3591, J9999, J7199, J7599, J7699, J7799, J8498, J8499, C9399, J7999, J8999, J8597, A9150, S5001, A9699, Q0181)	N/A	Medical necessity review required.
Ustekinumab subcutaneous	Stelara	J3357	N/A	• Subcutaneous vial and syringe not covered under the medical benefit. May be covered under the pharmacy benefit. • Exception criteria may be considered for the following patient populations: • Subcutaneous vial for pediatric patients < 60 kg

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• Subcutaneous syringes for patients with impaired manual dexterity, impaired vision, or who are unable to safely self-administer AND • Patient meets clinical criteria below • Adult patients with moderate to severe psoriasis with an inadequate response, contraindication, or intolerance to topical psoriasis treatments AND o adalimumab (e.g., Amjevita) OR infliximab (e.g., Inflectra) AND o secukinumab AND o one preferred IL-23 inhibitor (guselkumab, risankizumab), AND o at least two of the following*: ▪ 12-week trial of phototherapy ▪ acitretin ▪ methotrexate *Note: cyclosporine may also be counted towards 1 of the required therapies, but should not be required. • Pediatric/adolescent patients 6-17 years old with moderate to severe psoriasis who have contraindication or inadequate response to the following: o topical psoriasis treatment and o methotrexate or a 12-week trial of phototherapy and o secukinumab • For psoriatic arthritis in patients with failure, contraindication, or intolerance to: o At least one conventional synthetic disease modifying anti-rheumatic drug (csDMARD) (methotrexate preferred), and o Two of the following biologics (one of which must be adalimumab or infliximab) and: ▪ adalimumab (e.g., Amjevita) ▪ infliximab (e.g., Inflectra) ▪ secukinumab ▪ etanercept o Guselkumab Note: csDMARD not required for patients with axial disease or severe (rapidly progressive, erosive) disease • Adult patients with moderately to severely active Crohn's disease with: o Contraindication, or intolerance, to at least two TNF-inhibitors (e.g., adalimumab [Amjevita]), infliximab [Inflectra]) OR o Inadequate response or loss of response to at least one TNF-inhibitor

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				○ It is recommended that TNF-inhibitors are used in combination with azathioprine, 6-mercaptopurine, or methotrexate. • Adult patients with moderately to severely active ulcerative colitis who have contraindication, intolerance, or loss of response to at least one TNF-inhibitor (e.g., adalimumab [Amjevita]), infliximab [Inflectra]) and vedolizumab. It is recommended that the TNF-inhibitor is used in combination with azathioprine, 6-mercaptopurine, or methotrexate. Not covered for use in combination with disease modifying or other biologic therapies including (but not limited to): ○ infliximab, adalimumab, etanercept, vedolizumab, rituximab, abatacept, certolizumab, tocilizumab, golimumab, canakinumab, natalizumab, tofacitinib, upadacitinib, ozanimod, apremilast **Quantity Limit:** • Psoriasis: Patients ≤ 100 kg: starting dose 45 mg, max dose 45 mg. Administration at 0, 4 weeks, then every 12 weeks. Patients > 100 kg: starting dose 45 mg, max dose 90 mg. Administration at 0, 4 weeks, then every 12 weeks. • Psoriatic arthritis: 45 mg at week 0, followed by 45 mg 4 weeks later and every 12 weeks thereafter. Increase to 90 mg if patient is more than 100 kg • Crohn's disease and ulcerative colitis: For induction, max dose 520 mg. For maintenance, subcutaneous 90 mg dose every 8 weeks after the initial intravenous dose. ○ If patient has inadequate response or flare after 16 weeks of initiation of therapy, may request authorization for 90 mg every 4 weeks ○ Initial approval of every 4-week dosing for one year. ○ Reauthorization would require reassessment for reduction in signs and symptoms of disease. **Applicable codes:** *ICD-10 codes covered if selection criteria or medical necessity is met. Listing of code does not guarantee coverage or reimbursement. The following list is provided for reference purposes only and may not be all inclusive.* K50 - K50.919, L40.0, L40.1, L40.4, L40.8, L40.9, L40.50 - L40.59, K51 - K51.919
Ustekinumab intravenous	Stelara	J3358	N/A	• Adult patients with moderate to severe psoriasis who have not had an adequate response to topical psoriasis treatments AND ○ adalimumab (e.g., Amjevita) OR infliximab (e.g., Inflectra) AND ○ secukinumab AND ○ one preferred IL-23 inhibitor (guselkumab, risankizumab), AND ○ at least two of the following*: ▪ 12-week trial of phototherapy ▪ acitretin

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				▪ methotrexate *Note: cyclosporine may also be counted towards 1 of the required therapies, but should not be required. • Pediatric/adolescent patients 6-17 years old with moderate to severe psoriasis who have contraindication or inadequate response to the following: o topical psoriasis treatment and o methotrexate or a 12-week trial of phototherapy and o secukinumab • For psoriatic arthritis in patients with failure, contraindication, or intolerance to: o At least one conventional synthetic disease modifying anti-rheumatic drug (csDMARD) (methotrexate preferred), and o Two of the following biologics (one of which must be adalimumab or infliximab) and: ▪ adalimumab (e.g., Amjevita) ▪ infliximab (e.g., Inflectra) ▪ secukinumab ▪ etanercept o Guselkumab Note: csDMARD not required for patients with axial disease or severe (rapidly progressive, erosive) disease • Adult patients with moderately to severely active Crohn's disease with: o Contraindication, or intolerance, to at least two TNF-inhibitors (e.g., adalimumab [Amjevita]), infliximab [Inflectra]) OR o Inadequate response or loss of response to at least one TNF-inhibitor o It is recommended that TNF-inhibitors are used in combination with azathioprine, 6-mercaptopurine, or methotrexate. • Adult patients with moderately to severely active ulcerative colitis who have contraindication, intolerance, or loss of response to at least one TNF-inhibitor (e.g., adalimumab [Amjevita]), infliximab [Inflectra]) and vedolizumab. It is recommended that the TNF-inhibitor is used in combination with azathioprine, 6-mercaptopurine, or methotrexate. Not covered for use in combination with disease modifying or other biologic therapies including (but not limited to): o infliximab, adalimumab, etanercept, vedolizumab, rituximab, abatacept, certolizumab, tocilizumab, golimumab, canakinumab, natalizumab, tofacitinib, upadacitinib, ozanimod, apremilast **Quantity Limit:**

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• Psoriasis: Patients ≤ 100 kg: starting dose 45 mg, max dose 45 mg. Administration at 0, 4 weeks, then every 12 weeks. Patients > 100 kg: starting dose 45 mg, max dose 90 mg. Administration at 0, 4 weeks, then every 12 weeks. • Psoriatic arthritis: 45mg at week 0, followed by 45 mg 4 weeks later and every 12 weeks thereafter. Increase to 90 mg if patient is more than 100 kg • Crohn's disease and ulcerative colitis: For induction, max dose 520 mg. For maintenance, subcutaneous 90 mg dose every 8 weeks after the initial intravenous dose. o If patient has inadequate response or flare after 16 weeks of initiation of therapy, may request authorization for 90 mg every 4 weeks o Initial approval of every 4-week dosing for one year. o Reauthorization would require reassessment for reduction in signs and symptoms of disease. **Applicable codes:** *ICD-10 codes covered if selection criteria or medical necessity is met. Listing of code does not guarantee coverage or reimbursement. The following list is provided for reference purposes only and may not be all inclusive.* K50 - K50.919, L40.0, L40.1, L40.4, L40.8, L40.9, L40.50 - L40.59, K51 - K51.919
Valoctocogene roxaparvovec	Roctavian*	J1412	N/A	Covered for patients with diagnosis of hemophilia A (congenital factor VIII deficiency) who meet ALL of the following: • Prescribed by or in consultation with hematology • Patient is male and 18 years of age or older • Baseline factor VIII levels <1 IU/dL or phenotypically severe hemophilia A requiring prophylaxis (recurrent spontaneous bleeding, regardless of factor VIII level) • No history of factor VIII inhibitor, and results from a Bethesda assay with Nijmegen modification of <0.6 Bethesda Units (BU) on two consecutive occasions at least one week apart within the past 12 months • Patient has been on prophylactic emicizumab therapy for at least 12 months • Patient is at risk for significant morbidity due to disease process Baseline required assessment and labs: • Liver ultrasound and liver FibroScan within 6 months prior to administration • Documentation of the following in prior 12 months: number of spontaneous bleeds, trauma bleeds, and factor VIII infusions per month • The following labs within 3 months prior to administration: o AAV5 antibody test o Factor VIII inhibitor titer (two titers separated by at least one week)

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				○ Factor VIII activity (chromogenic bovine test if on emicizumab) ○ Hepatitis B, Hepatitis C, HIV ○ LFTs: ALT, AST, alkaline phosphatase, total bilirubin, GGT ○ INR ○ CBC with differential ○ Serum creatinine (SCr) ○ Alpha-fetoprotein (AFP) in patients with preexisting risk factors for hepatocellular carcinoma (e.g., in patients with history of hepatitis B or C, non-alcoholic fatty liver disease [NAFLD], chronic alcohol consumption, non-alcoholic steatohepatitis [NASH], and advanced age) Not covered for patients who are/have: • Positive test for antibodies to AAV5; or • Current or recent poor adherence to hemophilia treatment; or • Liver cirrhosis of any etiology as determined by gastroenterologist; or • Known significant hepatic fibrosis (stage 3 or 4 on the Batts-Ludwig scale or equivalent); or • Platelet count of <100 x 10^9/L; or • Creatinine ≥1.5 mg/dL; or • Any evidence of active infection or any immunosuppressive disorder; or • Active Hepatitis B or C; or • Active substance or alcohol use disorder; or • Active malignancy, except non-melanoma skin cancer; or • History of hepatic malignancy; or • History of arterial or venous thromboembolic events (e.g., deep vein thrombosis, nonhemorrhagic stroke, pulmonary embolism, myocardial infarction, arterial embolus), with the exception of catheter-associated thrombosis for which anti-thrombotic treatment is not currently ongoing; or • Prior treatment with any vector or gene transfer agent; or • Use of systemic immunosuppressive agents, not including corticosteroids, or live vaccines within 30 days before the valoctocogene roxaparvovec infusion Authorization duration: limited to a one-time (single infusion) treatment Note: Prior to treatment initiation, all patients should be reviewed by an Interregional Consultative Physician Panel.
Vedolizumab	Entyvio	J3380, 1 mg	See next column	• Adult patients with moderately to severely active ulcerative colitis with contraindication, intolerance, or loss of response to at least one preferred TNF-inhibitor (infliximab-dyyb [e.g., Inflectra], adalimumab [e.g., Amjevita]). It is recommended that the TNF-inhibitor should have been used in combination with azathioprine 6-mercaptopurine, or methotrexate. • Adult patients with moderately to severely active Crohn's disease with:

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				○ Contraindication, or intolerance, to at least two TNF-inhibitors (infliximab-dyyb [e.g., Inflectra], adalimumab [e.g., Amjevita]), OR ○ Inadequate response with or loss of response to at least one preferred TNF inhibitor. ○ It is recommended that TNF-inhibitors are used in combination with azathioprine, 6-mercaptopurine, or methotrexate. Not covered for use in combination with disease modifying or other biologic therapies including (but not limited to): • infliximab, adalimumab, etanercept, rituximab, abatacept, tocilizumab, certolizumab, golimumab ustekinumab, natalizumab, tofacitinib, upadacitinib, ozanimod, apremilast Note: May be approved if patient is > 60 years old due to an increased risk of infection, or in patients with a history of malignancy. **Quantity Limit:** 300 mg at 0, 2, and 6 weeks and then every 8 weeks thereafter. Dose escalation up to every 4 weeks may be considered medically necessary in patients who have had an inadequate response to every 8-week dosing. Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts. Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente Washington's Specialty Pharmacy Network for medications impacted by this change. **Applicable codes:** *ICD-10 codes covered if selection criteria or medical necessity is met. Listing of code does not guarantee coverage or reimbursement. The following list is provided for reference purposes only and may not be all inclusive.* K50.00-K50.919, K51.00-K51.919
Velaglucerase alfa	Vpriv	J3385 100 units	N/A	Covered for patients with a confirmed diagnosis of Type 1 Gaucher disease. Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts. Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies through Kaiser Permanente Specialty Home Infusion. There is no out-of-network benefit coverage for home infusion. See Infused Drugs Restricted to Kaiser Permanente

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				Washington's Specialty Pharmacy Network for medications impacted by this change.
Velmanase alfa-tycv	Lamzede	J0217	N/A	Medical necessity review required.
Vestronidase Alfa-VJBK	Mepsevii	J3397	N/A	Covered for patients who meet all of the following: • Diagnosis of mucopolysaccharidosis VII (MPS VII, Sly syndrome). • Documentation of genetic confirmation of MPSVII • Prescribed by or in consultation with a medical geneticist/genetic specialist. Reauthorization: Reassessment every 12 months to confirm clinical benefit including disease stability or improvement in symptoms and a current weight Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.
Viltolarsen	Viltepso*	J1427	N/A	Covered for patients with Duchenne muscular dystrophy (DMD) who meet ALL of the following: • Prescribed by or in consultation with Pediatric Neurology, Adult Neurology, or Physical Medicine & Rehabilitation • Documented deletion/mutation amenable to exon 53 skipping (must be confirmed by a geneticist) • At least 4 years old • Ambulatory without wheelchair dependency (cane or walker use acceptable) • Documented minimum distance for unassisted 6-minute walk test (6MWT) of 180 meters at baseline • Must be on a stable dose of glucocorticoid for at least 6 months • Forced Vital Capacity % (FVC%) greater than or equal to 50% predicted Not covered for patients who: • Are non-ambulatory • Are ambulatory with some level of wheelchair dependency • Require nocturnal ventilation (including BiPAP), but excluding CPAP • Prior or planned treatment with gene therapy for Duchenne muscular dystrophy Reassessment every 12 months to determine need for continued therapy. Patient must meet ALL of the following functional criteria for continued coverage: • Ambulation test: Greater than limited home level (e.g., home, limited community, or community independent) • Sit to stand test: Moderate assist or Independent

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• No ventilator support (excluding use of nocturnal CPAP) Note: Prior to treatment initiation, all patients should be reviewed by an Interregional Consultative Physician Panel. Note: Must be administered in a non-hospital setting. See site of care policy for criteria, reauthorization, and exceptions for new starts.

Voretigene neparvovec-rzyl	Luxturna*	J3398	N/A	Covered for patients with retinal dystrophy who meet all of the following:
				• Prescribed by Retinal Specialist
				• Documented genetic diagnosis of biallelic RPE65 gene mutations
				• Required documentation:
				  ○ Sufficient viable retinal cells defined as having any of the following:
				  ▪ an area of retina within the posterior pole of >100 µm on optical coherence tomography (OCT)
				  ▪ ≥3 disc areas of retina without atrophy or pigmentary degeneration within the posterior pole based on ophthalmoscopy
				  ▪ remaining visual field within 30 degrees of fixation as measured by a III4e isopter or equivalent
				  ○ Best-corrected visual acuity (BCVA) measured in each eye and averaged for both eyes
				  ○ Visual fields measured via Goldmann and/or Humphrey testing
				  ○ Full field Electroretinogram (ERG), if available
				
				Not covered for patients:
				• Age less than 12 months.
				• No light perception (NLP) on exam
				• Intraocular surgery within past 3 months
				• Prior gene therapy administered to the intended eye
				
				Note: Prior to external treatment referral, patients should be reviewed by an Interregional Consultative Physician Panel.

Vosoritide	Voxzogo*	Unspecified J3490, J3590	N/A	Covered for patients with achondroplasia who meet all of the following: • Prescribed by or in consultation with Geneticist or Pediatric Endocrinologist • Diagnosis of achondroplasia has been confirmed by genetic testing, with documentation of a mutation in the fibroblast growth factor receptor 3 (FGFR3) gene. • Clinical evidence of open growth plates (open epiphyses). • Patient is ambulatory and able to stand without assistance. Exclusion criteria: • Bone age is ≥ 14 (females) or ≥ 16 (males) Baseline Assessment within 3 months prior to initiation • Bone age x-ray • Height via standard stadiometer

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
				• Weight • Growth velocity • Blood pressure Initial authorization: 12 months Reassessment every 12 months to confirm criteria are still met including that growth plates are still open. Reauthorization not covered if any of the following discontinuation criteria are met: • No response or inadequate response to therapy (e.g., no increase in growth velocity) • No further growth potential as indicated by closure of epiphyses • Non-adherence to medication Note: Prior to external treatment referral, patients should be reviewed by an Interregional Consultative Physician Panel
Vutrisiran sodium	Amvuttra*	J0225	N/A	Covered for patients who meet all of the following criteria: • Prescribed by a Neurologist or Neuromuscular specialist • Age 18 years or older • Diagnosis of hereditary transthyretin mediated amyloidosis (hATTR) with polyneuropathy that is thought to be primarily due to amyloidosis • Documentation of genetic testing to confirm transthyretin (TTR) mutation • Karnofsky performance status score ≥50 • Objective weakness in motor strength exam consistent with diagnosis and with confirmation via electrodiagnostic studies (i.e., electromyogram, nerve conduction study) • Signs of large fiber neuropathy on exam and/or clinically significant autonomic findings (e.g., orthostatic hypotension, tachycardia, bradycardia, etc.) • Required baseline documentation: o Medical Research Council (MRC) strength testing scale (0-5) o electromyography (EMG)/nerve conduction studies (NCS) Reassess every 6 months to evaluate need for continued treatment. Therapy should be discontinued if: • Member non-adherent to medication or follow-up assessments, • Significant clinical decline with life expectancy of less than one year • Karnofsky performance status score of less than 30 • Patient requiring hospice care **Note: Prior to treatment initiation, patients should be reviewed by an Interregional Consultative Physician Panel.**

Generic Name	Brand Name	J Codes	Max J code unit per year	Coverage Criteria
Zilucoplan sodium	Zilbrysq	Unspecified J3490, J3590	N/A	Considered a self-administered medication for outpatient use. Not covered under the medical benefit (hospital, clinic, or home infusion). May be covered under the pharmacy benefit. Exceptions to self-administration may be considered based on the following: • First dose for new starts to allow for self-administration training OR • Documentation of impaired manual dexterity, impaired vision, or inability to safely self-administer AND • Must meet clinical criteria (refer to pharmacy benefit)
Ziv-aflibercept	Zaltrap	J9400	N/A	Ziv-aflibercept may be covered if all of the following are met: 1) Used in combination with Irinotecan based regimens. 2) Patient has metastatic colorectal cancer (mCRC) that is resistant to or has progressed followed an oxaliplatin-containing regimen. 3) Patient has contraindication/intolerance to bevacizumab. Ziv-aflibercept is not considered medically necessary when used in patients who have failed bevacizumab containing regimen.

*Internal notification for emerging therapeutics drugs