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Kaiser Foundation Health Plan of Washington Options, Inc.
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Provider Communications, RCR-A3W-04
PO Box 34262, Seattle WA 98124-1262

SEPTEMBER 21, 2023

THE FOLLOWING MEDICATIONS NOT COVERED UNDER THE MEDICAL BENEFIT: ADALIMUMAB (HUMIRA), ADALIMUMAB-ATTO (AMJEVITA), AND ETANERCEPT (ENBREL, ENBREL MINI)

Dear Provider,

Effective December 1, 2023, the medications listed in Table 1 will **NOT** be covered under the medical benefit. **This letter is a notification of the upcoming change in coverage for this medication under the medical benefit.** Pharmacy benefit coverage remains available for members who meet prior authorization criteria.

Specialty medications under the pharmacy benefit are restricted to Kaiser Permanente Washington Specialty Pharmacy (KPWASP) for non-Medicare members. Send prescriptions via fax to 1-800-340-4230 or call 1-800-483-3945.

Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington, Options, Inc. (Kaiser Permanente) require prior authorization for a select group of injectable drugs that may be administered under the medical benefit in a physician's office or by home infusion. These reviews are intended to ensure consistent benefit adjudication as well as appropriate utilization in accordance with the Kaiser Permanente Pharmacy & Therapeutics Committee's evidence-based criteria for coverage.

Table 1. List of medications not covered under the medical benefit

BRAND NAME	GENERIC NAME	HCPCS
Humira	Adalimumab	J0135
Amjevita	Adalimumab-atto	Unspecified
Enbrel, Enbrel Mini	Etanercept	J1438

Table 2. Prior Authorization Criteria for medications not covered under the medical benefit.

DRUG NAME	COVERAGE CRITERIA

ADALIMUMAB	**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:**

DRUG NAME	COVERAGE CRITERIA
	Failure, contraindication, or intolerance to an adalimumab biosimilar (e.g., Amjevita) AND one of the following below: • For patients with rheumatoid arthritis with failure, intolerance, or contraindications to methotrexate • Covered for patients ≥ 2 years old with juvenile idiopathic arthritis with failure, intolerance, or contraindications to methotrexate • For psoriatic arthritis in patients with contraindication, intolerance, or failure 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*****: o 12-week trial of phototherapy o acitretin o methotrexate ***Note**: cyclosporine may also be counted toward 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 Failed topical antibiotic therapy (clindamycin 1% topical lotion) o Failed one systemic antibiotic (doxycycline, minocycline, or clindamycin/rifampicin) 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. • 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, they may request authorization for 40 mg every week for 12 weeks.

DRUG NAME	COVERAGE CRITERIA
	○ Reauthorization would require reassessment for 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 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, they 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-ATTO	**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 rheumatoid arthritis with failure, intolerance, or contraindications to methotrexate

DRUG NAME	COVERAGE CRITERIA
	• Covered for patients ≥ 2 years old with juvenile idiopathic arthritis with failure, intolerance, or contraindications to methotrexate. • For psoriatic arthritis in patients with contraindication, intolerance, or failure to at least one conventional synthetic disease modifying anti-rheumatic drug (csDMARD) (methotrexate preferred) **Note**: csDMARD is 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*****: 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 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 Failed topical antibiotic therapy (clindamycin 1% topical lotion) o Failed one systemic antibiotic (doxycycline, minocycline, or clindamycin/rifampicin) 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. • 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. o If patient has inadequate response or flare after 12 weeks of initiation of therapy, they may request authorization for 40mg every week for 12 weeks. o Reauthorization would require reassessment demonstrating 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

DRUG NAME	COVERAGE CRITERIA
	▪ 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 160mg week 0, 80mg week 2, then 40mg every other week. o If patient has inadequate response or flare after 12 weeks of initiation of therapy, they may request authorization for 40mg every week for 12 weeks. o Reauthorization would require reassessment demonstrating 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 80mg week 0, 40 mg week 2, then 40 mg every other week.
ETANERCEPT	**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:** o **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 rheumatoid arthritis with failure, intolerance, or contraindication to methotrexate • For patients ≥ 2 years old with juvenile idiopathic arthritis with failure, intolerance, or contraindication to methotrexate • For psoriatic arthritis in patients with contraindication, intolerance, or failure to: o at least one conventional synthetic disease modifying anti-rheumatic drug (csDMARD) (methotrexate preferred) AND o adalimumab (e.g., Amjevita) OR infliximab (e.g., Inflectra)

DRUG NAME	COVERAGE CRITERIA
	Note: csDMARD not required for patients with axial disease or severe (rapidly progressive, erosive) disease • For treatment of active ankylosing spondylitis • For 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 ○ at least two of the following*****: (1) 12-week trial of phototherapy (2) acitretin (3) methotrexate ***Note**: cyclosporine may also be counted towards 1 of the required therapies but should not be required. • 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: ○ topical psoriasis treatment and ○ methotrexate or a 12-week trial of phototherapy 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)

Additional Information

A complete list of office-administered injectable drugs requiring prior authorization can be found on the Kaiser Permanente provider website at https://wa-provider.kaiserpermanente.org/provider-manual/clinical-review/officeinject.

To request prior authorization review, please use the Referral Request online form located on the Kaiser Permanente provider website at https://wa-provider.kaiserpermanente.org/provider-manual/clinical-review/preservice. You can also fax your request to the Review Services department toll-free at 1-888-282-2685.

Thank you for the care you provide to our members, your patients. If you have any questions about this process, please call Review Services at 1-800-289-1363, Monday through Friday from 8 a.m. to 5 p.m.

Sincerely,

Gurpreet Rawat, MD, Chair
Pharmacy & Therapeutics Committee