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JULY 19, 2021

ECULIZUMAB (SOLIRIS) AND RAVULIZUMAB (ULTOMIRIS) RESTRICTED TO ADMINISTRATION BY KAISER PERMANENTE SPECIALTY HOME INFUSION WHEN INFUSED IN THE HOME SETTING

Dear Provider,

Effective September 1, 2021, criteria for the infusion products listed in Table 1 will change. For home infusion, these specialty drug products and administration of these products is limited to Kaiser Permanente Specialty Home Infusion for **non-Medicare** Health Maintenance Organization (HMO) members. For patients who currently have an authorization to receive these products through a network home infusion provider, the criteria will go into effect when the provider authorization expires.

Table 1. List of Infusion Products that are limited to administration by Kaiser Permanente Specialty Home Infusion

BRAND NAME	GENERIC NAME	HCPCS
Soliris	Eculizumab	J1300
Ultomiris	Ravulizumab	J1303, C9052

To transition any patients or for additional questions specific to this change, contact Kaiser Permanente Specialty Home Infusion by telephone at 206-326-2990, Monday – Friday from 8:30 a.m. to 5 p.m.

The criteria for outpatient standalone clinics, infusion centers, provider offices, and hospitals are not affected. Hospital outpatient settings require site of care approval.

Prior authorization is still required for these drugs, and the prior authorization criteria is outlined below for the infusion products listed in Table 1. Kaiser Foundation Health Plan of Washington requires 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 clinical review criteria established Kaiser Foundation Health Plan of Washington's Medical Policy Committee.

Prior Authorization Criteria for Eculizumab (Soliris) and Ravulizumab (Ultomiris) (changes are in bold):

DRUG NAME	COVERAGE CRITERIA

ECULIZUMAB	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 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 in combination with maximum tolerated doses of either mycophenolate mofetil or azathioprine.
	• Required documentation:
	  ○ Complete blood count with differential
	  ○ Meningococcal vaccination status
	  ○ AQP4 antibody test
	• Note: Prior to treatment with eculizumab for NMOSD, review by an Inter-regional Consultative Physician Panel is required.
	• 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:
	  ○ 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 contingent upon documentation of 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.

<table>
<tr><th>DRUG NAME</th><th>COVERAGE CRITERIA</th></tr>
<tr><td></td><td>

Initial authorization: 6 months
Reauthorization contingent upon documentation of clinical benefit including disease stability or improvement in symptoms.

Quantity Limits:
<table>
<tr><td>Indication</td><td>Max Dose and Frequency</td></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>
**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.
Medical necessity review for other indications
<u>Note:</u> For HMO plan members, home infusion will only be covered through Kaiser Permanente Specialty Home Infusion. See site of service prior authorization coverage criteria: https://wa-provider.kaiserpermanente.org/static/pdf/provider/clinical-review/list-officeinject.pdf. Please submit a referral to KP Specialty Home Infusion at 206-326-2139 (fax).
<u>Note</u>: Must be administered in a non-hospital setting. See site of care prior authorization criteria for coverage criteria in a hospital outpatient setting and exceptions for new starts. Site of care restriction does NOT apply to patients < 13 years old.
</td></tr>
<tr><td>RAVULIZUMAB-CWVZ</td><td>
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 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 in combination with maximum tolerated doses of either mycophenolate mofetil or azathioprine.

</td></tr>
</table>

DRUG NAME	COVERAGE CRITERIA

	• Required documentation:
	  ○ Complete blood count with differential
	  ○ Meningococcal vaccination status
	  ○ AQP4 antibody test
	• Note: Prior to treatment with eculizumab for NMOSD, review by an Inter-regional Consultative Physician Panel is required.
	• 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:
	  ○ 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 contingent upon documentation of 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 contingent upon documentation of clinical benefit including disease stability or improvement in symptoms.
	
	Quantity Limits:
	<table><tr><td>Indication</td><td>Max Dose and Frequency</td></tr><tr><td>PNH</td><td rowspan="2">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></table>
	***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.*
	
	Medical necessity review for other indications

DRUG NAME	COVERAGE CRITERIA
	Note: For HMO plan members, home infusion will only be covered through Kaiser Permanente Specialty Home Infusion. See site of service prior authorization coverage criteria: https://wa-provider.kaiserpermanente.org/static/pdf/provider/clinical-review/list-officeinject.pdf. Please submit a referral to KP Specialty Home Infusion at 206-326-2139 (fax). Note: Must be administered in a non-hospital setting. See site of care prior authorization criteria for coverage criteria in a hospital outpatient setting and exceptions for new starts. Site of care restriction does NOT apply to patients < 13 years old.

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/ under the "Authorization & Clinical Review" section. Using the website search feature, search for the term "Non-Medicare Injectable Drugs Requiring Prior Authorization."

To request prior authorization review, please use the Referral Request online form located on the Kaiser Permanente provider website listed above. 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 – Friday from 8 a.m. to 5 p.m.

Sincerely,

Peter Barkett, MD, Chair
Pharmacy & Therapeutics Committee