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DECEMBER 23, 2022

RAVULIZUMAB-CWVZ (ULTOMIRIS) UPDATED PRIOR AUTHORIZATION CRITERIA

Dear Provider,

Ravulizumab-cwvz (Ultomiris) is on the **non-Medicare** list of office-administered drugs requiring prior authorization. **Effective March 1, 2023,** the criteria for ravulizumab-cwvz (Ultomiris) will be updated to include a quantity limit for the indication Myasthenia Gravis (MG). This letter is a notification of the change in prior authorization criteria required before administering this medication under the medical benefit.

Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente) 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 Kaiser Permanente Pharmacy & Therapeutics Committee's evidence-based criteria for coverage.

Prior Authorization Criteria for ravulizumab-cwvz (Ultomiris) (changes are in bold):

DRUG NAME	COVERAGE CRITERIA

RAVULIZUMAB-CWVZ	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:
	  ○ 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:

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

Positive serologic test for anti-acetylcholine receptor (AChR) antibodies
Myasthenia Gravis Activities of Daily Living (MG-ADL) score ≥5
Trial and failure of efgartigimod alfa-fcab (Vyvgart)
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)

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><td>Indication</td><td>Max Dose and Frequency</td></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>MG</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.
*https://wa-provider.kaiserpermanente.org/static/pdf/provider/clinical-review/infusion-site-care-policy.pdf

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.
*https://healthy.kaiserpermanente.org/content/dam/kporg/final/documents/formularies/wa/infused-drugs-wa-en.pdf
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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,

Peter Barkett, MD, Chair
Pharmacy & Therapeutics Committee