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**Kaiser Foundation Health Plan of Washington**
**Kaiser Foundation Health Plan of Washington Options, Inc.**
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**PO Box 34262, Seattle WA 98124-1262**

FEBRUARY 28, 2024

## ENZYME REPLACEMENT THERAPIES UPDATED PRIOR AUTHORIZATION CRITERIA

Dear Provider,

**Effective June 1, 2024,** the criteria for the medical genetics listed in Table 1 will be updated to include quantity limits. These products are on or will be added to the **non-Medicare** list of office-administered drugs requiring prior authorization. **This letter is a notification of the upcoming change in prior authorization criteria required before administering this medication in a physician's office.**

**Table 1. List of Medical Genetics that have updated prior authorization criteria:**

| BRAND NAME | GENERIC NAME | HCPCS |
|---|---|---|
| **Aldurazyme** | Laronidase | J1931 |
| **Cerezyme** | Imiglucerase | J1786 |
| **Elaprase** | Idursulfase | J1743 |
| **Elelyso** | Taliglucerase alfa | J3060 |
| **Elfabrio** | Pegunigalsidase alfa | J2508 |
| **Fabrazyme** | Agalsidase | J0180 |
| **Kanuma** | Sebelipase alfa | J2840 |
| **Lamzede** | Velmanase alfa-tycv | J0217 |
| **Mepsevii** | Vestronidase alfa-vjbk | J3397 |
| **Naglazyme** | Galsulfase | J1458 |
| **Pombiliti** | Cipaglucosidase alfa-atga | Unspecified |
| **Revcovi** | Elapegademase-lvlr | Unspecified |
| **Vpriv** | Velaglucerase alfa | J3385 |

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 Medical Genetics (changes are in bold):**

| DRUG NAME | COVERAGE CRITERIA |
|---|---|
| LARONIDASE | Covered for patients with a confirmed diagnosis of MPS I (Hurler, Scheie, and Scheie forms)<br>**Reauthorization: reassessment every 12 months to confirm clinical benefit, including disease stability or improvement in symptoms and a current weight**<br>**Quantity Limit: Up to 52 infusions per year; ≤ 0.58 mg/kg every week**<br>Note: Must be administered in a non-hospital setting. See Site of Care: Infusion Therapy and Clinic Administered Medicines* for criteria, reauthorization, and exceptions for new starts. |
| IMIGLUCERASE | Covered for patients with a confirmed diagnosis of Type 1 or Type 3 Gaucher disease<br>**Reauthorization: reassessment every 12 months to confirm clinical benefit, including disease stability or improvement in symptoms and a current weight**<br>**Quantity Limit: Up to 26 infusions per year; up to 60 units/kg every week**<br>Note: Must be administered in a non-hospital setting. See Site of Care: Infusion Therapy and Clinic Administered Medicines* for criteria, reauthorization, and exceptions for new starts.<br>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. |
| IDURSULFASE | Covered for patients with a confirmed diagnosis of MPS II (Hunter syndrome)<br>**Reauthorization: reassessment every 12 months to confirm clinical benefit, including disease stability or improvement in symptoms and a current weight**<br>**Quantity Limit: Up to 52 infusions per year; ≤ 0.5 mg/kg every week**<br>Note: Must be administered in a non-hospital setting. See Site of Care: Infusion Therapy and Clinic Administered Medicines* for criteria, reauthorization, and exceptions for new starts.<br>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. |
| TALIGLUCERASE ALFA | Covered for patients with a confirmed diagnosis of Type 1 Gaucher disease<br>**Reauthorization: reassessment every 12 months to confirm clinical benefit, including disease stability or improvement in symptoms and a current weight** |

| DRUG NAME | COVERAGE CRITERIA |
|---|---|
| | **Quantity Limit: Up to 26 infusions per year; up to 60 units/kg every week**<br><br>Note: Must be administered in a non-hospital setting. See Site of Care: Infusion Therapy and Clinic Administered Medicines* for criteria, reauthorization, and exceptions for new starts.<br><br>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. |
| PEGUNIGALSIDASE ALFA | Medical necessity review required.<br><br>**Reauthorization: reassessment every 12 months to confirm clinical benefit, including disease stability or improvement in symptoms and a current weight**<br><br>**Quantity Limit: Up to 26 infusions per year; ≤ 1 mg/kg every 2 weeks** |
| AGALSIDASE | Covered for patients with a confirmed diagnosis of Fabry disease<br><br>**Reauthorization: reassessment every 12 months to confirm clinical benefit, including disease stability or improvement in symptoms and a current weight**<br><br>**Quantity Limit: Up to 26 infusions per year; ≤ 1 mg/kg every 2 weeks**<br><br>Note: Must be administered in a non-hospital setting. See Site of Care: Infusion Therapy and Clinic Administered Medicines* for criteria, reauthorization, and exceptions for new starts.<br><br>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. |
| SEBELIPASE ALFA | Medical necessity review required.<br><br>**Reauthorization: reassessment every 6 months (if less than 1 year old) or every 12 months to confirm clinical benefit, including disease stability or improvement in symptoms and a current weight**<br><br>**Quantity Limit:**<br><br>• **Patients in first 6 months of life: Up to 52 infusions per year; ≤ 5 mg/kg every week**<br>• **Patients 6 months of age and older: Up to 26 infusions per year; ≤ 3 mg/kg every 2 weeks** |
| VELMANASE ALFA-TYCV | Medical necessity review required.<br><br>**Reauthorization: reassessment every 12 months to confirm clinical benefit including disease stability or improvement in symptoms**<br><br>**Quantity Limit: Up to 52 infusions per year; ≤ 1 mg/kg every week** |
| VESTRONIDASE ALFA-VJBK | Covered for patients who meet all of the following:<br><br>• Diagnosis of mucopolysaccharidosis VII (MPS VII, Sly syndrome) |

| DRUG NAME | COVERAGE CRITERIA |
|---|---|
| | • Documentation of genetic confirmation of MPSVII<br>• Prescribed by or in consultation with a medical geneticist/genetic specialist<br><br>**Reauthorization: reassessment every 12 months to confirm clinical benefit, including disease stability or improvement in symptoms and a current weight**<br><br>**Quantity limit: 4 mg/kg every 2 weeks; up to 26 IV infusions per year**<br><br>Note: Must be administered in a non-hospital setting. See Site of Care: Infusion Therapy and Clinic Administered Medicines* for criteria, reauthorization, and exceptions for new starts. |
| GALSULFASE | Covered for patients with a confirmed diagnosis of MPS VI (Maroteaux-Lamy syndrome)<br><br>**Reauthorization: reassessment every 12 months to confirm clinical benefit, including disease stability or improvement in symptoms and a current weight**<br><br>**Quantity Limit: Up to 52 infusions per year; ≤ 1 mg/kg every week**<br><br>Note: Must be administered in a non-hospital setting. See Site of Care: Infusion Therapy and Clinic Administered Medicines* for criteria, reauthorization, and exceptions for new starts.<br><br>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. |
| CIPAGLUCOSIDASE ALFA-ATGA | Medical necessity review required.<br><br>**Reauthorization: reassessment every 12 months to confirm clinical benefit, including disease stability or improvement in symptoms and a current weight**<br><br>**Quantity Limit: Up to 26 infusions per year; ≤ 20 mg/kg every 2 weeks** |
| ELAPEGADEMASE-LVLR | Medical necessity review required.<br><br>**Reauthorization: reassessment every 12 months to confirm clinical benefit, including disease stability or improvement in symptoms**<br><br>**Quantity Limits: Up to 104 intramuscular injections per year.** |
| VELAGLUCERASE ALFA | Covered for patients with a confirmed diagnosis of Type 1 Gaucher disease<br><br>**Reauthorization: reassessment every 12 months to confirm clinical benefit, including disease stability or improvement in symptoms and a current weight**<br><br>**Quantity Limit: Up to 26 infusions per year; up to 60 units/kg every week**<br><br>Note: Must be administered in a non-hospital setting. See Site of Care: Infusion Therapy and Clinic Administered Medicines* for criteria, reauthorization, and exceptions for new starts.<br><br>Members will have in-network benefit coverage for select home infused medications and supplies only when they get these medicines and supplies |

| DRUG NAME | COVERAGE CRITERIA |
|---|---|
| | 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. |

**Site of Care: Infusion Therapy and Clinic Administered Medicines URL*
*https://wa-provider.kaiserpermanente.org/static/pdf/provider/clinical-review/infusion-site-care-policy.pdf*
***Infused Drugs Restricted URL*
*https://healthy.kaiserpermanente.org/content/dam/kporg/final/documents/formularies/wa/infused-drugs-wa-en.pdf*

**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 (login required) 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,

Ravi Ubriani, MD, Chair
Pharmacy & Therapeutics Committee