AvMed

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-877-535-1391**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Vimizim® IV (elosulfase alfa) **(J1322) (Medical)**

****IV INFUSION PERFORMED ONLY AT AvMed INFUSION CENTERS****

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

****If approved, max dose allowed is 2mg/kg to be administered once weekly.**

- Due to high risk of anaphylaxis and infusion reactions, Vimizim® infusion should be administered **ONLY** by **trained medical professionals** and will **NOT** be approved for self-administration or for administration by home healthcare providers.

☐ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Approval – 24 weeks. Documentation (chart notes, diagnostics, and/or lab results) must be **within last 30 days.**

- ❑ Prescriber is a metabolic geneticist or endocrinologist

AND

- ❑ Member is at least 5 years of age

AND

- ❑ Member has a diagnosis of mucopolysaccharidosis type IVA (MPS IVA) as verified by genetic testing **(labs included)**

AND

- ❑ Member has a diagnosis of mucopolysaccharidosis type IVA (MPS IVA) as verified by genetic testing **(labs included)**

AND

- ❑ Member's current height: _____

  Member's current weight: _____

AND

Current FEV1 **(labs included)**: _____

Current MVV **(within last 30 days)**: _____

AND

- ❑ Member's current normalized urine keratin sulfate levels **(within last 30 days**:

AND

- ❑ Baseline 6 minute walk time of a distance of **at least** 30 meters is attached **with date noted**

AND

- ❑ Chart notes are attached to document symptoms, prior medical procedures, and prior therapies used in the treatment of MPS IVA

AND

Continued Approval – 12 months. Continued approval will be based on member maintaining sustained improved walk time above baseline walk time and evidence of clinical improvement. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

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- ❑ Current 6 minute walk time of one **within last 30 days** is attached **with date noted**: _____

AND

- ❑ Member's 6 minute walk time has sustained improvement from baseline

AND

- ❑ Member's current height: _____

  Member's current weight: _____

AND

Current FEV_1 **(within last 30 days)**: _____

Current MVV **(within last 30 days)**: _____

AND

- ❑ Member's current normalized urine keratan sulfate levels **(within last 30 days)**: _____

AND

- ❑ Chart notes are attached to document current disease status, any medical procedures performed since last approval of this medication, and evidence of clinical improvement from baseline

Medication being provided by AvMed Infusion Centers (complete information below):

- ❑ **Location/site of administration**: _____

  NPI or DEA # of administering location: _____

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.

***Approved by Pharmacy and Therapeutics Committee**: 4/19/2018
REVISED/UPDATED: ~~6/30/2018;~~ **(Reformatted)** ~~3/23/2019; 7/8/2019; 9/24/2019;~~ **10/11/2019**