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: ELAPRASE® (idursulfase) **(IV INFUSION ONLY) (J1743) (Medical)**

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:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

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

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

Weight (if applicable): _____ **Date weight obtained:** _____

❑ 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.

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 Authorization – 6 months. (Max approved dose will be 0.5mg/kg every 7 days)

- ❑ Member is ≥ 5 years of age
- ❑ Provider is a specialist in genetics or metabolic disorders
- ❑ Member has absence of severe cognitive impairment

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- ❑ Patient has a diagnosis of Hunter disease (also referred to as **Mucopolysaccharidosis II; MPS II)**
- ❑ Diagnosis of Hunter disease has been confirmed by **one** of the following:
  - ❑ Deficient iduronate 2-sulfatase (I2S) enzyme activity in white cells, fibroblasts, or plasma in the presence of normal activity of at least one other sulfatase;

    OR
  - ❑ Detection of pathogenic mutations in the IDS gene by molecular genetic testing
- ❑ Documented baseline value for urinary glycosaminoglycan (uGAG)
- ❑ Documented baseline values for at least **one** of the following:
  - ❑ Member ≥ 5 years of age: 6-minute walk test (6-MWT) and/or percent predicted forced vital capacity (FVC)

    OR
  - ❑ Member < 5 years of age: spleen volume; liver volume; FVC; and/or 6-minute walk test

EXCLUSION CRITERIA: Elaprase® is considered investigational when used for any indication not listed above.

Continuation of Therapy – 6 months Approval (Max dose 60 billable units every 7 days)

- ❑ Provider is a specialist in genetics or metabolic disorders, a cardiologist, or a nephrologist
- ❑ Member continues to meet the criteria in initial section
- ❑ Absence of unacceptable toxicity from the drug. Examples include the following: severe hypersensitivity including anaphylactic and anaphylactoid reactions; antibody development and serious adverse reactions; acute respiratory complications; acute cardiorespiratory failure; etc.
- ❑ Member does not have progressive/irreversible severe cognitive impairment
- ❑ Member has documented reduction in uGAG levels
- ❑ Member has demonstrated beneficial response to therapy compared to pretreatment baseline in one or more of the following
  - ❑ Members ≥5 years: stabilization or improvement in 6-MT and/or FVC

    OR
  - ❑ Members < 5 years: spleen volume, and/or liver volume or stabilization/improvement in FVC and/or 6-MWT

EXCLUSION CRITERIA: Elaprase® is considered investigational when used for any indication not listed above. Elaprase® does not penetrate blood brain barrier and there are limited studies on members with severe cognitive impairment.

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Medication being provided by (check applicable box below):

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

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy - PropriumRx**

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:** 5/17/2018
REVISED/UPDATED/REFORMATTED: 11/16/2019