SENTARA HEALTH PLANS

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 1-844-668-1550**. 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: Naglazyme® (galsulfase) **for IV Infusion (Medical) (J1458)**

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

Member Name: _____

Member Sentara #: _____ **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:** _____

Quantity Limit (Maximum Approvable Dose): 1mg/kg infused every 7 days

❑ 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 Authorization Approval: 6 months

❑ Provider is a metabolic geneticist or other specialist in treatment of this disease

❑ Member is 5 years of age or older and current weight must be noted: _____ (must submit chart notes documenting member's current weight)

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- ❑ Member has a definitive diagnosis of Mucopolysaccharidosis VI (MPS VI, or Maroteaux-Lamy syndrome) as confirmed by the following (must submit lab result documentation of all criteria)
  - ❑ Detection of pathogenic mutations in ARSB gene by molecular genetic testing

OR

  - ❑ Arylsulfatase B (ASB) enzyme activity of <10% of the lower limit of normal in cultured fibroblasts or isolated leukocytes

AND

  - ❑ Member has normal enzyme activity of a different sulfatase (excluding members with Multiple Sulfatase Deficiency [MSD])

AND

  - ❑ Member has an elevated urinary glycosaminoglycan (uGAG) level (i.e. dermatan sulfate or chondroitin sulfate) defined as being above the upper limit of normal by the reference laboratory
- ❑ Provider has attached documented baseline 12-minute walk test (12-MWT) or 3-minute stair climg test
- ❑ Provider has attached documented baseline pulmonary function tests (e.g., FEV_1, FVC; etc.)
- ❑ Provider has attached documented baseline lab value of urinary glycosaminoglycan (uGAG)

Continuation Approval: 6 months. 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.

- ❑ Member continues to meet all initial authorization criteria

AND

- ❑ Member's current weight must be noted: _____ (must submit chart notes documenting member's current weight)
- ❑ Member has absence of unacceptable toxicity from the drug, such as anaphylaxis or hypersensitivity reactions, immune-mediated reactions, acute respiratory complications, acute cardiorespiratory failure, severe infusion reactions, spinal or cervical cord compression; etc.

AND

- ❑ Member has had a clinically significant response to treatment since last approval as defined by improvement or stability from pre-treatment baseline by the following:
  - ❑ Reduction in uGAG level by ≥50% from baseline or maintenance of level at ≥50% below baseline

AND

  - ❑ Improvement in or stability of pulmonary function testing (e.g., FEV_1, FVC; etc.)

AND

  - ❑ Improvement in or stability of 12-minute walk test (12-MWT) from last approval

OR

  - ❑ Improvement in or stability of 3-minute stair climb test from last approval

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Medication being provided by (check box below that applies):

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

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – PropriumRx**

For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan'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**: 3/19/2020
REVISED/UPDATED: 7/1/2020