SENTARA HEALTH PLANS

PHARMACY/MEDICAL PRIOR AUTHORIZATION 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: Aldurazyme® (laronidase) **IV solution (J1931) (Medical)**

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 (max daily dose) [NDC unit]: 2.9mg vial; 92 vials every 28 days

Max Units (per dose and over time) [HCPCS unit]: 667 billable units 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 Approval Authorization – 6 months

❑ Member is ≥ 6 months of age

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- ❑ Member has a definitive diagnosis of MPS I confirmed by one of the following:
  - ❑ Detection of biallelic pathogenic mutations in the IDUA gene by molecular genetic testing
  - ❑ Fibroblast or leukocyte alpha-L-iduronidase (IDUA) enzyme activity level of less than 10% of the lower limit of the normal range of the measuring laboratory
- ❑ Member has diagnosis of one of the following
  - ❑ Diagnosis of Hurler (severe) or Hurler-Scheie (attenuated) forms of disease
  - ❑ Diagnosis of Scheie (attenuated) form of disease with moderate to severe symptoms
- ❑ Member has absence of severe cognitive impairment
- ❑ Documented baseline value for urinary glycosaminoglycan (uGAG)
- ❑ Documented baseline values for one or more of the following
  - ❑ Members 6 years or greater: percent predicted forced vital capacity (FVC) of ≤77% of the patient's predicted normal FVC value, 6-minute walk test (must be able to stand independently for 6 minutes and walk a minimum of 5 meters within 6 minutes), joint range of motion, left ventricular hypertrophy, growth, quality of life (CHAQ/HAQ/MPS HAQ);

    OR

  - ❑ Members 6 months to less than 6 years: cardiac status, upper airway obstruction during sleep, growth velocity, mental development, FVC, and/or 6-minute walk test (must be able to stand independently for 6 minutes and walk a minimum of 5 meters within 6 minutes)

Continuation of Therapy – 12 month Approval

- ❑ Member continues to meet all initial authorization criteria
- ❑ Member has absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: anaphylaxis and severe hypersensitivity reactions, acute respiratory complications, acute cardiorespiratory failure, severe infusion reactions, etc
- ❑ Member does not have progressive/irreversible severe cognitive impairment.
- ❑ Member has a documented reduction in uGAG levels compared to pretreatment baseline
- ❑ Member has demonstrated a beneficial response to therapy compared to pretreatment baseline in one or more of the following:
  - ❑ Members 6 years or greater: stability or improvement in percent predicted FVC and/or 6- minute walk test, increased joint range of motion, decreased left ventricular hypertrophy, improved growth, improved quality of life (clinically meaningful change in the CHAQ/HAQ/MPS HAQ disability index);

    OR

  - ❑ Members 6 months to less than 6 years: stability or improvement in cardiac status, upper airway obstruction during sleep, growth velocity, mental development, FVC and/or 6-minute walk test

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Medication being provided by: Please check applicable box below.

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

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call Sentara Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara'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:** 4/16/2020
REVISED/UPDATED: 7/1/2020