SENTARA COMMUNITY PLAN
(MEDICAID)

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 1-844-305-2331**. 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**.

Drug Requested: Mepsevii™ (vestronidase alpha-vjbk) **IV (J3397) (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:** _____

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.

If approved, the **MAXIMUM dose allowed is 4mg/kg to be administered every other week.

Quantity Limit: 460 billable units (460mg) every 14 days

Yearly reauthorization is required.**

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. (***Chart notes must be attached to document current disease status, any medical procedures performed since last approval of this medication, and evidence of clinical improvement from baseline.)**

Initial Approval - 6 Months

(Continued on next page)

- ❑ Member is at least 5 months of age
- ❑ Documented baseline age-appropriate values for one or more of the following have been obtained: 6-minute walk test (6-MWT), motor function [i.e., Bruininks-Oseretsky Test of Motor Proficiency (BOT-2)], liver and/or spleen volume, urinary excretion of glycosaminoglycans (GAGs) such as chondroitin sulfate and dermatan sulfate, skeletal involvement (i.e. Z-score), pulmonary function tests, shoulder flexion, visual acuity (**NOTE**: For very young patients in which FVC or 6-MWT are not suitable for measuring, requests will be reviewed on a case-by case basis)
- ❑ Therapy is being used to treat non-central nervous system manifestations of the disease and member does not have severe, irreversible cognitive impairment (* **NOTE**: Requests for continued therapy in patients with severe, irreversible cognitive impairment will be reviewed on a case-by case basis)
- ❑ Member has a definitive diagnosis of mucopolysaccharidosis VII (MPS VII) as confirmed by **BOTH** of the following:
  - ❑ Beta- glucuronidase enzyme deficiency in peripheral blood leukocytes, fibroblasts, or dried blood spots
  - ❑ Detection of pathogenic mutations in the GUSB gene by molecular genetic testing

Reauthorization Approval: 12 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 the relevant criteria identified in the initial criteria
- ❑ Member has an absence of unacceptable toxicity from the drug
- ❑ Member is being continuously monitored for a beneficial response to therapy

Medication being provided by: Please 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 Sentara Health Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health'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**: 3/15/2018
REVISED/UPDATED/REFORMATTED: ~~3/17/2018; 8/27/2018; 10/8/2018; 2/5/2019; 5/5/2019; 7/23/2019; 10/23/2019; 10/16/2020;~~ **6/10/2026**