OPTIMA HEALTH PLAN

PHARMACY/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: Mepsevii® (vestronidase alpha-vjbk) **IV (J3590) (Medical)**

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

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

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

- ❑ 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. Continued approval is based on patient maintaining sustained improved walk time above baseline walk time and evidence of clinical improvement.

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 - 12 months

- ❑ Prescriber must be a metabolic geneticist or endocrinologist
- ❑ Member must be aged 5 months to 25 years
- ❑ Member must have a diagnosis of mucopolysaccharidosis type VII (MPS VII or Sly syndrome) as verified by genetic testing or leukocyte or fibroblast glucuronidase enzyme assay **(include labs confirming diagnosis)**
- ❑ Member's current height: _____ Member's current weight: _____
- ❑ Member's current normalized urine glycosaminoglycan levels **(include labs)**: _____

(Continued on next page)

AND <u>Two (2) of the following</u>: (*Chart notes must be attached to document symptoms, prior medical procedures and/or prior therapies used in the treatment of MPS VII.**)**

- ❑ Current FVC **(include labs):** _____
- ❑ Baseline 6 minute walk time is attached **(with date noted)**
- ❑ Visual acuity
- ❑ BOT-2 fine motor precision scale
- ❑ BOT-2 gross motor
- ❑ Fatigue Pediatric Quality of Life Inventory (PedsQL) multidimensional fatigue scale

Continued Approval - 12 months. All criteria must be checked for approval. To support each line checked, all documentation (lab results, diagnostics, and/or chart notes) must be provided or request may be denied.

- ❑ Member's current height: _____ Member's current weight: _____
- ❑ Member's current normalized urine glycosaminoglycan levels must have decreased by at least 50% from baseline **(include labs)**: _____

<u>AND the previous two (2) tests completed upon initial approval</u>:

- ❑ Current 6 minute walk time is attached **(with date noted)**
- ❑ Member's 6 minute walk time must document sustained improvement from baseline
- ❑ Member's current height: _____ Member's current weight: _____
- ❑ Current FVC **(include labs)**: _____
- ❑ Visual acuity
- ❑ BOT-2 fine motor precision scale
- ❑ BOT-2 gross motor
- ❑ Fatigue Pediatric Quality of Life Inventory (PedsQL) multidimensional fatigue scale

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

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

  NPI or DEA # of administering location: _____

<u>OR</u>

- ❑ **Specialty Pharmacy - PropriumRx**

(Continued on next page; signature page is required to process request.)

(Please ensure signature page is attached to form.)

For urgent reviews: Practitioner should call Optima Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Optima'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.

Member Name: _____

Member Optima #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR NPI #: _____

***Approved by Pharmacy and Therapeutics Committee**: 3/15/2018
REVISED/UPDATED: ~~7/17/2018~~; ~~10/18/2018~~; **(Reformatted)** ~~3/18/2019~~; ~~7/7/2019~~; **9/24/2019**