

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: Cerezyme® (imiglucerase) (J1786) (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.

Note: There is currently insufficient clinical evidence that supports the combination use of enzyme replacement therapy with substrate reduction therapy e.g., Zavesca® (miglustat) or Cerdelga® (eliglustat)

Recommended Dosage:

Cerezyme® (imiglucerase)

Gaucher disease, type 1 or 3:

Initial range: 2.5 units/kg 3 times weekly, up to 60 units/kg every 2 weeks

1 vial (400 units) = 40 billable units; 720 billable units every 14 days

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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: 12 months

- ☐ Medication will be used as a single agent
- ☐ Member has a documented diagnosis of Type 1 or Type 3 Gaucher Disease confirmed by one of the following:
 - ☐ Significantly reduced or absent glucocerebrosidase enzyme activity as measured by a betaglucohydrolase leukocyte (BGL) test
 - ☐ Detection of mutations in the glucocerebrosidase (GBA) gene
- ☐ Member has non-central nervous system (CNS) manifestations of Type 1 or Type 3 Gaucher disease defined as one or more of the following:
 - ☐ Anemia-related symptoms [i.e., blood transfusion dependency and/or hemoglobin ≤ 11 g/dL (women and children) or ≤ 12 g/dL (men)]
 - ☐ Thrombocytopenia (platelet count $\leq 120,000/\text{mm}^3$)
 - ☐ Hepatomegaly or splenomegaly
 - ☐ Skeletal disease (e.g., lesions, remodeling defects and/or deformity of long bones, osteopenia/osteoporosis, etc.)
 - ☐ Symptomatic disease (e.g., bone pain, fatigue, dyspnea, abdominal distension, diminished quality of life, etc.)

Reauthorization: 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 (check applicable box(es) below):

- ☐ Physician's office 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.****