AvMed

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 1-877-535-1391**. 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.

Gaucher Disease Drugs (Enzyme Replacement Therapy)

Drug Requested: (select below drug that applies)

❑ **Cerezyme®** (imiglucerase) **(J1786)**	❑ **Elelyso®** (taliglucerase alfa) **(J3060)**	❑ **Vpriv®** (velaglucerase alfa) **(J3385)**

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

Member Name: _____

Member AvMed #: _____ **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)

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Recommended Dosage:

Cerezyme® (imiglucerase)	**Elelyso®** (taliglucerase alfa)	**Vpriv®** (velaglucerase alfa)
Gaucher disease, type 1 or 3: Initial range: 2.5 units/kg 3 times weekly, up to 60 units/kg every 2 weeks	**Gaucher disease, type 1:** 60 units/kg every 2 weeks	**Gaucher disease, type 1:** 60 units/kg every 2 weeks
1 vial (400 units) = 40 billable units	**1 vial (200 units) = 20 billable units**	**1 vial (400 units) = 4 billable units**

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

- ❑ Member meets **ONE** of the following age requirements:
  - ❑ For Cerezyme® requests, member is 2 years of age or older
  - ❑ For Eleyso® or Vpriv® requests, member is 4 years of age or older
- ❑ Prescribed by or in consultation with a metabolic geneticist or physician knowledgeable in the management of Gaucher disease
- ❑ Medication will be used as a single agent
- ❑ Member has a diagnosis of **ONE** of the following types of Gaucher Disease:
  - ❑ Type 1 Disease
  - ❑ Type 3 Disease with **ONE** of the following mutations:
    - ❑ No mutation (3A)
    - ❑ L444P/L444P (3B)
    - ❑ D409H/D409H (3C)
- ❑ Member has a documented diagnosis of Type 1 or 3 Gaucher Disease as confirmed by **ONE** of the following **(submit documentation)**:
  - ❑ Beta-glucocerebrosidase activity (in leukocytes or skin fibroblasts) of less than 30% of normal values
  - ❑ deoxyribonucleic acid (DNA) testing (mutations in the glucocerebrosidase gene)
- ❑ For Adults only (age ≥ 18): Member's disease has resulted in at least **ONE** of the following **(check all that apply; submit labs for baseline criteria)**:
  - ❑ Anemia [i.e., hemoglobin ≤ 11 g/dL (women) or 12 g/dL (men)] not attributed to iron, folic acid, or vitamin B12 deficiency
  - ❑ Moderate to severe hepatomegaly (liver size 1.25 or more times normal volume) or splenomegaly (spleen size 5 or more times normal volume)
  - ❑ Skeletal disease (e.g., lesions, remodeling defects and/or deformity of long bones, osteopenia/osteoporosis)

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- ❑ Symptomatic disease (e.g., bone pain, fatigue, dyspnea, angina, abdominal distension, diminished quality of life)
- ❑ Thrombocytopenia (platelet count ≤ 120,000/mm^3)

❑ Requested dosing is in accordance with the United States Food and Drug Administration approved labeling

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 is **NOT** on concomitant substrate reduction therapy

❑ Member has experienced disease response with treatment as defined by at least **ONE** of the following compared to pre-treatment baseline **(check all that apply; submit labs/progress notes)**:

- ❑ Improvement in symptoms (e.g., bone pain, fatigue, dyspnea, angina, abdominal distension, diminished quality of life)
- ❑ Reduction in size of liver or spleen
- ❑ Improvement in hemoglobin/anemia
- ❑ Improvement in skeletal disease (e.g., increase in lumbar spine and/or femoral neck BMD, no bone crises or bone fractures)
- ❑ Improvement in platelet counts

❑ Member has **NOT** experienced unacceptable toxicity from the drug (e.g., hypersensitivity reactions)

❑ Requested dosing is in accordance with the United States Food and Drug Administration approved labeling

Medication being provided by: Please check applicable box below.

❑ **Physician's office** ❑ **Specialty Pharmacy – PropriumRx** ❑ **Other:** _____

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