

The following policy is for medication that falls under the Medicare Part D benefit only.

**Prior Authorization Group:** Treatment of Gauchers Disease Type 1 Policy

**Drug(s):** CEREDASE (alglucerase), CEREZYME (imiglucerase), ZAVESCA (miglustat)

**Covered Uses:** Gaucher's Disease Type 1 confirmed by biochemical assay. All criteria in "other criteria" section must be met for coverage for all drugs.

**Required Medical Information:** Complete Blood Count (CBC) with differential, biochemical assay confirming diagnosis, chart notes identifying symptoms and other relevant medical information

**Age Restrictions:** Imiglucerase and alglucerase are restricted to greater than 2 years old. Miglustat is restricted to ages greater than 18 years and less than 65 years old.

**Prescriber Restrictions:** N/A

**Other Criteria:**

Coverage criteria for imiglucerase and alglucerase is as follows:

- diagnosis of Gaucher's Disease Type 1 is confirmed by biochemical assay  
**AND**
- member is experiencing symptomatic manifestations of the disease as evidenced by one of the following:
  1. documented skeletal disease (osteopenia, avascular osteosclerosis, marrow infiltration, lytic lesions);
  2. anemia (Hgb less than or equal to 11.5gm/dL females, Hgb less than or equal to 12.5gm/dL males or 1.0gm/dL below lower limit of normal for age and sex);
  3. thrombocytopenia (platelet count less than or equal to 120,000/mm<sup>3</sup>)
  4. hepatomegaly or splenomegaly.

Coverage criteria for miglustat is as follows:

- diagnosis of Gaucher's Disease Type 1 is confirmed by biochemical assay  
**AND**
- member is experiencing symptomatic manifestations of the disease **AND**
- member has a contraindication for use of enzyme replacement therapy such as allergy, hypersensitivity reaction or poor venous access.

**Exclusion Criteria:** The use of imiglucerase, alglucerase or miglustat will not be considered medically necessary in the following situations:

- members with Type 2 or Type 3 Gaucher's Disease.
- asymptomatic Type 1 disease.
- carriers of Gaucher's Disease.
- combination use of any of these agents.
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The following policy is for medication that falls under the Medicare Part D benefit only.

- Miglustat is not covered for severe disease (severe disease defined as a hemoglobin concentration below 9 g/dL or a platelet count below  $50 \times 10^9/L$  or active bone disease).
- Miglustat is not covered for diagnosis other than Type 1 Gaucher Disease.
- Miglustat is not covered if there is no documented allergy, hypersensitivity, or poor venous access to enzyme replacement therapy.
- These agents are not covered for any diagnosis other than Gaucher's disease.

**Coverage Duration:** 12 months