# Medical Policy Bulletin

Title:
Enzyme Replacement for the Treatment of Gaucher's Disease
Policy #:
MA08.023c

**This Policy Bulletin document describes the status of CMS coverage, medical terminology, and/or benefit plan documents and contracts at the time the document was developed. This Policy Bulletin will be reviewed regularly and be updated as Medicare changes their regulations and guidance, scientific and medical literature becomes available, and/or the benefit plan documents and/or contracts are changed.**

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## Policy

**Coverage is subject to the terms, conditions, and limitations of the member's Evidence of Coverage.**

**MEDICALLY NECESSARY**

- Imiglucerase (Cerezyme®), taliglucerase alfa (Elelyso®) and velaglucerase alfa (VPRIV®) are considered medically necessary and, therefore, covered, as long-term enzyme replacement therapy (ERT) for pediatric and adult individuals with a confirmed diagnosis of Type 1 Gaucher's disease or those with clinical non-neuropathic manifestations of Type 3 Gaucher's disease, when all of the following criteria are met, including dosing and frequency:
    - Diagnosis is confirmed by one of the following:
        - Deficiency of glucosylceramidase in peripheral blood leukocytes or other nucleated cells
        - Confirmation of biallelic pathogenic variant(s) in the GBA gene and resulting in one or more of the following conditions
            - Anemia
            - Bone disease
            - Hepatomegaly or splenomegaly
            - Thrombocytopenia
    - Dosing and frequency for imiglucerase (Cerezyme®): initial dosages range from 2.5 U/kg of body weight 3 times a week to 60 U/kg once every 2 weeks. Maintenance dosages 30-60 U/kg every 2 weeks.
    - Dosing and frequency for taliglucerase alfa (Elelyso®): initial dose 60 units/kg every 2 weeks, then dosing is individualized based on achievement and maintenance of therapeutic goals. If switching from imiglucerase therapy, use the same unit/kg dose in stable individuals.
    - Dosing and frequency for velaglucerase alfa (VPRIV®): initial dosage for VPRIV in naïve adults and naïve pediatric individuals 4 years of age and older is 60 Units/kg administered every other week. Dosages are further individualized.

**NOT ELIGIBLE FOR REIMBURSEMENT**

Alglucerase (Ceredase®) is no longer manufactured and has been withdrawn from market, therefore, it is not eligible for reimbursement.

**EXPERIMENTAL/INVESTIGATIONAL**

All other uses for imiglucerase (Cerezyme®), velaglucerase alfa (VPRIV™), or taliglucerase alfa (Elelyso™) are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the Company medical policy on off-label coverage for prescription drugs and biologics.

**DOSING AND FREQUENCY REQUIREMENTS**

The Company reserves the right to modify the Dosing and Frequency Requirements listed in this policy to ensure consistency with the most recently published recommendations for the use of imiglucerase (Cerezyme®), velaglucerase alfa (VPRIV®), or taliglucerase alfa (Elelyso®). Changes to these guidelines are based on a consensus of information obtained from resources such as, but not limited to: the US Food and Drug Administration (FDA); Company-recognized authoritative pharmacology compendia; or published peer-reviewed clinical research. The professional provider must supply supporting documentation (i.e., published peer-reviewed literature) in order to request coverage for an amount of imiglucerase (Cerezyme®), velaglucerase alfa (VPRIV®), or taliglucerase alfa (Elelyso®) outside of the Dosing and Frequency Requirements listed in this policy. For a list of Company-recognized pharmacology compendia, view our policy on off-label coverage for prescription drugs and biologics.

Accurate member information is necessary for the Company to approve the requested dose and frequency of this drug. If the member's dose, frequency, or regimen changes (based on factors such as changes in member weight or incomplete therapeutic response), the provider must submit those changes to the Company for a new approval based on those changes as part of the utilization management activities. The Company reserves the right to conduct post-payment review and audit procedures for any claims submitted for imiglucerase (Cerezyme®), velaglucerase alfa (VPRIV®), or taliglucerase alfa (Elelyso®).

**REQUIRED DOCUMENTATION**

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the drug.

When coverage of imiglucerase (Cerezyme®), velaglucerase alfa (VPRIV®), or taliglucerase alfa (Elelyso®) is requested outside of the Dosing and Frequency Requirements listed in this policy, the prescribing professional provider must supply documentation (i.e., published peer-reviewed literature) to the Company that supports this request.

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## Guidelines

There is no Medicare coverage determination addressing this service; therefore, the Company policy is applicable.

**BENEFIT APPLICATION**

Subject to the terms and conditions of the applicable Evidence of Coverage, enzyme replacement therapy for the treatment of Gaucher's disease is covered under the medical benefits of the Company's Medicare Advantage products when the medical necessity criteria including dosing and frequency requirements listed in this medical policy

are met.

Certain drugs are available through the member's medical benefit (Part B benefit) or pharmacy benefit (Part D benefit), depending on how the drug is prescribed, dispensed, or administered. This medical policy only addresses instances when enzyme replacement therapy for the treatment of Gaucher's disease is covered under a member's medical benefit (Part B benefit). It does not address instances when enzyme replacement therapy for the treatment of Gaucher's disease is covered under a member's pharmacy benefit (Part D benefit).

**US FOOD AND DRUG ADMINISTRATION (FDA) STATUS**

The FDA approved the use of alglucerase (Ceredase®) in April 1991 for long-term ERT for individuals who have a confirmed diagnosis of Type 1 Gaucher's disease.

The FDA approved the use of imiglucerase (Cerezyme®) in May 1994 for long-term ERT for individuals who have a confirmed diagnosis of Type 1 Gaucher's disease.

The FDA approved the use of velaglucerase alfa (VPRIV™) on February 26, 2010 for long-term ERT for adult individuals who have a confirmed diagnosis of Type 1 Gaucher's disease.

The FDA approved the use of taliglucerase alfa (Elelyso™) on May 1, 2012 for long-term ERT for adults who have a confirmed diagnosis of Type 1 Gaucher's disease.

The FDA approved the use of taliglucerase alfa (Elelyso®) on August 27, 2014, for long-term ERT for pediatric individuals who have a confirmed diagnosis of Type 1 Gaucher's disease.

The FDA approved the use of taliglucerase alfa (Elelyso®) on November 13, 2021, for long-term ERT for pediatric individuals four years and older who have a confirmed diagnosis of Type 1 Gaucher's disease.

**PEDIATRIC USE**

The safety and effectiveness of imiglucerase (Cerezyme®) have not been established in individuals younger than 2 years of age.

The safety and effectiveness of velaglucerase alfa (VPRIV™) have not been established in individuals younger than 4 years of age.

The safety and effectiveness of taliglucerase alfa (Elelyso™) have not been established in individuals younger than 4 years of age.

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## Description

Gaucher's disease, also called Gaucher disease**,** is a rare, genetic, metabolic disorder caused by a deficiency of the enzyme glucocerebrosidase. Deficiency of glucocerebrosidase causes an accumulation of glucosylceramide, which is highly insoluble, in storage cells of the liver, spleen, bone marrow, and lymph nodes. Disease variants are classified according to the presence or absence of neurologic involvement and the rate of its progression into three major clinical subtypes: Types 1, 2, and 3. Type 1**,** the most common, is a chronic, nonneuronopathic, or adult form; it is the most prevalent. Although Type 1 Gaucher's disease is sometimes referred to as the adult form, symptoms of Type 1 can manifest at any age. Symptoms include bruising easily; fatigue due to anemia and low blood platelets; an enlarged liver and spleen; skeletal disorders; and, in rare instances, lung and kidney involvement. In Type 2 Gaucher's disease, liver and spleen enlargement are apparent by 3 months of age. It is an acute, neuronopathic, or infantile form, characterized by rapid neurologic deterioration; survival beyond 2 years of age is rare. Type 3 is a subacute, neuronopathic, or juvenile form, with a variable course marked by slowly progressive neurologic involvement and some characteristics of Type 1 and 2. Liver and spleen enlargement is a variable, along with brain involvement, which becomes apparent when marked by seizures.

Based on current published research, systemic manifestations of Type 3 Gaucher's disease can be reduced in individuals treated with enzyme replacement therapy (ERT), but neurologic manifestations of Gaucher's disease are not affected by ERT. According to the evidence, replacement of the missing enzyme glucocerebrosidase through ERT may improve the health outcome and quality of life in individuals significantly affected by Type 3 Gaucher's disease. However, treatment with ERT is ineffective for individuals with Type 2 disease, the neuronopathic form, because it does not alter the neurodegenerative course of the Type 2 disease.

In April 1991 the US Food and Drug Administration (FDA) approved alglucerase (Ceredase®) as an orphan drug (a drug used to treat, prevent, or diagnose a rare disease) for use as long-term enzyme replacement therapy (ERT) for children, adolescents, and adult individuals with a confirmed diagnosis of Type 1 Gaucher's disease who have signs and symptoms severe enough to result in one or more of the following conditions:

- moderate-to-severe anemia
- thrombocytopenia with bleeding tendency
- bone disease
- significant hepatomegaly or splenomegaly

Alglucerase (Ceredase®) is a modified form of the human enzyme, beta-glucocerebrosidase, prepared from a large pool of human placental tissue collected from selected donors. The quantity of the drug is based on the amount that is collected from selected donors. Due to this limit, alglucerase (Ceredase®) was phased out and replaced with imiglucerase (Cerezyme®).

In May 1994 the FDA approved imiglucerase (Cerezyme®) as an orphan drug for use as a long-term ERT for pediatric and adult individuals with a confirmed diagnosis of Type 1 Gaucher's disease who have signs and symptoms severe enough to result in one or more of the following conditions:

- anemia
- thrombocytopenia
- bone disease
- hepatomegaly or splenomegaly

Imiglucerase (Cerezyme®) is an analogue of the human enzyme, beta-glucocerebrosidase, produced by recombinant DNA technology. It differs from placental glucocerebrosidase by one amino acid at position 495, where histidine is substituted for arginine. Imiglucerase (Cerezyme®) is equivalent to alglucerase (Ceredase®). In clinical trials, imiglucerase (Cerezyme®) improved anemia and thrombocytopenia, reduced spleen and liver size, and decreased cachexia to a degree similar to that observed with alglucerase (Ceredase®).

In February 2010 velaglucerase alfa (VPRIV™) was FDA-approved for long-term ERT for pediatric and adult individuals with Type 1 Gaucher's disease. Velaglucerase alfa (VPRIV™) has the same amino acid sequence as the naturally occurring human enzyme, glucocerebrosidase. The safety and effectiveness of velaglucerase alfa (VPRIV™) was assessed in three clinical studies of naïve individuals to ERT and individuals who switched from imiglucerase (Cerezyme®) to velaglucerase alfa (VPRIV™). Per the FDA-approved prescribing information, individuals switching from imiglucerase (Cerezyme®) to velaglucerase alfa (VPRIV™) can begin treatment with velaglucerase alfa (VPRIV™) at the same stable dose of imiglucerase (Cerezyme®).

In May 2012 taliglucerase alfa (Elelyso™) was FDA- approved for long-tern ERT for adult and pediatric individuals with a confirmed diagnosis of Type 1 Gaucher's disease. Taliglucerase alfa (Elelyso™) is a recombinant active form of the lysosomal enzyme, glucocerebrosidase. Taliglucerase alfa (Elelyso™) is the first FDA-approved plant-cell-based ERT for Gaucher disease derived using genetically engineered carrot cells. Safety and efficacy of taliglucerase alfa (Elelyso™) was established in three studies containing individuals naïve to ERT and individuals switching from imiglucerase (Cerezyme®) to taliglucerase alfa (Elelyso™). Most individuals in the studies showed an improvement in their anemia, thrombocytopenia, and/or a decrease in their liver and spleen size.

According to published research, systemic manifestations of Type 3 Gaucher's disease can be reduced in individuals treated with ERT, but neurologic manifestations of Gaucher's disease is not affected by ERT. There is evidence that replacement of the missing enzyme glucocerebrosidase through ERT may improve the health outcome and quality of life in individuals significantly affected by Type 3 Gaucher's disease**.** However, treatment with ERT was ineffective for

individuals with Type 2 disease, the neuronopathic form, as it does not alter the neurodegenerative course of the Type 2 disease.

On August 27, 2014, FDA approved the use of taliglucerase alfa (Elelyso®) for long-term ERT for pediatric individuals who have a confirmed diagnosis of Type 1 Gaucher's disease. In this clinical trial, the safety of Elelyso was assessed in individuals, 16 years and younger in 9 pediatric treatment-naïve individuals (ages two to 13 years) with Type 1 Gaucher disease in a 12 month randomized clinical trial. The most common adverse reaction (≥10%) was vomiting, which occurred in 4 of 9 patients. Two individuals had hypersensitivity reactions; one individual experienced severe vomiting and gastrointestinal inflammation, and one experienced mild throat irritation and chest discomfort. Both individuals were treated with antihistamines and continued treatment. In the clinical trial in individuals switching from Imiglucerase Treatment to Elelyso the safety of Elelyso was assessed in 31 patients (26 adult and 5 pediatric patients), ages 6 to 66 years old, with Type 1 Gaucher disease who had previously been receiving treatment with imiglucerase for a minimum of 2 years. Elelyso was administered for 9 months at the same number of units as each individual's previous imiglucerase dose.

On November 13, 2021, FDA approved the use of taliglucerase alfa (Elelyso®), for long-term ERT for pediatric individuals four years and older who have a confirmed diagnosis of Type 1 Gaucher's disease. The long-term efficacy and safety of Elelyso in pediatric individuals with Type 1 Gaucher disease who were treatment-naïve or previously treated with imiglucerase was evaluated in phase 3, multi-center, extension trial.

This pediatric-specific extension trial included 15 individuals aged two to 18 years from two study cohorts. The first study cohort included 10 previously treatment-naïve pediatric individuals treated with Elelyso (9 who completed) for up to 36 months (the first 24 months of which were conducted in a double-blind fashion) at 30 units per kg or 60 units per kg. The second study cohort included five pediatric individuals who were previously switched from imiglucerase (2 who completed) and administered Elelyso for a total of 33 months at the same dose as each individual's previous imiglucerase dose. At the end of the study, treatment-naïve individuals treated with Elelyso for 36 months demonstrated clinical improvements, as measured by a decrease in spleen and liver volume and an increase in platelet count. In patients previously switched from imiglucerase to Elelyso, mean spleen and liver volume, platelet count and hemoglobin value remained stable through 33 months of Elelyso treatment. The most common adverse events reported were upper respiratory tract infection, cough, headache, abdominal pain, diarrhea, nasopharyngitis, pain in extremity, swollen or enlarged lymph nodes, and fever.

There may be additional indications contained in the Policy section of this document due to evaluation of criteria highlighted in the Company's off-label policy, and/or review of clinical guidelines issued by leading professional organizations and government entities.

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## Coding

**Inclusion of a code in this table does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.**

**The codes listed below are updated on a regular basis, in accordance with nationally accepted coding guidelines. Therefore, this policy applies to any and all future applicable coding changes, revisions, or updates.**

**In order to ensure optimal reimbursement, all health care services, devices, and pharmaceuticals should be reported using the billing codes and modifiers that most accurately represent the services rendered, unless otherwise directed by the Company.**

**The Coding Table lists any CPT, ICD-10, and HCPCS billing codes related only to the specific policy in which they appear.**

## CPT Procedure Code Number(s)

N/A

## ICD - 10 Procedure Code Number(s)

N/A

## ICD - 10 Diagnosis Code Number(s)

E75.22 Gaucher disease

## HCPCS Level II Code Number(s)

**MEDICALLY NECESSARY**

J1786 Injection, imiglucerase, 10 units

J3060 Injection, taliglucerace alfa, 10 units

J3385 Injection, velaglucerase alfa, 100 units

**NOT ELIGIBLE FOR REIMBURSEMENT**

THE FOLLOWING CODE REPRESENTING ALGLUCERASE (CEREDASE®) IS NO LONGER MANUFACTURED AND HAS BEEN WITHDRAWN FROM THE MARKET:

J0205 Injection, alglucerase, per 10 units

## Revenue Code Number(s)

N/A

## Policy History

**Revisions to MA08.023c**

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|---|---|
| **3/22/2023** | **This policy has been reissued in accordance with the Company's annual review process.** |
| **05/04/2022** | **This policy has been reissued in accordance with the Company's annual review process.** |
| 06/07/2021 | This policy has been updated to be consistent with the US Food and Drug Administration (FDA) labeling. Added long-term ERT use for pediatric individuals for taliglucerase alfa (Elelyso®). |

**Revisions to MA08.023b**

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|---|---|
| 03/25/2020 | This policy has been reissued in accordance with the Company's annual review process. |
| 06/03/2019 | This policy has been updated to be consistent with the US Food and Drug Administration (FDA) labeling. Dosing and frequency requirements were added for all the agents. Laboratory and/or genetic testing was added for all diagnoses. Code S9357 (Home infusion therapy, enzyme replacement intravenous therapy) was removed from the policy document, but remains eligible for administration in a home setting. |

**Revisions to MA08.023a**

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|---|---|
| 10/24/2018 | This policy has been reissued in accordance with the Company's annual review process. |
| 07/19/2017 | This policy was reviewed and reissued in accordance with the Company's Policy Confirmation Review track. The references were updated accordingly. |
| 03/16/2016 | The policy has been reviewed and reissued to communicate the Company’s continuing position on enzyme replacement for the treatment of Gaucher's disease. |
| 02/11/2015 | This version of the policy will become effective 02/11/2015.<br><br>This policy was updated to be consistent with US Food and Drug Administration (FDA) Labeling and Drug Compendia. The coverage position for alglucerase (Ceredase®) was changed from medically necessary to not eligible for reimbursement. |

**Revisions to MA08.023**

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|---|---|
| 01/01/2015 | This is a new policy. |

Version Effective Date:
06/07/2021
Version Issued Date:
06/07/2021
Version Reissued Date:
05/04/2022