Intravenous Enzyme Replacement Therapy (ERT) for Gaucher Disease (for Ohio Only)

Policy Number: CSOH2024D0048.A
Effective Date: January 1, 2024

Instructions for Use

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Related Policies

None

Application

This Medical Benefit Drug Policy only applies to the state of Ohio. Any requests for services that are stated as unproven or services for which there is a coverage or quantity limit will be evaluated for medical necessity using Ohio Administrative Code 5160-1-01.

Coverage Rationale

This policy refers to the following drug products, all of which are intravenous enzyme replacement therapies used in the treatment of Gaucher disease:

- Cerezyme® (imiglucerase)
- Elelyso® (taliglucerase)
- VPRIV® (velaglucerase)

Cerezyme® (imiglucerase), Elelyso® (taliglucerase), and VPRIV (velaglucerase) are proven and medically necessary for the treatment of certain conditions outlined within the InterQual® criteria Type 1 Gaucher disease.

- Cerezyme®: For medical necessity clinical coverage criteria, refer to the current release of the InterQual® CP: Specialty Rx Non-Oncology, Imiglucerase (Cerezyme).
- Elelyso®: For medical necessity clinical coverage criteria, refer to the current release of the InterQual® CP: Specialty Rx Non-Oncology, Taliglucerase alfa (Elelyso).
- VPRIV®: For medical necessity clinical coverage criteria, refer to the current release of the InterQual® CP: Specialty Rx Non-Oncology, Velaglucerase alfa (VPRIV).

Click here to view the InterQual® criteria.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may

require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
J1786	Injection, imiglucerase, 10 units
J3060	Injection, taliglucerase alfa, 10 units
J3385	Injection, velaglucerase alfa, 100 units

Policy History/Revision Information

Date	Summary of Changes

01/01/2024	**Template Update**
	• Created state-specific policy version
	Application
	• Modified language to indicate this Medical Benefit Drug Policy only applies to the state of Ohio; any requests for services that are stated as unproven or services for which there is a coverage or quantity limit will be evaluated for medical necessity using *Ohio Administrative Code 5160-1-01*
	Coverage Rationale
	• Revised language to indicate:
	  ○ This policy refers to the following drug products, all of which are intravenous enzyme replacement therapies used in the treatment of Gaucher disease:
	  ▪ Cerezyme® (imiglucerase)
	  ▪ Elelyso® (taliglucerase)
	  ▪ VPRIV® (velaglucerase)
	  ○ Cerezyme® (imiglucerase), Elelyso® (taliglucerase), and VPRIV (velaglucerase) are proven and medically necessary for the treatment of certain conditions outlined within the InterQual® criteria for Type 1 Gaucher disease; for medical necessity clinical coverage criteria, refer to the current release of the InterQual® CP: Specialty Rx Non-Oncology:
	  ▪ Imiglucerase (Cerezyme)
	  ▪ Taliglucerase alfa (Elelyso)
	  ▪ Velaglucerase alfa (VPRIV)
	Applicable Codes
	• Removed list of applicable ICD-10 diagnosis codes
	Supporting Information
	• Removed *Background*, *Clinical Evidence*, *FDA*, and *References* sections
	• Archived previous policy version CS2022D0048P

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state (Ohio Administrative Code [OAC]), or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state (OAC), or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state (OAC), or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state (OAC), or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.