



## **RX.PA.062.CCH NEXVIAZYME (AVALGLUCOSIDASE)**

The purpose of this policy is to define the prior authorization process for Nexviazyme (avalglucosidase) for Pompe disease, late onset.

### **DEFINITIONS**

N/A

### **POLICY**

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.

The drug, Nexviazyme (avalglucosidase), is subject to the prior authorization process.

### **PROCEDURE**

#### **Initial Authorization Criteria:**

*Must meet all the criteria listed below:*

- Must be age 1 year or older
- Must be prescribed by or in consultation with a neurologist or a physician who specializes in the treatment of inherited metabolic disorders
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling
- Must have a diagnosis of alpha glucosidase deficiency (Pompe disease) confirmed through GAA enzyme assay (from blood, skin fibroblasts, lymphocytes, or muscle) and/or identification of GAA gene mutation

#### **Reauthorization Criteria:**

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

**Limitations:**

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.

**Codes:**

CPT Codes / HCPCS Codes / ICD-10 Codes		
Code	Brand	Description
J0219	Nexviazyme	Injection, avalglucosidase alfa-ngpt, 4 mg

**References:**

1. Nexviazyme (avalglucosidase alfa) [prescribing information]. Cambridge, MA: Genzyme Corporation; August 2021
2. van der Ploeg AT, Kruijshaar ME, Toscano A, et al; European Pompe Consortium. European consensus for starting and stopping enzyme replacement therapy in adult patients with Pompe disease: a 10-year experience. Eur J Neurol. 2017;24(6):768-e31. doi:10.1111/ene.13285

**Revision History**

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Initial review	05/2023

**Record Retention**

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

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**POLICY NUMBER: RX.PA.062.CCH**

**REVISION DATE: 05/2023**

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