Medical Policy

Nexviazyme (avalglucosidase alfa-ngpt)	
MEDICAL POLICY NUMBER	MED_Clin_Ops_087
POLICY OWNER	A. Bartley Bryt, MD, Chief Medical Officer
ORIGINAL EFFECTIVE DATE	11/1/2021
CURRENT VERSION NUMBER	2
CURRENT VERSION EFFECTIVE DATE	1/01/2024
APPLICABLE PRODUCT AND MARKET	Individual Family Plan: ALL Small Group: ALL Medicare Advantage: ALL

***IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY**: These services may or may not be covered by all Brand New Day/Central Health Medicare Plan Plans. Please refer to the member's plan document for specific coverage information.*

Brand New Day/Central Health Medicare Plan may use tools developed by third parties, such as MCG™ Care Guidelines and the ASAM Criteria™ to assist in administering health benefits. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Care Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice.
Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/Central Health Medicare Plan Medical Policy may contact the Health Plan.

Before using this policy, please check the member benefit plan document and any federal or state mandates, if applicable. Brand New Day/Central Health Medicare Plan policies and practices are compliant with all federal and state requirements, including mental health parity laws.

Nexviazyme (avalglucosidase alfa-ngpt)	
MEDICAL POLICY NUMBER	MED_Clin_Ops_087
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/Central Health Medicare Plan Medical Policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov for additional information.

PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity for Nexviazyme (avalglucosidase alfa-ngpt) therapy.

POLICY

Prior Authorization and Medical Review is required.

Coverage for Nexviazyme will be provided for 12 months and may be renewed.

1. Patient is 1 year of age or older; **AND**
2. Nexviazyme is prescribed by or in consultation with a geneticist, endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders; **AND**
3. Patient has a documented diagnosis of late-onset Pompe disease confirmed by **one** the following:
    a. Absence or deficiency (< 40% of the lab specific normal mean) acid alpha-glucosidase deficiency (GAA) activity in lymphocytes, fibroblasts, or muscle; **OR**
    b. Molecular genetic testing for deletion or mutations in the GAA gene; **AND**
4. Presence of clinical signs and symptoms of the disease (e.g., cardiac hypertrophy, respiratory distress, skeletal muscle weakness, etc.).

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value

BACKGROUND

Nexviazyme is an enzyme replacement therapy (ERT) designed to specifically target the mannose-6 phosphate (M6P) receptor, the key pathway for cellular uptake of enzyme replacement therapy in Pompe disease. FDA approval is based on results from the COMET study that compared Nexviazyme to avalglucosidase alfa in LOPD.

DEFINITIONS

1. NEXVIAZYME (avalglucosidase alfa-ngpt) for injection, for intravenous use. Initial U.S. Approval: 2021

a. NEXVIAZYME (avalglucosidase alfa-ngpt) for injection is supplied as a sterile, white to pale-yellow lyophilized powder in single-dose vials.
    i. One 100 mg vial in a carton: NDC 58468-0426-1

CODING

Applicable NDC Codes	
58468-0426-01	NEXVIAZYME, valglucosidase alfa-ngpt 100 mg

Applicable Procedure Code	
E74.02	Pompe disease

Applicable ICD-10 Codes	
J3490	Drugs unclassified injection

EVIDENCE BASED REFERENCES

1. Product Information: NEXVIAZYME(TM) intravenous injection, avalglucosidase alfa-ngpt intravenous injection. Genzyme Corporation (per FDA), Cambridge, MA, 2021.

POLICY HISTORY

Original Effective Date	11/1/2021
Revised Date	November 8, 2022 – Annual Review and approval (no policy revisions made) February 28, 2023 – Annual Review and approval (no policy revisions made) March 1, 2023 – Adopted by MA UM Committee (no policy revisions made) January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)
P&T Committee Endorsement	2/28/2023