Pharmacy Drug Policy & Procedure

Policy Name:	Nexviazyme (alglucosidase alfa-ngpt)	Policy #:	3047P

Purpose of the Policy

The purpose of this policy is to establish criteria for coverage of Nexviazyme.

Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Nexviazyme under the Specialty Medical benefit when the following criteria have been met.

Criteria

1. Coverage Criteria

1.1 Diagnosis of late-onset Pompe disease as supported by the following:
- Enzyme assay showing a deficiency of acid alpha-glucosidase (GAA) activity in the blood, skin, or muscle
- Genetic testing showing a mutation in the GAA gene

1.2 Age 1 year or older

1.3 Prescribed by a Geneticist or specialist in Pompe disease

1.4 Imaging rules out presence of cardiac hypertrophy

1.5 Documentation showing baseline percent-predicted forced vital capacity (FVC) and 6-minute walk test (6MWT)

1.6 Review of chart notes documenting diagnosis and confirming that patient has met all above requirements for treatment with Nexviazyme by both a pharmacist and medical director

2. Exclusion Criteria

2.1 Concomitant use with Lumizyme is considered a duplication of therapy and excluded from coverage

3. Approval Period

3.1 Initial: 12 months

3.2 Reapproval: 12 months with documentation of positive clinical response and toleration of therapy

References

1. Nexviazyme (avalglucosidase alfa-ngpt) [prescribing information]. Cambridge, MA: Sanofi Genzyme, Inc; May 2023.
2. Manera JD, Kishnani PS, Kushlaf H, et al. Safety and efficacy of avalglucosidase alfa versus alglucosidase alfa in patients with late-onset Pompe disease (COMET): a phase 3, randomised, multicentre trial. Lancet Neurol. 2021 Dec;20(12):1012-1026.
3. Pena LDM, Barohn RJ, Byrne BJ, et al; NEO1 Investigator Group. Safety, tolerability, pharmacokinetics, pharmacodynamics, and exploratory efficacy of the novel enzyme replacement therapy avalglucosidase alfa (neoGAA) in treatment-naïve and alglucosidase alfa-treated patients with late-onset Pompe disease: a phase 1, open-label, multicenter, multinational, ascending dose study. Neuromuscul Disord. 2019;29(3):167-186.

Pharmacy Drug Policy & Procedure

Created Date: 10/05/2022
Effective Date: 10/05/2022
Posted to Website: 10/05/2022
Revision Date: 10/04/2023

DISCLAIMER This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most Statement of the Policy Criteria Purpose of the Policy References appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage