



EVOLENT HEALTH LLC POLICY AND PROCEDURE

POLICY NUMBER: *RX.PA.136.E*
REVISION DATE: *10/15*
PAGE NUMBER: 1 of 3

POLICY TITLE: *Myozyme and Lumizyme (alglucosidase alfa)*
DEPARTMENT: *Clinical Pharmacy Services- Utilization Management*
ORIGINAL DATE: *April 2010 (as adopted from UPMC Health Plan)*

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	<input type="checkbox"/> HMO <input type="checkbox"/> PPO <i>Products:</i> <input type="checkbox"/> Small <i>Exchange:</i> <input type="checkbox"/> Shop <input checked="" type="checkbox"/> All <input type="checkbox"/> Indiv. <input type="checkbox"/> Indiv. <input type="checkbox"/> Large
OTHER	<input checked="" type="checkbox"/> Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Myozyme and Lumizyme (alglucosidase alfa).

Myozyme is indicated for use in patients with Pompe disease and has been shown to improve ventilator-free survival in patients with infantile-onset Pompe disease as compared to an untreated historical control.

Lumizyme is indicated for patients with Pompe disease.

Myozyme and Lumizyme consists of the human enzyme acid alpha-glucosidase (GAA) and are intended for intravenous infusion.

DEFINITIONS

Pompe Disease – A genetic absence or deficiency of acid alpha-glucosidase (GAA) resulting in build-up of glycogen in the cardiac and skeletal muscles, and in hepatic tissue. This results in the development of cardiomyopathy, progressive muscle weakness, and impairment of respiratory function.



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 Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drugs, Myozyme and Lumizyme (alglucosidase alfa), are subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by or in consultation with a physician who specializes in the treatment of inherited metabolic disorders or a neurologist
- Must have a confirmed diagnosis of alpha glucosidase deficiency (Pompe disease)
 - Diagnosis must be 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.



REFERENCES

1. Myozyme [package insert]. Genzyme Corp. Cambridge, MA, January 2009.
2. Lumizyme [package insert]. Genzyme Corp. Cambridge, MA, September 2014.
3. American Association of Neuromuscular & Electrodiagnostic Medicine. Diagnostic criteria for late-onset (childhood and adult) Pompe disease. *Muscle Nerve* 2009;40:149-160
4. Kishnani PS, Steiner RD, Bali D, et al. Pompe disease diagnosis and management guideline. *Genet Med* 2006;8(5):267-288
5. Kishnani PS, Amartino HM, Lindberg C, et al. Methods of diagnosis of patients with Pompe disease: data from the Pompe registry. *Mol Genet Metab* 2014;
<http://dx.doi.org/10.1016/j.ymgme.2014.07.014>

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.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
<i>Annual review</i>	<i>02/17, 02/18</i>

