COMMUNITY HEALTH CHOICE

Pombiliti™ (Cipaglucosidase alfa-atga)

Effective Date: 7/1/2024
Medical Care Management Committee Approval: 4/25/2024

Contents

Coverage Policy

This Medical Review Guideline (Guideline) is provided for informational purposes only and does not constitute medical advice. It is intended solely for the use of Community Health Choice, Inc. (Community) clinical staff as a guideline for use in determining medical necessity of requested procedures, medications and therapy. This Guideline does not address eligibility or benefit coverage. Other Policies and Coverage Determination Guidelines may apply. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Medical Review Guideline. If there is a discrepancy between this Guideline and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern. Community reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

This policy applies to the following Pombiliti™ (Cipaglucosidase alfa-atga) product:

HCPCS Code	Description	Maximum Dosage per Administration
J1203	Injection, cipaglucosidase alfa-atga, 5 mg	20 mg/kg

Diagnosis-Specific Criteria

Pombiliti™ (Cipaglucosidase alfa-atga) will be considered medically necessary for members meeting ALL of the following criteria:

1. Member is 18 years of age or older; AND
2. Members weighs 40 kg or greater; AND
3. Pombiliti will be used in combination with Opfolda; AND
4. Member has failed treatment with one of the following agents after a trial length of at least one year:
    a. Lumizyme (alglucosidase alfa)
    b. Nexviazyme (avalglucosidase alfa-ngpt); AND
5. Documentation of late-onset acid alpha-glucosidase deficiency (late-onset Pompe disease) with diagnosis established by one of the following:
    a. Laboratory test demonstrating deficient acid alpha-glucosidase activity in blood, fibroblasts, or muscle tissue

b. Molecular genetic test demonstrating biallelic pathogenic acid alpha-glucosidase gene (GAA) variants; AND

6. Medication is prescribed by, or in consultation with, with a geneticist, neurologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive.

HCPCS Code	Description
J1203	Injection, cipaglucosidase alfa-atga, 5 mg

Diagnosis Code	Description
E74.02	Pompe disease

Policy Revision History

Status	Effective Date	Description
Baseline	7/1/2024	Initial version of Cipaglucosidase alfa-atga diagnosis specific policy