

cipaglusosidase alfa-atga (Pombiliti®)

Medical Benefit Drug Policy

Place of Service

Office Administration

Outpatient Facility Administration

Infusion Center Administration

Drug Details

USP Category: GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT

Mechanism of Action: Hydrolytic lysosomal glycogen-specific enzyme

HCPCS:

- Through 3/31/2024: C9399, J3490, J3590
- Effective 4/1/2024 and after: J1203 per 5 mg

How Supplied:

105 mg lyophilized powder in a single-dose vial

- Contains one (1) 105 mg single-dose vial: 71904-200-01
- Contains ten (10) 105 mg single-dose vials: 71904-200-02
- Contains twenty-five (25) 105 mg single-dose vials: 71904-200-03

Condition(s) listed in policy (*see coverage criteria for details*)

- Late-onset Pompe Disease (LOPD)

Special Instructions and pertinent Information

The following condition(s) require Prior Authorization/Preservice:

Late-onset Pompe Disease (LOPD)

1. One of the following:
 - a. Genetic testing showing acid alpha-glucosidase (GAA) mutation, or
 - b. An enzyme assay showing absent or decreased GAA activity from blood, skin, or muscle tissues, AND
2. Age and weight consistent with FDA-approved indication (adults weighing ≥ 40 kg), AND
3. Used in combination with Opfolda (miglustat), AND
4. Inadequate response to one currently approved ERT for LOPD: Lumizyme (alglucosidase alfa) OR Nexviazyme (avalglucosidase alfa-ngpt)

Covered Doses:

20 mg/kg (of actual body weight) given intravenously every other week

Coverage Period:

Initial: 1 year

Reauthorization: Yearly if there is continued benefit from therapy

References

1. AHFS®. Available by subscription at <http://www.lexi.com>
2. DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
3. Pombiliti (cipaglucoisidase alfa-atga) [Prescribing information]. Philadelphia, PA: Amicus Therapeutics US, LLC; 9/2023.

Review History

Date of Last Annual Review: 2/28/2024

Date of last revision: 4/3/2024

Changes from previous policy version:

- Added Effective 4/1/2024 and after: J1203 per 5 mg

*Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee*