

POMBILITI (cipaglucosidase alfa-atga)

Pre - PA Allowance

None

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

1. Late-onset Pompe disease (acid alpha-glucosidase (GAA) deficiency)

AND ALL of the following:

- a. Patient has not improved on enzyme replacement therapy (ERT)
- b. Patient weight ≥40 kg
- c. Used in combination with Opfolda
- d. Prescriber agrees to monitor for hypersensitivity reactions and infusionassociated reactions and to initiate treatment as needed
- e. Prescriber agrees to frequently monitor the vitals of patients at risk for fluid volume overload during medication infusion
- f. Prescriber agrees to assess for cardiac issues such as cardiomyopathy, cardiac hypertrophy and arrhythmia using an echocardiogram and a 12 lead EKG prior to initiating therapy with Pombiliti
- g. Females of reproductive potential only: patient will be advised to use effective contraception during treatment and for 60 days after the last dose

Prior - Approval Limits

Duration 2 years

Prior – Approval Renewal Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

1. Late-onset Pompe disease (acid alpha-glucosidase (GAA) deficiency)



POMBILITI (cipaglucosidase alfa-atga)

AND ALL of the following:

- a. Patient weight ≥40 kg
- b. Used in combination with Opfolda
- c. Prescriber agrees to monitor for hypersensitivity reactions and infusionassociated reactions and to initiate treatment as needed
- d. Prescriber agrees to frequently monitor the vitals of patients at risk for fluid volume overload during medication infusion
- e. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment and for 60 days after the last dose

Prior - Approval Renewal Limits

Same as above