



**OPFOLDA
(miglustat)**

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 Pombiliti
- d. 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)

AND ALL of the following:

- a. Patient weight ≥ 40 kg
- b. Used in combination with Pombiliti
- c. 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