Health Alliance™ Pharmacy Drug Policy Checklist

POLICY NAME	Pombiliti and Opfolda (cipaglucosidase alfa and	POLICY #	2775P

Criteria

Coverage Criteria for the Treatment of Pompe Disease

- ☐ Diagnosis of late onset Pompe disease as supported by BOTH of the following:
  - Enzyme assay showing a deficiency of acid alpha-glucosidase (GAA) activity in the blood, skin, or muscle
  - Genetic testing showing a mutation in the GAA gene
- ☐ Patient has clear signs of Pompe disease such as impairment in lung function or ability to move
- ☐ Documentation showing baseline sitting forced vital capacity (FVC) >30% of the predicted value for healthy adults
- ☐ Documentation showing baseline 6-minute walk distance (6MWD) is at least 75 meters
- ☐ Age 18 years or older and at least 40kg
- ☐ Prescribed by or in consultation with a geneticist (genetic disorder doctor) or specialist in Pompe disease
- ☐ Documentation provided patient is no longer improving on enzyme replacement therapy (Lumizyme or Nexviazyme)
- ☐ Review of chart notes documenting diagnosis and confirming that patient has met all above requirements for treatment by both a pharmacist and medical director

Exclusion Criteria – Any of the following prevents coverage

- ☐ Concomitant use with enzyme replacement therapy is considered a duplication of therapy and excluded from coverage