Pharmacy Drug Policy Checklist

POLICY NAME	Pombiliti and Opfolda (cipaglucosidase alfa and	POLICY #	

Criteria

Exclusion Criteria – Any of the following prevents coverage

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

Coverage Criteria for the Treatment of Pompe Disease

☐ **1.1** 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

☐ **1.2** Patient has clear signs of Pompe disease such as impairment in lung function or ability to move

☐ **1.3** Documentation showing baseline sitting forced vital capacity (FVC) >30% of the predicted value for healthy adults

☐ **1.4** Documentation showing baseline 6-minute walk distance (6MWD) is at least 75 meters

☐ **1.5** Age 18 years or older and at least 40kg

☐ **1.6** Prescribed by or in consultation with a geneticist (genetic disorder doctor) or specialist in Pompe disease

☐ **1.7** Documentation provided patient is no longer improving on enzyme replacement therapy (Lumizyme or Nexviazyme)

☐ **1.8** Review of chart notes documenting diagnosis and confirming that patient has met all above requirements for treatment by both a pharmacist and medical director