Member Name: {{MEMFIRST}} {{MEMLAST}} **DOB:** {{MEMBERDOB}} **PA Number:** {{PANUMBER}}

{{PANUMCODE}}

{{DISPLAY_PAGNAME}}
{{PACDESCRIPTION}}

This fax machine is located in a secure location as required by HIPAA regulations. Fax complete signed and dated forms to {{COMPANY_NAME}} at {{CLIENT_PAG_FAX}}. Please contact {{COMPANY_NAME}} at {{CLIENT_PAG_PHONE}} with questions regarding the prior authorization process. When conditions are met, we will authorize the coverage of {{DRUGNAME}}.

Patient's Name: {{MEMFIRST}} {{MEMLAST}} **Date**: {{TODAY}}
Patient's ID: {{MEMBERID}} **Patient's Date of Birth:** {{MEMBERDOB}}
Physician's Name: {{PHYFIRST}} {{PHYLAST}} **Patient Phone:** <<MEMPHONE>>
Specialty: _____ **NPI#:** _____
Physician Office Telephone: {{PHYSICIANPHONE}} **Physician Office Fax:** {{PHYSICIANFAX}}
Physician Office Address: <<PHYADDRESS1>> <<PHYADDRESS2>> <<PHYCITY>>, <<PHYSTATE>> <<PHYZIP>>
Drug Name: {{DRUGNAME}}

Quantity: _____ **Frequency:** _____ **Strength:** _____
Route of Administration: _____ **Expected Length of Therapy:** _____
Diagnosis: <<DIAGNOSIS>> **ICD Code**: <<ICD9>>

ICD-10 Code: _____
Prescribed Drug and Dosage Form: _____
Is a loading dose required: ❑ Yes ❑ No
Prescribed Loading dose and duration: _____

Maintenance Dose and Frequency: _____

1. What is the prescribed medication?
   ❑ Opfolda ❑ Yargesa ❑ Zavesca ❑ miglustat (generic) ❑ Other _____

2. What is the diagnosis?
   ❑ Gaucher disease ❑ Niemann-Pick disease, type C
   ❑ Late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency)
   ❑ Other _____

Section A: Preferred Product - *Complete this section if Zavesca is prescribed.*

1. Has the patient failed treatment with the generic medication due to an intolerable adverse event (e.g., rash, nausea, vomiting)? ❑ Yes ❑ No

2. Was the intolerable adverse event an expected adverse event attributed to the ACTIVE ingredient as described in the prescribing information (i.e., known adverse reaction for both the brand and generic medication)?
   ❑ Yes ❑ No

3. Was this adverse event documented in the patient's chart? ***ACTION REQUIRED: If Yes, documentation is required for approval. Provide SPECIFIC and DETAILED chart documentation including description, date/time, and severity of the adverse event, dosage and duration of generic medication treatment, required intervention (if any), and relevant tests or laboratory data (if any) OR MedWatch form of this trial and failure including the adverse reaction.*** ❑ Yes ❑ No *Skip to diagnosis section.*

Section B: Preferred Products - *Complete this section if Yargesa or Opfolda are prescribed.*

1. Coverage for the requested drug is provided when the patient has tried and had a treatment failure with at least three of the formulary medications, or all of the formulary alternatives if there are fewer than three. The formulary alternatives for the requested drugs are:
   a. For Yargesa requests: Cerdelga
   b. For Opfolda requests: miglustat
   Can the patient's treatment be switched to a formulary alternative?
   If Yes, please fax a new prescription to the pharmacy and skip to diagnosis section.
   ❑ Yes - ***If Yes, please indicate:*** _____ ❑ No - Continue request for non-formulary medication

2. Has the patient tried and had a documented inadequate response or intolerable adverse reaction to at least three of the formulary medications, or all of the formulary alternatives if there are fewer than three? Note: Formulary medications should be prescribed first unless the patient is unable to use or receive treatment with the alternative.
   ❑ Yes ❑ No
   a. For Yargesa requests: Cerdelga
   b. For Opfolda requests: miglustat

   If Yes, indicate the formulary alternative(s) and the reason(s) for treatment failure and skip to #4.

   Drug name: _____ Reason for treatment failure: _____

3. Does the patient have a documented contraindication to all or at least three of the formulary alternatives:
   a. For Yargesa requests: Cerdelga
   b. For Opfolda requests: miglustat
   ❑ Yes ❑ No

   If Yes, specify the formulary alternative(s) the patient is unable to take and describe the contraindication(s).

   Drug name: _____ Contraindication: _____

4. Have chart notes or other documentation supporting the inadequate response, intolerable adverse reaction, or contraindication to at least three of the formulary medications, or all of the formulary alternatives if there are fewer than three been attached? ***ACTION REQUIRED: Submit chart note(s) or other documentation indicating prior treatment failure, severity of the adverse event (if any), and dosage and duration of the prior treatment, or contraindication to formulary alternatives.*** ❑ Yes ❑ No

Complete the following section based on the patient's diagnosis, if applicable.

Section C: Gaucher Disease

1. Was the diagnosis of Gaucher disease confirmed by an enzyme assay demonstrating a deficiency of beta-glucocerebrosidase (glucosidase) enzyme activity OR by genetic testing? ***ACTION REQUIRED: If Yes, attach supporting chart note(s) or test results.*** ❑ Yes ❑ No

2. Which variant of Gaucher disease does the patient have?
   ❑ Type 1 ❑ Type 2
   ❑ Type 3 ❑ Other _____

3. Is this request for continuation of therapy with the requested medication? *If Yes, skip to #5* ❑ Yes ❑ No

4. Does the patient have a documented inadequate response to, intolerable adverse event(s) with, or a clinical reason to not use enzyme replacement therapy (e.g., allergy, hypersensitivity, poor venous access)?
   ❑ Yes ❑ No *No further questions.*

5. Is the patient experiencing an inadequate response to or any intolerable adverse events from therapy with the requested medication? ❑ Yes ❑ No

Section D: Niemann-Pick Disease, Type C

1. Was the diagnosis of Niemann-Pick disease, type C confirmed by genetic testing results showing mutations in *NPC1* or *NPC2* genes? ***ACTION REQUIRED: If Yes, attach supporting chart note(s) or test results.***
   ❑ Yes ❑ No

2. Is this request for continuation of therapy with the requested medication?
   ❑ Yes ❑ No *If No, no further questions.*

3. Is the patient experiencing an inadequate response to or any intolerable adverse events from therapy with the requested medication? ❑ Yes ❑ No

Section E: Late-Onset Pompe Disease (Lysosomal Acid Alpha-Glucosidase [GAA] Deficiency)

1. Will the requested medication be taken in combination with Pombiliti (cipaglucosidase alfa-atga)?\
   ❑ Yes ❑ No

2. Is this request for continuation of therapy with the requested medication? ❑ Yes ❑ No *If No, skip to #4*

3. Is the patient responding to therapy (e.g., improvement, stabilization, or slowing of disease progression for motor function, walking capacity, respiratory function, or muscle strength)? ***ACTION REQUIRED: If Yes, attach chart notes documenting a positive response to therapy (e.g., improvement, stabilization, or slowing of disease progression for motor function, walking capacity, respiratory function, or muscle strength).***
   ❑ Yes ❑ No *No further questions.*

4. What is the patient's body weight?
   ❑ Greater than or equal to 40 kg
   ❑ Less than 40 kg

5. Was the diagnosis confirmed by enzyme assay demonstrating a deficiency of acid alpha-glucosidase enzyme activity OR by genetic testing? ***ACTION REQUIRED: If Yes, attach acid alpha-glucosidase enzyme assay or genetic testing results supporting diagnosis.*** ❑ Yes ❑ No

6. Is the patient improving on current enzyme replacement therapy (ERT) (e.g., Lumizyme, Nexviazyme)?
   ❑ Yes ❑ No

I attest that the medication requested is medically necessary for this patient. I further attest that the information provided is accurate and true, and that the documentation supporting this information is available for review if requested by the claims processor, the health plan sponsor, or, if applicable a state or federal regulatory agency.

_____

Prescriber (Or Authorized) Signature and Date