OPTIMA HEALTH PLAN

PHARMACY/MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **(Pharmacy) 1-800-750-9692**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Cerdelga® (eliglustat)

DRUG INFORMATION: Complete information below or authorization will be delayed if incomplete.

Drug Form/Strength: ______________________________

Dosing Schedule: ______________________ **Length of Therapy**: ______________

Diagnosis: ______________________ **ICD Code, if applicable:** ______________

CLINICAL CRITERIA: Check below **ALL** that apply. **ALL** criteria **must** be met for approval. **ALL** documentation including labs or chart notes (if required) **must** be submitted or request will be denied.

- ❑ Patient must be at least 18 years old
- ❑ Provider must be a metabolic geneticist or physician knowledgeable in the management of Gaucher disease
- ❑ Patient must have a diagnosis of Gaucher disease type I as confirmed by one of the following (lab test or genetic test results must be submitted):
  - ❑ Glucocerebrosidase activity less than or equal to 30% of normal activity in the white blood cells or skin fibroblasts

    OR
  - ❑ Genotype testing indicates mutation of two alleles of the glucocerebrosidase genome
- ❑ Individual is a CYP2D6 extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) as confirmed by a FDA-approved genotype test (lab results must be attached)
- ❑ Patient presents with at least two of the following (labs or diagnostics must be submitted for documentation):
  - ❑ Clinically significant splenomegaly (spleen volume ≥10 times normal) as confirmed by medical imaging such as volumetric magnetic resonance imaging (MRI)

    OR
  - ❑ Clinically significant hepatomegaly (liver volume ≥ 1.5 times normal) as confirmed by medical imaging such as volumetric MRI

    OR
  - ❑ Hemoglobin ≤11 g/dL for females and ≤12g/dL for males, or 1.0g/dL below lower limit for normal for age and sex

    OR
  - ❑ Platelet count ≤120,000mm^3

    OR

(Continued on next page)

  - ❑ Evidence of bone disease, such as avascular necrosis, osteopenia, pathological fracture, Erlenmeyer flask deformity, osteosclerosis or radiological evidence of joint deterioration, that is not attributed to another condition or diagnosis
- ❑ Medication will **NOT** be used in combination with Cerezyme, Vpriv, Elelyso, Zavesca or other enzyme replacement or substrate-reducing therapy for treatment of Gaucher disease
- ❑ Cerdelga (eliglustat) may **NOT** be approved for any of the following:
  - ❑ Moderate renal impairment, severe renal impairment, or end-stage renal disease (ESRD)
  - ❑ Mild, moderate, or severe hepatic impairment or cirrhosis
  - ❑ Partial or total splenectomy within the last 3 years
  - ❑ Pre-existing cardiac disease or long QT syndrome
  - ❑ Ultra-rapid or indeterminate CYP2D6 metabolizers
  - ❑ Gaucher disease type 2 or 3
- ❑ Maximum allowed daily dose for CYP2D6 poor metabolizers: 1 capsule (84mg total) daily
- ❑ Maximum allowed daily dose for CYP2D6 extensive and intermediate metabolizers: 2 capsules (168mg total) daily

CLINICAL CRITERIA FOR CONTINUED 12 MONTH APPROVAL: <u>ALL</u> criteria below **<u>must</u>** be met for approval. Chart notes and lab results must be submitted for documentation.

- ❑ All of the criteria for initial approval (above) has been satisfied
- ❑ All of the following must be met for continued 12 month approval:
  - ❑ Spleen volume has decreased by ≥15% from baseline
  - ❑ Liver volume has decreased from baseline
  - ❑ Hemoglobin level has increased by ≥0.5g/dL from baseline or has remained stable at baseline level
  - ❑ Platelet count has increased by ≥15% from baseline

Medication being provided by Specialty Pharmacy - PropriumRx

*****<u>Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.</u>*****

****<u>Previous therapies will be verified through pharmacy paid claims or submitted chart notes.</u>****

Patient Name: ____

Member Optima #: ____________________________ Date of Birth: ________________

Prescriber Name: ____

Prescriber Signature: ____________________________________ Date: ______________

Office Contact Name: ____

Phone Number: ____________________________ Fax Number: ____________________

DEA OR NPI #: ____

***Approved by Pharmacy and Therapeutics Committee**: 1/17/2019
REVISED/UPDATED: 3/5/2019