

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Eliglustat (Cerdelga)

Initiation (new start) criteria: Non-formulary **eliglustat (Cerdelga)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Patient is at least 18 years of age
- Diagnosis of Gaucher disease type 1 with no neuropathic symptoms confirmed by:
 - 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 (*GBA* gene)
- Patient has one of the following cytochrome P450 (CYP) 2D6 activity levels as detected:
 - CYP2D6 extensive metabolizer
 - CYP2D6 intermediate metabolizer
 - CYP2D6 poor metabolizer
- Eliglustat is not used with other medications that interact with eliglustat based on the how the patient metabolizes medication
- Eliglustat is not given in combination with miglustat (Zavesca), or Gaucher disease enzyme replacement therapies [i.e., imiglucerase (Cerezyme), taliglucerase alfa (Elelyso), or velaglucerase alfa (VPRIV)]

Continued use criteria (12 months after initiation): Non-formulary **eliglustat (Cerdelga)** will continue to be covered for 12 months on the prescription drug benefit when the following criteria are met:

- Documentation of positive clinical response to eliglustat therapy: Improvement in or stabilization from baseline of ONE of the following:
 - Spleen volume
 - Hemoglobin level
 - Liver volume
 - Platelet count
 - Growth
 - Bone pain