



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELIGLUSTAT TARTRATE

Generic	Brand	HICL	GCN	Exception/Other
ELIGLUSTAT TARTRATE	CERDELGA		36988	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of type 1 (non-neuronopathic) Gaucher disease, and meets the following criteria?

- is a CYP2D6 extensive metabolizer (EMs)
- is not a CYP2D6 ultra-rapid metabolizer
- is not a CYP2D6 indeterminate metabolizer
- is age 18 years of age and older

If yes, **approve for 12 months by GPID with a quantity limit of #2 capsules per day.**
If no, continue to #2.

2. Does the patient have a diagnosis of type 1 (non-neuronopathic) Gaucher disease, and meets the following criteria?

- is a CYP2D6 intermediate metabolizer (IMs)
- is not a CYP2D6 ultra-rapid metabolizer
- is not a CYP2D6 indeterminate metabolizer
- is age 18 years of age and older

If yes, **approve for 12 months by GPID with a quantity limit of #2 capsules per day.**
If no, continue to #3.

3. Does the patient have a diagnosis of type 1 (non-neuronopathic) Gaucher disease, and meets the following criteria?

- is a CYP2D6 poor metabolizer (PMs)
- is not CYP2D6 ultra-rapid metabolizer
- is not CYP2D6 indeterminate metabolizer
- is age 18 years of age and older

If yes, **approve for 12 months by GPID with a quantity limit of #1 capsule per day.**
If no, do not approve.

DENIAL TEXT: See text at the end of the guideline.

CONTINUE ON NEXT PAGE



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

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GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: Our guideline for **ELIGLUSTAT TARTRATE** requires a diagnosis of type 1 (non-neuronopathic) Gaucher's disease in a patient at least 18 years of age. Twice daily dosing will be approved for patients who are extensive or immediate metabolizers of CYP2D6 inhibitors. Once daily dosing will be approved for patients who are poor metabolizers of CYP2D6. This medication is not approved for the following patients: CYP2D6 ultra-rapid metabolizers or CYP2D6 indeterminate metabolizers.

RATIONALE

Promote appropriate utilization and dosing of Cerdelga (eliglustate tartrate) based on the FDA approved indication. Eliglustat is a CYP2D6 and CYP3A substrate. Drugs that inhibit CYP2D6 and CYP3A metabolism pathways may significantly increase the exposure to eliglustat and result in prolongation of the PR, QTc, and/or QRS cardiac intervals that could result in cardiac arrhythmias.

The recommended dosage of CERDELGA is 84 mg twice daily in CYP2D6 extensive metabolizers (EMs), and intermediate metabolizers (IMs). The recommended dosage in CYP2D6 poor metabolizers (PMs) is 84 mg once daily.

Some inhibitors of CYP2D6 and CYP3A are contraindicated with CERDELGA depending on the patient's metabolizer status. Co-administration of CERDELGA with other CYP2D6 and CYP3A inhibitors may require dosage adjustment depending on the patient's CYP2D6 metabolizer status to reduce the risk of potentially significant adverse reactions.

Reduce the dosage of CERDELGA to 84 mg once daily for:

- CYP2D6 EMs and IMs taking strong or moderate CYP2D6 inhibitors
- CYP2D6 EMs taking strong or moderate CYP3A inhibitors

CONTINUE ON NEXT PAGE



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ELIGLUSTAT TARTRATE

RATIONALE (CONTINUED)

Table 1. Established and other potentially significant drug interactions: Alteration in Cerdelga Dosage May be Recommended Based on Predicted Interaction in Extensive Metabolizers (EM) and Intermediate Metabolizers (IM)

	Recommended CERDELGA Dosage, by CYP2D6 Metabolizer Status	
	EM	IM
CYP450 Inhibitors		
Strong or Moderate CYP2D6 inhibitors concomitantly with Strong or Moderate CYP3A inhibitors	Contraindicated	Contraindicated
Strong CYP2D6 inhibitors e.g., paroxetine	84 mg once daily	84 mg once daily
Moderate CYP2D6 inhibitors e.g., terbinafine	84 mg once daily	84 mg once daily
Strong CYP3A inhibitors e.g., ketoconazole	84 mg once daily	Contraindicated
Moderate CYP3A inhibitors e.g., fluconazole	84 mg once daily	Not recommended

Table 2. Established and other potentially significant drug interactions: Alteration in Cerdelga Dosage May be Recommended Based on Predicted Interaction in Poor Metabolizers

CYP450 Inhibitors	Recommended CERDELGA Dosage for PMs
Strong CYP3A inhibitors e.g., ketoconazole	Contraindicated
Moderate CYP3A inhibitors e.g., fluconazole	Not recommended
Weak CYP3A inhibitors e.g., ranitidine	Not recommended

CONTINUE ON NEXT PAGE



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PRIOR AUTHORIZATION GUIDELINES

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FDA APPROVED INDICATIONS

CERDELGA is a glucosylceramide synthase inhibitor indicated for the long term treatment of adult patients with Gaucher disease type 1 who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an FDA-cleared test.

Limitations of Use:

- CYP2D6 ultra-rapid metabolizers may not achieve adequate concentrations of CERDELGA to achieve a therapeutic effect
- A specific dosage cannot be recommended for CYP2D6 indeterminate metabolizers

REFERENCES

- Cerdelga [Prescribing Information]. Waterford, Ireland: Genzyme; August 2014

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

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