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THIS IS A SAMPLE LETTER--PLEASE RETYPE IT ON YOUR OWN LETTERHEAD

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(Date)
(Contact Name)
(Address)

Patient Name:
Subscriber ID#:
Group #:
Subject: Intent to Treat with Cerdelga® (eliglustat) capsules

Dear **(Contact Name)**

I am writing to inform you that I plan to treat **[patient name]** with Cerdelga, a substrate reduction therapy. 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. CYP2D6 ultra-rapid metabolizers may not achieve adequate concentrations of Cerdelga to achieve a therapeutic effect. A specific dose cannot be recommended for CYP2D6 indeterminate metabolizers. Cerdelga is an oral therapy taken once or twice daily depending on CYP2D6 status, concomitant medications and/or degree of renal and hepatic impairment.

Documentation Enclosed

The attached Statement of Medical Necessity contains information pertaining to **[Patient Name]**'s clinical history, diagnosis and signs and symptoms - demonstrating that the use of Cerdelga is medically indicated for treatment of [his/her] Gaucher disease type 1. Initially, my prescribed dosing regimen will be 84mg administered **[ ]** per day.

Action Requested

Please send verification of **[Patient Name]**'s insurance coverage for substrate reduction therapy with Cerdelga as soon as possible. If you have any questions pertaining to **[Patient Name]**'s clinical history and/or my treatment plan, please call me at **[Phone Number]**.

Indication and Usage

CERDELGA is indicated for the long-term treatment of adult patients with Gaucher disease type 1 (GD1) who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an FDA-cleared test.
Limitations of Use:

- Patients who are CYP2D6 ultra-rapid metabolizers (URMs) may not achieve adequate concentrations of CERDELGA to achieve a therapeutic effect.
- A specific dosage cannot be recommended for those patients whose CYP2D6 genotype cannot be determined (indeterminate metabolizers).

Important Safety Information

CONTRAINDICATIONS

CERDELGA is contraindicated in the following patients based on CYP2D6 metabolizer status due to the risk of cardiac arrhythmias from prolongation of the PR, QTc, and/or QRS cardiac intervals:

- Extensive Metabolizers (EMs) taking a strong or moderate CYP2D6 inhibitor concomitantly with a strong or moderate CYP3A inhibitor, EMs with moderate or severe hepatic impairment, or EMs with mild hepatic impairment and taking a strong or moderate CYP2D6 inhibitor.
- Intermediate Metabolizers (IMs) taking a strong or moderate CYP2D6 inhibitor concomitantly with a strong or moderate CYP3A inhibitor, IMs taking a strong CYP3A inhibitor, or IMs with any degree of hepatic impairment.
- Poor Metabolizers (PMs) taking a strong CYP3A inhibitor, or PMs with any degree of hepatic impairment.

WARNINGS AND PRECAUTIONS

CERDELGA is predicted to cause increases in ECG intervals (PR, QTc, and QRS) at substantially elevated plasma concentrations and may increase risk of cardiac arrhythmias. Use of CERDELGA is contraindicated, to be avoided, or requires dosage adjustment in patients taking CYP2D6 or CYP3A inhibitors, depending CYP2D6 metabolizer status, type of inhibitor, or degree of hepatic impairment. Avoid use of CERDELGA in patients with pre-existing cardiac disease, long QT syndrome, or in combination with Class IA or Class III antiarrhythmic medications.

ADVERSE REACTIONS

The most common adverse reactions (≥10%) to CERDELGA include: fatigue, headache, nausea, diarrhea, back pain, pain in extremities, and upper abdominal pain.

DRUG INTERACTIONS

Coadministration of CERDELGA with CYP2D6 or CYP3A inhibitors may increase eliglustat concentrations, which may increase the risk of cardiac arrhythmias from prolongations of the PR, QTc, and/or QRS cardiac interval. Use of CERDELGA is contraindicated, to be avoided, or may require dosage adjustment depending on the concomitant drug and CYP2D6 metabolizer status. See section 7 of the full Prescribing Information for more details and other potentially significant drug interactions.

USE IN SPECIFIC POPULATIONS

Available data on the use of CERDELGA in pregnant women is not sufficient to assess drug-associated risks of major birth defects, miscarriage, or adverse maternal or fetal outcomes. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for CERDELGA and any potential adverse effects on the breastfed child from CERDELGA or from the underlying maternal condition.

Use of CERDELGA in patients with renal impairment is based on the patient's CYP2D6 metabolizer status. Avoid use of CERDELGA in EMs with end-stage renal disease (ESRD), and IMs and PMs with any degree of renal impairment.

Use of CERDELGA is contraindicated or may require dosage adjustment in patients with hepatic impairment based on CYP2D6 metabolizer status, concomitant use of CYP2D6 or CYP3A inhibitors, and degree of hepatic impairment.

Thank you for your immediate attention to this request.

Sincerely,
[Physician Name]

Enclosure: Statement of Medical Necessity Cc: **[Patient Name/Legal Guardian]**