Initial approval criteria: Non-formulary eliglustat (Cerdelga®) will be covered for 12 months on the prescription drug benefit when the following criteria are met:

- Patient is at least 18 years of age
- AND-
- 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)
- AND-
- Patient is one of the following cytochrome P450 (CYP) 2D6 activity levels as detected by an FDA-cleared test:
  - CYP2D6 extensive metabolizer (EM)
  - CYP2D6 intermediate metabolizer (IM)
  - CYP2D6 poor metabolizer (PM)
- AND-
- Eliglustat is not used concomitantly with any of the following:

<table>
<thead>
<tr>
<th>EM or IM patients:</th>
<th>moderate or strong CYP2D6 inhibitor (e.g., paroxetine, terbinafine) with a moderate or strong CYP3A inhibitor (e.g., ketoconazole)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IM patients:</td>
<td>moderate or strong CYP3A inhibitor (e.g., ketoconazole, fluconazole)</td>
</tr>
<tr>
<td>PM patients:</td>
<td>weak, moderate, or strong CYP3A inhibitor (e.g., ranitidine, ketoconazole, fluconazole)</td>
</tr>
<tr>
<td>EM, IM, or PM patients:</td>
<td>strong CYP3A inducers (e.g., rifampin, phenytoin)</td>
</tr>
</tbody>
</table>

- AND-
- Eligustat 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: 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