This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

WEB-PEC-0495-16

Zavesca (miglustat)

<table>
<thead>
<tr>
<th>Override(s)</th>
<th>Approval Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td>1 year</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medications</th>
<th>Quantity Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zavesca (miglustat) 100mg capsules</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**APPROVAL CRITERIA**

I. Individual is 18 years of age or older; AND

II. Individual has a diagnosis of Type 1 (non-neuropathic) Gaucher disease confirmed by either of the following (Weinreb et al. 2004, Wang et al. 2011):
   A. Glucocerebrosidase activity less than or equal to 30% of normal activity in the white blood cells or skin fibroblasts; OR
   B. Genotype testing indicates mutation of two alleles of the glucocerebrosidase genome;

AND

III. There are clinically significant manifestations of Gaucher disease, including any of the following:
   A. Skeletal disease as demonstrated by radiologic evidence of any of the following:
      1. Avascular necrosis; OR
      2. Erlenmeyer flask deformity (failure of bone remodeling); OR
      3. Lytic disease; OR
      4. Marrow infiltration; OR
      5. Osteopenia; OR
      6. Osteosclerosis; OR
      7. Pathological fracture; OR
      8. Joint deterioration or replacement; OR
   B. Presents with at least two of the following (Weinreb et al. 2004, Mistry et al. 2015):
      1. Clinically significant hepatomegaly as confirmed by medical imaging [such as but not limited to, volumetric magnetic resonance imaging (MRI)]; OR
      2. Clinically significant splenomegaly as confirmed by medical imaging (such as but not limited to, volumetric MRI); OR
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