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.

CRX-ALL-0251-18

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### Market Applicability

| Market | DC | FL & FHK | FL MMA | FL LTC | GA | KS | KY | MD | NJ | NV | NY | TN | TX | WA |
|--------|----|---------|--------|--------|----|----|----|----|----|----|----|----|----|----|----|
| Applicable | X | X | NA | NA | X | NA | X | X | X | X | X | NA | NA | X |

*FHK- Florida Healthy Kids

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**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>
</tr>
</thead>
<tbody>
<tr>
<td>Zavesca (miglustat) 100mg capsules</td>
</tr>
</tbody>
</table>

### APPROVAL CRITERIA

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

II. Individual has a diagnosis of type 1 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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CRX-ALL-0251-18
### Market Applicability

| Market       | DC | FL & FHK | FL MMA | FL LTC | GA | KS | KY | MD | NJ | NV | NY | TN | TX | WA |
|--------------|----|----------|--------|--------|----|----|----|----|----|----|----|----|----|----|----|
| Applicable   | X  | X        | NA     | NA     | X  | NA | X  | X  | X  | X  | X  | NA | NA | X  |

*FHK- Florida Healthy Kids


DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.

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