Kanuma (sebelipase alfa)  
**Effective 09/01/2021**

<table>
<thead>
<tr>
<th>Plan</th>
<th>Program Type</th>
<th>Benefit</th>
<th>Specialty Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>MassHealth</td>
<td>☒ Prior Authorization</td>
<td>☐ Pharmacy Benefit</td>
<td>N/A</td>
</tr>
<tr>
<td>Commercial/Exchange</td>
<td></td>
<td>☒ Medical Benefit (NLX)</td>
<td></td>
</tr>
</tbody>
</table>

**Specialty Medications**
- All Plans  
  - Phone: 866-814-5506  
  - Fax: 866-249-6155

**Non-Specialty Medications**
- MassHealth  
  - Phone: 877-433-7643  
  - Fax: 866-255-7569
- Commercial  
  - Phone: 800-294-5979  
  - Fax: 888-836-0730
- Exchange  
  - Phone: 855-582-2022  
  - Fax: 855-245-2134

**Medical Specialty Medications (NLX)**
- All Plans  
  - Phone: 844-345-2803  
  - Fax: 844-851-0882

**Exceptions**
- N/A

**Overview**
Kanuma (sebelipase alfa) is a recombinant enzyme that binds to cell surface receptors via glycans and is indicated for lysosomal acid lipase deficiency.

**Coverage Guidelines**
Authorization may be granted for members who are currently receiving treatment with Kanuma excluding when the product is obtained as samples or via manufacturer’s patient assistance programs. **OR**
Authorization of 12 months may be granted for members when all the following criteria are met, and documentation is provided:
1. Member has a diagnosis of LAL deficiency as confirmed by enzyme assay demonstrating a deficiency of lysosomal acid lipase enzyme activity or by genetic testing; AND
2. Member has alanine aminotransferase level (ALT) $\geq 1.5$ times the upper limit of normal (based on the age- and gender-specific normal ranges) on two consecutive ALT measurements obtained at least one week apart.

**Continuation of Therapy**
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for lysosomal acid lipase (LAL) deficiency who are responding to therapy (e.g., improvement, stabilization, or slowing of disease progression for weight-for-age z-score if exhibiting growth failure, low-density lipoprotein [LDL], high-density lipoprotein [HDL], triglycerides, or alanine aminotransferase [ALT]).
Limitations
1. Initial approvals and reauthorizations will be granted for 12 months

References
1. Kanuma (sebelipase alfa) [prescribing information]. Cheshire, CT: Alexion Pharmaceuticals; December 2015.

Review History
01/20/2021—Reviewed P&T, changed from CVS template to custom template; overview included. Effective 09/01/2021.

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