Market Applicability/Effective Date

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

*FHK- Florida Healthy Kids

Aldurazyme (laronidase)
CG-DRUG-58

<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>Aldurazyme (laronidase)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

APPROVAL CRITERIA

Requests for Aldurazyme (laronidase) may be approved if the following criteria are met:
I. Individual has a diagnosis of Mucopolysaccharidosis I (MPS I); **AND**
II. Individual has any of the following MPS I syndromes:
   A. Hurler syndrome; **OR**
   B. Hurler-Scheie syndrome; **OR**
   C. Scheie syndrome, moderate to severe manifestations including any of the following:
      1. Cardiac valve abnormalities (such as aortic or mitral valve regurgitation, with or without insufficiency or stenosis); **OR**
      2. Corneal clouding, open-angle glaucoma, and retinal degeneration, progressive; **OR**
      3. Craniofacial or growth retardation; **OR**
      4. Frequent, moderate to severe upper respiratory infections; **OR**
      5. Hepatosplenomegaly; **OR**
      6. Hernias (such as hiatal, inguinal, or umbilical); **OR**
      7. Neurological symptoms resulting from cervical instability or cervical spinal cord compression; **OR**
      8. Skeletal and joint involvement, progressive (such as, arthropathy, back pain, joint stiffness, lumbar spondylolisthesis, lumbar spinal compression, osteopenia, or osteoporosis); **AND**
   D. Diagnosis is confirmed by either of the following:
      1. Documented deficiency in alpha-L-iduronidase enzyme activity of less than 10% of the lower limit of normal range as measured in fibroblasts or leukocytes; **OR**

Laronidase is considered **not medically necessary** for all other indications, including the treatment of an individual with the Scheie form of MPS I who has mild symptoms.

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-0539-16
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-0539-16