Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Aldurazyme (laronidase)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications	Dosing Limit
Aldurazyme (laronidase) 2.9 mg vial	0.58 mg/kg once per week

APPROVAL CRITERIA

Requests for Aldurazyme (laronidase) may be approved if the following criteria are met:

I. Individual has a diagnosis of any of the following Mucopolysaccharidosis I (MPS I) syndromes:
   A. Hurler syndrome; **OR**
   B. Hurler-Scheie syndrome; **OR**
   C. Scheie syndrome, moderate to severe manifestations including any of the following (Thomas 2010, Wang 2011):
      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**

II. Diagnosis is confirmed by either of the following (Clarke 2016, Lehman 2011):
   A. Documented deficiency in alpha-L-iduronidase enzyme activity as measured in fibroblasts or leukocytes; **OR**
   B. Documented alpha-L-iduronidase gene mutation.

Requests for Aldurazyme (laronidase) may not be approved for the following:

I. All other indications not included above; **OR**

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

II. Individual with the Scheie syndrome of MPS I with mild symptoms.

Note:
Aldurazyme has a black box warning for anaphylaxis. Life-threatening anaphylactic reactions have occurred during Aldurazyme infusions so appropriate medical support should be available during Aldurazyme administration. Individuals with compromised respiratory function or acute respiratory disease may be at risk of serious acute exacerbation of their respiratory disease and require additional monitoring.

State Specific Mandates		
State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

Key References:

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3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lehman TJA, Miller Nicole, Norquist B, et al. Diagnosis of the mucopolysaccharidoses. *Rheumatology*. 2011; 50:V41-V46.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
6. Muenzer J, Wraith HE, Clark LA, International Consensus Panel on Management and Treatment of Mucopolysaccharidosis I. Mucopolysaccharidosis I: management and treatment guidelines. *Pediatrics.* 2009 Jan;123(1):19-29.
7. Thomas JA, Beck M, Clarke JTR, Cox GF. Childhood onset of Scheie syndrome, the attenuated form of mucopolysaccharidosis I. *Journal of Inherited Metabolic Disease*. 2010; 33(4):421-427.
8. Wang RY, Bodamer OA, Watson MS, Wilcox WR. American College of Medical Genetics (ACMG) Work Group on Diagnostic Confirmation of Lysosomal Storage Diseases. Lysosomal storage diseases: diagnostic confirmation and management of presymptomatic individuals. *Genet Med*. 2011; 13(5):457-484.