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

Override(s)	Approval Duration
Prior Authorization	1 year

Medications	Quantity Limit
Aldurazyme (laronidase)	N/A

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**
      2. Documented alpha-L-iduronidase gene sequencing.

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.

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

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Notes:

1. Aldurazyme (laronidase) has been shown to improve pulmonary function and walking capacity.
2. Aldurazyme has a black box warning for risk of anaphylaxis. Life-threatening anaphylactic reactions have been observed in some individuals during infusions, and appropriate medical support should be readily available when Aldurazyme is administered. Individuals with compromised respiratory function or acute respiratory disease may be at risk of serious acute exacerbation of their respiratory compromise due to infusion reactions, 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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4. Jameson E, Jones S, Remmington T. Enzyme replacement therapy with laronidase (Aldurazyme®) for treating mucopolysaccharidosis type I. Cochrane Database Syst Rev. 2016;(4):CD009354.
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6. Laronidase (Aldurazyme) Monograph. Lexicorp® Online, American Hospital Formulary Service® (AHFS®) Online; Hudson, Ohio, Lexi-Corp., Inc. Last revised December 2013. Accessed on September 21, 2016.
7. Ratko TA, Marbella A, Godfrey, Aronson N. Enzyme replacement therapies for lysosomal storage disease [Internet]. 2013. Agency for Healthcare Research and Quality (US): Rockville, MD. Available at http://www/ncbi.nlm.nih.gov/books/NBK117219/. Accessed on September 21, 2016.
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.