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

Elaprase (idursulfase)

CG-DRUG-57

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Elaprase (idursulfase) 6mg/3mL Intravenous Solution

APPROVAL CRITERIA

I. Elaprase (idursulfase) may be approved for the treatment of mucopolysaccharidosis II (MPS II, Hunter syndrome) when the following criteria are met:
   A. Documented deficiency in iduronate 2-sulfatase enzyme activity as measured in fibroblasts or leukocytes *combined with* normal enzyme activity level of another sulfatase; **OR**
   B. Documented pathologic iduronate 2-sulfatase gene mutation;

AND

II. The individual to be treated has symptoms attributable to MPS II such as:
   A. Developmental delay or cognitive impairment; **OR**
   B. Frequent infections; **OR**
   C. Hearing loss; **OR**
   D. Hepatosplenomegaly; **OR**
   E. Hernias; **OR**
   F. Impaired respiratory function; **OR**
   G. Joint pain; **OR**
   H. Skeletal deformities; **OR**
   I. Sleep apnea; **OR**
   J. Valvular heart disease.

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

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Idursulfase is **may not** be approved when the criteria above are not met and for all other indications.

Notes:

1. Elaprase (idursulfase) has been shown to improve walking capacity in individuals 5 years of age or older.
2. Elaprase has been shown to reduce spleen volume in individuals 16 months to 5 years of age, similarly to that of children 5 years of age and older.
3. Elaprase has a black box warning for risk of anaphylaxis. Life-threatening anaphylactic reactions, presenting as respiratory distress, hypoxia, hypotension, urticaria, and/or angioedema of throat or tongue have occurred in some individuals during and up to 24 hours after infusions, regardless of duration of the course of treatment. Individuals should be closely observed during and after administration with preparations available to manage anaphylaxis. Inform individuals of the signs and symptoms of anaphylaxis and have them seek immediate medical care should symptoms occur. Individuals with compromised respiratory function or acute respiratory disease may be at risk of serious acute exacerbation of their respiratory compromise due to hypersensitivity reactions, and require additional monitoring.

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

Key References:

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

1. Idursulfase. In: DrugPoints System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated November 27, 2017. Available at: http://www.micromedexsolutions.com. Accessed on February 26, 2018.
2. Idursulfase Monograph. Lexicomp® Online, American Hospital Formulary Service® (AHFS®) Online, Hudson, Ohio, Lexi-Comp., Inc. Last revised March 8, 2017. Accessed on March 15, 2017.
3. Idursulfase. [Product Information] Cambridge, MA. Shire Human Genetic Therapies Inc. June 24, 2013. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/125151s0184lbl.pdf. Accessed on February 26, 2018.
4. Scarpa M, Almássy Z, Beck M, et al. Mucopolysaccharidosis type II: European recommendations for the diagnosis and multidisciplinary management of a rare disease. Orphanet J Rare Dis. 2011; 6:72.
5. Wang RY, Bodamer OA, Watson MS, et al. Lysosomal storage diseases: diagnostic confirmation and management of presymptomatic individuals. Genet Med. 2011; 13(5):457-484.