Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Elaprase (idursulfase)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***September 2009 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Elaprase (idursulfase).

Elaprase (idursulfase) is a purified form of a lysosomal enzyme (iduronate-2-sulfatase) indicated for patients with Hunter Syndrome (Mucopolysaccharidosis II, MPS II). Idursulfase (Elaprase) has been shown to improve walking capacity in these patients.

DEFINITIONS

Hunter Syndrome – a serious progressive genetic disorder caused by a deficiency or absence of the lysosomal enzyme (iduronate-2-sulfatase) required for the degradation of glycosaminoglycans (GAG) resulting in accumulation of GAG in cells throughout the body. Hunter Syndrome affects males almost exclusively.

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy &

Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Elaprase (idursulfase), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by or in consultation with a physician who specializes in the treatment of inherited metabolic disorders
- Must have a confirmed diagnosis of Hunter syndrome (Mucopolysaccharidosis type II, MPS II)

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Elaprase [package insert]. Shire Human Genetic Therapies Inc. Cambridge MA, October 2007.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/17, 02/18*