Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	February 14, 2011 April 20, 2012, July 7, 2022

ELAPRASE® (idursulfase)

LENGTH OF AUTHORIZATION: UP TO ONE YEAR

REVIEW CRITERIA:

- Patient must be ≥ 16 months of age.
- Patient must have a documented diagnosis of Hunter Syndrome or Mucopolysaccharidosis (MPS) II (clinical testing and documentation are required).
- Documentation of baseline values including:
  - Body weight
  - Urinary glycosaminoglycan (uGAG)

CONTINUATION OF THERAPY

- Patient met initial review criteria; AND
- Documentation of improved clinical response; AND
- Patient has not experienced any treatment-restricting adverse effects; AND
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 6 mg/3 mL (2 mg/mL) single-use vial.