Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	March 13, 2023

Mucopolysaccharidosis Agents

Preferred: N/A

Non-Preferred: Aldurazyme® (laronidase), Elaprase® (idursulfase), Mepsevii™ (vestronidase alfa-vjbk), Naglazyme® (galsulfase), Vimizim® (elosulfase alfa)

LENGTH OF AUTHORIZATION: Up to one year

REVIEW CRITERIA:

Aldurazyme (laronidase)

- Patient must be ≥ 6 months of age.
- Must have a diagnosis of Mucopolysaccharidosis I (MPS I) classified as one of the following subtypes (clinical testing and documentation are required):
  - Hurler form (severe)
  - Hurler-Scheie form (attenuated)
  - Scheie form (attenuated) with moderate to severe symptoms
- Documentation of baseline values including:
  - 6-minute walk test (6-MWT)
  - Forced Vital Capacity (FVC)
- Documentation of patient's body weight within 30 days of request.

Elaprase (idursulfase)

- Patient must be ≥ 16 months of age.
- Patient must have a diagnosis of Hunter Syndrome or Mucopolysaccharidosis II (MPS II) (clinical testing and documentation are required).
- Documentation of baseline values including:
  - Body weight
  - Urinary glycosaminoglycan (uGAG)
  - 6-minute walk test (6-MWT)
  - Forced Vital Capacity (FVC)

Mepsevii (vestronidase alfa-vjbk)

- Patient must have a diagnosis of Mucopolysaccharidosis type VII (Sly syndrome) confirmed in medical records or patient health conditions (clinical testing and documentation are required).
- Documentation of baseline values including:
  - Urinary glycosaminoglycan (uGAG)
  - 6-minute walk test (6-MWT)
  - Forced Vital Capacity (FVC)
- Documentation of patient's body weight within 30 days of request.

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Naglazyme (galsulfase)

- Patient must be ≥ 3 months of age.
- Patient must have a diagnosis of Mucopolysaccharidosis VI (MPS VI; Maroteaux-Lamy syndrome) (clinical testing and documentation are required).
- Documentation of baseline values including:
  - 3-minute stair climb test
  - 12-minute walk test (12-MWT)
- Documentation of patient's body weight within 30 days of request.

Vimizim (elosulfase alfa)

- Patient must be ≥ 5 years of age.
- Must have a diagnosis of Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome) (clinical testing and documentation are required).
- Documentation of patient's body weight within 30 days of request.
- Documentation of baseline values:
  - 6-minute walk test (6-MWT)
  - 3-minute stair climb test
  - Urine glycosaminoglycans keratan sulfate (Urine KS)

CONTINUATION OF THERAPY:

- Patient met initial review criteria.
- Documentation of improved clinical response from baseline (e.g., Stability or improvement in baseline values).
- Prescriber attestation (or medical records support) the absence of life-threatening adverse events or unacceptable toxicity from the drug.
- 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/