Naglazyme® (galsulfase) (Intravenous)

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Medical Guideline Disclaimer

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LENGTH OF AUTHORIZATION

Coverage will be provided for 12 months and may be renewed.

DOSING LIMITS

A. Max Units (per dose and over time) [Medical Benefit]:
   • 115 billable units every 7 days

Guideline

I. INITIAL APPROVAL CRITERIA

Mucopolysaccharidosis VI (MPS VI; Maroteaux-Lamy syndrome) †

• Patient has a definitive diagnosis of MPS VI confirmed by the following:
  o Detection of pathogenic mutations in the ARSB gene by molecular genetic testing; OR
  o Arylsulfatase B (ASB) enzyme activity of <10% of the lower limit of normal in cultured fibroblasts or isolated leukocytes; AND
    ▪ Patient has normal enzyme activity of a different sulfatase (excluding patients with Multiple Sulfatase Deficiency [MSD]); AND
    ▪ Patient has an elevated urinary GAG level as defined as being above the upper limit of normal by the reference laboratory; AND
  • Patient aged 5 years or older; AND
  • Documented baseline 12-minute walk test (12-MWT), 3-minute stair climb test, and/or pulmonary function tests (e.g., FEV1, etc.); AND
• Documented baseline value for urinary glycosaminoglycan (uGAG)

† FDA-approved indication(s)

II. RENEWAL CRITERIA

Authorizations can be renewed based on the following criteria:

• Patient continues to meet the criteria identified in section I; AND

• Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: anaphylaxis and allergic reactions, immune-mediated reactions, acute respiratory complications, acute cardiorespiratory reactions, severe infusion reactions, spinal or cervical cord compression, etc.; AND

• Disease response with treatment as defined by improvement or stability from pre-treatment baseline by the following:
  • Reduction in uGAG levels; AND
  o 12-minute walk test (12-MWT); OR
  o 3-minute stair climb test compared to pre-treatment baseline; OR
  o Pulmonary function testing (e.g., FEV1, etc.)

Limitations/Exclusions

Naglazyme is not considered medically necessary for indications other than those listed above due to insufficient evidence of therapeutic value.

Applicable Procedure Codes

| J1458 | Injection, galsulfase, 1 mg; 1 billable unit = 1 mg |

Applicable NDCs

| 68135-0020-xx | Naglazyme 5 mg per 5 mL solution; single-use vial |

Applicable Diagnosis Codes

| E76.29 | Other mucopolysaccharidoses |

Revision History

N/A

References

