Naglazyme (galsulfase) will be considered for coverage when the following criteria are met:

Mucopolysaccharidosis VI (MPS VI; Maroteaux-Lamy syndrome)

For initial authorization:
1. Medication must be prescribed by or in consultation with a geneticist, metabolic specialist, or pediatrician experienced with managing mucopolysaccharidoses; AND
2. Member has a diagnosis of MPS VI confirmed by at least one of the following:
   a) ASB enzyme activity is less than 10% of the lower limit of normal AND activity of a second sulfatase is normal (to exclude Multiple Sulfatase Deficiency), and/or
   b) Molecular genetic analysis identifying mutations of the ARSB gene; AND
3. Chart notes must include baseline urinary GAG (uGAG) levels showing elevated dermatan sulfate.
4. Dosage allowed/Quantity limit: 1 mg/kg once weekly as an IV infusion

If all the above requirements are met, the medication will be approved for 6 months.

For reauthorization:
1. Chart notes must show improvement or stabilized signs and symptoms of disease such as improved endurance (e.g. walk test or stair climb) and/or reduced uGAG levels.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Naglazyme (galsulfase) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.
References:


Effective date: 01/01/2022
Revised date: 07/09/2021