Reference number
2691-A

STANDARD MEDICARE PART B MANAGEMENT

NAGLAZYME (galsulfase)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Naglazyme is indicated for patients with Mucopolysaccharidosis VI (MPS VI, Maroteaux-Lamy syndrome). Naglazyme has been shown to improve walking and stair-climbing capacity.

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

Mucopolysaccharidosis VI (MPS VI)
Indefinite authorization may be granted for treatment of MPS VI when the diagnosis of MPS VI was confirmed by enzyme assay demonstrating a deficiency of N-acetylgalactosamine 4-sulfatase (arylsulfatase B) enzyme activity or by genetic testing.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Indefinite authorization may be granted when all of the following criteria are met:
A. The member is currently receiving therapy with Naglazyme
B. Naglazyme is being used to treat an indication enumerated in Section II
C. The medication has been effective for treating the diagnosis or condition.

IV. REFERENCES

1. Naglazyme [package insert]. Novato, CA: BioMarin Pharmaceutical Inc.; December 2019.