Reference number(s)
4205-A

STANDARD MEDICARE PART B MANAGEMENT

VIMIZIM (elosulfase alfa)

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 Indication[1]
Vimizim is indicated for patients with Mucopolysaccharidosis type IVA (MPS IVA, Morquio A syndrome).

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. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
For initial requests: N-acetylgalactosamine 6-sulfatase enzyme assay or genetic testing results supporting diagnosis.

III. CRITERIA FOR INITIAL APPROVAL

Mucopolysaccharidosis IVA (MPS IVA)
Indefinite authorization may be granted for treatment of MPS IVA when the diagnosis of MPS IVA was confirmed by enzyme assay demonstrating a deficiency of N-acetylgalactosamine 6-sulfatase enzyme activity or by genetic testing.

IV. 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 Vimizim
B. Vimizim is being used to treat an indication enumerated in Section III
C. The member is receiving benefit from therapy.

V. REFERENCES

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

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