

<b>Reference number</b>
2057-A

## **SPECIALTY GUIDELINE 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 Indications

Vimizim is indicated for patients with Mucopolysaccharidosis IVA (MPS IVA, Morquio A syndrome).

All other indications are considered experimental/investigational and are not a covered benefit.

##### **II. 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.

##### **III. CONTINUATION OF THERAPY**

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

##### **IV. REFERENCES**

1. Vimizim [package insert]. Novato, CA: BioMarin Pharmaceutical Inc.; February 2014.