

Reference number
2052-A

# SPECIALTY GUIDELINE MANAGEMENT

## ELAPRASE (idursulfase)

### 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

Elaprase is indicated for patients with Hunter syndrome (Mucopolysaccharidosis II, MPS II). Elaprase has been shown to improve walking capacity in patients 5 years and older. In patients 16 months to 5 years of age, no data are available to demonstrate improvement in disease-related symptoms or long term clinical outcome; however, treatment with Elaprase has reduced spleen volume similarly to that of adults and children 5 years of age and older. The safety and efficacy of Elaprase have not been established in pediatric patients less than 16 months of age.

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

#### II. REQUIRED DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: iduronate 2-sulfatase enzyme assay or genetic testing results supporting diagnosis.

#### III. CRITERIA FOR INITIAL APPROVAL

##### **Mucopolysaccharidosis II (MPS II)**

Authorization of 12 months may be granted for treatment of MPS II when the diagnosis of MPS II was confirmed by enzyme assay demonstrating a deficiency of iduronate 2-sulfatase enzyme activity or by genetic testing.

#### IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for Mucopolysaccharidosis II (MPS II) who are responding to therapy (e.g., improvement, stabilization, or slowing of disease progression for 6-minute walk test [6-MWT], percent predicted forced vital capacity [%-predicted FVC], spleen volume, or liver volume).

#### V. REFERENCES

1. Elaprase [package insert]. Lexington, MA: Shire Human Genetic Therapies, Inc.; November 2018.