CVS/caremark™

POLICY Document for Elaprase

The overall objective of this policy is to support the appropriate and cost effective use of the medication, specific to use of lower cost site of care and overall clinically appropriate use. This document provides specific information to each section of the overall policy.

Section 1: Site of Care
- Policy information specific to site of care (outpatient, hospital outpatient, home infusion)

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Site of Care

Site of Care Criteria
Administration of Intravenous Elaprase

POLICY

I. CRITERIA FOR APPROVAL FOR ADMINISTRATION IN OUTPATIENT HOSPITAL SETTING

This policy provides coverage for administration of Elaprase in an outpatient hospital setting for up to 8 doses when a member is new to therapy.

This policy provides coverage for administration of Elaprase in an outpatient hospital setting for a longer course of treatment when ANY of the following criteria are met:

A. The member has experienced an adverse reaction that did not respond to conventional interventions (eg, acetaminophen, steroids, diphenhydramine, fluids or other pre-medications) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after an infusion.
B. The member has developed idursulfase IgG antibodies which increases the risk for infusion related reactions.
C. The member is medically unstable (eg respiratory, cardiovascular, or renal conditions).
D. The member has severe venous access issues that require the use of a special intervention.
E. The member has significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver.
F. Alternative infusion sites are not available.
G. The member is less than 21 years of age or 65 years of age or older.

For situations where administration of Elaprase does not meet the criteria for outpatient hospital infusion, coverage for Elaprase is provided when administered in alternative sites such as; physician office, home infusion or ambulatory care.

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the site of care prior authorization review (where applicable):

A. Medical records supporting the member has experienced an adverse reaction that did not respond to conventional interventions or a severe adverse event during or immediately after an infusion
B. Medical records supporting the member has developed idursulfase IgG antibodies

C. Medical records supporting the member is medically unstable
D. Medical records supporting the member has severe venous access issues
E. Medical records supporting the member has behavioral issues and/or physical or cognitive impairment and no access to a caregiver
F. Records supporting alternative infusion sites are not available

Section 2: Clinical Criteria

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 Indications
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. CRITERIA FOR INITIAL APPROVAL

Mucopolysaccharidosis II (MPS II)
Indefinite authorization 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.

III. CONTINUATION OF THERAPY

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

REFERENCES:

SECTION 1

1. Elaprase [package insert]. Lexington, MA: Shire Human Genetic Therapies, Inc.; March 2016.
2. Bagewadi S, Roberts J, Mercer J, Jones S, Stephenson J, Wraith JE. Home treatment with Elaprase and Naglazyme is safe in patients with mucopolysaccharidoses types II and VI, respectively. *J Inherit Metab Dis.* 2008;31(6):733-737.
3. Burton BK, Guffon N, Roberts J, van der Ploeg AT, Jones SA, investigators HOS. Home treatment with intravenous enzyme replacement therapy with idursulfase for mucopolysaccharidosis type II - data from the Hunter Outcome Survey. *Mol Genet Metab.* 2010;101(2-3):123-129.

SECTION 2

1. Elaprase [package insert]. Lexington, MA: Shire Human Genetic Therapies, Inc.; June 2013.