



Prior Authorization Approval Criteria

Elaprase (idursulfase)

Generic name:	Idursulfase
Brand name:	Elaprase
Medication class:	Metabolic agent (recombinant metabolic enzyme)
FDA-approved uses:	Hunter Syndrome (mucopolysaccharidosis II)
Available dosage forms:	Solution for injection: 2 mg/mL
Usual dose range:	For adults, adolescents, and children at least 5 years of age: 0.5 mg/kg dose diluted in 100 mL 0.9% sodium chloride injection USP infused intravenously over 1-3 hours (at least 1 hour, no more than 8 hours) every week.
Duration of therapy:	Based on clinical response and toleration of agent
Approximate monthly cost:	6 mg single-use vial = \$3153.84 (based on AWP 2006)

Criterion for use: Clinically documented Hunter Syndrome.

Criterion for continuation of therapy: Clinical response and toleration of agent.

Cautions:

- Possibly life-threatening hypersensitivity reactions, including respiratory distress, drop in blood pressure, and seizure.

Monitoring:

- Hypersensitivity reactions: make appropriate medical support readily available during administration of agent. Patients with compromised respiratory function or acute respiratory disease may be at risk for serious acute exacerbation of their respiratory compromise because of infusion reactions, and may require additional monitoring.
- Laboratory monitoring not necessary.

Contraindications: None known.

Not approved if:

- Patient does not meet the above-stated criteria.

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 12/13/06