Idursulfase (Elaprase) – PA Criteria

HCPC: J1743

Idursulfase (Elaprase) is an enzyme replacement therapy indicated for the treatment of mucopolysaccharidosis II (Hunter Syndrome). It is covered by South Dakota Medicaid following prior authorization when the following criteria are met:

- **Initial Therapy (must meet all):**
  - Therapy is prescribed by or in consult with a geneticist with expertise in the treatment of mucopolysaccharidosis
  - Individual has a diagnosis of mucopolysaccharidosis II (Hunter syndrome) demonstrated by **one of the following:**
    - Enzyme assay demonstrating a deficiency in iduronate 2-sulfatase enzyme activity as measured in fibroblasts or leukocytes combined with normal enzyme activity of another sulfatase
    - Genetic testing confirming an iduronate 2-sulfatase gene mutation
  - Individual is ≥16 months of age
  - Baseline disease is documented with **one of the following:**
    - Urinary glycosaminoglycan (uGAG) levels are elevated defined by laboratory reference range
    - Baseline 6-minute walk test (6MWT)
    - Hepatomegaly (liver size ≥1.25x normal)
    - Splenomegaly (spleen size >5x normal)
  - Approval duration: 6 months
- **Continuation of Therapy:**
  - Individual has had a positive response to therapy
  - Approval duration: 1 year