

Field Name	Field Description
Prior Authorization Group Description	Mucopolysaccharidosis II (Hunter Syndrome) Agents
Drugs	Elaprase (idursulfase)
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	N/A
Required Medical Information	“See Other Criteria”
Age Restrictions	Patient is \geq 16 months of age
Prescriber Restrictions	Prescribed by or in consultation with a specialist in genetics or metabolic disorders
Coverage Duration	Initial Authorization: 6 months Reauthorization: 12 months
Other Criteria	<p>Initial Authorization</p> <ul style="list-style-type: none"> • Diagnosis of Mucopolysaccharidosis II as confirmed by one of the following: <ul style="list-style-type: none"> ○ Enzyme assay demonstrating a deficiency of iduronate 2-sulfatase activity ○ Genetic testing • Patient’s weight • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines <p>Reauthorization</p> <ul style="list-style-type: none"> • Patient has demonstrated a beneficial response (i.e., stabilization or improvement in 6-minute walk test [6-MWT], forced vital capacity [FVC]), urinary glycosaminoglycan (GAG) levels, liver volume, spleen volume, etc.) • Patient’s weight • Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines <p>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</p>
Revision/Review Date 7/2023	

PerformRx recommends approving the Mucopolysaccharidosis II (Hunter Syndrome) Agents prior authorization criteria with no changes for ACOH.