Ucopol 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 ≥ 16 months of age
Prescriber Restrictions	Prescribed by or in consultation with a specialist in the management Mucopolysaccharidosis II (geneticist, endocrinologist, neurologist, rheumatologist, etc.)
Coverage Duration	Initial Authorization: 6 months Reauthorization: 12 months

Other Criteria
 	
Revision/Review Date 7/2024
	Initial Authorization
	• Diagnosis of Mucopolysaccharidosis II as confirmed by one of the following:
	  o Enzyme assay demonstrating a deficiency of iduronate 2-sulfatase activity
	  o Genetic testing
	• Patient's weight
	• Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines
	
	Reauthorization
	• 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
	
	Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.