

Field Name	Field Description
Prior Authorization Group Description	Qalsody
Drugs	Qalsody (tofersen)
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	See “Other Criteria”
Required Medical Information	See “Other Criteria”
Age Restrictions	According to package insert
Prescriber Restrictions	Prescribed by or in consultation with a neurologist, neuromuscular specialist, or physician specializing in the treatment of amyotrophic lateral sclerosis (ALS)
Coverage Duration	If all the criteria are met, initial and renewal requests will be approved for 6 months
Other Criteria	<p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> • Diagnosis of ALS • Documentation of genetic test confirming a mutation in the superoxide dismutase 1 (SOD1) gene • Member is not dependent on invasive ventilation or tracheostomy • Documentation of slow vital capacity (SVC) $\geq 50\%$ • Medication is prescribed at an FDA approved dose <p><u>Re-Authorization:</u></p> <ul style="list-style-type: none"> • Documentation or provider attestation of positive clinical response (e.g., reduction in the mean concentration of neurofilament light [NfL] chains in the plasma, reduction in concentration of SOD1 in cerebrospinal fluid (CSF), or improvement in the Revised ALS Functional Rating Scale (ALSFRS-R) total score) • Member is not dependent on invasive ventilation or tracheostomy • Medication is prescribed at an FDA approved dose
Review/Revision Date: 7/2024	If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.