

Field Name	Field Description
<u>Prior Authorization Group Description</u>	<u>Qalsody (tofersen)</u>
<u>Drugs</u>	<u>Qalsody (tofersen)</u>
<u>Covered Uses</u>	<u>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.</u>
<u>Exclusion Criteria</u>	<u>See “Other Criteria”</u>
<u>Required Medical Information</u>	<u>See “Other Criteria”</u>
<u>Age Restrictions</u>	<u>According to package insert</u>
<u>Prescriber Restrictions</u>	<u>Prescribed by or in consultation with a neurologist, neuromuscular specialist, or physician specializing in the treatment of amyotrophic lateral sclerosis (ALS)</u>
<u>Coverage Duration</u>	<u>If all the criteria are met, initial and renewal requests will be approved for 6 months</u>
<u>Other Criteria</u>	<u>**Drug is being requested through the member’s medical benefit**</u> <u>Initial Authorization:</u> <ul style="list-style-type: none"> <u>• Diagnosis of ALS</u> <u>• Documentation of genetic test confirming a mutation in the superoxide dismutase 1 (SOD1) gene</u> <u>• Member is not dependent on invasive ventilation or tracheostomy</u> <u>• Documentation of slow vital capacity (SVC) ≥ 50%</u> <u>• Medication is prescribed at an FDA approved dose</u> <u>Re-Authorization:</u> <ul style="list-style-type: none"> <u>• 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)</u> <u>• Member is not dependent on invasive ventilation or tracheostomy</u> <u>• Medication is prescribed at an FDA approved dose</u> <u>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</u>
<u>Review/Revision Date: 7/2023</u>	