

**Included Products:** Qalsody (tofersen)

Nonformulary for outpatient benefit. PA required on medical benefit.

Created: 09/14/2023

Revised: 09/14/2023

Reviewed: 09/14/2023

Updated: 10/01/2023

## Diagnosis

Initial Criteria		If yes	If no
1.	Does the member have a diagnosis of ALS, with genetic testing confirming a mutation in the superoxide dismutase 1 (SOD1) gene (SOD1-ALS).	Continue to #2.	Do not approve.
2.	Is Qalsody being prescribed by a neurologist, neuromuscular specialist, or physician specializing in the treatment of ALS?	Continue to #3.	Do not approve.
3.	Is the member 18 years of age or older?	Continue to #4.	Do not approve.
4.	Does the member have FVC $\geq$ 50% from sitting position?	Continue to #5.	Do not approve.
5.	Approve for 6 months.		
Renewal Criteria		If yes	If no
1.	Is there medical record documentation of clinical benefit from treatment with Qalsody, such as a slowing of disease progression, reduction in decline on the Revised Amyotrophic Lateral Sclerosis Functional Rating Scale (ALSFRS-R), or reductions in plasma NfL levels?	Continue to #2.	Forward to medical director to review medical necessity.
2.	Approve for 6 months.		