Mass General Brigham
Health Plan

Qalsody (tofersen)
Effective 07/01/2025

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview
Qalsody (tofersen) is indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 (SOD1) gene. This indication is approved under accelerated approval based on reduction in plasma neurofilament light chain (NfL) observed in patients treated with Qalsody.

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members new to the plan who are currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members when ALL the following criteria are met:

1. Diagnosis of Amyotrophic Lateral Sclerosis (ALS)
2. Member is ≥18 years of age
3. Prescriber is a neurologist, neuromuscular specialist, or other specialist in the treatment of ALS, or consult notes from specialist are provided
4. Genetic test confirming SOD1 mutation
5. Pre-treatment ALSFRS-R questionnaire score (within the past 12 weeks)*
6. Appropriate dosing
7. **ONE** of the following:
    a. Requested agent will be used in combination with riluzole
    b. Adverse reaction or contraindication to riluzole
8. Member is not dependent on invasive mechanical ventilation by intubation or tracheostomy

Continuation of Therapy
Reauthorizations may be approved if prescriber provides documentation of **BOTH** of the following:

1. Prescriber submits a current copy of the ALSFRS-R questionnaire including scores on each individual domain (within the past 12 weeks)*
2. Member is not dependent on invasive mechanical ventilation by intubation or tracheostomy

***** A completed ALSFRS-R questionnaire should include scores of each individual domain

Limitations

1. Initial approvals may be granted for 6 months
2. Reauthorizations may be granted for 1 year

References

1. Qalsody [package insert]. Cambridge (MA): Biogen, Inc.; 2024 Nov.

Review History

2/14/24 – Created for P&T. Matched MH criteria for Qalsody. Effective 3/4/24
06/11/25 – Reviewed and updated for P&T. Part of annual UM review. Updated formatting and references. Effective 7/1/25