Mass General Brigham
Health Plan

Qalsody (tofersen)
Effective 10/01/2023

Plan	☐ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | Fax: 844-403-1029		
Exceptions	N/A		

Overview
Qalsody is indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 (SOD1) gene.

Coverage Guidelines
Authorization may be granted for members new to General Brigham Health Plan who are currently receiving treatment with Qalsody, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization may be granted for members meeting ALL the following criteria:

1. Member is 18 years of age or older
2. The medication is being prescribed by or in consultation with a neurologist, neuromuscular specialist or physician specializing in the treatment of ALS
3. Member has weakness attributable to ALS confirming by diagnostic testing (e.g., medical history and/or diagnostic testing including nerve conduction studies, imaging and laboratory values to support the diagnosis)
4. Medical charts documenting genetic testing confirming a SOD1 mutation
5. Forced Vital Capacity (FVC) or Slow Vital Capacity (SVC) $\geq$ 45% of predicted value for gender, height, and age
6. Member does not have a tracheostomy

Continuation of Therapy
Reauthorization may be granted for continued treatment when provider attestation of all the following are met:

1. Clinical benefit from Qalsody therapy
2. Invasive ventilation or tracheostomy is not required

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months

References

1. Qalsody [package insert]. Cambridge, MA: Biogen MA, Inc.; April 2023.
2. Miller TM, Cudkowicz ME, Genge A, et al. VALOR and OLE Working Group. Trial of Antisense Oligonucleotide Tofersen for SOD1 ALS. *N Engl J Med*. 2022 Sep 22;387(12):1099-1110
3. EFNS Task Force on Diagnosis and Management of Amyotrophic Lateral Sclerosis; Andersen PM, et al. EFNS guidelines on the Clinical Management of Amyotrophic Lateral Sclerosis (MALS) – revised report of an EFNS task force. *Eur J Neurol*. 2012;19(3):360-75.

Review History

08/9/2023 - Reviewed at August P&T, Effective 10/1/23