Tofersen (Qalsody™)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:
POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Qalsody 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 observed in patients treated with Qalsody. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
Chart notes, ~~or~~ medical record documentation, and/or laboratory results supporting use as applicable in section IV and V.

A. Initial Requests:
   1. ~~Member has~~ Weakness attributable to ALS ~~confirmed by diagnostic tests including imaging, nerve conduction studies, laboratory values.~~
   2. Genetic testing confirming SOD1 mutation
   3. Forced Vital Capacity (FVC) ~~≥ 45% of predicted value for gender, height and age~~ or Slow Vital Capacity (SVC) results.

B. Continuation Requests:
   1. Documentation of clinical benefit from therapy with the requested medication. ~~Qalsody therapy~~

III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a neurologist, neuromuscular specialist, or physician specializing in the treatment of amyotrophic lateral sclerosis (ALS).

IV. CRITERIA FOR INITIAL APPROVAL

Amyotrophic Lateral Sclerosis (ALS)
Authorization of 12 months may be granted for treatment of ALS when all of the following criteria are met:
A. Member is 18 year of age or older
B. Member has weakness attributable to ALS ~~confirmed by diagnostics testing~~ (e.g., medical history and /or diagnostic testing including nerve conduction studies, imaging and laboratory values to support the diagnosis)
C. Member has a ~~Genetic testing confirming a~~ SOD1 mutation confirmed via genetic testing
D. Member has a forced vital capacity (FVC) or slow vital capacity (SVC) ≥ 45% of predicted value for gender, height, and age
E. Member does not have a tracheostomy

V. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for members continuation of ~~continuing~~ ~~with Qalsody~~ therapy ~~for the treatment of ALS~~ when both of the following criteria are met:
A. Member has had a documented ~~There is a~~ clinical benefit from ~~Qalsody~~ therapy with the requested medication
B. Invasive ventilation or tracheostomy is not required

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

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.

EFFECTIVE DATE

ID_CHS