TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Tofersen (Qalsody®)	**CRITERIA ID:** TX.CC.PHAR.28
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy, Medical Directors, Claims
EFFECTIVE DATE: 11/01/2023	**PRODUCT(S):** STAR, STAR PLUS, STAR HEALTH, STAR KIDS, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: 11/03/23, 04/03/2024	
REGULATOR MOST RECENT APPROVAL DATE(S): N/A	

CRITERIA STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for Tofersen (Qalsody®).

PURPOSE:
Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan. While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical criteria and prior authorization requirements.

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
ALS = Amyotrophic lateral sclerosis
SOD1 = Superoxide dismutase 1
NfL = Neurofilament light chain

POLICY:
It is the policy of Superior HealthPlan and Centene Pharmacy Services to follow state guidance for medical necessity review of tofersen (Qalsody®); procedure code: J1304.

Description/Mechanism of Action:
Tofersen (Qalsody®) is an antisense oligonucleotide indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 (SOD1) gene.

FDA Approved Indication(s):
Tofersen (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)

PROCEDURE:
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

II. Initial Approval Criteria

A. Amyotrophic lateral sclerosis (ALS) (must meet all):

1. The client is 18 years of age or older.
2. Documentation of diagnostic testing that confirms that the client has amyotrophic lateral sclerosis (ALS) (diagnosis code: G12.21).
3. Documentation of genetic testing that confirms there is the presence of a mutation in the superoxide dismutase 1 (SOD1) gene.
4. Documentation of client's baseline measure of the plasma neurofilament light chain (NfL).
5. Documentation of client's baseline functional ability (e.g., climbing stairs, walking, and speech) prior to treatment initiation.
6. Documentation of the requested antisense oligonucleotide dosage and administration schedule, including the number of injections to be administered during the prior authorization period, the requested units per injection, and the dosage calculation.

Approval duration: 6 months

II. Continued Therapy

A. Amyotrophic lateral sclerosis (ALS) (must meet all):

1. The client has met all initial prior authorization approval criteria at the time of initial approval.
2. Prescriber attestation that client has been compliant with the treatment.
3. Documentation that the client has responded positively to therapy as evidenced by any improvement or maintenance in the plasma neurofilament light chain (NfL) measurement as compared to baseline.
4. Documentation that the client has stabilization in disease state and has shown a slowed pattern in the disease progression.
   Note: Qalsody should not be continued on clients who experience decreased physical function while on the medication.
5. Documentation of absence of unacceptable toxicities (aseptic meningitis, serious myelitis and/or radiculitis, papilledema and elevated cranial pressure) from Qalsody therapy.
6. Documentation of the requested antisense oligonucleotide dosage and administration schedule, including the number of injections to be administered during the prior authorization period, the requested units per injection, and the dosage calculation.

Approval duration: 12 months

REFERENCES:
Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook
Qalsody Package Insert; Eisai Inc.; April 2023

ATTACHMENTS:

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy		11/01/2023
Ad Hoc Review	For section I.A, added diagnosis code to criteria step 2 and added criteria step 6. For section II.A., added criteria steps 2 and 3 and added Exclusion statement to criteria step 5 to align with TMHP manual updates posted in Nov 2023	11/03/2023
Ad Hoc Review	Updated to TX.CC.PHAR format template Added Centene copyright statement and updated Jcode from C9157 to J1304	04/03/2024