SENTARA COMMUNITY PLAN
(MEDICAID)

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-305-2331**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

Drug Requested: Qalsody™ (tofersen) **J1304 (MEDICAL)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member Optima #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

☐ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

A. Quantity Limit (max daily dose) [NDC Unit]:

- Qalsody 100 mg/15 mL single-dose vial: 1 vial every 14 days x 3 doses, then 1 vial every 28 days
- 100 mg/15 mL = 100 billable units

B. Max Units (per dose and over time) {HCPCS Unit]:

- Initial dose: 100 mg every 14 days, for 3 doses only
- Subsequent doses: 100 mg every 28 days thereafter

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CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

- ❑ Prescriber is a Neurologist with expertise in the diagnosis of ALS
- ❑ Member is 18 years of age or older
- ❑ Member has a diagnosis of amyotrophic lateral sclerosis (ALS) **(submit documentation)**
- ❑ Member has the presence of a mutation in the superoxide dismutase 1 (SOD1) gene **(submit documentation)**
- ❑ Member has a slow vital capacity (%SVC) ≥ 50% of predicted value for gender, height and age **(submit documentation)**
- ❑ Member is stable on **ONE** of the following medications **(verified by chart notes or pharmacy paid claims)**:
  - ❑ riluzole (Exservan®/Rilutek®/Tiglutik®)
  - ❑ Radicava® (edaravone)
  - ❑ Relyvrio® (Sodium Phenylbutrate & Taurursodiol)
- ❑ Provider must submit baseline documentation of retained functionality for most activities of daily living [i.e., ALS Functional Rating Scale – Revised (ALSFRS-R)] **(submit scale)**
- ❑ Provider must submit member's baseline plasma neurofilament light chain (NfL): _____
- ❑ Member does **NOT** require permanent assisted ventilation and is **NOT** dependent on invasive ventilation or tracheostomy

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member continues to meet all initial authorization criteria
- ❑ Member has experienced an absence of unacceptable toxicity from the drug (e.g., serious myelitis and radiculitis, papilledema and elevated cranial pressure or aseptic meningitis)
- ❑ Member has had improvement in plasma neurofilament light chain (NfL) level which is defined as a decrease in the level compared to baseline **(submit documentation)**
- ❑ Member has experienced a positive response to therapy as demonstrated by disease stability or mild progression indicating a slowing of decline on the ALSFRS-R **(submit documentation)**
- ❑ Member has **NOT** experienced rapid disease progression while on therapy
- ❑ Member does **NOT** require permanent assisted ventilation and is **NOT** dependent on invasive ventilation or tracheostomy

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Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____
  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call Optima Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Optima's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee:** ~~8/17/2023;~~ **9/26/2024**
REVISED/UPDATED: ~~10/17/2023;~~ **10/15/2024**