OPTIMA HEALTH PLAN

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 1-844-668-1550**. 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**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Qalsody™ (tofersen) **J3490 (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:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

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

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

Weight: _____ **Date:** _____

☐ 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.

Preparation: 100 mg/15 mL solution in a single-dose glass vial (preservative free); NDC: 64406-0109-xx

Recommended Dosing: 100 mg (15 mL) per intrathecal administration

- Initiate QALSODY treatment with 3 loading doses administered at 14- day intervals. A maintenance dose should be administered once 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., score of 2 or better on each individual item of the ALS Functional Rating Scale – Revised (ALSFRS-R)] **(submit actual assessment with total score obtained within the last 60 days)**
- ❑ 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 does **NOT** have a cumulative score on the ALSFRS-R of ≤ 3 **(Maximum possible cumulative score on the ALSFRS-R is 48; a cumulative score of 3 indicates loss/significant impairment [i.e., item score of zero in nine or more items on the 12-item questionnaire])**

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- ❑ 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

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**
REVISED/UPDATED: 10/17/2023