

Clinical Oversight Review Board (CORB) Criteria for Prescribing Tofersen (Qalsody)

Notes:

- Quantity Limits: No

Non-Formulary **tofersen (Qalsody)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

Initiation (new start) criteria, and criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously: Non-formulary **tofersen (Qalsody)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescribed by a neurologist with expertise/interest in diagnosing and treating patients with amyotrophic lateral sclerosis (ALS)
- Patient is 18 years or older
- Patient has weakness attributed to ALS
- Patient has a forced vital capacity (FVC) of 50% or higher within 2 months prior to treatment
- Documentation of genetic testing confirming positive SOD1 mutation
- Patient does not have a tracheostomy
- Patient does not have a current hepatitis B or HIV infection

Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary **tofersen (Qalsody)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Patient has a FVC of 50% or higher
- Prescribed for the treatment of ALS
- Documentation of genetic testing confirming positive SOD1 mutation
- Patient does not require tracheotomy or non-invasive ventilation all day
- Patient is not currently enrolled in hospice care

Continued use criteria for patients previously approved per the above criteria who are currently stable on the medication: Non-formulary **tofersen (Qalsody)** will

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Revised: 09/14/23
Effective: 11/16/23

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continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescribed by neurologist with expertise/interest in diagnosing/treating patients with ALS
- Patient has a FVC of 50% or higher
- Patient does not require tracheotomy or non-invasive ventilation all day
- Patient has NOT experienced a significant clinical decline in ALSFRS-R and/or %FVC status
- Patient is not currently enrolled in hospice care

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