Tofersen (Qalsody) – PA Criteria

HCPC: J1304

Tofersen (Qalsody) is an antisense oligonucleotide indicated for the treatment of amytrophic lateral sclerosis (ALS) in the treatment of adults who have a mutation in the superoxide dismutase 1 (SOD1) gene. It is covered by South Dakota Medicaid following prior authorization when the patient meets the following criteria:

- **Initial Therapy (must meet all):**
  - Therapy is prescribed by or in consult with a neurologist
  - Individual has a diagnosis of ALS with documentation supporting **both** of the following
    - Muscle weakness attributed to ALS
    - Documentation of SOD1 mutation
  - Baseline ALS Functional Rating Scale-Revised (ALSFRS-R) is provided and indicates a score of ≥2 in all areas
  - Individual has a baseline slow vital capacity (SVC) of ≥50% of predicted value for age, sex and height (from sitting position)
  - Individual is not ventilator dependent
  - Individual is ≥18 years of age
  - Approval duration: 6 months
- **Continuation of Therapy (must meet all):**
  - Individual continues to meet initial criteria and remains non-ventilator dependent
  - Japanese ALS Severity Scale grade documented at time of therapy renewal
  - ALS Functional Rating Scale-Revised (ALSFRS-R) scores documented at time of renewal
  - Approval duration: 1 year