Provider Network News

Prior Authorization Criteria Addition for Qalsody Begins Oct. 1, 2023

Background:

HHSC implemented prior authorization criteria for Qalsody (procedure code C9157) on Oct. 1, 2023.

Key Details:

Qalsody (Tofersen) 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.

Authorization requirements

HHSC will consider prior authorization approval of Qalsody (Tofersen) therapy when all the following criteria are met:

- Client is 18 years of age or older.
- Diagnostic testing confirms client has amyotrophic lateral sclerosis (ALS).
- Genetic testing must confirm there is the presence of a mutation in the superoxide dismutase 1 (SOD1) gene.
- Documentation of baseline measure of the plasma neurofilament light chain (NfL).
- Documentation of baseline functional ability (e.g., climbing stairs, walking, and speech) prior to treatment initiation.

Renewal or Continuation Therapy

For renewal or continuation therapy, the client must meet all the following requirements:

- Client has met all initial authorization approval criteria at the time of initial approval.
- Client has responded positively to therapy as evident by any improvement in the plasma neurofilament light chain (NfL) measurement as compared to baseline.
- Documentation that client has stabilization in disease state and has shown a slowed pattern in the disease progression.
- Absence of unacceptable toxicities (aseptic meningitis, serious myelitis and/or radiculitis, papilledema and elevated cranial pressure) from Tofersen therapy.

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