1. **Background:**

Xyrem® (sodium oxybate) is a central nervous system depressant indicated for the treatment of excessive daytime sleepiness (EDS) and cataplexy in patients with narcolepsy.\(^1\)

Xyrem is classified as a Schedule III controlled substance by Federal law. The active ingredient, sodium oxybate or gamma-hydroxybutyrate (GHB), is listed in the most restrictive schedule of the Controlled Substances Act (Schedule I). Thus, non-medical uses of Xyrem are classified under Schedule I.

Xyrem is available only through restricted distribution, the Xyrem REMS Program. Prescribers and patients must enroll in this program at www.XYREMREMS.com, or by calling 1-866-XYREM88 (1-866-997-3688). The REMS Program provides educational materials to the prescriber and the patient explaining the risks and proper use of Xyrem, and the required prescription form. Once it is documented that the patient has read and/or understood the materials, the drug will be shipped to the patient. The Xyrem REMS Program also recommends patient follow-up every 3 months. Physicians are expected to report all serious adverse events to the manufacturer.

Members will be required to meet the coverage criteria below.
2. Coverage Criteria:

A. Narcolepsy with Cataplexy (i.e., Narcolepsy Type 1)

1. Initial Authorization

   a. Xyrem will be approved based on all of the following criteria:

      (1) Submission of medical records (e.g., chart notes, laboratory values) documenting a diagnosis of narcolepsy with cataplexy (i.e., Narcolepsy Type 1) with both of the following:

             (a) The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months.

             -AND-

             (b) A mean sleep latency of ≤ 8 minutes and two or more sleep onset REM periods (SOREMPs) on an MSLT performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT.

             -AND-

      (2) Physician attestation to both of the following:

             (a) Patient has experienced cataplexy defined as more than one episode of sudden loss of muscle tone with retained consciousness

             -AND-

             (b) Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications, or other sleep disorders).

             -AND-

      (3) Prescribed by one of the following:

             (a) Neurologist
             (b) Psychiatrist
             (c) Sleep Medicine Specialist

   Authorization will be issued for 3 months.
2. Reauthorization

a. Xyrem will be approved for continuation of therapy based on one of the following criteria:

   (1) Documentation demonstrating a reduction in frequency of cataplexy attacks associated with Xyrem therapy

   –OR–

   (2) Documentation demonstrating reduction in symptoms of excessive daytime sleepiness associated with Xyrem therapy

Authorization will be issued for 12 months.

B. Narcolepsy without Cataplexy (i.e., Narcolepsy Type 2)

1. Initial Authorization

a. Xyrem will be approved based on all of the following criteria:

   (1) Submission of medical records (e.g. chart notes, lab values) documenting a diagnosis of narcolepsy without cataplexy (i.e., Narcolepsy Type 2) with both of the following:

      (a) The patient has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months.

      (b) A mean sleep latency of \( \leq \) 8 minutes and two or more sleep onset REM periods (SOREMPs) are found on a MSLT performed according to standard techniques following a normal overnight polysomnogram. A SOREMP (within 15 minutes of sleep onset) on the preceding nocturnal polysomnogram may replace one of the SOREMPs on the MSLT.

   (2) Physician attestation to the following:

      (a) Other causes of sleepiness have been ruled out or treated (including but not limited to obstructive sleep apnea, insufficient sleep syndrome, shift work, the effects of substances or medications or their withdrawal, sleep phase disorder, or other sleep disorders).

      –AND–

   (3) History of failure, contraindication, or intolerance of all of the following:

      (a) One of the following:

         i. Amphetamine based stimulant (e.g., amphetamine, dextroamphetamine)
3. **Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.
4. References: