

Market Applicability/Effective Date														
Market	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	NA

\*FHK- Florida Healthy Kids

## Xyrem (sodium oxybate)

Override(s)	Approval Duration
Prior Authorization	Initial requests – 3 months
Quantity Limit	Renewal requests - 6 months

Medications	Quantity Limit
Xyrem (sodium oxybate) 500mg/mL	18 mL per day

### APPROVAL CRITERIA

**Initial** requests for Xyrem (sodium oxybate) may be approved if the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
  - II. Individual has a diagnosis of Narcolepsy type 1 (narcolepsy with cataplexy) confirmed by the presence of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months and documentation of at least one of the following:
    - a. Clear cataplexy (defined as “more than one episode of generally brief [less than 2 minutes] usually bilaterally symmetrical, sudden loss of muscle tone with retained consciousness”); **AND**
    - b. Multiple sleep latency test (MSLT) showing one of the following:
      - i. Mean sleep latency of less than 8 minutes with evidence of two sleep-onset rapid eye movement periods (SOREMPs) (ICSD-3, 2014); **OR**
      - ii. At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG);
- OR**
- c. Cerebrospinal fluid hypocretin-1 deficiency (less than [ $<$ ] 110 pg/mL or less than one-third of the normative values with the same standardized assay);

**Initial** requests for Xyrem (sodium oxybate) may also be approved if the following criteria are met, (I and II) and either III or IV:

- I. Individual is 18 years of age or older; **AND**
- II. Individual has a diagnosis of Narcolepsy type 2 (narcolepsy without cataplexy) confirmed by the following

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

Market Applicability/Effective Date														
Market	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	NA

\*FHK- Florida Healthy Kids

- a. Dailey periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months; **AND**
- b. Documentation of Multiple Sleep Latency Test (MSLT) showing one of the following:
  - i. Mean sleep latency of less than 8 minutes with evidence of two sleep-onset repaid eye movement periods (SOREMPs) (ICSD-3, 2014); **OR**
  - ii. At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG);
- c. The absence of cataplexy; **AND**
- d. Exclusion of alternative causes of excessive daytime sleepiness by history, physical exam and polysomnography.

**AND**

- III. Individual has had a previous trial of and inadequate response or intolerance to two of the following medications:
  - a. One of the following wakefulness promoting medications
    - i. Modafinil; **OR**
    - ii. Nuvigil (armodafinil);

**AND**

- b. One of the following stimulants:
  - i. Methylphenidate; **OR**
  - ii. Dextroamphetamine; **OR**
  - iii. Amphetamine/dextroamphetamine salt immediate-release;

**OR**

- IV. Trials of wakefulness promoting agents and stimulant agents are not are not acceptable due to concomitant clinical situations including but not limited to the following:
  - a. Cardiovascular disease; **OR**
  - b. Drug interactions.

**Renewal** requests for Xyrem (sodium oxybate) may be approved if the following criteria are met:

- I. Individual has met initial diagnostic criteria as noted above; **AND**
- II. Xyrem use has resulted in a reduction in frequency of cataplexy attacks compared to baseline; **OR**
- III. Xyrem use has resulted in a reduction in excessive daytime sleepiness (EDS) as measured by improvement in Epworth Sleepiness Scale (ESS) measurements or Maintenance of Wakefulness Test (MWT) compared to baseline.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

Market Applicability/Effective Date														
Market	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	NA

\*FHK- Florida Healthy Kids

Requests for Xyrem (sodium oxybate) may **not** be approved for the following:

- I. Individual is using in combination with other sedative hypnotic agents; **OR**
- II. Individual is using in combination with alcohol; **OR**
- III. Individual has been diagnosed with succinic semialdehyde dehydrogenase deficiency.

**Note:** Xyrem (sodium oxybate) has black box warnings for central nervous system (CNS) depression and misuse and abuse. Respiratory depression can occur with use. Sodium oxybate is the sodium salt of gamma hydroxybutyrate (GHB). Abuse or misuse of GHB is associated with CNS adverse reactions, including seizures, respiratory depression, decreased consciousness, coma, and death. Because of the risks of CNS depression, abuse, and misuse, Xyrem is available only through a restricted distribution program called the XYREM REMS Program(R), using a centralized pharmacy. Prescribers and individuals must enroll in the program; call 1-866-XYREM88 for additional information.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

**Key References:**

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2016. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

Market Applicability/Effective Date														
Market	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	NA

\*FHK- Florida Healthy Kids

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2016; Updated periodically.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.