

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Xyrem

A. Prescriptions That Require Prior Authorization

All prescriptions for Xyrem must be prior authorized.

B. Clinical Review Guidelines and Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Xyrem, the determination of whether the requested prescription is medically necessary will take into account whether the recipient:

1. Is 16 years of age or older

AND

2. Has a diagnosis of narcolepsy with excessive daytime sleepiness (EDS) and/or cataplexy as confirmed by a sleep study followed by multiple sleep latency testing (MSLT)

AND

3. Is being prescribed Xyrem by a Sleep Specialist enrolled in the Xyrem REMS Program

AND

4. Is enrolled in the Xyrem REMS Program

AND

5. Does not have a history of succinic semialdehyde dehydrogenase deficiency

AND

6. Is not receiving concurrent treatment with sedative hypnotics or Central Nervous System (CNS) depressants

AND

7. Has a recent urine drug screen negative for benzodiazepines, opiates and illicit drugs

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

AND

8. Has a documented history of abstinence from alcohol

AND

9. Does not have a history of substance abuse, addiction or diversion

AND

10. Does not have a condition which would require a restricted intake of sodium such as but not limited to CHF, hypertension or stage 4-5 renal impairment.

AND

11. For narcolepsy with Excessive Daytime Sleepiness (EDS):

a. Was evaluated and treated for all other etiologies for EDS

AND

b. Has documented history of therapeutic failure of the following, as documented by an Epworth Sleepiness scale of greater than or equal to 10 or repeated Maintenance of Wakefulness Test (MWT) or MSLT with a mean sleep latency of 8 minutes or less:

i. Modafanil or armodafanil at maximum recommended doses

AND

ii. Methylphenidate, methamphetamine or dextroamphetamine at maximum recommended doses

OR

iii. Has documented history of contraindication or intolerance to

a) Modafanil or armodafanil

AND

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- b) Methylphenidate, methamphetamine or dextroamphetamine

AND

12. For narcolepsy with cataplexy, has a documented history of therapeutic failure, contraindication or intolerance to:

- a. Tricyclic antidepressants

AND

- b. SSRIs or SNRIs

OR

13. Does not meet the clinical review guidelines listed above, but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

FOR RENEWALS OF PRESCRIPTIONS FOR XYREM -The determination of medical necessity of requests for prior authorization of renewals of prescriptions for Xyrem that were previously approved, will take into account whether the recipient:

- 1. For Narcolepsy with EDS, has documented reduction in daytime sleepiness by an improved Epworth Sleepiness Scale, MWT or MSLT

AND

- 2. For Narcolepsy with Cataplexy, has a documented reduction in the incidence of cataplexy attacks

AND

- 3. Is not receiving concurrent treatment with sedative hypnotics or CNS depressants

AND

- 4. Has a recent urine drug screen negative for benzodiazepines, opiates and illicit drugs

AND

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

5. Has a documented history of abstinence from alcohol

AND

6. Does not have a condition which would require a restricted intake of sodium such as but not limited to CHF, hypertension or stage 4-5 renal impairment.

OR

7. Does not meet the clinical review guidelines listed above, but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient

In addition, if a prescription for Xyrem is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B above, to assess the medical necessity of the request for a prescription for Xyrem. All prior authorization requests for Xyrem will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when:

1. The clinical guidelines in Section B are met, OR
2. The clinical guidelines in Section B are not met, but in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

D. Dose and Duration of Therapy

The Department will limit approvals of requests for prior authorization of Xyrem as follows:

1. For initial prescriptions, 4 months
2. For renewals of prescriptions that were previously approved, 6 months

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

E. References:

1. Xyrem Package Insert, Jazz Pharmaceuticals, Inc. March 2015
2. UpToDate: Treatment of Narcolepsy, accessed 1/21/11
3. Littner, MR et al. Practice Parameters for Clinical Use of the Multiple Sleep Latency Test and the Maintenance of Wakefulness Test An American Academy of Sleep Medicine Report Standards of Practice Committee of the American Academy of Sleep Medicine Sleep. 2005; 28 (1)