Market Applicability					
Market	**GA**	**KY**	**MD**	**NJ**	**NY**
Applicable	X	NA	X	X	X

Xyrem (sodium oxybate), Xywav (calcium, magnesium, potassium and sodium oxybates)

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

Medications	Quantity Limit
Xyrem (sodium oxybate) 500mg/mL Xywav (calcium, magnesium, potassium and sodium oxybates) 500mg/mL	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Xyrem (sodium oxybate), Xywav (calcium, magnesium, potassium and sodium oxybates) may be approved if the following criteria are met:

I. Individual is 7 years of age or older; **AND**

II. Documentation is provided that individual has a diagnosis of Narcolepsy type 1 confirmed by the presence of daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months and 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:
      1. Mean sleep latency of less than 8 minutes with evidence of two sleep-onset rapid eye movement periods (SOREMPs) (ICSD-3, 2014); **OR**
      2. 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).

AND

III. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to Wakix (pitolisant), unless one of the following:

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Market Applicability					
Market	**GA**	**KY**	**MD**	**NJ**	**NY**
Applicable	X	NA	X	X	X

A. Individual is between the age of 7 and 18; **OR**
B. Individual has severe hepatic impairment; **OR**
C. Individual is currently stabilized on Xyrem or Xywav;

AND

IV. If request is for Xywav, documentation is provided that individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to Xyrem for the treatment of cataplexy in narcolepsy;
OR
V. Xywav may be approved if individual has a requirement for reduced sodium intake and requires an agent with lower sodium content (including but not limited to heart failure, kidney disease, and high blood pressure).

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

I. Individual is 7 years of age or older; **AND**
II. Documentation is provided that individual has a diagnosis of Narcolepsy type 2 confirmed by the following:
    A. Daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months; **AND**
    B. Multiple Sleep Latency Test (MSLT) with one of the following:
        1. Mean sleep latency of less than 8 minutes with evidence of two sleep-onset rapid eye movement periods (SOREMPs) (ICSD-3, 2014); **OR**
        2. At least one SOREMP on MSLT and a SOREMP (less than 15 minutes) on the preceding overnight polysomnography (PSG); **AND**
    C. The absence of cataplexy; **AND**
    D. Exclusion of alternative causes of excessive daytime sleepiness by history, physical exam and polysomnography;

AND

III. Documentation is provided that individual has had a previous trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of and inadequate response or intolerance to two of the following medications:
    A. One of the following wakefulness promoting medications:
        1. Modafinil; **OR**
        2. Armodafinil; **OR**
        3. Sunosi (solrifametol); **OR**
        4. Wakix (pitolisant);

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Market Applicability					
Market	**GA**	**KY**	**MD**	**NJ**	**NY**
Applicable	X	NA	X	X	X

AND

B. One of the following stimulants:
    1. Methylphenidate; **OR**
    2. Dextroamphetamine; **OR**
    3. Amphetamine/dextroamphetamine salt immediate-release;

OR

IV. Documentation is provided that 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), Xywav (calcium, magnesium, potassium and sodium oxybates) may be approved if the following criteria are met:

I. Individual has met initial diagnostic criteria as noted above; **AND**
II. Documentation is provided that Xyrem or Xywav use has resulted in a reduction in frequency of cataplexy attacks compared to baseline; **OR**
III. Documentation is provided that Xyrem or Xywav 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.

Requests for Xyrem (sodium oxybate), Xywav (calcium, magnesium, potassium and sodium oxybates) 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), Xywav (calcium, magnesium, potassium and sodium oxybates) have 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 and Xywav are available only through a restricted distribution program called the XYREM or XYWAV REMS Program,

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Market Applicability					
Market	**GA**	**KY**	**MD**	**NJ**	**NY**
Applicable	X	NA	X	X	X

using a centralized pharmacy. Prescribers and individuals must enroll in the program; call 1-866-997-3688 for additional information.

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Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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