Clinical Policy Title:	oxybate salt products
Policy Number:	RxA.309
Drug(s) Applied:	Xywav®, Wakix®
Original Policy Date:	02/07/2020
Last Review Date:	01/01/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Narcolepsy with Cataplexy (must meet all)**:**

1. Prescribed for the treatment of cataplexy in members with narcolepsy;
2. Diagnosis has been confirmed through any one of the followings (a or b):
   a. Sleep lab evaluation [e.g., polysomnography and/or multiple sleep latency test (MSLT)];
   b. Lumbar puncture shows cerebrospinal fluid (CSF) hypocretin-1 level ≤ 110 pg/mL;
3. Prescribed by or in consultation to a sleep specialist or neurologist;

Approval duration

All Lines of Business (except Medicare): 12 months

B. Narcolepsy with Excessive Daytime Sleepiness (must meet all)**:**

1. Prescribed for the treatment of EDS in members with narcolepsy;
2. Diagnosis has been confirmed through sleep lab evaluation [e.g., polysomnography and/or multiple sleep latency test (MSLT)];
3. Prescribed by or in consultation to a sleep specialist or neurologist;
4. Trial and failure of at least one (1) CNS stimulant (e.g., methylphenidate, dextroamphetamine or modafinil) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced.

Approval duration

All Lines of Business (except Medicare): 12 months

C. Idiopathic Hypersomnia (must meet all)**:**

1. Diagnosis of Idiopathic Hypersomnia;
2. Prescribed by or in consultation with a neurologist or sleep medicine specialist;
3. Request is for Xywav
4. Trial and failure of at least one (1) CNS stimulant (e.g., methylphenidate, dextroamphetamine or modafinil) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;

Approval duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

All Indications in Section I (must meet all)**:**

1. Member is currently receiving medication, excluding manufacturer samples;

Approval duration

All Lines of Business (except Medicare): 12 months

References

1. Morgenthaler TI, Kapur VK, Brown T, et al. Practice Parameters for the Treatment of Narcolepsy and other Hypersomnias of Central Origin an American Academy of Sleep Medicine Report: An American Academy of Sleep Medicine Report. Sleep. 2007; 30(12): 1705-1711. Available at: https://aasm.org/resources/practiceparameters/pp_narcolepsy.pdf. Accessed December 08, 2023.
2. Wise MS, Arand DL, Auger RR, Brooks SN, Watson NF. Treatment of Narcolepsy and other Hypersomnias of Central Origin: An American Academy of Sleep Medicine Review. Sleep. 2007;30(12):1712-1727. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2276130/. Accessed December 08, 2023.
3. Scammell TE. The neurobiology, diagnosis, and treatment of narcolepsy. Ann Neurol 2003; 53: 154 –166. Available at: https://pubmed.ncbi.nlm.nih.gov/12557281/. Accessed December 08, 2023.
4. Swick TJ. Treatment paradigms for cataplexy in narcolepsy: past, present, and future. Nat Sci. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4686331/. Accessed December 08, 2023.
5. Billiard M. Narcolepsy: current treatment options and future approaches. Neuropsychiatric Disease and Treatment. 2008; 4(3): 557-566. Available at: https://pubmed.ncbi.nlm.nih.gov/18830438/. Accessed December 08, 2023.
6. Moldofsky H, Inhaber NH, Guinta DR, et al. Effects of sodium oxybate on sleep physiology and sleep/wakerelated symptoms in patients with fibromyalgia syndrome: a double-blind, randomized, placebo-controlled study. J Rheumatol. 2010; 37(10): 2156-2166. Available at: https://pubmed.ncbi.nlm.nih.gov/20682669/. Accessed December 08, 2023.
7. Scharf MB, et al. The effects of sodium oxybate on clinical symptoms and sleep patterns in patients with fibromyalgia. J Rheumatol. 2003; 30(5): 1070-1074. Available at: https://pubmed.ncbi.nlm.nih.gov/12734908/. Accessed December 08, 2023.
8. Abad VC, Guilleminault C. New developments in the management of narcolepsy. Nat Sci Sleep. 2017;9:39-57. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5344488/. Accessed December 08, 2023.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Clinical Policy Title and lines of business updated. 2. Continued therapy II.A.1. was rephrased to “Currently receiving medication that has been authorized by RxAdvance….”. 3. Initial and continued therapy approval duration was updated from “Length of benefit” to 12 months for Commercial and included Medicaid & HIM approval duration. 4. References were reviewed and updated.	06/26/2020	09/14/2020
Policy reviewed and updated. 1. Xywav added to the policy. 2. Initial criteria for approval and duration of approval updated. 3. References updated.	01/29/2021	03/09/2021
Policy was reviewed:	12/02/2021	01/17/2022

1. Initial Approval Criteria, I.5 : Updated trial and failure criteria from Failed at least two (2) of the following antidepressants, each used for one-month or longer, unless all are contraindicated or clinically significant adverse effects are experienced selective serotonin inhibitor (e.g., fluoxetine, sertraline, paroxetine),tricyclic antidepressant (e.g., clomipramine, protriptyline),or venlafaxine to Failure at least two (2) of the following antidepressants, each used for one-month or longer, unless all are contraindicated or clinically significant adverse effects are experienced (a, b or c):: a. A selective serotonin inhibitor (e.g., fluoxetine, sertraline, paroxetine);, b. Ticyclic antidepressant (e.g., clomipramine, protriptyline);, c. or venlafaxine. 2. Initial approval criteria I.B.7 was updated to remove , For members 18 years of age or older, the member has tried and failed at least a one-month trial of solriamfetol (Sunosi™) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced; 3. Initial Approval Criteria, 1.C: Updated to include approval criteria for indication, Idiopathic Hypersomnia. 4. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 5. Therapeutic Alternatives was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance..". 6. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria, I.A.2: Updated diagnostic criteria from Diagnosis has been confirmed through sleep lab evaluation [e.g., polysomnography and/or multiple sleep latency test (MSLT)];to Diagnosis has been confirmed through any one of the followings (a or b) a. sleep lab evaluation [e.g., polysomnography and/or multiple sleep latency test (MSLT)]; b. Lumbar puncture shows cerebrospinal fluid (CSF) hypocretin-1 level ≤ 110 pg/mL; 2. Initial Approval Criteria,I.A.5: Updated to remove trial and failure criteria for two antidepressants. 3. Initial Approval Criteria, I.B.5: Updated to remove amphetamine and dextroamphetamine immediate release and extended release. 4. Initial Approval Criteria, I.B.6: Updated trial and failure criteria from Age ≥ 18 years, the member has tried and	10/18/2022	01/17/2023

failed at least a one-month trial of armodafinil or modafinil, unless contraindicated or clinically significant adverse effects are experienced; to Age ≥ 17 years, the member has tried and failed at least a one-month trial of armodafinil or modafinil at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced; 5. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed. 1. Updated approval duration. 2. Removed prior dosing criteria. 3. Removed requirement to try/fail Nuvigil or Provigil for Narcolepsy with Excessive Daytime Sleepiness. 4. Removed reauthorization requirement for positive response to therapy. 5. References were reviewed and updated.	12/08/2023	01/01/2024