SmartPA Criteria Proposal

Drug/Drug Class:	Narcolepsy Inhibitors Clinical Edit
First Implementation Date:	August 27, 2013
Proposed Date:	September 16, 2021
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of narcolepsy inhibitors

Why Issue Selected: Narcolepsy is a chronic sleep disorder characterized by excessive daytime sleepiness and a neurological inability to regulate sleep-wake cycles. It affects an estimated 1 in 2,000 people in the United States. Excessive Daytime Sleepiness (EDS) is the primary symptom of narcolepsy, characterized by the inability to stay awake and alert during the day and resulting in unplanned lapses into sleep or drowsiness. The sleepiness may be so severe that patients with narcolepsy can rapidly doze off with little warning. Other primary symptoms include cataplexy, sleep related hallucinations, sleep paralysis, and sleep disruption. While all patients with narcolepsy experience excessive daytime sleepiness, they may not experience all primary symptoms. Obstructive Sleep Apnea (OSA) is the most common sleep-related breathing disorder and is also associated with excessive daytime sleepiness. The estimated prevalence of OSA in the United States is approximately 15% in males and 5% in females. Although the underlying cause is different, EDS in OSA is treated similarly to EDS due to narcolepsy.

Provigil® (modafinil) and Nuvigil® (armodafinil) are indicated to improve wakefulness in adult patients with excessive sleepiness associated with OSA, narcolepsy, or shift work disorder; these first-line therapies have been widely and safely used since 1998. Sunosi® (solriamfetol), FDA approved in 2019, is indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or OSA. Also FDA approved in 2019, Wakix® (pitolisant) is indicated for treatment of excessive daytime sleepiness or cataplexy in adult patients with narcolepsy; Wakix is the first H3 receptor antagonist and the first non-controlled substance approved to treat narcolepsy.

Xyrem® (sodium oxybate) was FDA approved in 2002 and is indicated for the treatment of cataplexy or excessive daytime sleepiness in patients ≥ 7 years old with narcolepsy. In July 2020, the FDA approved Xywav™ (calcium, magnesium, potassium, and sodium oxybates), a low-sodium alternative to Xyrem with the same indications as Xyrem. Then on August 12, 2021, the FDA granted another indication to Xywav for the treatment of idiopathic hypersomnia in adults. Idiopathic hypersomnia is a chronic neurologic sleep disorder characterized by EDS that persists even with adequate or prolonged nighttime sleep. Both Xyrem and Xywav

can cause decreased consciousness and are subject to a REMS program due to risks of CNS depression and abuse.

Program-Specific Information:

Date Range FFS 7-1-2020 to 6-30-2021			
Drug	**Claims**	**Spend**	**Avg Spend per Claim**
NUVIGIL 50 MG TAB	39	$812.84	$20.84
NUVIGIL 150 MG TAB	235	$9,935.70	$42.27
NUVIGIL 200MG TAB	73	$2,406.99	$32.97
NUVIGIL 250 MG TAB	493	$22,536.44	$45.71
PROVIGIL 100 MG TAB	524	$16,190.56	$30.89
PROVIGIL 200 MG TAB	1,122	$42,920.83	$38.25
SUNOSI 75MG TAB	43	$26,459.12	$615.32
SUNOSI 150MG TAB	78	$49,510.41	$634.74
WAKIX 4.45 MG TAB	8	$11,799.16	$1,474.89
WAKIX 17.8 MG TAB	55	$545,318.28	$9,914.87
XYREM 500 MG/ML SOLN	125	$1,788,469.20	$14,307.75
XYWAV 0.5 GM/ML SOLN	15	$184,173.27	$12,278.21

Type of Criteria: ☒ **Increased risk of ADE** ☐ **Preferred Drug List** ☒ **Appropriate Indications** ☒ **Clinical Edit**

Data Sources: ☐ **Only Administrative Databases** ☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Narcolepsy inhibitors
- Age range: All appropriate MO HealthNet participants aged 7 years and older

Approval Criteria

- Documented compliance to current therapy ~~without concurrent stimulant use~~ (90 days in the past 120 days) **OR**
- For modafinil and armodafinil:
  - ~~Participant age ≥ 16 years for modafinil AND~~
  - Participant age ≥ 17 years ~~for armodafinil~~ **AND**
  - Documented diagnosis of one of the following:
    - Obstructive sleep apnea with history of CPAP
    - Shift work disorder
    - Narcolepsy
    - Hypersomnia
    - Fatigue related to multiple sclerosis
- For Sunosi:
  - Participant age ≥ 18 years **AND**
  - Documented trial of modafinil or armodafinil in the past year **AND**
  - Documented diagnosis of obstructive sleep apnea with history of CPAP **OR**
  - Documented diagnosis of narcolepsy
    - Documented trial of a stimulant in the past year
- For Wakix:
  - Participant age ≥ 18 years **AND**
  - **Documented diagnosis of narcolepsy with cataplexy OR**
  - Documented diagnosis of narcolepsy
    - Documented trial of modafinil or armodafinil in the past year **AND**

        - Documented trial of a stimulant in the past year **AND**
        - Documented trial of Sunosi in the past year **OR**
    - **Documented diagnosis of idiopathic hypersomnia**
        - **Documented trial of modafinil or armodafinil in the past year AND**
        - **Documented trial of a stimulant in the past year**
- For Xyrem **or Xywav**:
    - **Claim for Xywav: Clinical Consultant Review required**
    - Documented diagnosis of narcolepsy with cataplexy
        - Participant age ≥ 7 years and < 18 years
        - **Participant age ≥ 18 years: documented trial of Wakix in the past year**
    - Documented diagnosis of narcolepsy with excessive daytime sleepiness
        - Participant age ≥ 7 years and < 18 years: documented trial of a stimulant in the past year
        - Participant age ≥ 18 years:
            - Documented trial of modafinil or armodafinil in the past year **AND**
            - Documented trial of a stimulant in the past year **AND**
            - Documented trial of Sunosi in the past year **AND**
            - Documented trial of Wakix in the past year
    - **Documented diagnosis of idiopathic hypersomnia:**
        - **Participant age ≥ 18 years AND**
        - **Documented trial of modafinil or armodafinil in the past year AND**
        - **Documented trial of a stimulant in the past year AND**
        - **Documented trial of Wakix in the past year**

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Claim exceeds daily dosing limitations (see Appendix A)
- For Xyrem:
    - Documented history of substance abuse **OR**
    - Documented history of renal impairment **OR**
    - Documented history of heart failure **OR**
    - Documented history of uncontrolled hypertension in the past year **OR**
    - Documented history of suicide attempt
- **For Xywav:**
    - **Documented history of substance abuse OR**
    - **Documented history of suicide attempt**
- For Wakix: Documented diagnosis of severe hepatic impairment

Required Documentation

Laboratory Results:		Progress Notes:	
MedWatch Form:		Other:	X

Disposition of Edit

Denial: Exception code “0682” (Clinical Edit)
Rule Type: CE

Default Approval Period

1 year

Appendix A

Drug Description	Generic Equivalent	Max Units per Day
Nuvigil 150 mg tablet	armodafinil	1 tablet
Nuvigil 200 mg tablet	armodafinil	1 tablet
Nuvigil 250 mg tablet	modafinil	1 tablet
Nuvigil 50 mg tablet	armodafinil	1 tablet
Provigil 100 mg tablet	modafinil	2 tablets
Provigil 200 mg tablet	modafinil	2 tablets
Sunosi 150mg tablet	solriamfetol	1 tablet
Sunosi 75mg tablet	solriamfetol	1 tablet
Wakix 17.8mg tablet	pitolisant	2 tablets
Wakix 4.45mg tablet	pitolisant	2 tablets
Xyrem 500 mg/ml solution	sodium oxybate	18 milliliters
Xywav 500 mg/ml solution	**sod, cal, mag, pot oxybate**	**18 milliliters**

References

- NUVIGIL® (armodafinil) [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; July 2019.
- PROVIGIL® (modafinil) [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; August 2021.
- SUNOSI® (solriamfetol) [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; June 2019.
- WAKIX® (pitolisant) [package insert]. Plymouth Meeting, PA: Harmony Biosciences, LLC; March 2021.
- XYREM® (sodium oxybate) [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; September 2020.
- XYWAV™ (calcium, magnesium, potassium, and sodium oxybates) [package insert]. Palo Alto, CA: Jazz Pharmaceuticals, Inc.; August 2021.
- Maski K, et al. Treatment of central disorders of hypersomnolence: an American Academy of Sleep Medicine clinical practice guideline. Journal of Clinical Sleep Medicine. Published online April 23, 2021. https://doi.org/10.5664/jcsm.9328
- Trotti LM, Arnulf I. Idiopathic Hypersomnia and Other Hypersomnia Syndromes. Neurotherapeutics 18, 20–31 (2021). https://doi.org/10.1007/s13311-020-00919-1
- Trotti LM, Becker LA, Friederich Murray C, Hoque R. Medications for daytime sleepiness in individuals with idiopathic hypersomnia. Cochrane Database Syst Rev. 2021;5(5):CD012714. Published 2021 May 25. doi:10.1002/14651858.CD012714.pub2
- IPD Analytics. CNS: Sleep Disorders. Accessed August 5, 2021.
- IPD Analytics. New Drug Approval: Sunosi (solriamfetol). May 2019.
- IPD Analytics. New Drug Approval: Wakix (pitolisant). September 2019.