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**Request for Prior Authorization for Narcoleptic Agents**
**Website Form – www.highmarkhealthoptions.com**
**Submit request via: Fax - 1-855-476-4158**

All requests for Drug/Class require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

For all requests for Xywav (calcium, magnesium, potassium, and sodium oxybates), Xyrem (sodium oxybate), Lumryz (sodium oxybate) Wakix (pitolisant), Sunosi (solriamfeteol) and similar agents all of the following criteria must be met:

- Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- Must be prescribed by or in consultation with a neurologist or sleep specialist
- Documentation within any time frame that the member has had daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months.
- For Sunosi: Ensure underlying airway obstruction is treated (e.g., with continuous positive airway pressure (CPAP) for minimum 30 days prior to initiating. Modalities to treat underlying airway obstruction should be continued during treatment.

For all requests for Provigil (modafinil) and Nuvigil (armodafinil) all of the following criteria must be met:

- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature
- The member is not receiving concurrent treatment with a sedative hypnotic for the diagnosis of Narcolepsy or Obstructive Sleep Apnea/Hypopnea Syndrome.

Coverage may be provided with a diagnosis of **excessive daytime sleepiness (EDS) associated with narcolepsy** the following criteria is met:

- Documentation of a baseline Epworth Sleepiness Scale score or Epworth Sleepiness Scale (Child and Adolescent) Score
- Documentation of at least one of the following:
  - Cerebrospinal fluid hypocretin-1 deficiency one-third less than normal or <110 pg/mL
  - Polysomnography sleep study test with REM sleep latency ≤ 15 minutes.
  - Multiple sleep latency testing with a mean sleep latency ≤ 8 minutes and ≥ 2 sleep onset REM sleep periods (SOREMP)
- For Wakix:
  - must provide documentation showing the member has tried and failed three (3) products, two (2) of which must be a preferred product and one of which must be Sunosi, required before product will be approved.

- For Xywav:
  - must provide documentation showing the member has tried and failed three (3) products, two (2) of which must be a preferred product and one of which must be Sunosi, required before product will be approved.
  - Must also provide documentation showing the member has tried and failed or had an intolerance or contraindication to Xyrem (sodium oxybate),
- For Lumryz:
  - must provide documentation showing the member has tried and failed or had an intolerance or contraindication to Xyrem (sodium oxybate)
- For all other medications:
  - Must provide documentation showing the member has tried and failed or had an intolerance or contraindication to one of the following: (please note all require a prior authorization)
    - Modafinil
    - Armodafinil

Coverage may be provided with a diagnosis of **excessive daytime sleepiness (EDS) associated with obstructive sleep apnea** for Sunosi the following criteria is met:

- Documentation of a baseline Epworth Sleepiness Scale score or Epworth Sleepiness Scale (Child and Adolescent) Score
- Documentation of at least one of the following:
  - Cerebrospinal fluid hypocretin-1 deficiency one-third less than normal or <110 pg/mL
  - Polysomnography sleep study test with REM sleep latency ≤ 15 minutes.
  - Multiple sleep latency testing with a mean sleep latency ≤ 8 minutes and ≥ 2 sleep onset REM sleep periods (SOREMP)
- Must provide documentation showing the member has tried and failed or had an intolerance or contraindication to one of the following: (please note all require a prior authorization)
    - Modafinil
    - Armodafinil

Coverage may be provided with a diagnosis of **cataplexy with narcolepsy** for Wakix, Xyrem, Xywav, Lumryz, Provigil and Nuvigil the following criteria for is met:

- Documentation of weekly cataplexy attacks at baseline prior to treatment with Xywav OR Xyrem
- Documentation of at least one of the following:
  - Cerebrospinal fluid hypocretin-1 deficiency one-third less than normal or <110 pg/mL
  - Polysomnography sleep study test with REM sleep latency ≤ 15 minutes.
  - Multiple sleep latency testing with a mean sleep latency ≤ 8 minutes and ≥ 2 sleep onset REM sleep periods
- If requesting Xywav or Lumryz (sodium oxybate), must provide documentation showing the member has tried and failed or had an intolerance or contraindication to Xyrem (sodium oxybate).
- For Provigil or Nuvigil: Documentation within any time frame that the member has daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least 3 months.

Coverage may be provided with a diagnosis of **narcolepsy without cataplexy** for Nuvigil or Provigil and the following criteria is met:

- Documentation within any time frame that the member has 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:

- Cerebrospinal fluid (CSF) hypocretin-1 deficiency one-third less than normal or <110 pg/mL
- Polysomnogram sleep study test with REM sleep latency ≤ 15 minutes
- Multiple sleep latency testing with a mean sleep latency ≤ 8 minutes with ≥ 2 sleep onset REM sleep periods (SOREMP)

Coverage may be provided with a diagnosis of **idiopathic hypersomnia** Nuvigil, Provigil and Xywav if the following criteria is met:

- Documentation of a baseline Epworth Sleepiness Scale score OR documentation of a baseline Idiopathic Hypersomnia Severity Score
- Insufficient sleep syndrome is confirmed absent via at least a week of wrist actigraphy or lack of improvement after an adequate trial of increased nocturnal time in bed
- Documentation of a MSLT showing fewer than 2 SOREMPs, OR, no SOREMPs, if the REM latency on the preceding sleep study was ≥ 15 minutes
- Cataplexy is confirmed to be absent
- Must provide documentation of at least one of the following:
  - MSLT shows a mean sleep latency of ≤8 minutes
  - Total 24-hour sleep time is ≥660 minutes (typically 12 to 14 hours) on 24-hour polysomnography or by wrist actigraphy in association with a sleep log
- For Xywav must provide documentation showing the member has tried and failed or had an intolerance or contraindication to one of the following: (please note all require a prior authorization for members 21 years of age and older)
  - Modafinil
  - Armodafinil

Coverage may be provided with a diagnosis of **Obstructed Sleep Apnea/Hypopnea Syndrome (OSAHS)** for Nuvigil, Provigil and the following criteria is met:

- OSAHS is documented by at least one of the following tests: Polysomnogram, Apnea Hypopnea Index and/or a Respiratory Disturbance Index (RDI) score showing greater than 5 obstructive apneas per hour, each greater than 10 seconds in duration
- Must have documentation from the physician that the member is compliant with using a CPAP (continuous positive airway pressure) machine on a regular basis, defined by at least four (4) hours a night on at least 70% of the nights
- Must have documentation from the physician that the CPAP machine failed to resolve excessive daytime sleepiness demonstrated by either Epworth Sleepiness Scale (ESS) greater than 10 or Multiple Sleep Latency Test less than 6 minutes.

Coverage may be provided with a diagnosis of **Chronic Fatigue due to Multiple Sclerosis** Provigil (modafinil) and the following criteria is met:

- The member is receiving, or is intolerant to, treatment for multiple sclerosis
- The member experienced a trial and failure of amantadine

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Coverage may be provided with a diagnosis of **Shift-work Sleep Disorder** for Nuvigil, Provigil and the following criteria is met:

- Member has chronic excessive sleepiness for at least 3 months
- There is documentation of the member's recurring work schedule with a minimum of 5 night shifts per month
- Documentation is provided that indicates shift-work results in sleepiness on the job or insomnia at home which interferes with activities of daily living
- Primary symptoms are associated with a work period (particularly night shift) that occurs during the habitual sleep phase
- Documentation of a sleep log or actigraphy for at least 14 days

**For Lumryz, Wakix, Xyrem, Xywav:**

**Initial Duration of Approval:** 3 months
**Reauthorization criteria**
- For Excessive daytime sleepiness associated with narcolepsy
  - Documentation of an improvement in Epworth Sleepiness Scale score from baseline
- For cataplexy with narcolepsy
  - Documentation of a decrease in the number of cataplexy attacks from baseline
- For idiopathic hypersomnia
  - Documentation of an improvement in Epworth Sleepiness Scale score from baseline OR improvement in Idiopathic Hypersomnia Severity Score.

**Reauthorization Duration of Approval:** 12 months

**For Nuvigil, Provigil:**

**Initial Duration of Approval:**
For idiopathic hypersomnia: 3 months
For all other above diagnoses: 12 months
**Reauthorization criteria**
For idiopathic hypersomnia:
- Documentation of an improvement in Epworth Sleepiness Scale score from baseline OR improvement in Idiopathic Hypersomnia Severity Score.

For shift-work sleep disorder:
- Documentation the member has experienced an improvement in symptoms
- Documentation is submitted showing the member's recurring work schedule showing a minimum of 5 night shifts per month

For all other above diagnoses:
- Documentation the member has experienced an improvement in symptoms

**Reauthorization Duration of approval:** 12 months

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Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only the branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product is medically necessary.

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**NARCOLEPTIC AGNETS: Kawix, Lumryz, Sunosi, Xyrem, Xywav -PRIOR AUTHORIZATION FORM (page 1 of 2)**

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX: (855) 476-4158**
If needed, you may call to speak to a Pharmacy Services Representative.
**PHONE**: (844) 325-6251 Monday through Friday 8:00am to 7:00pm

**PROVIDER INFORMATION**

| | |
|---|---|
| Requesting Provider: | NPI: |
| Provider Specialty: | Office Contact: |
| Office Address: | Office Phone: |
| | Office Fax: |

**MEMBER INFORMATION**

| | | |
|---|---|---|
| Member Name: | DOB: | |
| Member ID: | Member weight: | Height: |

**REQUESTED DRUG INFORMATION**

| | | |
|---|---|---|
| Medication: | Strength: | |
| Directions: | Quantity: | Refills: |
| Is the member currently receiving requested medication? ☐ Yes ☐ No | Date Medication Initiated: | |

Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No

**Billing Information**

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

**Place of Service Information**

| | |
|---|---|
| Name: | NPI: |
| Address: | Phone: |
| | |

Diagnosis: ☐ Excessive daytime sleepiness with narcolepsy ☐ Cataplexy associated with narcolepsy ☐ Idiopathic hypersomnia ☐ Other: _____
(Please provide chart documentation to support the above diagnosis please include sleep study results)

If member has excessive daytime sleepiness associated with narcolepsy, please provide a baseline Epworth Sleepiness Scale score or Epworth Sleepiness Scale Child and Adolescent Score: _____ Date taken:_____

If the member has cataplexy, please provide baseline number of weekly cataplexy attacks _____ Date: _____

If the member has idiopathic hypersomnia, please provide a baseline Epworth Sleepiness Scale score OR Idiopathic Hypersomnia Severity Score. ☐ ESS:_____ ☐ IHSS:_____ Date:_____

**CURRENT or PREVIOUS THERAPY**

| Medication Name | Strength/ Frequency | Dates of Therapy | Status (Discontinued & Why/Current) |
|---|---|---|---|
| | | | |
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| NARCOLEPTIC AGENTS: Kawix, Lumryz, Sunosi, Xyrem, Xywav – PRIOR AUTHORIZATION FORM (PAGE 2 OF 2) |
|---|
| Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX:** (855) 476-4158<br>If needed, you may call to speak to a Pharmacy Services Representative.<br>**PHONE**: (844) 325-6251 Monday through Friday 8:00am to 7:00pm |

| **MEMBER INFORMATION** | | |
|---|---|---|
| Member Name: | DOB: | |
| Member ID: | Member weight: | Height: |

**REAUTHORIZATION**

Has the member experienced a significant improvement with treatment? ☐ Yes ☐ No

If member has excessive daytime sleepiness associated with narcolepsy please provide an Epworth Sleepiness Scale score taken after initiating therapy: _____ Date taken:_____

If the member has cataplexy please provide the number of weekly cataplexy attacks since initiating therapy _____
Date: _____

If the member has idiopathic hypersomnia, please provide a Epworth Sleepiness Scale score OR Idiopathic Hypersomnia Severity Score since initiating therapy. ☐ ESS:_____ ☐ IHSS:_____ Date:_____

**SUPPORTING INFORMATION or CLINICAL RATIONALE**

| **Prescribing Provider Signature** | Date |
|---|---|
| | |

NARCOLEPTIC AGENTS: Provigil (Modafinil) and Nuvigil (Armodafinil) Prior Authorization Form – next page.

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**NARCOLEPTIC AGENTS: PROVIGIL (MODAFINIL) AND NUVIGIL (ARMODAFINIL)**
**PRIOR AUTHORIZATION FORM (page 1 of 2)**

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX:** (855) 476-4158
If needed, you may call to speak to a Pharmacy Services Representative.
**PHONE**: (844) 325-6251 Monday through Friday 8:00am to 7:00pm

**PROVIDER INFORMATION**

| | |
|---|---|
| Requesting Provider: | NPI: |
| Provider Specialty: | Office Contact: |
| Office Address: | Office Phone: |
| | Office Fax: |

**MEMBER INFORMATION**

| | | |
|---|---|---|
| Member Name: | DOB: | |
| Member ID: | Member weight: | Member height: |

**REQUESTED DRUG INFORMATION**

| | |
|---|---|
| Medication: | Strength: |
| Frequency: | Duration: |
| Is the member currently receiving requested medication? ☐ Yes ☐ No | Date Medication Initiated: |

Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient?
☐ Yes ☐ No

**Billing Information**

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

**Place of Service Information**

| | |
|---|---|
| Name: | NPI: |
| Address: | Phone: |
| | |

**MEDICAL HISTORY (Complete for ALL requests)**

Diagnosis:

| | |
|---|---|
| ☐ **Narcolepsy** | Is the patient receiving concurrent treatment with a sedative hypnotic? ☐ Yes ☐ No<br>Is a sleep study attached? ☐ Yes ☐ No<br>**For reauthorization only:**<br>Has the member experienced an improvement in symptoms? ☐ Yes ☐ No |
| ☐ **Obstructive Sleep Apnea/Hypopnea Syndrome (OSAHS)** | Is the patient receiving concurrent treatment with a sedative hypnotic? ☐ Yes ☐ No<br>Is a sleep study attached? ☐ Yes ☐ No<br>Please provide documentation of patient's compliance with a CPAP machine.<br>**For reauthorization only:**<br>Has the member experienced an improvement in symptoms? ☐ Yes ☐ No |
| ☐ **Shift-work Sleep Disorder** | Please provide documentation of the member's recurring work schedule.<br>Please provide chart documentation that shift-work results in sleepiness on the job or insomnia at home that interferes with daily living.<br>Are there any other medical, mental, or sleep disorders that could account for symptoms of excessive sleepiness? If yes, please list: ☐ Yes ☐ No<br>_____<br>Please provide documentation of a sleep log or actigraphy for at least 14 days.<br>**For reauthorization only:**<br>Has the member experienced an improvement in symptoms? ☐ Yes ☐ No<br>Please provide member's work schedule |

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| NARCOLEPTIC AGENTS: PROVIGIL (MODAFINIL) AND NUVIGIL (ARMODAFINIL)<br>PRIOR AUTHORIZATION FORM (page 2 of 2) | |
|---|---|
| Member Name: | DOB: |
| Member ID: | Member weight: _____pounds or _____kg |
| **Fatigue secondary to Multiple Sclerosis (MS) (modafinil only)** | Is the member on an agent to treat multiple sclerosis?<br>☐ Yes ☐ No<br>Has the member had a trial and failure of amantadine?<br>☐ Yes ☐ No<br>If no, provide clinical rationale as to why amantadine cannot be used:<br>_____<br>**For reauthorization only:**<br>Has the member experienced an improvement in symptoms?<br>☐ Yes ☐ No |
| **Idiopathic Hypersomnia** | Is the member experiencing cataplexy? ☐<br>Yes ☐ No<br>Is the sleep study or actigraphy attached?<br>☐ Yes ☐ No |

**REFERENCE VALUES**

| Lab | Initial (Pre-Treatment) Score | Date | Post-Therapy Score (Reauthorization only) | Date |
|---|---|---|---|---|
| **Maintenance of Wakefulness Test (MWT) [for Narcolepsy or OSAHS only)** | | | | |
| **Epworth Sleepiness Scale (ESS) [ OSAHS and idiopathic hypersomnia]** | | | | |
| **Idiopathic Hypersomnia Severity Score ( idiopathic hypersomnia only)** | | | | |
| **Multiple Sleep Latency Test (MSLT) [not necessary for Chronic Fatigue secondary to MS]** | | | | |

**CURRENT or PREVIOUS THERAPY**

| Medication Name | Strength/ Frequency | Dates of Therapy | Status (Discontinued & Why / Current) |
|---|---|---|---|
| | | | |
| | | | |

**SUPPORTING INFORMATION or CLINICAL RATIONALE**

| Prescribing Provider Signature | Date |
|---|---|
| | |