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ForwardHealth UPDATE

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PHARMACY POLICY CHANGES EFFECTIVE NOVEMBER 1, 2019

This ForwardHealth Update announces that effective November 1, 2019, ForwardHealth has renamed the stimulants—related agents—armodafinil and modafinil drug class to stimulants, related agents - wake promoting. Armodafinil and modafinil remain preferred drugs in this class and do not require prior authorization (PA). ForwardHealth has established clinical criteria for non-preferred drugs in the stimulants, related agents - wake promoting class.

Sunosi has been added to the stimulants, related agents - wake promoting class as a non-preferred drug and requires PA. A dose limit of 150 mg per day has been established for Sunosi. (The dose limits of 250 mg per day for armodafinil and 400 mg per day for modafinil continue to apply.) Sunosi is scheduled to be reviewed by the PA Advisory Committee meeting in November 2019.

AFFECTED PROGRAMS

BadgerCare Plus, Medicaid, SeniorCare

TO

Blood Banks, Community Health Centers, Dentists, Hospital Providers, Nurse Practitioners, Nursing Homes, Pharmacies, Physician Assistants, Physician Clinics, Physicians, Podiatrists, Rural Health Clinics, Tribal Federally Qualified Health Centers, HMOs and Other Managed Care Programs

The information provided in this ForwardHealth Update is published in accordance with Wis. Stat. § 49.45(49).

WISCONSIN DEPARTMENT of HEALTH SERVICES

Additionally, this Update announces revisions to the clinical criteria for Dupixent, a non-preferred drug in the immunomodulators, atopic dermatitis drug class, and introduces clinical criteria for Dupixent for members with chronic rhinosinusitis with nasal polyposis (CRSwNP).

Stimulants, Related Agents - Wake Promoting

New PA Form for Non-Preferred Stimulants, Related Agents - Wake Promoting

ForwardHealth has created the Prior Authorization Drug Attachment for Non-Preferred Stimulants, Related Agents - Wake Promoting form, F-02537 (11/2019), and established clinical criteria that must be documented on PA requests for non-preferred drugs in the stimulants, related agents - wake promoting class. PA requests for non-preferred drugs in the stimulants, related agents - wake promoting class submitted on and after November 1, 2019, must be submitted on the new form or the request will be returned to the provider. Providers may refer to the Forms page of the ForwardHealth Portal for a copy of the form and instructions beginning November 1, 2019.

Submitting PA Requests for Non-Preferred Stimulants, Related Agents - Wake Promoting

PA requests for non-preferred drugs in the stimulants, related agents - wake promoting class must be completed, signed, and dated by the prescriber. The PA form must be sent to the pharmacy where the prescription will be filled. The prescriber may send the PA form to the pharmacy, or the member may carry the PA form with the prescription to the pharmacy. The pharmacy provider will use the completed PA form to submit a PA request to ForwardHealth. Prescribers should **not** submit the PA form to ForwardHealth.

PA requests for non-preferred drugs in the stimulants, related agents - wake promoting class should be submitted using the Prior Authorization Drug Attachment for Non-Preferred Stimulants, Related Agents - Wake Promoting form and the Prior Authorization Request Form (PA/RF), F-11018 (05/2013).

PA requests for non-preferred drugs in the stimulants, related agents - wake promoting class may be submitted on the Portal, by fax, or by

NEW PA FORM

Prior Authorization Drug Attachment for Non-Preferred Stimulants, Related Agents – Wake Promoting, F-02537

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mail (but **not** using the Specialized Transmission Approval Technology-Prior Authorization [STAT-PA] system).

Conditions for Which PA Requests for Non-Preferred Stimulants, Related Agents - Wake Promoting Drugs Will Be Considered for Review

PA requests for non-preferred drugs in the stimulants, related agents - wake promoting class will only be approved for use to treat the following identified clinical conditions:

- Excessive daytime sleepiness associated with narcolepsy
- Excessive daytime sleepiness associated with obstructive sleep apnea (OSA)

Clinical Criteria for Non-Preferred Stimulants, Related Agents - Wake Promoting Drugs for Members With Narcolepsy

Clinical criteria for approval of PA requests for non-preferred drugs in the stimulants, related agents - wake promoting class for members with narcolepsy are **all** of the following:

- The member is 18 years of age or older.
- The member has excessive daytime sleepiness associated with narcolepsy.
- An overnight polysomnogram (PSG) sleep study and multiple sleep latency test have been performed for the member using standard protocols, and the prescribing provider has submitted medical record documentation supporting a clinical correlation between the test results and a diagnosis of narcolepsy.
- The overnight PSG test results and provider interpretation have been submitted with the PA request and include documentation of the following:
  - The member's total sleep time was at least 360 minutes.
  - The member experienced minimal sleep interruptions (for example, respiratory events or periodic leg movements).
  - The provider interpretation indicates that an adequate night's sleep was achieved.
- The multiple sleep latency test results and provider interpretation have been submitted with the PA request and include documentation of the following:

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Stimulants, Related Agents - Wake Promoting (#19878)

  - The multiple sleep latency test was conducted the morning after the overnight PSG.
  - The average sleep latency for all naps was eight minutes or less.
  - The member achieved at least two sleep onset rapid eye movement periods. (A sleep onset rapid eye movement period within 15 minutes of sleep onset on the preceding nocturnal PSG may replace one of the sleep onset rapid eye movement periods on the multiple sleep latency test.)
- The member is not currently taking any other drugs in the stimulants, related agents - wake promoting class.
- The member is not taking any sedative hypnotics.
- For members currently taking central nervous system depressants (for example, anxiolytics, barbiturates, or opioids), the prescriber has evaluated the central nervous system depressants and determined they are not contributing to the member's excessive daytime sleepiness.
- **At least one** of the following is true:
  - The member has tried armodafinil and experienced an unsatisfactory therapeutic response after the medication had been titrated to a maximum recommended daily dose.
  - The member experienced a clinically significant adverse drug reaction with armodafinil.
  - The member has a medical condition that prevents treatment with armodafinil.
  - There is a clinically significant drug interaction with another medication the member is taking and armodafinil.
- **At least one** of the following is true:
  - The member has tried modafinil and experienced an unsatisfactory therapeutic response after the medication had been titrated to a maximum recommended daily dose.
  - The member experienced a clinically significant adverse drug reaction with modafinil.
  - The member has a medical condition that prevents treatment with modafinil.
  - There is a clinically significant drug interaction with another medication the member is taking and modafinil.

If initial clinical criteria for non-preferred drugs in the stimulants, related agents - wake promoting class for members with narcolepsy are met, PA

requests may be approved for up to a maximum of 183 days. Renewal PA requests for non-preferred drugs in the stimulants, related agents - wake promoting class may be approved for up to a maximum of 365 days.

Clinical Criteria for Non-Preferred Stimulants, Related Agents - Wake Promoting Drugs for Members With OSA

Clinical criteria for approval of PA requests for non-preferred drugs in the stimulants, related agents - wake promoting class for members with OSA are **all** of the following:

- The member is 18 years of age or older.
- The member has excessive daytime sleepiness associated with OSA.
- The member has had an overnight PSG sleep study with an apnea-hypopnea index greater than or equal to five events per hour, confirming the member has OSA. The date of the PSG and the resulting apnea-hypopnea index must be included with the PA request.
- The member is not currently taking any other drugs in the stimulants class **or** the stimulants, related agents - wake promoting class.
- The member is currently using continuous positive airway pressure (CPAP) and will continue to use CPAP in combination with the non-preferred stimulants, related agents - wake promoting drug.
- **At least one** of the following is true:
  - The member has tried armodafinil and experienced an unsatisfactory therapeutic response after the medication had been titrated to a maximum recommended daily dose.
  - The member experienced a clinically significant adverse drug reaction with armodafinil.
  - The member has a medical condition that prevents treatment with armodafinil.
  - There is a clinically significant drug interaction with another medication the member is taking and armodafinil.
- **At least one** of the following is true:
  - The member has tried modafinil and experienced an unsatisfactory therapeutic response after the medication had been titrated to a maximum recommended daily dose.
  - The member experienced a clinically significant adverse drug reaction with modafinil.
  - The member has a medical condition that prevents treatment with modafinil.

QUICK LINKS

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- There is a clinically significant drug interaction with another medication the member is taking and modafinil.

Note: If requested by ForwardHealth, the provider is required to submit the test results and provider interpretation for the PSG.

If initial clinical criteria for non-preferred drugs in the stimulants, related agents - wake promoting class for members with OSA are met, PA requests may be approved for up to a maximum of 183 days. Renewal PA requests for non-preferred stimulants, related agents - wake promoting drugs may be approved for up to a maximum of 365 days.

Stimulants and Stimulants, Related Agents - Wake Promoting Drugs Quantity Limits

Quantity limits apply to all preferred and non-preferred stimulants **and** stimulants, related agents - wake promoting drugs, with the exception of liquid dosage forms. When a claim is submitted with a quantity that exceeds the limit, the claim will be denied. Quantity limits do not apply to liquid dosage forms.

All drugs in the stimulants class **and** stimulants, related agents - wake promoting class (with the exception of liquid dosage forms) have a cumulative quantity limit of 136 units per month. Members are limited to a combined total of 136 units (tablets, capsules, or patches) per month, with the exception of members with narcolepsy. Members with narcolepsy are allowed a quantity limit override to receive up to 136 units of stimulants in addition to 250 mg of armodafinil per day **or** 400 mg of modafinil per day **or** 150 mg of Sunosi per day.

> **Members with narcolepsy may receive up to 136 units of stimulants in addition to 250 mg of armodafinil or 400 mg of modafinil or 150 mg of Sunosi.**

ForwardHealth will not consider dose limit overrides for drugs in the stimulants, related agents - wake-promoting class.

The Quantity Limit Drugs and Diabetic Supplies data table on the Pharmacy Resources page of the Portal contains the most current quantity limits.

Dupixent

ForwardHealth has revised the existing clinical criteria for use of Dupixent and has added clinical criteria for treatment of chronic rhinosinusitis with

nasal polyposis (CRSwNP). ForwardHealth will honor PA requests approved before November 1, 2019, until they expire or until the approved days' supply is used up.

Submitting PA Requests for Dupixent

PA requests for Dupixent must be completed, signed, and dated by the prescriber. PA requests for Dupixent should be submitted using Section VI of the Prior Authorization/Drug Attachment (PA/DGA) form, F-11049 (07/2016), and the PA/RF. Clinical documentation supporting the use of Dupixent must be submitted with the PA request.

The PA form must be sent to the pharmacy where the prescription will be filled. The prescriber may send the PA form to the pharmacy, or the member may carry the PA form with the prescription to the pharmacy. The pharmacy provider will use the completed PA form to submit a PA request to ForwardHealth. Prescribers should **not** submit the PA form to ForwardHealth.

PA requests for Dupixent may be submitted on the Portal, by fax, or by mail (but **not** using the STAT-PA system).

PA requests will not be approved for Dupixent that will be administered in a medical office or medical facility.

Note: ForwardHealth will not consider the following as criteria to support the need for Dupixent:

- Non-adherence to previous medication therapies
- Member or prescriber preference
- The use of samples to start a member on a medication

Conditions for Which PA Requests for Dupixent Will Be Considered for Review

PA requests for Dupixent will only be approved for use to treat the following identified clinical conditions:

- CRSwNP
- Moderate to severe atopic dermatitis
- Moderate to severe asthma with an eosinophilic phenotype
- Oral corticosteroid dependent asthma

QUICK LINKS

Prior Authorization/Drug Attachment (#15937)

The information provided in this ForwardHealth Update is published in accordance with Wis. Stat. § 49.45(49).

Clinical Criteria for Dupixent for Members With CRSwNP

Clinical criteria that must be documented for approval of a PA request for Dupixent for members with CRSwNP are **all** of the following:

- The member is 18 years of age or older.
- The member has CRSwNP.
- The following documentation must be submitted:
  - Size and location of nasal polyps
  - Severity of nasal congestion
  - Past nasal surgery history
  - Plans for future nasal surgery
- The prescription is written by or through consultation with an allergist or an ear, nose, and throat specialist.
- The member has been adherent to and maintained on a maximized CRSwNP treatment regimen, including an intranasal corticosteroid for at least three months prior to requesting Dupixent. Documentation should include the CRSwNP drug treatment names, doses, and start dates.
- The member will not use Dupixent in combination with other interleukin receptor antagonists (for example, Cinqair, Fasenra, or Nucala) or Xolair.

A copy of the member's medical records must be submitted with all PA requests for Dupixent. Medical records should document the following:

- The member's medical condition being treated
- Details regarding previous medication use
- The member's current treatment plan

If clinical criteria for Dupixent are met, initial PA requests may be approved for up to a maximum of 183 days. Renewal PA requests for Dupixent may be approved for up to a maximum of 365 days.

Renewal PA requests for members who have CRSwNP must meet the clinical criteria for initial PA requests for Dupixent. Renewal requests must include copies of the current medical records demonstrating that the member had a significant reduction in nasal polyp size or severity of congestion compared to the member's baseline prior to the initiation of Dupixent, and that the member has not had recent nasal polyp surgery. Members must also continue to take their maximized CRSwNP treatment

QUICK LINKS

Immunomodulators, Atopic Dermatitis (#8857)

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regimen, including the intranasal corticosteroid, during treatment with Dupixent.

Note: All renewal PA requests require the member to be adherent to the prescribed treatment regimen.

Clinical Criteria for Dupixent for Members With Moderate to Severe Atopic Dermatitis

Clinical criteria that must be documented for approval of a PA request for Dupixent for members with moderate to severe atopic dermatitis are **all** of the following:

- The member is 12 years of age or older.
- The member has moderate to severe atopic dermatitis. Documentation must include the approximate body surface area involved and the area(s) affected.
- The prescription is written by or through consultation with a dermatologist, an allergist, or an immunologist.
- Exacerbating factors that may contribute to the member's atopic dermatitis, such as member non-compliance with therapy, environmental factors, dietary factors, and other similar dermatologic conditions, have been ruled out.
- **At least one** of the following is true:
  - The member has a recent history (within six months of the clinical visit when Dupixent was first prescribed) of use of at least a medium potency topical corticosteroid for at least two months and experienced an unsatisfactory therapeutic response.
  - The member has used at least a medium potency corticosteroid and experienced a clinically significant adverse drug reaction.
- **At least one** of the following is true:
  - The member has a recent history (within six months of the clinical visit when Dupixent was first prescribed) of topical calcineurin inhibitor use for at least two months and experienced an unsatisfactory therapeutic response
  - The member used a topical calcineurin inhibitor and experienced a clinically significant adverse drug reaction.
- The member will not use Dupixent in combination with other interleukin receptor antagonists (for example, Cinqair, Fasenra, or Nucala) or Xolair.

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A copy of the member's medical records must be submitted with all PA requests for Dupixent. Medical records should document the following:

- The member's medical condition being treated
- Details regarding previous medication use
- The member's current treatment plan

If clinical criteria for Dupixent are met, initial PA requests may be approved for up to a maximum of 183 days. Renewal PA requests for Dupixent may be approved for up to a maximum of 365 days.

Renewal PA requests for members who have moderate to severe atopic dermatitis must meet the clinical criteria for initial PA requests for Dupixent. Renewal requests must include copies of current medical records demonstrating the member had a significant reduction in the area(s) affected or severity of atopic dermatitis.

Note: All renewal PA requests require the member to be adherent to the prescribed treatment regimen.

Clinical Criteria for Dupixent for Members With Moderate to Severe Asthma With an Eosinophilic Phenotype

Clinical criteria that must be documented for approval of a PA request for Dupixent for members with moderate to severe asthma with an eosinophilic phenotype are **all** of the following:

- The member is 12 years of age or older.
- The member has moderate to severe asthma with an eosinophilic phenotype. A baseline blood eosinophil count of greater than 150 cells/mcL within the previous three months must be documented.
- The prescription is written by or through consultation with an asthma specialist (for example, an allergist, an immunologist, or a pulmonologist).
- **At least one** of the following is true:
  - The member has a history of two or more asthma exacerbations that required treatment with systemic corticosteroids or an emergency department visit or hospitalization for the treatment of asthma in the past year. Documentation should include the approximate dates and what interventions took place for each exacerbation.

DOCUMENT CHECKLIST

- PA/DGA, F-11049 (07/2016)
- PA/RF, F-11018 (05/2013)
- Clinical documentation

  - The member's baseline forced expiratory volume in one second is less than 80 percent predicted. A baseline forced expiratory volume in one second percent predicted from the previous three months must be documented.
- The member has been adherent to and maintained on a maximized asthma treatment regimen, including a high-dose inhaled corticosteroid (ICS) in combination with a long-acting beta-agonist (LABA) for at least three months prior to requesting Dupixent. Documentation should include the ICS and LABA names, doses, and start dates.
- Exacerbating factors that may contribute to the member's asthma, such as member non-compliance with therapy, environmental factors, dietary factors, and other similar respiratory conditions, have been ruled out.
- The member will not use Dupixent in combination with other interleukin receptor antagonists (for example, Cinqair, Fasenra, or Nucala) or Xolair.

A copy of the member's medical records must be submitted with all PA requests for Dupixent. Medical records should document the following:

- The member's medical condition being treated
- Details regarding previous medication use
- The member's current treatment plan

If clinical criteria for Dupxient are met, initial PA requests may be approved for up to a maximum of 183 days. Renewal PA requests for Dupixent may be approved for up to a maximum of 365 days.

Renewal PA requests for members who have moderate to severe asthma with an eosinophilic phenotype must meet the clinical criteria for initial PA requests for Dupixent. Renewal requests must include copies of current medical records demonstrating the member had a decrease in the number of asthma exacerbations or an increase in forced expiratory volume in one second percent predicted compared to their baseline prior to the initiation of Dupixent. Members must also continue to take their maximized asthma treatment regimen, including an ICS and a LABA, during treatment with Dupixent.

Note: All renewal PA requests require the member to be adherent to the prescribed treatment regimen.

Clinical Criteria for Dupixent for Members With Oral Corticosteroid Dependent Asthma

Clinical criteria that must be documented for approval of a PA request for Dupixent for members with oral corticosteroid dependent asthma are **all** of the following:

- The member is 12 years of age or older.
- The member has oral corticosteroid dependent asthma.
- The prescription is written by or through consultation with an asthma specialist (for example, an allergist, an immunologist, or a pulmonologist).
- The member has been adherent to and maintained on a maximized asthma treatment regimen, including a high-dose ICS in combination with a LABA for at least three months prior to requesting Dupixent. Documentation should include the ICS and LABA names, doses, and start dates.
- The member has required daily oral corticosteroid treatment for at least three months prior to requesting Dupixent. Documentation should include the oral corticosteroid name, daily dose, and start date.
- Exacerbating factors that may contribute to the member's asthma, such as member non-compliance with therapy, environmental factors, dietary factors, and other similar respiratory conditions, have been ruled out.
- The member will not use Dupixent in combination with other interleukin receptor antagonists (for example, Cinqair, Fasenra, or Nucala) or Xolair.

A copy of the member's medical records must be submitted with all PA requests for Dupixent. Medical records should document the following:

- The member's medical condition being treated
- Details regarding previous medication use
- The member's current treatment plan

If clinical criteria for Dupixent are met, initial PA requests may be approved for up to a maximum of 183 days. Renewal PA requests for Dupixent may be approved for up to a maximum of 365 days.

Renewal PA requests for members who have oral corticosteroid dependent asthma must meet the clinical criteria for initial PA requests for Dupixent. Renewal requests must include copies of the current medical records demonstrating the member's daily oral corticosteroid dose has decreased

QUICK LINKS

ForwardHealth Forms Page

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while maintaining asthma control compared to their baseline prior to initiation of Dupixent. Members must also continue to take their maximized asthma treatment regimen, including an ICS and a LABA, during treatment with Dupixent.

Note: All renewal PA requests require the member to be adherent to the prescribed treatment regimen.

Documentation Retention

Providers are reminded that they must follow documentation retention requirements found in the Record Retention topic (#204) of the Online Handbook. Providers are required to produce and/or submit the documentation to ForwardHealth upon request. ForwardHealth may deny or recoup payment for services that fail to meet this requirement.

Information Regarding Managed Care Organizations

This Update contains fee-for-service policy for members enrolled in Medicaid and BadgerCare Plus who receive pharmacy services on a fee-for-service basis only. Pharmacy services for Medicaid members enrolled in the Program of All Inclusive Care for the Elderly (PACE) and the Family Care Partnership are provided by the member's managed care organization. Medicaid and BadgerCare Plus HMOs must provide at least the same benefits as those provided under fee-for-service.

CONTACT INFORMATION

Provider Services,
800-947-9627

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This Update was issued on 10/11/2019 and information contained in this Update was incorporated into the Online Handbook on 11/01/2019.