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## JULY 2020 PREFERRED DRUG LIST CHANGES AND OTHER PHARMACY POLICY CHANGES

This ForwardHealth Update announces updates to the Preferred Drug List (PDL), major changes to certain PDL drug classes for BadgerCare Plus, Medicaid, and SeniorCare programs, form changes, and other pharmacy policy changes effective July 1, 2020, unless otherwise noted. On May 6, 2020, the Wisconsin Medicaid Pharmacy Prior Authorization (PA) Advisory Committee met to review existing therapeutic drug classes on the PDL.

## **Drug Status Changes on the Preferred Drug List**

Attachment A of this Update lists the drugs that have changed their preferred or non-preferred status as a result of the May 2020 PDL review. The <a href="Preferred Drug List Quick Reference">Preferred Drug List Quick Reference</a> data table contains a complete list of preferred and non-preferred drugs.

For drugs that were previously preferred and will become nonpreferred, pharmacists should work with prescribers to transition

## WISCONSIN DEPARTMENT of HEALTH SERVICES

#### 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

#### **CONTACT INFORMATION**

- Provider Services, 800-947-9627
- Drug Authorization and Policy Override Center, 800-947-9627

members to a preferred drug or complete the appropriate PA request forms for non-preferred drugs.

As a reminder, new drugs are usually added to existing drug classes on the PDL as non-preferred drugs until the next scheduled drug class review by the Wisconsin Medicaid Pharmacy PA Advisory Committee. This means that some drugs listed in the table have not previously been reviewed and were added to the PDL with an interim status of non-preferred. These drugs have now been reviewed, and their PDL status is included in Attachment A.

### A Brief Overview of the Preferred Drug List

ForwardHealth makes recommendations to the Wisconsin Medicaid Pharmacy PA Advisory Committee about whether certain PDL drugs should be preferred or non-preferred. These recommendations are based primarily on objective evaluations of a drug's relative safety, effectiveness, clinical outcomes, and relative cost (to Wisconsin Medicaid) in comparison with other therapeutically interchangeable alternative agents in the same drug class.

New drugs are usually added to existing drug classes on the PDL as nonpreferred drugs until their next scheduled class review by the Wisconsin Medicaid Pharmacy PA Advisory Committee.

The PDL is not a drug formulary and is not a comprehensive list of covered drugs.

Most drugs and drug classes included on the PDL are covered by BadgerCare Plus, Wisconsin Medicaid, and SeniorCare, but certain drugs may have restrictions (for example, diagnosis, quantity limits, age limits). Prescribers are encouraged to write prescriptions for preferred drugs if medically appropriate. Non-preferred drugs may be covered with an approved PA request. Most preferred drugs do not require PA, except in designated classes identified on the Preferred Drug List Quick Reference. Noncovered drugs (for example, drugs used for hair loss or cosmetic purposes) are not reimbursed, even with PA.



When initially accessing Online Handbook topic links available throughout this Update, providers need to click the "I accept" button at the bottom of the licensure agreement page of the Online Handbook. After 30 minutes of inactivity, providers will need to click "I accept" again before going to their intended topic.

#### IMPORTANT REMINDERS OF CURRENT POLICY

For prescribers' responsibilities for PA for PDL drugs, refer to

<u>A Prescriber's Responsibilities for Prior Authorization for Preferred Drug List</u>

<u>Drugs topic (#1987) of the ForwardHealth Online Handbook.</u>

For pharmacy providers' responsibilities for PA for PDL drugs, refer to

A Pharmacy Provider's Responsibilities for Prior Authorization for Preferred

Drug List Drugs topic (#10937) of the Online Handbook.

### **Changes to Pharmacy-Related PA Forms and Instructions**

Attachment B of this Update lists the PA forms and instructions that are new, have been revised, renamed, or discontinued as a result of the May 2020 PDL review or as a result of other pharmacy policy changes. The Forms page of the ForwardHealth Portal contains current copies of all PA forms and instructions.

More information regarding changes to clinical criteria or PA request submission options is noted in the applicable drug class section of this Update.

The Online Handbook contains current policy and procedures.

### **Archive Page for Pharmacy-Related PA Forms and Instructions**

The <u>Pharmacy-Related Forms and Instructions</u> link under the Archives Quick Links box on the <u>Pharmacy Resources</u> page of the Portal contains previous versions of pharmacy-related forms and instructions for reference purposes.

## **New Drug Class**

The lipotropics, adenosine triphosphate-citrate lyase (ACL) inhibitors drug class will be added to the PDL on July 1, 2020.

### Lipotropics, Adenosine Triphosphate-Citrate Lyase Inhibitors

All drugs in the lipotropics, ACL inhibitors drug class are non-preferred and require PA.

## Conditions for Which PA Requests for Use of Lipotropics, Adenosine Triphosphate-Citrate Lyase Inhibitors Drugs Will Be Considered for Review

ForwardHealth will only consider PA requests for lipotropics, ACL inhibitors drugs to treat the following identified clinical conditions:

- Clinical atherosclerotic cardiovascular disease (ASCVD)
- Heterozygous familial hypercholesterolemia (HeFH)

## **QUICK LINKS**

- Pharmacy Resources page
- Online Handbook
- Forms page

## Clinical Criteria for Lipotropics, Adenosine Triphosphate – Citrate Lyase Inhibitors Drugs for Members With Clinical Atherosclerotic Cardiovascular Disease

ForwardHealth has established the clinical PA criteria for lipotropics, ACL inhibitors drugs for members with clinical ASCVD.

The clinical criteria for approval of an initial PA request for lipotropics, ACL inhibitors drugs for members with clinical ASCVD are all of the following:

- The member has clinical ASCVD, as evidenced by one of the following:
  - The member has cardiovascular disease, which is supported by a history of one of the following:
    - Myocardial infarction (heart attack)
    - Coronary revascularization
    - Angina pectoris
  - The member has a history of non-hemorrhagic stroke.
  - The member has symptomatic peripheral arterial disease as evidenced by one of the following:
    - Intermittent claudication with an ankle-brachial index of less than
       0.85
    - Peripheral arterial revascularization procedure or amputation due to atherosclerotic disease
- The member must have taken a maximized statin regimen for at least three continuous months with failure to reach a low-density lipoprotein (LDL) less than or equal to 70 mg/dL. If additional lipid lowering is required, ezetimibe 10 mg daily with a maximized statin regimen must be attempted for at least three continuous months with failure to reach an LDL less than or equal to 70 mg/dL. The member must continue to take the maximally tolerated dose of a statin during treatment with a lipotropics, ACL inhibitor drug.

Initial and Renewal PA Requests for Lipotropics, Adenosine Triphosphate– Citrate Lyase Inhibitors Drugs for Members With Clinical Atherosclerotic Cardiovascular Disease

If the clinical criteria for lipotropics, ACL inhibitors drugs for members with clinical ASCVD are met, initial PA requests may be approved for up to 120 days.

Renewal PA requests may be approved for up to 365 days.

Renewal PA requests for lipotropics, ACL inhibitors drugs for members who have clinical ASCVD must meet the clinical criteria for initial PA requests and demonstrate evidence of LDL reduction of at least 30 to 50 percent from the pre-treatment baseline or a decrease to 100 mg/dL or less. Members also must continue to take the maximally tolerated dose of a statin during treatment with a lipotropics, ACL inhibitor drug.

All renewal PA requests require the member to be adherent with the prescribed treatment regimen. A copy of the current lipid panel report (within the past 30 days) must be included with the PA request.

## Clinical Criteria for Lipotropics, Adenosine Triphosphate – Citrate Lyase Inhibitors Drugs for Members With Heterozygous Familial Hypercholesterolemia

ForwardHealth has established the clinical PA criteria for lipotropics, ACL inhibitors drugs for members with HeFH.

The clinical criteria for approval of an initial PA request for lipotropics, ACL inhibitors drugs for members with HeFH are **all** of the following:

- The member has HeFH, as evidenced by clinical documentation that supports a definitive diagnosis of HeFH using either World Health Organization criteria (Dutch Lipid Clinic Network clinical criteria with a score greater than eight) or Simon Broome diagnostic criteria.
- The member must have taken a maximized statin regimen for at least three continuous months with failure to reach an LDL less than or equal to 100 mg/dL. If additional lipid lowering is required, ezetimibe 10 mg daily with a maximized statin regimen must be attempted for at least three continuous months with failure to reach an LDL less than or equal to 100 mg/dL. The member must continue to take the maximally tolerated dose of a statin during treatment with a lipotropics, ACL inhibitor drug.

Initial and Renewal PA Requests for Lipotropics, Adenosine Triphosphate– Citrate Lyase Inhibitors Drugs for Members With Heterozygous Familial Hypercholesterolemia

If the clinical criteria for lipotropics, ACL inhibitors drugs for members with HeFH are met, initial PA requests may be approved for up to 120 days.

Renewal PA requests may be approved for up to 365 days.

Renewal PA requests for lipotropics, ACL inhibitors drugs for members who have HeFH must meet the clinical criteria for initial PA requests and demonstrate evidence of LDL reduction of at least 30 to 50 percent from the pre-treatment baseline or a decrease to 130 mg/dL or less. Members also must continue to take the maximally tolerated dose of a statin during treatment with a lipotropics, ACL inhibitor drug.

All renewal PA requests require the member to be adherent with the prescribed treatment regimen. A copy of the current lipid panel report (within the past 30 days) must be included with the PA request.

## Submitting PA Requests for Lipotropics, Adenosine Triphosphate – Citrate Lyase Inhibitors Drugs

PA requests for lipotropics, ACL inhibitors drugs must be completed and signed by the prescriber. PA requests for lipotropics, ACL inhibitors drugs should be submitted using <u>Section VI</u> (Clinical Information for Drugs With Specific Criteria Addressed in the ForwardHealth Online Handbook) of the Prior Authorization/Drug Attachment (PA/DGA), F-11049 (07/2016).

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. The prescriber should **not** submit the PA form to ForwardHealth.

Pharmacy providers are required to submit the completed PA/DGA form and a completed Prior Authorization Request Form (PA/RF), F-11018 (05/2013), to ForwardHealth.

Clinical documentation supporting the use of a lipotropics, ACL inhibitor drug also must be submitted with the PA request.

PA requests for lipotropics, ACL inhibitors drugs may be submitted on the Portal, by fax, or by mail (but **not** using the Specialized Transmission Authorization Technology-Prior Authorization [STAT-PA] system).

The following must be submitted with initial PA requests for lipotropics, ACL inhibitors drugs:

 Medical records demonstrating that the member has clinical ASCVD or HeFH

## **QUICK LINKS**

Prior Authorization/Drug
Attachment topic (#15937)

Note: This topic will be updated on July 1, 2020. Providers should refer to the Clinical Information for Drugs With Specific Criteria Addressed in the ForwardHealth Online Handbook section in topic #15937.

## DOCUMENT CHECKLIST

- ✓ PA/DGA, F-11049 (07/2016)
- ✓ PA/RF, F-11018 (05/2013)
- Medical records

- Current lipid panel lab report
- Documentation of the member's current lipid-lowering drug therapies, including the following:
  - Drug name and dosage
  - Dates taken
  - Lipid panel report prior to and during drug therapy (including dates taken)

## **Changes to Antiemetics, Cannabinoid Drug Class**

## Revised Clinical Criteria for Dronabinol for Anorexia Associated With Weight Loss With AIDS

ForwardHealth has revised the clinical criteria for dronabinol for the treatment of anorexia associated with weight loss with AIDS.

The clinical criteria for approval of a PA request for dronabinol for the treatment of anorexia associated with weight loss with AIDS for members who are **not** currently receiving dronabinol are **all** of the following:

- The member has AIDS.
- The member is experiencing anorexia associated with weight loss.
- One of the following is true:
  - The member's current body mass index (BMI) is 18.5 or greater, and the member had a 10 percent or greater decrease in weight from baseline in the past six months.
  - The member's current BMI is less than 18.5.
- The member's daily caloric intake has been optimized.

The clinical criteria for approval of a PA request for dronabinol for the treatment of anorexia associated with weight loss with AIDS for members who are currently receiving dronabinol are **one** of the following:

- The member's current BMI is less than 18.5.
- The member's current BMI is in the normal range (18.5–24.9) and has been stabilized in this range for less than six months.

Note: Members whose BMI has been stabilized in the normal range or above (18.5 or greater) for at least six months will **not** be granted a dronabinol PA renewal.

## **QUICK LINKS**

Antiemetics, Cannabinoids topic (#8377)

Note: This topic will be updated on July 1, 2020.

## Revised Clinical Criteria for Dronabinol and Cesamet for Chemotherapy-Related Nausea and Vomiting

ForwardHealth has revised the clinical criteria for dronabinol and Cesamet for chemotherapy-related nausea and vomiting.

The clinical criteria for approval of a PA request for dronabinol or Cesamet for the treatment of chemotherapy-related nausea and vomiting are **all** of the following:

- The member is currently receiving chemotherapy.
- The member is experiencing chemotherapy-related nausea and vomiting.
- At least one of the following is true:
  - The member has experienced an unsatisfactory therapeutic response or a clinically significant adverse drug reaction with ondansetron or granisetron.
  - The member is unable to take **both** ondansetron and granisetron due to one of the following:
    - There is a clinically significant drug interaction between another drug(s) the member is taking and **both** ondansetron and granisetron.
    - The member has a medical condition(s) that prevents the use of both ondansetron and granisetron.
- The member has experienced an unsatisfactory therapeutic response or a clinically significant adverse drug reaction with at least one of the following chemotherapy-related nausea and vomiting treatments: dexamethasone, haloperidol, lorazepam, metoclopramide, olanzapine, prochlorperazine, or promethazine.

#### Revised and Renamed Antiemetics, Cannabinoids Form

ForwardHealth has revised and renamed the Prior Authorization/Preferred Drug List (PA/PDL) for Antiemetics, Cannabinoids form, F-00194 (07/2017). The form has been renamed the Prior Authorization Drug Attachment for Antiemetics, Cannabinoids form, F-00194 (07/2020).

Effective July 1, 2020, pharmacy providers are required to submit PA requests for antiemetics, cannabinoids using this revised form. ForwardHealth will return PA requests that are not submitted with this form.

ForwardHealth will honor PA requests that have already been approved before July 1, 2020, until they expire or until the approved days' supply is used up.



#### **Submitting PA Requests for Antiemetics, Cannabinoids Drugs**

PA is required for all antiemetics, cannabinoids drugs. PA requests for antiemetics, cannabinoids drugs must be completed, signed, and dated by the prescriber. PA requests for antiemetics, cannabinoids drugs should be submitted using the Prior Authorization Drug Attachment for Antiemetics, Cannabinoids form. Clinical documentation supporting the use of antiemetics, cannabinoids drugs 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.

Pharmacy providers are required to submit the completed Prior Authorization Drug Attachment for Antiemetics, Cannabinoids form and a completed PA/RF to ForwardHealth.

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

A copy of the member's current medical records must be submitted with all PA requests for antiemetics, cannabinoids drugs. Medical records must document the member's medical work-up for the condition being treated including complete problem and medication lists.

If the clinical criteria for antiemetics, cannabinoids drugs are met, PA requests may be approved for up to 183 days.

## **Changes to Growth Hormone Drug Class**

### Revised Growth Hormone Stimulation Testing Requirements for Adults

ForwardHealth has revised the clinical criteria for growth hormone stimulation testing requirements for adults.

Growth hormone stimulation testing should not be considered in adults without suggestive history of growth hormone deficiency such as a history of growth hormone deficiency diagnosed in childhood, hypothalamic pituitary disease, or cranial irradiation. In cases where there is suggestive history of growth hormone deficiency and a serum insulin-like growth factor-1

## DOCUMENT CHECKLIST

- Prior Authorization Drug Attachment for Antiemetics, Cannabinoids, F-00194 (07/2020)
- ✓ PA/RF, F-11018 (05/2013)
- Medical records

## **QUICK LINKS**

Growth Hormone Drugs topic (#1988)

Note: This topic will be updated on July 1, 2020.

concentration below the age- and gender-specific lower limit of normal, growth hormone stimulation testing may be considered.

Growth hormone stimulation testing should be conducted after an overnight fast, using a well-standardized protocol, and should be conducted for the appropriate duration of time specific to the agents used to ensure the peak growth hormone level is captured. When two growth hormone stimulation tests are required, both stimulation tests can be administered on the same day. When growth hormone stimulation testing has been performed, complete testing results must be submitted with the PA request including the following:

- Confirmation that the member was fasting
- The type of stimulation test and the dose of the stimulating agent
- A copy of the medical notes taken during the entire testing procedure, including vital signs and blood glucose levels
- The time and results from each blood sample taken
- The provider interpretation of the testing results

For members with thyroid deficiency, ForwardHealth only accepts results of the growth hormone stimulation tests that are performed after thyroid deficiency is adequately treated because growth hormone secretion may be subnormal merely as a result of hypothyroidism.

Growth hormone stimulation testing performed in a non-validated or substandard manner will not be considered by ForwardHealth to be an acceptable growth hormone stimulation test.

Growth hormone deficiency in an adult could be considered if the member has failed to respond to validated growth hormone stimulation testing performed using a well-standardized protocol, demonstrating a growth hormone peak response of less than the established level of the agent(s) given. Examples of agents commonly used in adult growth hormone stimulation testing include insulin, glucagon, and macimorelin. The peak response determining growth hormone deficiency for an adult differs based on the agent used, including the following:

Insulin tolerance test: A growth hormone peak response of less than 5 mcg/L at every time point during the hypoglycemic phase of the test (If adequate hypoglycemia is not achieved [less than 40 mg/dL], then growth hormone deficiency cannot be diagnosed.)

- Glucagon test: A growth hormone peak response of less than 3 mcg/L at every time point during testing for members with BMI less than 25 kg/m<sup>2</sup> or a growth hormone peak response of less than 1 mcg/L at every time point during testing in patients with a BMI greater than or equal to 25 kg/m<sup>2</sup>
- Macimorelin-stimulation test: A growth hormone peak response of less than 2.8 ng/mlµg/L for members with a BMI of 40 kg/m² or less. Strong cytochrome P450 3A4 inducers should be discontinued with sufficient washout time prior to testing with macimorelin. Strong cytochrome P450 3A4 inducers may reduce the plasma macimorelin concentrations and may lead to false positive test results. (Note: The safety and diagnostic performance of macimorelin have not been established with a BMI greater than 40 kg/m².)

Growth hormone testing can provide useful information, but due to the recognized limitations of growth hormone stimulation testing and the risk of false positive results, ForwardHealth will consider the results of the growth hormone stimulation testing in the context of the entire clinical record for the PA request determination decision.

Note: Following the recommendation of the 2019 "American Association of Clinical Endocrinologists and American College of Endocrinology Guidelines for Management of Growth Hormone Deficiency in Adults and Patients Transitioning From Pediatric to Adult Care," ForwardHealth will not accept arginine stimulation testing for adults. The arginine stimulation tests have shown to exhibit a low sensitivity and specificity for adults and have not been systematically evaluated and validated.

## Documentation Requirements for PA Requests for Growth Hormone for Adults

Detailed documentation of the medical work-up and testing used to determine the need for growth hormone treatment must be submitted with the PA request, including the following:

- Detailed endocrinology and medical work-up including medical problem list, current medication list, and medication history
- Copies of the most recent insulin-like growth factor-1 lab reports
- Thyroid-stimulating hormone level
- Nutrition assessment
- Any other relevant testing, such as advanced imaging of the hypothalamicpituitary region, if performed

## DID YOU KNOW?

Providers can find specific forms on the Forms page by entering the form number into the Keyword field of the Search Criteria and clicking Search.

#### **Submitting PA Requests for Growth Hormone Drugs**

PA requests for the following growth hormone drugs must be submitted on the Prior Authorization/Preferred Drug List (PA/PDL) for Growth Hormone Drugs form, F-11092 (07/2020):

- Serostim
- Zorbtive
- Growth hormone drugs for children and adolescents
- Growth hormone drugs for adults

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.

Pharmacy providers are required to submit the completed PA/PDL for Growth Hormone Drugs form and a completed PA/RF to ForwardHealth.

PA requests for Serostim and Zorbtive may be submitted to ForwardHealth using the STAT-PA system, on the Portal, by fax, or by mail.

PA requests for growth hormone drugs for children and adolescents may be submitted using the STAT-PA system when the member meets **both** of the following:

- The member has growth failure or short stature associated with one of the following congenital conditions:
  - Noonan syndrome
  - Prader-Willi syndrome
  - SHOX gene deficiency disorder
  - Turner syndrome
- The member is less than 14 years of age.

All other PA requests for preferred or non-preferred growth hormone drugs may be submitted on the Portal, by fax, or by mail, but **not** using the STAT-PA system.

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

#### **Revised PA Form for Growth Hormone Drugs**

ForwardHealth has revised the PA/PDL for Growth Hormone Drugs form.



Effective July 1, 2020, pharmacy providers are required to submit PA requests for growth hormone drugs using this revised form. ForwardHealth will return PA requests that are not submitted with this form.

ForwardHealth will honor PA requests that have already been approved before July 1, 2020, until they expire or until the approved days' supply is used up.

### Changes to Hepatitis C Agents Drug Class

Sofosbuvir/velpatasvir will become a preferred drug in the hepatitis C agents drug class. Epclusa and Mavyret remain preferred drugs in the hepatitis C agents drug class. Preferred drugs do not require PA.

Harvoni and Zepatier will become non-preferred drugs in the hepatitis C agents drug class. Ledipasvir/sofosbuvir, Sovaldi, and Vosevi remain non-preferred drugs in the hepatitis C agents drug class. Non-preferred drugs require PA.

#### **Revised Clinical Criteria for Hepatitis C Agents**

ForwardHealth has revised the clinical criteria for non-preferred hepatitis C agents.

The requested non-preferred hepatitis C agent is being prescribed in a manner consistent with the Food and Drug Administration-approved product labeling.

Note: Only eight weeks of Harvoni treatment will be approved for treatment-naive members who have hepatitis C virus (HCV) genotype 1 infection without cirrhosis, have an HCV-ribonucleic acid level less than 6 million IU/mL, and are HIV uninfected.

The clinical criteria for approval of a PA request for non-preferred hepatitis C drugs are **all** of the following:

- The member is unable to take the preferred hepatitis C agent drugs due to **one** of the following:
  - There is a clinically significant drug interaction with another drug the member is taking and the preferred drugs.
  - The member has a medical condition(s) that prevents the use of the preferred drugs.
- The member does not have a significant or uncontrolled concurrent disease that would significantly reduce their life expectancy or limit adherence (for example, cardiovascular disease, cancer, pulmonary disease).



Hepatitis C Agents topic (#18297)

Note: This topic will be updated on July 1, 2020.

- For PA requests for Sovaldi, Vosevi, or Zepatier, the member does not have cirrhosis with moderate liver functional compromise (that is, Child-Turcotte-Pugh class B).
- The member does not have cirrhosis with severe liver functional compromise (that is, Child-Turcotte-Pugh class C). Currently, there is no evidence to support that HCV treatment of members with end-stage liver disease impacts morbidity or mortality. The severity of liver damage present in decompensated liver disease makes it unlikely that treating the underlying infection would lead to meaningful liver function improvement. The only definitive treatment for end-stage liver disease is a liver transplant.

In addition to meeting all of the above clinical criteria and HCV treatment program requirements, **Zepatier** requests for members with HCV genotype 1a infection must be tested for the presence of nonstructural protein 5A resistance-associated polymorphisms.

For members who have received a liver transplant, ForwardHealth will consider the requested HCV treatment regimen based on the member's entire medical record. The level of clinical evidence for the requested HCV treatment regimen will be considered. If there is low clinical evidence of the treatment's effectiveness, the PA request will be denied.

For members who have received prior HCV treatment, ForwardHealth will consider the requested HCV treatment regimen based on the member's entire medical record in addition to the HCV treatment history and response (for example, null response, partial response, or relapse). The level of clinical evidence for the requested HCV treatment regimen will be considered. If there is low clinical evidence of the treatment's effectiveness, the PA request will be denied.

#### Revised PA Form for Hepatitis C Agents

ForwardHealth has revised the Prior Authorization Drug Attachment for Hepatitis C Agents form, F-01247 (07/2020).

Effective July 1, 2020, pharmacy providers are required to submit PA requests for non-preferred hepatitis C agents using this revised form. ForwardHealth will return PA requests that are not submitted with this form.

ForwardHealth will honor PA requests that have already been approved before July 1, 2020, until they expire or until the approved days' supply is used up.



#### Submitting PA Requests for Non-Preferred Hepatitis C Agents

PA requests for non-preferred hepatitis C agents must be completed, signed, and dated by the prescriber. PA requests for non-preferred hepatitis C agents should be submitted using the Prior Authorization Drug Attachment for Hepatitis C Agents form.

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. The prescriber should **not** submit the PA form to ForwardHealth.

Pharmacy providers are required to submit the completed Prior Authorization Drug Attachment for Hepatitis C Agents form and a completed PA/RF to ForwardHealth.

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

## Pharmacy Provider-Specific PA Requests for Non-Preferred Hepatitis C Agents

PA requests for non-preferred hepatitis C agents are approved as pharmacy provider-specific. This approach is used to ensure continuity of care for members approved for treatment with these complex drug therapies. When a PA request is approved for drugs in this class, the pharmacy provider will be notified of the pharmacy provider-specific PA status via the decision notice letter. ForwardHealth recommends that the pharmacy provider inform the member of the pharmacy provider-specific PA requirement. The pharmacy provider should explain to the member that the drug therapy authorized must be dispensed by the pharmacy provider approved under the PA request.

Pharmacy providers should not submit PA requests for non-preferred hepatitis C agents if they do not intend to also dispense the entire drug therapy approved under the PA request to the member. If the member needs to discontinue receiving the drug from the approved pharmacy provider once the approved treatment has begun, the pharmacy provider is required to contact <a href="Provider Services">Provider Services</a>. Provider Services will work with the pharmacy provider on the approved PA request to ensure the member does not experience a

## **DOCUMENT CHECKLIST**

- ✓ Prior Authorization Drug Attachment for Hepatitis C Agents, F-01247 (07/2020)
- ✓ PA/RF, F-11018 (05/2013)
- ✓ Medical records

disruption of therapy, and if necessary, will facilitate the transfer of the PA to a new pharmacy provider.

## Clinical Information That Must Be Documented on PA Requests for Non-Preferred Hepatitis C Agents

A copy of the member's medical records that document the following must be submitted with the PA request:

- HCV assessment and treatment plan
- Current history and physical, including complete problem and medication list
- Lab tests (performed within the last six months) for:
  - Albumin
  - Complete blood count
  - International normalized ratio
  - Liver function panel
  - Serum creatinine
  - HCV-ribonucleic acid level
- HCV genotype and subtype
- HCV clinical data and medication treatment history, including the following:
  - Likely source of the HCV infection and date diagnosed
  - Liver biopsy, imaging studies, or blood assay tests to determine hepatic fibrosis
  - History of previous hepatitis C drug therapy including medication name(s), dates taken, and treatment results (for example, null response, partial response, or relapse)
- If the member has cirrhosis, documentation of the following clinical assessments:
  - Child-Turcotte-Pugh class and score
  - Hepatocellular carcinoma status based on an imaging study performed within the last six months
  - Presence or treatment of any of the following:
    - Ascites
    - Hepatic encephalopathy
    - Portal hypertension
    - Hepatocellular carcinoma

If the required documentation is not submitted with the PA request, the PA request will be considered incomplete and will be returned to the provider, or it may be denied.

## Changes to Hypoglycemics, Glucagon-Like Peptide Agents Drug Class

#### Revised Clinical Criteria for Glucagon-Like Peptide Agents

ForwardHealth has removed the PA criterion requirement that the member does not currently have gastroparesis or have a history of gastroparesis.

The remaining clinical criteria for non-preferred glucagon-like peptide (GLP-1) agents have not changed.

#### Revised PA Form for Glucagon-Like Peptide Agents

ForwardHealth has revised the Prior Authorization Drug Attachment for Glucagon-Like Peptide (GLP-1) Agents form, F-00238 (07/2020).

Effective July 1, 2020, pharmacy providers are required to submit PA requests for GLP-1 agents using this revised form. ForwardHealth will return PA requests that are not submitted with this form.

ForwardHealth will honor PA requests that have already been approved before July 1, 2020, until they expire or until the approved days' supply is used up.

#### **Submitting PA Requests for Glucagon-Like Peptide Agents**

PA requests for non-preferred GLP-1 agents must be completed, signed, and dated by the prescriber. PA requests for non-preferred GLP-1 agents must be submitted using the Prior Authorization Drug Attachment for GLP-1 Agents form.

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. The prescriber should **not** submit the PA form to ForwardHealth.

Pharmacy providers are required to submit the completed Prior Authorization Drug Attachment for GLP-1 Agents form and a completed PA/RF to ForwardHealth.

## QUICK LINKS

- Hypoglycemics, GLP-1
   Agents topic (#8858)

   Note: This topic will be updated on July 1, 2020.
- Forms page

## **DOCUMENT CHECKLIST**

- Prior Authorization Drug
   Attachment for GLP-1
   Agents, F-00238 (07/2020)
- ✓ PA/RF, F-11018 (05/2013)
- Medical records

PA requests for non-preferred GLP-1 agents may be submitted on the Portal, by fax, or by mail (but **not** using the STAT-PA system).

## Changes to Hypoglycemics, Insulins and Hypoglycemics, Insulins Long-Acting Drug Classes



## Changes to Immunomodulators, Atopic Dermatitis Drug Class

#### **Revised Clinical Criteria for Eucrisa**

ForwardHealth has removed the PA criterion requirement that the member be 2 years of age or older.

The remaining clinical criteria for Eucrisa have not changed.

#### **Revised PA Form for Eucrisa**

ForwardHealth has revised the Prior Authorization/Preferred Drug List (PA/PDL) for Eucrisa form, F-02572 (07/2020).

Effective July 1, 2020, pharmacy providers are required to submit PA requests for Eucrisa using this revised form. ForwardHealth will return PA requests that are not submitted with this form.

ForwardHealth will honor PA requests that have already been approved before July 1, 2020, until they expire or until the approved days' supply is used up.

#### **Submitting PA Requests for Eucrisa**

PA requests for Eucrisa must be completed, signed, and dated by the prescriber. PA requests for Eucrisa must be submitted on the PA/PDL for Eucrisa form.

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.

## **QUICK LINKS**

- Immunomodulators, Atopic
   Dermatitis topic (#8857)
  - Note: This topic will be updated on July 1, 2020.
- Forms page

Pharmacy providers are required to submit the completed PA/PDL for Eucrisa form and a completed PA/RF to ForwardHealth.

PA requests for Eucrisa may be submitted using the STAT-PA system, on the Portal, by fax, or by mail.

## Changes to Lipotropics, Proprotein Convertase Subtilisin/ **Kexin Type 9 Inhibitors Drug Class**

#### Renewal PA Requests for Praluent and Repatha

Effective July 1, 2020, renewal PA requests for Praluent and Repatha may be approved for up to 365 days for members with the following clinical conditions:

- Praluent for members with clinical ASCVD
- Praluent for members with HeFH
- Repatha for members with clinical ASCVD
- Repatha for members with HeFH
- Repatha for members with homozygous familial hypercholesterolemia

The clinical criteria for Praluent and Repatha with the respective clinical conditions listed above have not changed.

### **Reorganization of Migraine Agents Drug Classes**

Effective July 1, 2020, ForwardHealth will reorganize and rename the migraine agents drug classes on the PDL to the following four headache agents drug classes:

- Headache agents, acute treatment
- Headache agents, preventative treatment
- Headache agents, triptans injectable
- Headache agents, triptans non-injectable

#### **Headache Agents, Acute Treatment Drug Class**

The headache agents, acute treatment drug class will be added to the PDL on July 1, 2020.

#### New Clinical Criteria for Headache Agents, Acute Treatment Drugs

ForwardHealth has established the clinical PA criteria for drugs in the headache agents, acute treatment drug class. All drugs in the headache agents, acute treatment drug class are non-preferred and require PA.

# DOCUMENT CHECKLIST ✓ PA/PDL for Eucrisa, F-02572

- PA/RF, F-11018 (05/2013)

Lipotropics, PCSK9 Inhibitors

topic (#18737)

Note: This topic will be updated on July 1, 2020.

Emgality 100 mg will become a non-preferred drug in the headache agents, acute treatment drug class. The clinical criteria and PA submission requirements for Emgality 100 mg have not changed.

Nurtec ODT, Reyvow, and Ubrelvy will remain non-preferred and will be moved to the headache agents, acute treatment drug class.

The clinical criteria for approval of a PA request for headache agents, acute treatment drugs (excluding Emgality 100 mg) are all of the following:

- The member is 18 years of age or older.
- The prescriber has evaluated and diagnosed the member as having a history of migraines, with or without aura, according to International Classification of Headache Disorders, 3rd edition diagnostic criteria.
- One of the following is true:
  - The member has experienced an unsatisfactory therapeutic response or a clinically significant adverse drug reaction with at least two preferred drugs from the headache agents, triptans non-injectable drug class.
  - The member has a medical condition(s) that prevents the use of triptans.

A copy of the member's medical records must be submitted with all PA requests for headache agents, acute treatment drugs. Medical records must document the member's medical work-up for migraines including complete problem and medication lists.

Starting a member on a medication by using manufacturer-provided samples or manufacturer patient assistance programs will not be considered as previous medication history for PA review.

If the clinical criteria for headache agents, acute treatment drugs are met, PA requests may be approved for up to 365 days.

Note: Emgality 100 mg has separate clinical PA criteria.

#### New PA Form for Headache Agents, Acute Treatment

ForwardHealth has a created the Prior Authorization Drug Attachment for Headache Agents, Acute Treatment form, F-02666 (07/2020). PA requests received on and after July 1, 2020, must be submitted on the new form, or they will be returned to the provider.

## **QUICK LINKS**

Migraine Agents, CGRP
Antagonists topic (#21117)

Note: This topic will be updated and the topic title renamed Headache Agents, Preventative Treatment on July 1, 2020. The clinical criteria and PA submission requirements for Emgality 100 mg in topic #21117 will be moved to a new topic Headache Agents, Acute Treatment on July 1, 2020.



#### **Submitting PA Requests for Headache Agents, Acute Treatment Drugs**

PA requests for headache agents, acute treatment drugs must be completed, signed, and dated by the prescriber. PA requests for headache agents, acute treatment drugs must be submitted on the Prior Authorization Drug Attachment for Headache Agents, Acute Treatment form.

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.

Pharmacy providers are required to submit the completed Prior Authorization Drug Attachment for Headache Agents, Acute Treatment form and a completed PA/RF to ForwardHealth.

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

Note: Emgality 100 mg has separate PA submission requirements.

## Changes to the Migraine Agents, Calcitonin Gene-Related Peptide Antagonists Drug Class

Effective July 1, 2020, the migraine agents, calcitonin gene-related peptide antagonists drug class will be renamed the headache agents, preventative treatment drug class.

#### **Headache Agents, Preventative Treatment Drug Class**

Ajovy will become a preferred drug in the headache agents, preventative treatment drug class, and Emgality 120 mg will remain a preferred drug in the headache agents, preventative treatment drug class. Preferred drugs do not require PA.

Aimovig is a non-preferred drug in the headache agents, preventative treatment drug class. Non-preferred drugs require PA.

## New Clinical Criteria for Non-Preferred Headache Agents, Preventative Treatment Drugs

ForwardHealth has established the clinical PA criteria for non-preferred drugs in the headache agents, preventative treatment drug class.

## **DOCUMENT CHECKLIST**

- ✓ Prior Authorization Drug Attachment for Headache Agents, Acute Treatment,
   F-02666 (07/2020)
- ✓ PA/RF, F-11018 (05/2013)
- Medical records

The clinical criteria for approval of an initial PA request for non-preferred headache agents, preventative treatment drugs are **all** of the following:

- The member is 18 years of age or older.
- The prescriber has evaluated and diagnosed the member as having a history of migraines, with or without aura, according to International Classification of Headache Disorders, 3rd edition diagnostic criteria.
- The member's current prescribed migraine medication treatment regimen must be documented. The prescriber is required to indicate the member's current migraine preventative and rescue medications (drug name[s], dose, and dosing frequency) including Botox (if applicable).
- The member has taken Ajovy for at least three consecutive months and experienced an unsatisfactory therapeutic response or experienced a clinically significant adverse drug reaction.
- The member has taken Emgality 120 mg for at least three consecutive months and experienced an unsatisfactory therapeutic response or experienced a clinically significant adverse drug reaction.

A copy of the member's current medical records must be submitted with all PA requests (initial, initial renewal, and subsequent renewal) for non-preferred headache agents, preventative treatment drugs. Medical records must document the member's medical work-up for migraines including complete problem and medication lists.

Starting a member on a medication by using manufacturer-provided samples or manufacturer patient assistance programs will not be considered as previous medication history for PA review.

If the clinical criteria for non-preferred headache agents, preventative treatment drugs are met, initial PA requests may be approved for up to 183 days.



When initially accessing Online Handbook topic links available throughout this Update, providers need to click the "I accept" button at the bottom of the licensure agreement page of the Online Handbook. After 30 minutes of inactivity, providers will need to click "I accept" again before going to their intended topic.

## Initial Renewal PA Requests for Non-Preferred Headache Agents, Preventative Treatment Drugs

Clinical criteria that must be documented for approval of initial renewal PA requests for non-preferred headache agents, preventative treatment drugs are **all** of the following:

- The member experienced a clinically significant decrease in the number of migraine days per month and/or a decrease in migraine duration compared to their baseline prior to initiation of treatment with a headache agents, preventative treatment drug.
- The member's current prescribed migraine medication treatment regimen has been documented. The prescriber is required to indicate the member's current migraine preventative and rescue medications (drug name[s], dose, and dosing frequency) including Botox (if applicable).
- The member has been compliant with their prescribed migraine medication treatment regimen.

Initial renewal PA requests for non-preferred headache agents, preventative treatment drugs may be approved for up to 365 days.

## Subsequent Renewal PA Requests for Non-Preferred Headache Agents, Preventative Treatment Drugs

Clinical criteria that must be documented for approval of subsequent renewal requests for non-preferred headache agents, preventative treatment drugs are **all** of the following:

- The member has sustained a clinically significant decrease in the number of migraine days per month and/or a decrease in migraine duration compared to their baseline prior to initiation of treatment with a headache agents, preventative treatment drug.
- The member's current prescribed migraine medication treatment regimen
  has been documented. The prescriber is required to indicate the member's
  current migraine preventative and rescue medications (drug name[s], dose,
  and dosing frequency) including Botox (if applicable).
- The member has been compliant with their prescribed migraine medication treatment regimen.

Subsequent renewal PA requests for non-preferred headache agents, preventative treatment drugs may be approved for up to 365 days.

#### New PA Form for Headache Agents, Preventative Treatment

ForwardHealth has created a new form, Prior Authorization Drug Attachment for Headache Agents, Preventative Treatment, F-02667 (07/2020). PA requests received on and after July 1, 2020, must be submitted on the new form, or they will be returned to the provider.



## Discontinued PA Form for Migraine Agents, Calcitonin Gene-Related Peptide Antagonists

Effective July 1, 2020, the Prior Authorization Drug Attachment for Migraine Agents, Calcitonin Gene-Related Peptide (CGRP) Antagonists form, F-02371 (07/2019), is being discontinued and will no longer be accepted. It will be removed from the Forms page of the Portal and placed on the Pharmacy-Related Forms and Instructions archive page linked under the Archives section on the Pharmacy Resources page of the Portal.

ForwardHealth will honor PA requests that have already been approved before July 1, 2020, until they expire or until the approved days' supply is used up.

## Submitting PA Requests for Headache Agents, Preventative Treatment Drugs

PA requests for non-preferred headache agents, preventative treatment drugs must be completed, signed, and dated by the prescriber. PA requests for non-preferred headache agents, preventative treatment drugs should be submitted using the Prior Authorization Drug Attachment for Headache Agents, Preventive Treatment form. Clinical documentation supporting the use of non-preferred headache agents, preventative treatment drugs 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.

Pharmacy providers are required to submit the completed Prior Authorization Drug Attachment for Headache Agents, Preventative Treatment form and a completed PA/RF to ForwardHealth.

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

## DOCUMENT CHECKLIST

- Prior Authorization Drug Attachment for Headache Agents, Preventative Treatment, F-02667 (07/2020)
- PA/RF. F-11018 (05/2013)
- Medical records

#### Changes to Migraine Agents, Injectable Drug Class

Effective July 1, 2020, the migraine agents, injectable drug class will be renamed the headache agents, triptans injectable drug class.

#### Headache Agents, Triptans Injectable Drug Class

Sumatriptan injectable is a preferred drug and will be moved to the headache agents, triptans injectable drug class. Preferred drugs do not require PA.

Zembrace is a non-preferred drug and will be moved to the headache agents, triptans injectable drug class. Non-preferred drugs require PA.

#### New Clinical Criteria for Headache Agents, Triptans Injectable Drugs

The clinical criteria for approval of non-preferred headache agents, triptans injectable drugs follows the clinical criteria for non-preferred drugs submitted with the Prior Authorization/Preferred Drug List (PA/PDL) Exemption Request form, F-11075 (09/2013).

## Submitting PA Requests for Non-Preferred Headache Agents, Triptans Injectable Drugs

Effective July 1, 2020, PA requests for non-preferred headache agents, triptans injectable drugs must be submitted on the PA/PDL Exemption Request form. ForwardHealth will return PA requests that are not submitted with this form.

PA requests for non-preferred headache agents, triptans injectable drugs must be completed, signed, and dated by the prescriber. PA requests for nonpreferred headache agents, triptans injectable drugs must be submitted using the PA/PDL Exemption Request form.

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.

Pharmacy providers are required to submit the completed PA/PDL Exemption Request form and a completed PA/RF to ForwardHealth.

PA requests for headache agents, triptans injectable drugs may be submitted using the STAT-PA system, on the Portal, by fax, or by mail.

# DOCUMENT CHECKLIST ✓ PA/PDL Exemption Request, F-11075 (09/2013)

## Discontinued Prior Authorization/Preferred Drug List for Migraine Agents, Injectable Form

Effective July 1, 2020, the Prior Authorization/Preferred Drug List (PA/PDL) for Migraine Agents, Injectable form, F-00622 (06/2012), is being discontinued and will no longer be accepted. It will be removed from the Forms page of the Portal and placed on the Pharmacy-Related Forms and Instructions archive page linked under the Archives section on the Pharmacy Resources page of the Portal.

ForwardHealth will honor PA requests that have already been approved before July 1, 2020, until they expire or until the approved days' supply is used up.

#### **Changes to Migraine Agents, Other Drug Class**

Effective July 1, 2020, the migraine agents, other drug class will be renamed the headache agents, triptans non-injectable drug class.

#### Headache Agents, Triptans Non-Injectable Drug Class

Naratriptan will become a preferred drug in the headache agents, triptans non-injectable drug class. Preferred drugs do not require PA.

Non-preferred drugs in the headache agents, triptans non-injectable drug class require PA.

Non-preferred drug Cambia will be moved to the non-steroidal antiinflammatory drugs drug class.

## New Clinical Criterion for Non-Preferred Headache Agents, Triptans Non-Injectable Drugs

ForwardHealth has established the clinical PA criterion for non-preferred drugs in the headache agents, triptans non-injectable drug class.

The **sole clinical criterion** for approval of a PA request for non-preferred headache agents, triptans non-injectable drugs is that the member has experienced an unsatisfactory therapeutic response or a clinically significant adverse drug reaction with **at least three** preferred drugs from the headache agents, triptans non-injectable drug class.

If the clinical criterion for non-preferred headache agents, triptans noninjectable drugs is met, PA requests may be approved for up to 365 days.

## QUICK

Migraine Agents, Other topic (#9878)

Note: This topic will be updated and the topic title renamed Headache Agents, Triptans Non-Injectable on July 1, 2020.

#### New PA Form for Headache Agents, Triptans Non-Injectable Drugs

ForwardHealth has created the Prior Authorization/Preferred Drug List (PA/PDL) for Headache Agents, Triptans Non-Injectable form, F-02668 (07/2020). PA requests received on and after July 1, 2020, must be submitted on the new form, or they will be returned to the provider.



## Discontinued Prior Authorization/Preferred Drug List for Migraine Agents, Other Form

Effective July 1, 2020, the Prior Authorization/Preferred Drug List (PA/PDL) for Migraine Agents, Other form, F-00280 (07/2013), is being discontinued and will no longer be accepted. It will be removed from the Forms page of the Portal and placed on the Pharmacy-Related Forms and Instructions archive page linked under the Archives section on the Pharmacy Resources page of the Portal.

ForwardHealth will honor PA requests that have already been approved before July 1, 2020, until they expire or until the approved days' supply is used up.

## Submitting PA Requests for Headache Agents, Triptans Non-Injectable Drugs

PA requests for non-preferred headache agents, triptans non-injectable drugs must be submitted on the PA/PDL for Headache Agents, Triptans Non-Injectable form.

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.

Pharmacy providers are required to submit the completed PA/PDL for Headache Agents, Triptans Non-Injectable form and a completed PA/RF to ForwardHealth.

PA requests for headache agents, triptans non-injectable drugs may be submitted using the STAT-PA system, on the Portal, by fax, or by mail.

## DOCUMENT CHECKLIST

- ✓ PA/PDL for Headache Agents, Triptans Non-Injectable, F-02668 (07/2020)
- ✓ PA/RF, F-11018 (05/2013)

## Changes to the Multiple Sclerosis Agents, Immunomodulators Drug Class

Tecfidera will become a preferred drug in the multiple sclerosis (MS) agents, immunomodulators drug class. Preferred drugs do not require PA.

Non-preferred drugs in the MS agents, immunomodulators drug class require PA.

## Revised Clinical Criteria for Non-Preferred Interferons, Multiple Sclerosis Agents, Immunomodulators

ForwardHealth has revised the clinical criteria for non-preferred interferons, MS agents, immunomodulators (interferon agents).

## Clinical Criteria for Members Currently Being Treated With the Requested Non-Preferred Interferon Agent

The clinical criteria for approval of a PA request for a non-preferred interferon agent for members currently being treated with the requested non-preferred interferon agent are **all** of the following:

- The member and prescriber are following established monitoring guidelines outlined in the Food and Drug Administration-approved patient labeling.
- The member has been adherent with the interferon agent treatment regimen.
- The member's MS is stable and well-controlled, without disease-progressing symptoms.

In addition to **all** of the above clinical criteria, **one** of the following must be true:

- The member is new to ForwardHealth (that is, the member has been granted eligibility for ForwardHealth within the past month) and has taken the requested non-preferred drug continuously for the last 30 days or longer and had a measurable therapeutic response. (Note: Medical records must be provided to demonstrate the member meets this criterion.)
- The member had an approved PA issued by ForwardHealth that recently expired for the requested non-preferred drug, and the member has taken the requested non-preferred drug continuously for the last 30 days or longer and had a measurable therapeutic response.

## **QUICK LINKS**

Multiple Sclerosis Agents,
<a href="mailto:limmunomodulators">lmmunomodulators</a> topic
(#10997)

Note: This topic will be updated on July 1, 2020.

Note: Starting a member on a medication by using manufacturer-provided samples or manufacturer patient assistance programs will not be considered as previous medication history for PA review.

## Clinical Criteria for Members Not Currently Being Treated With the Requested Non-Preferred Interferon Agent

The clinical criteria for approval of a PA request for a non-preferred interferon agent for members not currently being treated with the requested non-preferred interferon agent are that the member must experience an unsatisfactory therapeutic response or a clinically significant adverse drug reaction to at least two preferred interferon agents.

PA requests must include detailed documentation regarding why the member has previously discontinued preferred interferon agent treatments.

Note: Medical records must be provided to demonstrate that the member meets this criterion.

The following will **not** be considered as criteria to support the need for a non-preferred interferon agent:

- Nonadherence to previous MS treatment
- Member or prescriber preference for the use of a non-preferred interferon agent
- Member or prescriber preference for a less frequent dosing schedule

## Revised Clinical Criteria for Non-Preferred Oral Multiple Sclerosis Agents, Immunomodulators

ForwardHealth is revising the clinical criteria for non-preferred oral MS agents, immunomodulators (oral agents).

## Clinical Criteria for Members Currently Being Treated With the Requested Non-Preferred Oral Agent

The clinical criteria for approval of a PA request for a non-preferred oral agent for members currently being treated with the requested non-preferred oral agent are **all** of the following:

 The member and prescriber are following established monitoring guidelines outlined in the Food and Drug Administration-approved product labeling.

- The member has been adherent with the oral agent treatment regimen.
- The member's MS is stable and well-controlled, without diseaseprogressing symptoms.

In addition to **all** of the above clinical criteria, **one** of the following must be true:

- The member is new to ForwardHealth (that is, the member has been granted eligibility for ForwardHealth within the past month) and has taken the requested non-preferred drug continuously for the last 30 days or longer and had a measurable therapeutic response. (Note: Medical records must be provided to demonstrate the member meets this criterion.)
- The member had an approved PA issued by ForwardHealth that recently expired for the requested non-preferred drug, and the member has taken the requested non-preferred drug continuously for the last 30 days or longer and had a measurable therapeutic response.

Note: Starting a member on a medication by using manufacturer-provided samples or manufacturer patient assistance programs will not be considered as previous medication history for PA review.

## Clinical Criteria for Members Not Currently Being Treated With the Requested Non-Preferred Oral Agent

The clinical criteria for approval of a PA request for a non-preferred oral agent for members not currently being treated with the requested non-preferred oral agent are **all** of the following:

- The requested non-preferred oral agent is being prescribed in a manner consistent with the Food and Drug Administration-approved product labeling.
- The member is unable to take Aubagio due to **one** of the following:
  - The member experienced a clinically significant adverse drug reaction.
  - There is a clinically significant drug interaction with another drug the member is taking.
  - The member has a medical condition(s) that prevents use of the drug.
- The member is unable to take Gilenya due to **one** of the following:
  - The member experienced a clinically significant adverse drug reaction.
  - There is a clinically significant drug interaction with another drug the member is taking.
  - The member has a medical condition(s) that prevents use of the drug.

- The member is unable to take Tecfidera due to **one** of the following:
  - The member experienced a clinically significant adverse drug reaction.
  - There is a clinically significant drug interaction with another drug the member is taking.
  - The member has a medical condition(s) that prevents use of the drug.

PA requests must include detailed documentation regarding why the member is unable to take or has previously discontinued treatment with Aubagio, Gilenya, and Tecfidera.

Note: Medical records must be provided to demonstrate that the member meets these criteria.

The following will **not** be considered as criteria to support the need for a non-preferred oral agent:

- Nonadherence to previous MS treatment
- Member or prescriber preference for the use of a non-preferred oral agent

#### **Clinical Criteria for Glatopa**

The clinical criteria for Glatopa have not changed.

## Revised and Renamed Multiple Sclerosis Agents, Immunomodulators Form

ForwardHealth has revised and renamed the Prior Authorization/Preferred Drug List (PA/PDL) for Multiple Sclerosis (MS) Agents, Immunomodulators form, F-00805 (07/2018). The form has been renamed the Prior Authorization Drug Attachment for Multiple Sclerosis (MS) Agents, Immunomodulators form, F-00805 (07/2020).

Effective July 1, 2020, pharmacy providers are required to submit PA requests for MS agents, immunomodulators using this revised form. ForwardHealth will return PA requests that are not submitted with this form.

ForwardHealth will honor PA requests that have already been approved before July 1, 2020, until they expire or until the approved days' supply is used up.

## Submitting PA Requests for Immunomodulators to Treat Multiple Sclerosis

PA requests for non-preferred immunomodulators to treat MS must be completed, signed, and dated by the prescriber. PA requests for non-preferred immunomodulators to treat MS must be submitted using the Prior Authorization Drug Attachment for MS Agents, Immunomodulators form.



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.

Pharmacy providers are required to submit the completed Prior Authorization Drug Attachment for MS Agents, Immunomodulators form and a completed PA/RF to ForwardHealth.

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

### **Changes to Opioid Dependency Agents Drug Class**

The opioid dependency agents drug class contains the following subclasses:

- Opioid dependency agents—buprenorphine
- Opioid dependency agents—methadone
- Opioid dependency agents—rescue agent
- Opioid dependency and alcohol abuse/dependency agents

#### **Opioid Dependency Agents—Buprenorphine**

Buprenorphine-naloxone tablets and Sublocade will become preferred drugs in the opioid dependency agents—buprenorphine drug class. Suboxone Film and Zubsolv remain preferred drugs in the opioid dependency agents—buprenorphine drug class. Preferred drugs do not require PA.

Bunavail, buprenorphine tablets without naloxone, and buprenorphine/ naloxone film remain non-preferred drugs in the opioid dependency buprenorphine drug class. Non-preferred drugs require PA.

Effective July 1, 2020, buprenorphine/naloxone film, a non-preferred drug in the opioid dependency agents—buprenorphine drug class, will be subject to brand before generic policy.

Suboxone film, a preferred drug in the opioid dependency agents—buprenorphine drug class, will have a generic copay.

Drugs in the opioid dependency agents—buprenorphine drug class **are** diagnosis restricted.

## **DOCUMENT CHECKLIST**

- ✓ Prior Authorization Drug Attachment for MS Agents, Immunomodulators, F-00805 (07/2020)
- PA/RF, F-11018 (05/2013)
- ✓ Medical records

## **QUICK LINKS**

Opioid Dependency Agents topic (#8917)

Note: This topic will be updated on July 1, 2020.

Note: The policy for obtaining <u>provider-administered drugs</u> still applies to Sublocade.

## Revised Clinical Criteria for Non-Preferred Buprenorphine-Naloxone Drugs

ForwardHealth has revised the clinical criteria for non-preferred buprenorphine-naloxone drugs.

The clinical criteria for approval of a PA request for non-preferred buprenorphine-naloxone drugs are **both** of the following:

- The member meets the clinical criteria for opioid dependency agents buprenorphine.
- The prescriber has submitted detailed clinical justification for prescribing a non-preferred buprenorphine-naloxone drug instead of buprenorphine-naloxone tablets, Suboxone film, and Zubsolv, including clinical information explaining why the member cannot use buprenorphine-naloxone tablets, Suboxone film, and Zubsolv and why it is medically necessary that the member receive a non-preferred buprenorphine-naloxone drug instead of buprenorphine-naloxone tablets, Suboxone film, and Zubsolv.

#### Revised Opioid Dependency Agents—Buprenorphine Form

ForwardHealth has revised the Prior Authorization/Preferred Drug List (PA/PDL) for Opioid Dependency Agents—Buprenorphine form, F-00081 (07/2020).

Effective July 1, 2020, pharmacy providers are required to submit PA requests for opioid dependency agents—buprenorphine drugs using this revised form. ForwardHealth will return PA requests that are not submitted with this form.

ForwardHealth will honor PA requests that have already been approved before July 1, 2020, until they expire or until the approved days' supply is used up.

#### Submitting PA Requests for Opioid Dependency Agents— Buprenorphine Form

PA requests for non-preferred opioid dependency agents—buprenorphine drugs in the opioid dependency agents—buprenorphine drug class must be submitted using the PA/PDL for Opioid Dependency Agents—Buprenorphine form.



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.

Pharmacy providers are required to submit the completed PA/PDL for Opioid Dependency Agents—Buprenorphine form and a completed PA/RF to ForwardHealth.

PA requests for buprenorphine tablets without naloxone for BadgerCare Plus, Medicaid, and SeniorCare members may be submitted using the STAT-PA system, on the Portal, by fax, or by mail.

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

PA requests for non-preferred buprenorphine-naloxone drugs may be approved for up to 365 days.

PA requests for buprenorphine tablets without naloxone (for pregnant women only) may be approved for the lesser of one of the following:

- Up to 14 days past the member's expected due date entered on the PA/PDL for Opioid Dependency Agents—Buprenorphine form
- Up to 300 days

Buprenorphine tablets without naloxone (for pregnant women only) are available through an expedited emergency supply request, which may be granted for up to a 14-day supply.

## **Other Pharmacy Policy Changes**

### **Copay for Brand Name Drugs Preferred Over Generic Drugs**

ForwardHealth generally applies a generic copay to a brand name drug when a drug that previously required brand medically necessary PA becomes a preferred drug on the PDL and the available generic equivalents are non-preferred drugs.

This does not include brand name drugs that were preferred over generic equivalents because the generic equivalents are new to the marketplace and not yet cost-effective when compared to brand pricing.

## DOCUMENT CHECKLIST

- ✓ PA/PDL for Opioid
   Dependency Agents—
   Buprenorphine, F-00081
   (07/2020)
- ✓ PA/RF, F-11018 (05/2013)

For drugs included in this policy, ForwardHealth will automatically apply the generic copay when a specific brand name drug is preferred over a generic equivalent. Providers do not need to indicate a National Council for Prescription Drug Programs Dispense as Written/Product Selection code on claims to ensure the generic copay deduction.

The following table includes the most current list of drugs for which this policy applies. This list is available on the last page of the <a href="Preferred Drug List Quick Reference">Preferred Drug List Quick Reference</a> data table on the Portal. Review the following list to identify future changes.

DRUG CLASS	DRUG NAME	EFFECTIVE DATE
Acne Agents, Topical	Differin 0.1% cream	01/01/2012
	Differin 0.3% gel	02/01/2017
	pump	
	Retin-A (not micro)	07/01/2016
Anticonvulsants	Tegretol suspension	01/01/2016
	Tegretol tablet	01/01/2016
Antihypertensives,	Catapres-TTS	01/01/2014
Sympatholytics		
Hypoglycemics, Insulins	Humalog Jr Kwikpen	05/01/2020
	Humalog Mix	05/01/2020
	Humalog U-100	07/01/2019
	Kwikpen/Vial	
	Novolog Mix	01/01/2020
	Novolog U-100	01/01/2020
	Pen/Vial	
Ophthalmics, Antibiotic-	Tobradex	01/01/2012
Steroid Combinations	suspension	
Ophthalmics, Glaucoma-	Alphagan P 0.15%	01/01/2012
Other		
Opioid Dependency Agents-	Suboxone film	07/01/2020
Buprenorphine		
Stimulants	Concerta	01/01/2018

#### **Expedited Emergency Supply Request Drugs Data Table**

As a result of the changes made during the May 2020 PDL review, the Expedited Emergency Supply Request Drugs data table on the Pharmacy Resources page will be updated.

#### **Retention of Documentation Reminder**

Providers are reminded that they must follow the documentation retention requirements, per Wis. Admin. Code § <u>DHS 106.02(9)</u>. Information about those requirements are explained in the following Online Handbook topics:

- Financial Records (#201)
- Medical Records (#202)
- Preparation and Maintenance of Records (#203)
- Record Retention (#204)
- Availability of Records to Authorized Personnel (#1640)

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. Refusal to produce documentation may result in sanctions including, but not limited to, termination from the Medicaid program.

### **Information Regarding Managed Care Organizations**

This Update contains 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) are provided by the member's managed care organization.

The information provided in this ForwardHealth Update is published in accordance with Wis. Stat. § 49.45(49) and Wis. Admin. Code § DHS 107.10.

This Update was issued on 06/22/2020 and information contained in this Update was incorporated into the Online Handbook on 07/01/2020.

The ForwardHealth Update is the first source of program policy and billing information for providers.

Wisconsin Medicaid, BadgerCare Plus, SeniorCare, and Wisconsin Chronic Disease Program are administered by the Division of Medicaid Services within the Wisconsin Department of Health Services (DHS). The Wisconsin AIDS Drug Assistance Program and the Wisconsin Well Woman Program are administered by the Division of Public Health within DHS.

For questions, call Provider Services at 800-947-9627 or visit our website at www.forwardhealth.wi.gov/.

## **ATTACHMENT A**

## Changes to Preferred or Non-Preferred Status of Drugs on the Preferred Drug List

The following table lists the drugs that changed their preferred or non-preferred status as a result of the May 2020 Preferred Drug List Review. Unless otherwise noted, the updated statuses are effective July 1, 2020. Drugs that have not been previously reviewed by the Wisconsin Medicaid Pharmacy Prior Authorization Advisory Committee are marked with a footnote number 1. The complete Preferred Drug List Quick Reference can be referenced on the Pharmacy Resources page of the ForwardHealth Portal.

DRUG CLASS	DRUG NAME	STATUS EFFECTIVE JULY 1, 2020, UNLESS OTHERWISE NOTED
Acne Agents, Topical	Aklief <sup>1</sup>	Non-Preferred
	Amzeeq <sup>1</sup>	Non-Preferred
	clindamycin/benzoyl peroxide (Duac)	Preferred
	erythromycin gel	Non-Preferred
	tretinoin gel¹	Non-Preferred
Analgesics, Opioids Long-Acting	hydrocodone ER (Zohydro ER) <sup>1</sup>	Non-Preferred
Analgesics, Opioids Short-Acting	benzhydrocodone/apap tablet¹	Non-Preferred
Angiotensin Modulators, ARBs and	aliskiren tablets (Tekturna)¹	Non-Preferred
DRIs	irbesartan	Preferred
	irbesartan/HCTZ	Preferred
	olmesartan	Preferred
	olmesartan/HCTZ	Preferred
Antibiotics, Beta-Lactam	cefixime capsule <sup>1</sup>	Non-Preferred
Antibiotics, Vaginal	metronidazole	Non-Preferred
Antiemetic/Antivertigo	doxylamine succinate/pyridoxine	Non-Preferred
	(Diclegis) <sup>1</sup>	
Antifungals, Oral	posaconazole (Noxafil) <sup>1</sup>	Non-Preferred
Antifungals, Topical	ciclopirox suspension <sup>1</sup>	Non-Preferred
	naftifine gel¹	Non-Preferred
Bone Resorption Suppression	Forteo	Preferred
	ibandronate	Preferred

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DRUG CLASS	DRUG NAME	STATUS EFFECTIVE JULY 1, 2020, UNLESS OTHERWISE NOTED
Calcium Channel Blocking Agents	Katerzia suspension <sup>1</sup>	Non-Preferred
Headache Agents, Acute Treatment	Emgality 100 mg <sup>1</sup>	Non-Preferred
	Nurtec ODT¹	Non-Preferred
	Reyvow <sup>1</sup>	Non-Preferred
	Ubrelvy <sup>1</sup>	Non-Preferred
Headache Agents, Preventative Treatment	Ajovy	Preferred
Headache Agents, Triptans Non- Injectable	naratriptan	Preferred
Hepatitis C Agents	Harvoni	Non-Preferred
	sofosbuvir/velpatasvir (Epclusa)	Preferred
	Zepatier	Non-Preferred
Hypoglycemics, GLP 1	Rybelsus tablets <sup>1</sup>	Non-Preferred
Hypoglycemics, Insulins	Humulin R U-500 Kwikpen	Preferred
	insulin aspart U-100 cartridge	Non-Preferred
	(Novolog) <sup>1</sup>	
	insulin aspart U-100 pen (Novolog)¹	Non-Preferred
	insulin aspart U-100 vial (Novolog)¹	Non-Preferred
	insulin aspart/protamine pen (Novolog Mix) <sup>1</sup>	Non-Preferred
	insulin aspart/protamine vial (Novolog Mix) <sup>1</sup>	Non-Preferred
Hypoglycemics, Other	Invokamet	Preferred
,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	Riomet ER solution <sup>1</sup>	Non-Preferred
	Xigduo XR	Preferred
Lipotropics, Other	Ezallor sprinkles <sup>1</sup>	Non-Preferred
Multiple Sclerosis Agents,	Mavenclad <sup>1</sup>	Non-Preferred
Immunomodulators	Mayzent <sup>1</sup> Non-Preferred	
	Tecfidera	Preferred
	Vumerity DR capsule <sup>1</sup>	Non-Preferred
Multiple Sclerosis Agents, Other	Ampyra ER	Preferred

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DRUG CLASS	DRUG NAME	STATUS EFFECTIVE JULY 1, 2020, UNLESS OTHERWISE NOTED
Opioid Dependency Agents-	buprenorphine/naloxone tablet	Preferred
Buprenorphine	Sublocade	Preferred
Prenatal Vitamins	Concept DHA capsule	Preferred
	Concept OB capsule	Preferred
	Prenaissance Plus softgel <sup>1</sup>	Non-Preferred
	Purefe Plus capsule	Preferred
	Purefe OB Plus capsule	Preferred
	Provida OB capsule	Preferred
	Tricare Prenatal tablet	Preferred
Pulmonary Arterial Hypertension	ambrisentan tablet¹	Preferred
	bosentan tablet¹	Non-Preferred
	sildenafil suspension <sup>1</sup>	Non-Preferred
Skeletal Muscle Relaxants	Norgesic Forte tablet <sup>1</sup>	Non-Preferred
Ulcerative Colitis	mesalamine DR capsule <sup>1</sup>	Non-Preferred
	mesalamine ER capsule (Apriso) <sup>1</sup>	Non-Preferred

<sup>&</sup>lt;sup>1</sup> Drug was not previously reviewed by the Wisconsin Medicaid Pharmacy Prior Authorization Advisory Committee. For more information, providers should refer to the <u>Drug Status Changes on the Preferred</u> Drug List section of this ForwardHealth Update.

The information provided in this ForwardHealth Update is published in accordance with Wis. Stat. § 49.45(49) and Wis. Admin. Code § DHS 107.10.

### **ATTACHMENT B**

## Changes to Pharmacy-Related Prior Authorization Forms and Instructions

The table below lists the pharmacy-related prior authorization forms and instructions that are new, revised, renamed, or discontinued as a result of the May 2020 Preferred Drug List review or as a result of other pharmacy policy changes. Providers should refer to the <a href="Forms page">Forms page</a> of the ForwardHealth Portal for current copies of these forms and instructions. The previous versions of these forms and instructions will be moved to the <a href="Pharmacy-Related Forms and Instructions archive page">Pharmacy-Related Forms and Instructions archive page</a>. For more information regarding clinical criteria or submission options, refer to the applicable drug class in this ForwardHealth Update.

FORM NAME	FORM NUMBER	NEW, REVISED, RENAMED, OR DISCONTINUED	EFFECTIVE DATE
Prior Authorization Drug Attachment	F-00238	Revised	07/2020
for Glucagon-Like Peptide (GLP-1)			
Agents			
Instructions	F-00238A	Revised	07/2020
Prior Authorization Drug Attachment	F-02666	New	07/2020
for Headache Agents, Acute			
Treatment			
Instructions	F-02666A	New	07/2020
Prior Authorization Drug Attachment	F-02667	New	07/2020
Headache Agents, Preventative			
Treatment			
Instructions	F-02667A	New	07/2020
Prior Authorization Drug Attachment	F-01247	Revised	07/2020
for Hepatitis C Agents			
Instructions	F-01247A	Revised	07/2020
Prior Authorization Drug Attachment	F-02371	Discontinued	07/2020
for Migraine Agents, Calcitonin Gene-			
Related Peptide (CGRP) Antagonists			
Instructions	F-02371A	Discontinued	07/2020
Prior Authorization/Preferred Drug	F-00194	Revised and Renamed: Prior	07/2020
List (PA/PDL) for Antiemetics,		Authorization Drug Attachment	
Cannabinoids		for Antiemetics, Cannabinoids	
Instructions	F-00194A	Revised	07/2020

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FORM NAME	FORM NUMBER	NEW, REVISED, RENAMED, OR DISCONTINUED	EFFECTIVE DATE
Prior Authorization/Preferred Drug	F-02572	Revised	07/2020
List (PA/PDL) for Eucrisa			
Instructions	F-02572A	Revised	07/2020
Prior Authorization/Preferred Drug	F-11092	Revised	07/2020
List (PA/PDL) for Growth Hormone			
Drugs			
Instructions	F-11092A	Revised	07/2020
Prior Authorization/Preferred Drug	F-02668	New	07/2020
List (PA/PDL) for Headache Agents,			
Triptans Non-Injectable			
Instructions	F-02668A	New	07/2020
Prior Authorization/Preferred Drug	F-00622	Discontinued	07/2020
List (PA/PDL) for Migraine Agents,			
Injectable			
Instructions	F-00622A	Discontinued	07/2020
Prior Authorization/Preferred Drug	F-00280	Discontinued	07/2020
List (PA/PDL) for Migraine Agents,			
Other			
Instructions	F-00280A	Discontinued	07/2020
Prior Authorization/Preferred Drug	F-00805	Revised and Renamed: Prior	07/2020
List (PA/PDL) for Multiple Sclerosis		Authorization Drug Attachment	
(MS) Agents, Immunomodulators		for Multiple Sclerosis (MS)	
		Agents, Immunomodulators	
Instructions	F-00805A	Revised and Renamed	07/2020
Prior Authorization/Preferred Drug	F-00081	Revised	07/2020
List (PA/PDL) for Opioid Dependency			
Agents—Buprenorphine			
Instructions	F-00081A	Revised	07/2020

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