June 21, 2017: This *Update* has been revised with additional information since its original publication. Information under Olysio[®] as Combined with Sovaldi[®] has been added in red text on page 17 of the *Update*.



Update June 2017

No. 2017-17

Affected Programs: BadgerCare Plus, Medicaid, SeniorCare

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

July 2017 Preferred Drug List Review and Other Pharmacy Policy Changes

This *ForwardHealth Update* provides information for prescribers and pharmacy providers about changes to the Preferred Drug List and other pharmacy policy changes effective for dates of service on and after July 1, 2017, unless otherwise noted.

This *ForwardHealth Update* provides information for prescribers and pharmacy providers about changes to the Preferred Drug List (PDL) and other pharmacy policy changes effective for dates of service (DOS) on and after July 1, 2017, unless otherwise noted.

This *Update* provides an overview of the major changes to certain PDL drug classes for BadgerCare Plus, Medicaid, and SeniorCare programs but does not address all of the changes made in PDL drug classes. For additional information about covered drugs on the PDL for BadgerCare Plus, Medicaid, and SeniorCare, providers may refer to the Preferred Drug List Quick Reference on the Pharmacy Resources page of the Providers area of the ForwardHealth Portal at *mmm.forwardhealth.wi.gov/.*

Changes to Pharmacy-Related Forms and Completion Instructions

Attachment 1 of this *Update* lists the prior authorization (PA) forms and completion instructions that have been revised or discontinued as a result of the July 2017 PDL review or as a result of other pharmacy policy changes. Providers should

refer to the Forms page of the Portal for current copies of all PA forms and completion instructions. Unless otherwise noted, all forms listed in Attachment 1 are effective July 1, 2017. Additional information regarding changes to clinical criteria or submission options is noted in the applicable drug class section of this *Update*.

Archive Page for Pharmacy-Related Forms and Completion Instructions

Providers may reference the Pharmacy-Related Forms and Completion Instructions link under the Archives section on the Pharmacy Resources page of the Portal for old versions of pharmacy-related forms and completion instructions. These archives are provided for reference purposes only. Providers should refer to the ForwardHealth Online Handbook for current policy and procedures and to the Forms page of the Portal for current forms and completion instructions.

A Brief Overview of the PDL

ForwardHealth makes recommendations to the Wisconsin Medicaid Pharmacy PA Advisory Committee on 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 of the drug, clinical outcomes, and the relative cost of the drug (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 non-preferred drugs until their next scheduled class review by the 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, Medicaid, and SeniorCare, but certain drugs may have restrictions (e.g., 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 (e.g., drugs used for hair loss or cosmetic purposes) are not reimbursed, even with PA.

A Prescriber's Responsibilities for PA for PDL Drugs

Prescribers are encouraged to write prescriptions for preferred drugs.

Prescribers are encouraged to prescribe **more than one** preferred drug before a non-preferred drug is prescribed.

Prescribers are required to provide clinical information so that pharmacy providers can request and obtain PA. Prescribers are required to complete the Prior Authorization/Preferred Drug List (PA/PDL) Exemption Request form, F-11075 (09/13), for non-preferred drugs that do not require a drug- or drug class-specific PA form.

Clinical Criteria for Non-Preferred Drugs

Clinical criteria for approval of a PA request for a nonpreferred drug are **at least one** of the following, unless drug class-specific clinical criteria have been established and published by ForwardHealth:

• The member has experienced an unsatisfactory therapeutic response or a clinically significant adverse

drug reaction with **at least one** of the preferred drugs from the same PDL drug class as the drug being requested.

- There is a clinically significant drug interaction between another drug the member is taking and **at least one** of the preferred drugs from the same PDL drug class as the drug being requested.
- The member has a medical condition(s) that prevents the use of **at least one** of the preferred drugs from the same PDL drug class as the drug being requested.

Alternate Clinical Criteria for Non-Preferred Drugs in Eligible Drug Classes Only

The following drug classes have alternate clinical criteria that may be considered if the member does not meet the previously listed clinical criteria for non-preferred drugs:

- Alzheimer's agents drug class
- Anticonvulsants drug class
- Antidepressants, other drug class
- Antidepressants, selective serotonin reuptake inhibitor drug class
- Antiparkinson's agents drug class
- Antipsychotics drug class
- Pulmonary arterial hypertension drug class

Alternate clinical criteria may be considered if a member does not meet the previously listed clinical criteria for nonpreferred drugs. Alternate clinical criteria are **one** of the following:

- The member is new to ForwardHealth (i.e., the member has been granted eligibility for ForwardHealth within the past month) and has taken the requested nonpreferred drug continuously for the last 30 days or longer and had a measurable therapeutic response.
- The member had an approved PA request issued by ForwardHealth that recently expired for the nonpreferred 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.
- The member was recently discharged from an inpatient stay in which the member was stabilized on the non-preferred drug being requested.

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.

Completing a PA Form

If a non-preferred drug or a preferred drug that requires clinical PA is medically necessary for a member, the prescriber is required to do the following:

- Complete the appropriate PA form for the drug.
- Send the PA form to the pharmacy where the prescription will be filled.
- Include accurate and complete answers and clinical information about the member's medical history on the PA form.
- Provide their handwritten signature and date on the form.

The PA form may be faxed or mailed to the pharmacy, or the member may carry the 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.

Prescribers are required to retain a completed, signed, and dated copy of the PA form and any supporting documentation. Pharmacy providers may not reuse PA forms from previously approved PA requests for subsequent PA request submissions.

Note: If additional information needs to be addressed and can be provided by the pharmacy provider (e.g., medication refill history and compliance), the pharmacy provider should add the information to the Prior Authorization Fax Cover Sheet, F-01176 (12/11), which is available on the Forms page of the Portal, or to the Additional Information section available on most PA forms. The representative for the pharmacy provider should sign and date the entry to clearly identify the information source.

A Pharmacy Provider's Responsibilities for PA for PDL Drugs

Pharmacy providers should review the Preferred Drug List Quick Reference for the most current list of preferred and non-preferred drugs.

If a member presents a prescription for a non-preferred drug, the pharmacy provider is encouraged to contact the prescriber to discuss preferred drug options. The prescriber may choose to change the prescription to a preferred drug, if medically appropriate for the member, or the prescriber may complete the appropriate PA form.

Pharmacy providers are required to do the following:

- Submit the PA request using the PA form received from the prescriber and using the PA request submission option most appropriate for the drug. Pharmacy providers may submit PA requests using the Specialized Transmission Approval Technology-Prior Authorization (STAT-PA) system (when applicable), on the Portal, by fax, or by mail.
- Retain a completed, signed, and dated copy of the PA form and any supporting documentation received from the prescriber.

Pharmacy providers may not reuse PA forms from previously approved PA requests for subsequent PA request submissions.

Note: If additional information needs to be addressed and can be provided by the pharmacy provider (e.g., medication refill history and compliance), the pharmacy provider should add the information to the Prior Authorization Fax Cover Sheet, which is available on the Forms page of the Portal, or to the Additional Information section available on most PA forms. The representative for the pharmacy provider should sign and date the entry to clearly identify the information source.

Changes to the Preferred or Non-Preferred Status of Drugs on the PDL

On May 10, 2017, the Pharmacy PA Advisory Committee met to review new and existing therapeutic drug classes on the PDL. Providers may refer to Attachment 2 for a table listing all of the drugs that have had a change in their preferred or nonpreferred status as a result of this meeting. The updated statuses are effective July 1, 2017. Providers should review the Preferred Drug List Quick Reference on the Portal for a complete list of preferred and non-preferred drugs.

For drugs that were previously preferred and will become non-preferred, pharmacists should work with prescribers to transition members to a preferred drug or to complete the appropriate PA request forms.

As a reminder, new drugs are usually added to existing drug classes on the PDL as non-preferred drugs until the next scheduled class review by the Pharmacy PA Advisory Committee; therefore, some drugs listed in the table had not been reviewed previously and were added to the PDL with an interim status of non-preferred. These drugs have now been reviewed and their PDL status resulting from the May 10, 2017, meeting are effective July 1, 2017, and are included in Attachment 2.

For some drugs in Attachment 2, additional information is provided in the applicable drug class section of this *Update*.

Alzheimer's Agents

Memantine

Memantine solution and memantine tablets will no longer be diagnosis restricted.

Memantine tablets will remain a preferred drug, and memantine solution will become a preferred drug in the Alzheimer's agents drug class; however, because the safety and effectiveness of these products for pediatric patients has not been established, coverage will be restricted to adult members who are 18 years of age or older.

ForwardHealth will not cover memantine products for members 17 years of age or younger. PA requests submitted for memantine products for members 17 years of age or younger will be returned as a noncovered service. Members do not have appeal rights for noncovered services.

Namenda XR®

Namenda XR[®] will remain a non-preferred drug in the Alzheimer's agents drug class.

Namenda XR[®] will continue to be diagnosis restricted. Providers may refer to the Diagnosis Restricted Drugs data table on the Pharmacy Resources page of the Providers area of the Portal for the most current list of allowable diagnosis codes.

Pharmacy providers may submit PA requests for Namenda XR[®] with an allowable diagnosis code using the STAT-PA system, on the Portal, by fax, or by mail.

Note: BadgerCare Plus, Medicaid, and SeniorCare members previously identified to be taking memantine, Namenda, or Namenda XR[®] will continue to be allowed to receive memantine, Namenda, or Namenda XR[®] products without PA until further notice. For more information about these previously identified members, providers may refer to the Alzheimer's Agents topic (topic #15037) in the Preferred Drug List chapter of the Prior Authorization section of the Pharmacy service area of the Online Handbook.

Antibiotics, GI

Xifaxan[®] will become a preferred drug in the antibiotics, GI drug class.

Quantity limits continue to apply to Xifaxan[®] 200 mg tablets. Members are limited to a maximum of nine tablets per 68 days.

Providers may refer to the Quantity Limit Drugs and Diabetic Supplies data table on the Pharmacy Resources page of the Providers area of the Portal for the most current quantity limits.

Antiemetics, Cannabinoids

Dronabinol will become a non-preferred drug in the antiemetics, cannabinoids drug class.

Revised Prior Authorization/Preferred Drug List for Antiemetics, Cannabinoids Form

ForwardHealth has revised the Prior Authorization/Preferred Drug List (PA/PDL) for Antiemetics, Cannabinoids form, F-00194 (07/2017). The previous version will be removed from the Forms page of the Portal and placed on the Pharmacy-Related Forms and Completion Instructions archive page linked under the Archives section of the Pharmacy Resources page of the Portal. PA requests submitted on and after July 1, 2017, must be submitted on the revised form or the PA request will be returned to the provider.

PA requests that have already been approved will be honored until they expire or until the approved days' supply is used up.

Clinical PA is required for all antiemetic, cannabinoid drugs. To request PA, prescribers are required to complete and submit the PA/PDL for Antiemetics, Cannabinoids form to the pharmacy where the prescription will be filled. PA requests for antiemetic, cannabinoid drugs may be submitted on the ForwardHealth Portal, by fax, or by mail (but **not** using the STAT-PA system).

PA requests for antiemetic, cannabinoid drugs will be approved for up to a maximum of 183 days. Medical records must be submitted to support the need for an antiemetic, cannabinoid drug.

ForwardHealth has revised the clinical criteria for drugs in the antiemetics, cannabinoids drug class.

Clinical Criteria for Dronabinol for HIV- and AIDS-Related Weight Loss or Cachexia

Clinical criteria for approval of a PA request for dronabinol for the treatment of weight loss or cachexia caused by HIV or AIDS for members who are **not** currently receiving dronabinol are **all** of the following:

- **One** of the following is true:
 - ✓ The member's baseline weight is typically in the normal weight range or above, and either the member's current body mass index (BMI) falls into

the underweight range or the member had a 20 percent or greater decrease in weight from baseline in the past six months.

- The member's baseline weight is normally in the underweight range and the member has had a 5 percent or greater decrease in weight from baseline.
- The member's daily caloric intake has been optimized.
- The member has been advised about and is following an appropriate dietary plan.

Clinical criteria for approval of a PA request for dronabinol for the treatment of weight loss or cachexia caused by HIV or AIDS for members who are currently receiving dronabinol are **both** of the following:

- The member's BMI is **not** in the overweight or obese range.
- **One** of the following is true:
 - ✓ The member's BMI remains in the underweight range.
 - ✓ The member's BMI has been stabilized in the normal range for less than six months.

Note: Members whose weight has been stabilized in the normal range for at least six months will **not** be granted a dronabinol PA renewal.

Clinical Criteria for Dronabinol and Cesamet[®] for Chemotherapy-Related Nausea and Vomiting

Clinical criteria for approval of a PA request for dronabinol or Cesamet[®] for the treatment of chemotherapy-related nausea and vomiting are **both** of the following:

- 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 for each:
 - There is a clinically significant drug interaction between another drug(s) the member is taking and ondansetron/granisetron.
 - The member has a medical condition(s) that prevents the use of ondansetron/granisetron.

- At least one of the following is true:
 - ✓ The member has experienced an unsatisfactory therapeutic response or a clinically significant adverse drug reaction with Emend[®].
 - ✓ There is a clinically significant drug interaction between another drug(s) the member is taking and Emend[®].
 - ✓ The member has a medical condition(s) that prevents the use of Emend[®].

Cytokine and Cell Adhesion Molecule Antagonist Drugs

ForwardHealth has revised the list of non-preferred drugs used to treat psoriasis to include Siliq[™].

The clinical criteria for which PA requests are considered for cytokine and cell adhesion molecule (CAM) antagonist drugs used to treat psoriasis has not changed.

For more information about cytokine and CAM antagonist drugs, providers may refer to the Cytokine and Cell Adhesion Molecule Antagonist Drugs topic (topic #16217) in the Preferred Drug List chapter of the Prior Authorization section of the Pharmacy service area of the Online Handbook.

GI Motility, Chronic

Due to the addition of multiple drugs to the gastrointestinal (GI) motility, chronic drug class, the GI motility, chronic drug class will be split to include subclasses for constipation and diarrhea on the Preferred Drug List Quick Reference. ForwardHealth will monitor the subclasses separately.

The subclasses will be named GI motility, chronic — constipation and GI motility, chronic — diarrhea.

GI Motility, Chronic — Constipation

Relistor[®] and Trulance[™] will become non-preferred drugs in the GI motility, chronic — constipation drug class.

GI Motility, Chronic — Diarrhea

Viberzi[®] will become a non-preferred drug in the GI motility, chronic — diarrhea drug class.

In addition to being added as a preferred drug in the antibiotics, GI drug class, Xifaxan[®] 550 mg will also will be added as a preferred drug in the GI motility, chronic — diarrhea drug class.

Providers should review the Preferred Drug List Quick Reference on the Portal for a complete list of preferred and non-preferred drugs in both the GI motility, chronic constipation drug class and the GI motility, chronic diarrhea drug class.

Growth Hormone Drugs

Genotropin[®] will become a preferred drug in the growth hormone drugs drug class.

Nutropin AQ[®] will become a non-preferred drug in the growth hormone drugs drug class.

Members should transition to a preferred product unless it is medically necessary for a member to continue to use Nutropin AQ[®]. If Nutropin AQ[®] is medically necessary for a member, the pharmacy provider should work with the prescriber to complete and sign a Prior Authorization/Preferred Drug List (PA/PDL) for Growth Hormone Drugs form, F-11092 (07/2017); the pharmacy provider should then submit a request for PA for the member.

Revised PA/PDL for Growth Hormone Drugs Form

ForwardHealth has revised the PA/PDL for Growth Hormone Drugs form. The previous version will be removed from the Forms page of the Portal and placed on the Pharmacy-Related Forms and Completion Instructions archive page linked under the Archives section of the Pharmacy Resources page of the Portal. PA requests submitted on and after July 1, 2017, must be submitted on the revised form or the PA request will be returned to the provider.

PA requests that have already been approved will be honored until they expire or until the approved days' supply is used up. PA requests for growth hormone drugs must be submitted on the PA/PDL for Growth Hormone Drugs form. PA requests for growth hormone drugs may be submitted using the STAT-PA system (for some conditions or indications), on the Portal, by fax, or by mail.

All growth hormone prescriptions must be written by an endocrinologist or through an endocrinology consultation, except prescriptions written for Serostim[®] or Zorbtive[®].

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

Clinical Criteria for Serostim®

ForwardHealth covers Serostim[®] for members with AIDS wasting disease or cachexia.

If clinical criteria for Serostim[®] are met, initial PA requests for Serostim[®] may be approved for up to a maximum of 365 days. PA requests for Serostim[®] must be submitted on the PA/PDL for Growth Hormone Drugs form and may be submitted to ForwardHealth using the STAT-PA system, on the Portal, by fax, or by mail.

Clinical Criteria for Zorbtive®

ForwardHealth covers Zorbtive[®] for members with short bowel syndrome with dependence on parenteral nutrition. Members are limited to a 28-day course of the drug to reduce dependence on parenteral nutrition.

PA requests for Zorbtive[®] must be submitted on the PA/PDL for Growth Hormone Drugs form and may be submitted to ForwardHealth using the STAT-PA system, on the Portal, by fax, or by mail.

Clinical Criteria for Growth Hormone Drug Coverage for Pediatric Members

ForwardHealth does not cover growth hormone drugs for the following members and conditions:

• Pediatric members with idiopathic short stature, which is a growth failure or short stature not associated with growth hormone deficiency or disease state • Pediatric members post kidney transplant

PA requests submitted for growth hormone drugs for idiopathic short stature or post kidney transplant will be returned as noncovered services. Members do not have appeal rights for noncovered services.

ForwardHealth covers growth hormone drugs for the following indications:

- Growth failure or short stature associated with growth hormone deficiency confirmed with at least two appropriate growth hormone stimulation tests demonstrating a growth hormone peak response of less than 10 ng/mL and the member's height must be more than two standard deviations below the mean for chronological age. Providers are required to include detailed documentation of the medical work-up and testing used to determine the need for growth hormone treatment. Other causes for short stature, such as growth inhibiting medication, chronic disease, other congenital conditions, or under-nutrition, have been ruled out. The medical work-up should include growth velocity, IGF-1 (insulin-like growth factor-1), IGF-BP3 (insulin-like growth factor binding protein-3), and bone age results. If these results are normal, best clinical practice would indicate growth hormone stimulation testing is not necessary since growth hormone deficiency can effectively be excluded without the need for growth hormone stimulation testing. If IGF-1/IGF-BP3 results are low, under-nutrition should be evaluated and addressed before proceeding with growth hormone stimulation testing. Growth hormone stimulation testing can be useful information, but it has not been shown to be a definitive tool by itself for diagnosing growth hormone deficiency. ForwardHealth will consider the entire clinical record for the PA request determination decision.
- Evidence of panhypopituitarism involving at least two pituitary hormone deficiencies, not including growth hormone, and history of a hypothalamic-pituitary structural lesion(s). Providers are required to include detailed documentation of the medical work-up and testing used to determine the need for growth hormone treatment.

- Evidence of a history of cranial irradiation and low IGF-1 measurement below the age-appropriate level with normal thyroid function and adequate nutrition. Providers are required to include detailed documentation of the medical work-up and testing used to determine the need for growth hormone treatment.
- Growth failure or short stature associated with one of the following congenital conditions:
 - ✓ Noonan syndrome
 - ✓ Prader-Willi syndrome
 - ✓ Short stature homeobox-containing gene deficiency
 - ✓ Turner syndrome
- Growth failure or short stature associated with chronic renal insufficiency in pre-kidney transplant members.
 Providers are required to include detailed documentation of the medical work-up and testing used to determine the need for growth hormone treatment.
- Members born small for gestational age (SGA) who are 2 years of age or older with a height that remains more than two standard deviations below the mean for chronological age. SGA is defined as infants with a birth weight below the 10th percentile for gestational age. Providers are required to include detailed documentation of the medical work-up and testing used to determine the need for growth hormone treatment. Other causes for short stature, such as growth inhibiting medication, chronic disease, other congenital conditions, or under-nutrition, have been ruled out.

Detailed documentation of the medical work-up and testing must include, at a minimum, the following:

- Medical office notes
- Clinically appropriate growth charts for weight and height (including growth velocity, growth percentiles, and Z-scores)
- Lab testing results (including IGF-1 and IGF-BP3)
- Bone age results

Additional required documentation to be submitted with the PA request, when applicable, includes the following:

- Growth plate results
- Other imaging results (e.g., computed tomography [CT], MRI)
- Nutritional assessment

• Growth hormone stimulation testing

Growth hormone stimulation testing should be conducted after an overnight fast, using a well-standardized protocol. When growth hormone stimulation testing has been performed, complete testing results must be included with the PA request, including the following:

- The type of stimulation test and the dose of stimulating agent
- A copy of the medical notes taken during the entire testing procedure
- The time and results from each blood sample taken
- The provider interpretation of the testing results

With the exception of PA requests for pediatric members with a history of cranial irradiation or hypothalamic-pituitary structural lesion(s), PA requests for growth hormone therapy will be denied in the following circumstances:

- Closed epiphyses
- Growth velocity less than 2 cm/year or a growth velocity that does not demonstrate a significant increase
- Bone age greater than 14 years for a female and 16 years for a male
- Mid-parental height is achieved. Mid-parental height = (father's height + mother's height) divided by 2, plus 2.5 inches (male) or minus 2.5 inches (female)
- Non-compliance with prescribed growth hormone therapy

Clinical Criteria for Growth Hormone Drug Coverage for Adults and Adolescents with Skeletal Maturity

ForwardHealth does not cover growth hormone drugs for members who do not comply with their prescribed growth hormone therapy.

ForwardHealth covers growth hormone drugs for the following indications:

 History of panhypopituitarism during childhood involving at least two other pituitary hormone deficiencies, not including growth hormone, and treatment with a growth hormone drug during childhood.

- History of hypopituitarism during childhood involving at least one other pituitary hormone deficiency, not including growth hormone, and treatment with a growth hormone drug during childhood. The diagnosis of growth hormone deficiency must be reconfirmed after stopping growth hormone treatment for at least three months with an IGF-1 measurement below the ageappropriate level and at least one standard appropriate growth hormone peak response of less than the established adult reference values of the specific stimulation tests performed.
- History of treatment with a growth hormone drug during childhood without evidence of other pituitary hormone deficiencies. The diagnosis of growth hormone deficiency must be reconfirmed after stopping growth hormone treatment for at least three months with an IGF-1 measurement below the age appropriate level and at least two standard appropriate growth hormone stimulation tests demonstrating a growth hormone peak response of less than the established adult reference values of the specific stimulation tests performed.
- History of a head injury, hypothalamic-pituitary structural lesion(s), or cranial irradiation and evidence of panhypopituitarism involving at least three other pituitary hormone deficiencies, not including growth hormone.
- History of a head injury, hypothalamic-pituitary structural lesion(s), or cranial irradiation and evidence of hypopituitarism with at least one other pituitary hormone deficiency, not including growth hormone. Growth hormone deficiency must be confirmed with an IGF-1 measurement below the age appropriate level and at least one standard appropriate growth hormone stimulation test demonstrating a growth hormone peak response of less than the established adult reference values of the specific stimulation tests performed.
- History of a head injury, hypothalamic-pituitary structural lesion(s), or cranial irradiation without evidence of other pituitary hormone deficiencies. Growth hormone deficiency must be confirmed with an IGF-1 measurement below the age appropriate level and at least two standard appropriate growth hormone

stimulation tests demonstrating a growth hormone peak response of less than the established adult reference values of the specific stimulation tests performed.

Note: For individuals being treated for growth hormone deficiency due to trauma or subarachnoid hemorrhage, growth hormone deficiency must be reconfirmed at one year after the event for therapy to continue. If retesting does not confirm growth hormone deficiency, continued treatment will not be approved.

Growth hormone stimulation testing should be conducted after an overnight fast, using a well-standardized protocol. When growth hormone stimulation testing has been performed, complete testing results must be included with the PA request, including the following:

- The type of stimulation test and the dose of the stimulating agent
- A copy of the medical notes taken during the entire testing procedure
- The time and results from each blood sample taken
- The provider interpretation of the testing results

Providers are required to include detailed documentation of the medical work-up and testing used to determine the need for growth hormone treatment, including, but not limited to, the following:

- Medical office notes
- Image results
- Lab testing results

Hepatitis C Agents

Revised Prior Authorization Drug Attachment for Hepatitis C Agents Form

ForwardHealth has revised the Prior Authorization Drug Attachment for Hepatitis C Agents form, F-01247 (07/2017). The previous version will be removed from the Forms page of the Portal and placed on the Pharmacy-Related Forms and Completion Instructions archive page linked under the Archives section of the Pharmacy Resources page of the Portal. PA requests submitted on and after July 1, 2017, must be submitted on the revised form or the PA request will be returned to the provider. PA requests that have already been approved will be honored until they expire or until the approved days' supply is used up.

Prior Authorization Drug Attachment for Hepatitis C Agents Renewal Form Being Discontinued

Effective on and after **December 1, 2017,** the Prior Authorization Drug Attachment for Hepatitis C Agents Renewal form, F-01248 (08/2016), will no longer be accepted. This form is being discontinued. It will be removed from the Forms page of the Portal and placed on the Pharmacy-Related Forms and Completion Instructions archive page linked under the Archives section on the Pharmacy Resources page of the Portal. PA requests approved prior to July 1, 2017, that require a renewal PA request for the member to complete their HCV treatment regimen should continue to use the Prior Authorization Drug Attachment for Hepatitis C Agents Renewal form until the member's treatment regimen is completed.

Clinical PA is required for all hepatitis C agents, including preferred drugs.

Viekira Pak[™]/Viekira XR[™] and Zepatier[®] are the preferred drugs for members who have chronic hepatitis C virus (HCV) genotype 1 infection. PA requests for other hepatitis C agents for members who have chronic HCV genotype 1 infection will not be considered unless the member is clinically ineligible for treatment with Viekira Pak[™]/Viekira XR[™] and Zepatier[®] due to a medical or medication contraindication.

Epclusa[®] is the preferred drug for members who have chronic HCV genotype 2 or 3 infection. PA requests for other hepatitis C agents for members who have chronic HCV genotype 2 or 3 infection will not be considered unless the member is clinically ineligible for treatment with Epclusa[®] due to a medical or medication contraindication.

Technivie[™] and Zepatier[®] are the preferred drugs for members who have chronic HCV genotype 4 infection. PA requests for other hepatitis C agents for members who have chronic HCV genotype 4 infection will not be considered unless the member is clinically ineligible for treatment with Technivie[™] and Zepatier[®] due to a medical or medication contraindication.

PA requests for hepatitis C agents must be completed and signed by prescribers. PA requests for hepatitis C agents must be submitted on the Prior Authorization Drug Attachment for Hepatitis C Agents form.

Note: If additional information needs to be addressed and can be provided by the pharmacy provider (e.g., medication refill history and compliance), the pharmacy provider should add the information to the Prior Authorization Fax Cover Sheet form or to the Additional Information section available on most PA request forms. The representative for the pharmacy provider should sign and date the entry to clearly identify the information source.

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

Note: When two or more hepatitis C agents are used as a **combined** treatment (e.g., Daklinza[™] as a combined treatment with Sovaldi[®]), providers should not submit a separate PA request form for each drug. Hepatitis C agents that are used for a combined treatment must be submitted on **one** Prior Authorization Drug Attachment for Hepatitis C Agents form and one completed PA/RF.

ForwardHealth has revised the clinical criteria for hepatitis C agents.

Clinical Information That Must Be Documented on All Initial PA Requests for Hepatitis C Agents

For PA requests for hepatitis C agents, prescribers are required to complete and sign the Prior Authorization Drug Attachment for Hepatitis C Agents form and submit the form to the pharmacy where the prescription will be filled. Pharmacy providers are required to submit the completed Prior Authorization Drug Attachment for Hepatitis C Agents form and a completed PA/RF to ForwardHealth. The clinical information that must be submitted with all PA requests for hepatitis C agents are **all** of the following:

- Lab data (within the last six months), including the following:
 - \checkmark Albumin test
 - \checkmark Complete blood count
 - ✓ Hepatitis B virus screening
 - ✓ HCV genotype
 - ✓ HCV-ribonucleic acid (HCV-RNA) level
 - \checkmark International normalized ratio
 - ✓ Liver function test
 - ✓ Serum creatinine test
- Tests (if performed), including the following:
 - ✓ Liver CT scan, ultrasound, or MRI results
 - ✓ Liver biopsy results
 - ✓ Transient ultrasound elastography (FibroScan[®]) results
 - ✓ Magnetic resonance elastography results
 - ✓ Shear wave elastography results
 - ✓ Blood tests to assess liver fibrosis (i.e., FibroTest/FibroSure[®], FIBROSpect[®])
- HCV clinical data, including the following:
 - ✓ Likely source of the HCV infection and date diagnosed
 - ✓ Current medical records for HCV assessment and treatment
 - ✓ History of coinfection with hepatitis B or HIV
 - ✓ History of liver transplant or on liver transplant wait list
- If cirrhotic, documentation of the following clinical assessments:
 - ✓ Child-Turcotte-Pugh (CTP) score
 - ✓ Hepatocellular carcinoma status based on liver CT, ultrasound, or MRI performed within the last six months
 - \checkmark Presence and treatment of any of the following:
 - o Ascites
 - o Esophageal varices
 - o Hepatic encephalopathy
 - o Jaundice
 - o Portal hypertension
- Hepatitis C medication treatment history, including the following:
 - Details of when treatment occurred

- ✓ Medications taken and compliance
- ✓ Treatment results (e.g., null response, partial response, or relapse)
- Current medical history and physical, including complete problem list and medication list
- Current and past psychosocial history including alcohol and IV drug use
- Planned HCV treatment regimen

If the required documentation is not included on or with the Prior Authorization Drug Attachment for Hepatitis C Agents form, the PA request will be considered incomplete and will be returned to the provider or denied.

For members who have received a liver transplant, PA requests for all hepatitis C agents will be reviewed for the following: the member's HCV genotype, current liver disease status, past HCV treatment history, current medications, other comorbidities, and requested HCV treatment regimen. ForwardHealth will consider the member's entire clinical record and the level of clinical evidence for the PA request determination decision, and if the requested HCV treatment regimen has low clinical evidence of effectiveness, the PA request will be denied.

Approved PA requests for hepatitis C agents will be authorized for the full treatment course approved by ForwardHealth for the member.

PA requests for retreatment of members due to reinfection will be denied.

Pharmacy Provider-Specific PA Requests for Hepatitis C Agents

PA requests for hepatitis C agents included in the hepatitis C agents drug class on the PDL 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-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 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 Provider Services. Provider Services will work with the pharmacy provider on the approved PA request to ensure the member does not experience a disruption of therapy, and if necessary, will facilitate the transfer of the PA to a new pharmacy provider.

Hepatitis C Agents, Epclusa®

Epclusa[®] is a preferred drug that requires clinical PA for members who have chronic HCV genotype 2 or 3 infection.

Epclusa[®] is a non-preferred drug that requires clinical PA for members who have chronic HCV genotype 1, 4, 5, or 6 infection.

Only PA requests for Epclusa[®] for members with genotype 1, 2, 3, 4, 5, or 6 HCV liver infection will be considered for review. The member must meet **one** of the following:

- For HCV genotype 1 infection, the member must be clinically ineligible for treatment with Viekira Pak[™]/Viekira XR[™] and Zepatier[®] due to a medical or medication contraindication.
- For moderate decompensated cirrhosis (i.e., CTP class
 B) HCV genotype 1 infection, the member must be clinically ineligible for treatment with Harvoni[®] due to a medical or medication contraindication.
- For HCV genotype 4, the member must be clinically ineligible for treatment with Technivie[™] and Zepatier[®] due to a medical or medication contraindication.
- For HCV genotype 5 or 6 infection, the member must be clinically ineligible for treatment with Harvoni[®] due to a medical or medication contraindication.

Epclusa[®] treatment regimens will only be approved for a maximum of 12 weeks of treatment.

Conditions or Circumstances for Which PA Requests Will Be Denied

PA requests for Epclusa[®] will be denied in the following circumstances:

- The member has chronic HCV genotype 1 infection and does not have a medical or medication contraindication for treatment with Viekira Pak[™]/Viekira XR[™] and Zepatier[®].
- The member has chronic HCV genotype 1 infection with moderate decompensated cirrhosis (i.e., CTP class B) and does not have a medical or medication contraindication for treatment with Harvoni[®].
- The member has chronic HCV genotype 4 infection and does not have a medical or medication contraindication for treatment with Technivie[™] and Zepatier[®].
- The member has chronic HCV genotype 5 or 6 infection and does not have a medical or medication contraindication for treatment with Harvoni[®].
- The member has acute HCV.
- The member has a significant or uncontrolled concurrent disease that would significantly reduce life expectancy or limit adherence (e.g., cardiovascular disease, cancer, pulmonary disease).
- The member has HCV infection and cirrhosis with severe liver functional compromise (i.e., CTP 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.
- The member has cirrhosis or an alcohol use disorder and has not abstained from alcohol for at least six months prior to and during HCV treatment.
- The member has taken a prior course of therapy with Epclusa[®], Harvoni[®], Sovaldi[®], or a sofosbuvir-containing product.
- The member has a significant active substance use disorder that could contribute to unreliable compliance with a prescribed HCV treatment regimen or a recent history of non-compliance with prescribed medical care

including, but not limited to, the following: medications, lab testing, and medical visits.

• The member is less than 18 years of age.

Members with recent IV drug use must be participating in a recovery program and must no longer be actively using IV drugs for at least three months prior to and during HCV treatment.

In addition, the member's other medications will be evaluated to determine if a significant drug interaction may occur, which may result in denial of the PA request.

Hepatitis C Agents, Technivie™

Technivie[™] is a preferred drug that requires clinical PA for members who have chronic HCV genotype 4 infection.

Only PA requests for Technivie[™] for members with genotype 4 HCV liver infection will be considered for review.

Conditions or Circumstances for Which PA Requests Will Be Denied

PA requests for Technivie[™] will be denied in the following circumstances:

- The member has acute HCV.
- The member has a significant or uncontrolled concurrent disease that would significantly reduce life expectancy or limit adherence (e.g., cardiovascular disease, cancer, pulmonary disease).
- The member has cirrhosis.
- The member has an alcohol use disorder and has not abstained from alcohol for at least six months prior to and during HCV treatment.
- The member has taken a prior course of therapy with Technivie[™] or Viekira Pak[™]/Viekira XR[™].
- The member has a significant active substance use disorder that could contribute to unreliable compliance with a prescribed HCV treatment regimen or a recent history of non-compliance with prescribed medical care including, but not limited to, the following: medications, lab testing, and medical visits.

Members with recent IV drug use must be participating in a recovery program and must no longer be actively using IV drugs for at least three months prior to and during HCV treatment.

In addition, the member's other medications will be evaluated to determine if a significant drug interaction may occur, which may result in denial of the PA request.

Hepatitis C Agents, Viekira Pak™/Viekira XR™

Viekira Pak[™] and Viekira XR[™] are preferred drugs that require clinical PA for members who have chronic HCV genotype 1 infection.

Only PA requests for Viekira Pak[™]/Viekira XR[™] for members with genotype 1 HCV liver infection will be considered for review.

Conditions or Circumstances for Which PA Requests Will Be Denied

PA requests for Viekira Pak[™]/Viekira XR[™] will be denied in the following circumstances:

- The member has acute HCV.
- The member has a significant or uncontrolled concurrent disease that would significantly reduce life expectancy or limit adherence (e.g., cardiovascular disease, cancer, pulmonary disease).
- The member has cirrhosis with moderate or severe liver functional compromise (i.e. CTP class B or C).
- The member has cirrhosis or an alcohol use disorder and has not abstained from alcohol for at least six months prior to and during HCV treatment.
- The member has taken a prior course of therapy with Technivie[™] or Viekira Pak[™]/Viekira XR[™].
- The member has a significant active substance use disorder that could contribute to unreliable compliance with a prescribed HCV treatment regimen or a recent history of non-compliance with prescribed medical care including, but not limited to, the following: medications, lab testing, and medical visits.
- The member is less than 18 years of age.

• The member is less than 18 years of age.

Members with recent IV drug use must be participating in a recovery program and must no longer be actively using IV drugs for at least three months prior to and during HCV treatment.

In addition, the member's other medications will be evaluated to determine if a significant drug interaction may occur, which may result in denial of the PA request.

Hepatitis C Agents, Zepatier®

Zepatier[®] is a preferred drug that requires clinical PA for members who have chronic HCV genotype 1 or 4 infection.

Only PA requests for Zepatier[®] for members with genotype 1 or 4 HCV liver infection will be considered for review.

Members with genotype 1a infection must be tested for the presence of HCV with NS5A resistance-associated polymorphisms prior to initiating a PA request for Zepatier[®].

Conditions or Circumstances for Which PA Requests Will Be Denied

PA requests for Zepatier[®] will be denied in the following circumstances:

- The member has acute HCV.
- The member has a significant or uncontrolled concurrent disease that would significantly reduce life expectancy or limit adherence (e.g., cardiovascular disease, cancer, pulmonary disease).
- The member has cirrhosis with moderate or severe liver functional compromise (i.e., CTP class B or C).
- The member has cirrhosis or an alcohol use disorder and has not abstained from alcohol for at least six months prior to and during HCV treatment.
- The member has taken a prior course of therapy with Zepatier[®].
- The member has a significant active substance use disorder that could contribute to unreliable compliance with a prescribed HCV treatment regimen or a recent history of non-compliance with prescribed medical care including, but not limited to, the following: medications, lab testing, and medical visits.
- The member is less than 18 years of age.

Members with recent IV drug use must be participating in a recovery program and must no longer be actively using IV drugs for at least three months prior to and during HCV treatment.

In addition, the member's other medications will be evaluated to determine if a significant drug interaction may occur, which may result in denial of the PA request.

Hepatitis C Agents, Daklinza™

Daklinza[™] (combined with Sovaldi[®] with or without ribavirin) is a non-preferred drug that requires clinical PA for members who have chronic HCV genotype 1, 2, or 3 infection.

Only PA requests for Daklinza[™] for members with genotype 1, 2, or 3 HCV liver infection will be considered for review. The member must meet **one** of the following:

- For HCV genotype 1 infection, the member must be clinically ineligible for treatment with Viekira Pak[™]/Viekira XR[™] and Zepatier[®] due to a medical or medication contraindication.
- For moderate decompensated cirrhosis (i.e., CTP class
 B) HCV genotype 1 infection, the member must be clinically ineligible for treatment with Harvoni[®] due to a medical or medication contraindication.
- For HCV genotype 2 and 3 infection, the member must be clinically ineligible for treatment with Epclusa[®] due to a medical or medication contraindication.

Members with genotype 1a infection with cirrhosis must be screened for the presence of NS5A polymorphisms at amino acid positions M28, Q30, L31, and Y93. If the presence of NS5A polymorphisms at amino acid positions M28, Q30, L31, and Y93 is detected, treatment will not be considered for review.

Daklinza[™] treatment regimens will only be approved for a maximum of 12 weeks of treatment.

Conditions or Circumstances for Which PA Requests Will Be Denied for Use of Daklinza[™] as a Combined Treatment with Sovaldi[®] with or Without Ribavirin

PA requests for the use of Daklinza[™] as a combined treatment with Sovaldi[®] with or without ribavirin will be denied in the following circumstances:

- The member has chronic HCV genotype 1 infection and does not have a medical or medication contraindication for treatment with Viekira Pak[™]/Viekira XR[™] and Zepatier[®].
- The member has chronic HCV genotype 1 infection with moderate decompensated cirrhosis (i.e., CTP class B) and does not have a medical or medication contraindication for treatment with Harvoni[®].
- The member has chronic HCV genotype 2, 3 infections and does not have a medical or medication contraindication for treatment with Epclusa[®].
- The member has acute HCV.
- The member has a significant or uncontrolled concurrent disease that would significantly reduce life expectancy or limit adherence (e.g., cardiovascular disease, cancer, pulmonary disease).
- The member has cirrhosis with severe liver functional compromise (i.e., CTP 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.
- The member has cirrhosis or an alcohol use disorder and has not abstained from alcohol for at least six months prior to and during HCV treatment.
- The member has taken a prior course of therapy with Daklinza[™], Epclusa[®], Harvoni[®], Sovaldi[®], or a sofosbuvir-containing product.
- The member has a significant active substance use disorder that could contribute to unreliable compliance with a prescribed HCV treatment regimen or a recent history of non-compliance with prescribed medical care

including, but not limited to, the following: medications, lab testing, and medical visits.

• The member is less than 18 years of age.

Members with recent IV drug use must be participating in a recovery program and must no longer be actively using IV drugs for at least three months prior to and during HCV treatment.

In addition, the member's other medications will be evaluated to determine if a significant drug interaction may occur, which may result in denial of the PA request.

Hepatitis C Agents, Harvoni®

Harvoni[®] is a non-preferred drug that requires clinical PA for members who have chronic HCV genotype 1, 4, 5, or 6 infection.

Only PA requests for Harvoni[®] for members with genotype 1, 4, 5, or 6 HCV liver infection will be considered for review. The member must meet **one** of the following:

- For HCV genotype 1 infection, the member must be clinically ineligible for treatment with Viekira Pak[™]/Viekira XR[™] and Zepatier[®] due to a medical or medication contraindication.
- For HCV genotype 4, the member must be clinically ineligible for treatment with Technivie[™] and Zepatier[®] due to a medical or medication contraindication.

For treatment-naïve members who have HCV genotype 1 infection without cirrhosis, an HCV-RNA level less than 6 million IU/mL, are non-Black, HIV-uninfected, and meet the above criteria for PA request review consideration, only eight weeks of Harvoni[®] treatment will be considered for review.

Harvoni[®] treatment regimens will only be approved for a maximum of 12 weeks.

Conditions or Circumstances for Which PA Requests Will Be Denied

PA requests for Harvoni[®] will be denied in the following circumstances:

- The member has chronic HCV genotype 1 infection and does not have a medical or medication contraindication for treatment with Viekira Pak[™]/Viekira XR[™] and Zepatier[®].
- The member has chronic HCV genotype 4 infection and does not have a medical or medication contraindication for treatment with Technivie[™] and Zepatier[®].
- The member has acute HCV.
- The member has a significant or uncontrolled concurrent disease that would significantly reduce life expectancy or limit adherence (e.g., cardiovascular disease, cancer, pulmonary disease).
- The member has HCV genotype 4, 5, or 6 infection and cirrhosis with moderate or severe liver functional compromise (i.e., CTP class B or C).
- The member has HCV genotype 1 infection and cirrhosis with severe liver functional compromise (i.e., CTP 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 liver function improvement. The only definitive treatment for end-stage liver disease is a liver transplant.
- The member has cirrhosis or an alcohol use disorder and has not abstained from alcohol for at least six months prior to and during HCV treatment.
- The member has taken a prior course of therapy with Epclusa[®], Harvoni[®], Sovaldi[®], or a sofosbuvircontaining product.
- The member has a significant active substance use disorder that could contribute to unreliable compliance with a prescribed HCV treatment regimen or a recent history of non-compliance with prescribed medical care including, but not limited to, the following: medications, lab testing, and medical visits.
- The member is less than 12 years of age.

Members with recent IV drug use must be participating in a recovery program and must no longer be actively using IV drugs for at least three months prior to and during HCV treatment.

In addition, the member's other medications will be evaluated to determine if a significant drug interaction may occur, which may result in denial of the PA request.

Hepatitis C Agents, Olysio®

Olysio[®] (combined with pegylated interferon and ribavirin) is a non-preferred drug that requires clinical PA for members who have chronic HCV genotype 1 or 4 infection.

Only PA requests for Olysio[®] (combined with pegylated interferon and ribavirin) for members with genotype 1 or 4 HCV liver infection will be considered for review. The member must meet **one** of the following:

- For HCV genotype 1 infection, the member must be clinically ineligible for treatment with Viekira Pak[™]/Viekira XR[™] and Zepatier[®] due to a medical or medication contraindication.
- For HCV genotype 4 infection, the member must be clinically ineligible for treatment with Technivie[™] and Zepatier[®] due to a medical or medication contraindication.

Conditions or Circumstances for Which PA Requests Will Be Denied for Use of Olysio[®] with Pegylated Interferon and Ribavirin

PA requests for the use of Olysio[®] with pegylated interferon and ribavirin will be denied in the following circumstances:

- The member has chronic HCV genotype 1 infection and does not have a medical or medication contraindication for treatment with Viekira Pak[™]/Viekira XR[™] and Zepatier[®].
- The member has chronic HCV genotype 4 infection and does not have a medical or medication contraindication for treatment with Technivie[™] and Zepatier[®].
- The member has acute HCV.
- The member has a significant or uncontrolled concurrent disease that would significantly reduce life expectancy or limit adherence (e.g., cardiovascular disease, cancer, pulmonary disease).

- The member has cirrhosis with moderate or severe liver functional compromise (i.e., CTP class B or C).
- The member has cirrhosis or an alcohol use disorder and has not abstained from alcohol for at least six months prior to and during HCV treatment.
- The member has taken a prior course of therapy with a treatment regimen that includes Olysio[®] or any other HCV protease inhibitor.
- The member has a significant active substance use disorder that could contribute to unreliable compliance with a prescribed HCV treatment regimen or a recent history of non-compliance with prescribed medical care including, but not limited to, the following: medications, lab testing, and medical visits.
- The member is less than 18 years of age.

Members with recent IV drug use must be participating in a recovery program and must no longer be actively using IV drugs for at least three months prior to and during HCV treatment.

Members with HCV genotype 1a infection must be screened for the NS3 Q80K polymorphism. If the NS3 Q80K polymorphism is detected, the PA request will not be considered for review.

In addition, the member's other medications will be evaluated to determine if a significant drug interaction may occur, which may result in denial of the PA request.

Conditions or Circumstances for Which PA Requests Will Be Considered for Review for Use of Olysio[®] as a Combined Treatment with Sovaldi[®]

Olysio[®] (combined with Sovaldi[®]) is a non-preferred drug that requires clinical PA for members who have chronic HCV genotype 1 infection.

Only PA requests for Olysio[®] (combined with Sovaldi[®]) for members with genotype 1 HCV liver infection will be considered for review.

PA requests for use of Olysio[®] as a combined treatment with Sovaldi[®] will only be considered for members who have contraindications to the use of Daklinza[™], Harvoni[®], ribavirin, Viekira Pak[™]/Viekira XR[™], and Zepatier[®]. Providers are required to clearly document why the member is unable to take Daklinza[™], Harvoni[®], ribavirin, Viekira Pak[™]/Viekira XR[™], and Zepatier[®].

Conditions or Circumstances for Which PA Requests Will Be Denied for Use of Olysio[®] as a Combined Treatment with Sovaldi[®]

PA requests for the use of Olysio[®] as a combined treatment with Sovaldi[®] will be denied in the following circumstances:

- The member does not have a medical or medication contraindication for treatment with Viekira Pak[™]/Viekira XR[™] and Zepatier[®].
- The member has acute HCV.
- The member has a significant or uncontrolled concurrent disease that would significantly reduce life expectancy or limit adherence (e.g., cardiovascular disease, cancer, depression, diabetes, pulmonary disease).
- The member has cirrhosis with moderate or severe liver functional compromise (i.e., CTP class B or C).
- The member has cirrhosis or an alcohol use disorder and has not abstained from alcohol for at least six months prior to and during HCV treatment.
- The member has taken a prior course of therapy with Epclusa[®], Harvoni[®], Olysio[®], Sovaldi[®], a sofosbuvir-containing product, or any other HCV protease inhibitor.
- The member has a significant active substance use disorder that could contribute to unreliable compliance with a prescribed HCV treatment regimen or a recent history of non-compliance with prescribed medical care including, but not limited to, the following: medications, lab testing, and medical visits.
- The member is less than 18 years of age.

Members with recent IV drug use must be participating in a recovery program and must no longer be actively using IV drugs for at least three months prior to and during HCV treatment.

In addition, the member's other medications will be evaluated to determine if a significant drug interaction may occur, which may result in denial of the PA request.

Hepatitis C Agents, Sovaldi®

Sovaldi[®] is a non-preferred drug that requires clinical PA for members who have chronic HCV genotype 1, 2, 3, or 4 infection.

Only PA requests for Sovaldi[®] for members with genotype 1, 2, 3, or 4 HCV liver infection will be considered for review. The member must meet **one** of the following:

- For HCV genotype 1 infection, the member must be clinically ineligible for treatment with Viekira Pak[™]/Viekira XR[™] and Zepatier[®] due to a medical or medication contraindication.
- For HCV genotype 2 or 3 infection, the member must be clinically ineligible for treatment with Epclusa[®] due to a medical or medication contraindication.
- For HCV genotype 4 infection, the member must be clinically ineligible for treatment with Technivie[™] and Zepatier[®] due to a medical or medication contraindication.

Sovaldi[®] treatment regimens for genotype 1 infection will only be approved for a maximum of 12 weeks of treatment with pegylated interferon and ribavirin. Sovaldi[®] treatment regimens for genotype 2 infection will only be approved for a maximum of 12 weeks of treatment with ribavirin. Sovaldi[®] treatment regimens for genotype 3 will only be approved for a maximum of 24 weeks of treatment with ribavirin. Sovaldi[®] treatment regimens for genotype 4 infection will only be approved for a maximum of 12 weeks of treatment with pegylated interferon and ribavirin.

Conditions or Circumstances for Which PA Requests Will Be Denied

PA requests for Sovaldi[®] will be denied in the following circumstances:

- The member has chronic HCV genotype 1 infection and does not have a medical or medication contraindication for treatment with Viekira Pak[™]/Viekira XR[™] and Zepatier[®].
- The member has chronic HCV genotype 2, 3 infection and does not have a medical or medication contraindication for treatment with Epclusa[®].

- The member has chronic HCV genotype 4 infection and does not have a medical or medication contraindication for treatment with Technivie[™] and Zepatier[®].
- The member has acute HCV.
- The member has a significant or uncontrolled concurrent disease that would significantly reduce life expectancy or limit adherence (e.g., cardiovascular disease, cancer, pulmonary disease).
- The member has cirrhosis with moderate or severe liver functional compromise (i.e., CTP class B or C).
- The member has cirrhosis or an alcohol use disorder and has not abstained from alcohol for at least six months prior to and during HCV treatment.
- The member has taken a prior course of therapy with Epclusa[®], Harvoni[®], Sovaldi[®], or a sofosbuvircontaining product.
- The member has a significant active substance use disorder that could contribute to unreliable compliance with a prescribed HCV treatment regimen or a recent history of non-compliance with prescribed medical care including, but not limited to, the following: medications, lab testing, and medical visits.
- The member is less than 12 years of age.

Members with recent IV drug use must be participating in a recovery program and must no longer be actively using IV drugs for at least three months prior to and during HCV treatment.

In addition, the member's other medications will be evaluated to determine if a significant drug interaction may occur, which may result in denial of the PA request.

Hypoglycemics, GLP-1 Agents

Victoza[®] will become a preferred drug in the hypoglycemics, glucagon-like peptide (GLP-1) agents drug class.

Tanzeum[®] will become a non-preferred drug in the in hypoglycemics, GLP-1 agents drug class.

Members should transition to a preferred product unless it is medically necessary for a member to continue to use Tanzeum[®]. If Tanzeum[®] is medically necessary for a member, the pharmacy provider should work with the prescriber to complete and sign a Prior Authorization/Preferred Drug List (PA/PDL) for Glucagon-Like Peptide (GLP-1) Agents form, F-00238 (07/2017); the pharmacy provider should then submit a request for PA.

Note: Members currently taking Tanzeum[®] who have had previous claims for Tanzeum[®] paid by ForwardHealth will be allowed to receive PA request approval as long as the PA request demonstrates that the member is currently stable on Tanzeum[®] and has been adherent with treatment.

Revised PA/PDL for GLP-1 Agents Form

ForwardHealth has revised the PA/PDL for GLP-1 Agents form. The previous version will be removed from the Forms page of the Portal and placed on the Pharmacy-Related Forms and Completion Instructions archive page linked under the Archives section of the Pharmacy Resources page of the Portal. PA requests submitted on and after July 1, 2017, must be submitted on the revised form or the PA request will be returned to the provider.

PA requests that have already been approved will be honored until they expire or until the approved days' supply is used up.

Due to the addition of multiple drugs to the hypoglycemics, GLP-1 agents PDL drug class, the hypoglycemics, GLP-1 agents drug class will be split to include a subclass for combinations on the Preferred Drug List Quick Reference. ForwardHealth will monitor the subclasses separately.

The subclass will be named hypoglycemics, GLP-1 agents — combinations.

Hypoglycemics, GLP-1 Agents — Combinations

Soliqua[®] and Xultophy[®]

Soliqua[®] and Xultophy[®] will become non-preferred drugs in the hypoglycemics, GLP-1 agents — combinations drug class. PA requests for Soliqua[®] and Xultophy[®] must be completed and signed by the prescriber. PA requests for Soliqua[®] and Xultophy[®] should be submitted using Section VI (Clinical Information for Drugs with Specific Criteria Addressed in the ForwardHealth Online Handbook) of the PA/DGA form and the PA/RF. Clinical documentation supporting the use of Soliqua[®] and Xultophy[®] must be submitted with the PA request.

PA requests for Soliqua[®] and Xultophy[®] may be submitted on the Portal, by fax, or by mail (but **not** using the STAT-PA system).

If clinical criteria for hypoglycemics, GLP-1 agents combinations drugs are met, initial PA requests may be approved for up to a maximum of 183 days. Renewal PA requests may be approved for up to a maximum of 365 days.

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.

ForwardHealth has established clinical criteria for hypoglycemics, GLP-1 agents — combinations drugs.

Clinical Criteria for Soliqua®

Clinical criteria that must be documented for approval of a PA request for Soliqua[®] are **all** of the following:

- The member has type 2 diabetes mellitus.
- The member is 18 years of age or older.
- The member does not currently have or have a history of pancreatitis.
- The member does not currently have or have a history of gastroparesis.
- The member's target hemoglobin A1c (HbA1c) treatment goal has been provided.
- The member's current HbA1c (measured within the past three months) has been provided.
- The member is not taking any meal-time insulin.
- The member has used Lantus[®] concurrently with Adlyxin[®] for **at least three** consecutive months and

reached their target HbA1c treatment goal. **Both** of the following dose requirements must be met:

- ✓ Lantus[®] dose must be less than or equal to 60 units taken once daily.
- ✓ Adlyxin[®] dose must be less than or equal to 20 mcg taken once daily.
- PA requests for Soliqua[®] will only be considered for once daily dosing. PA requests for twice daily dosing will be denied.

A copy of the member's diabetes management medical records must be provided to demonstrate the member meets the clinical criteria listed above.

Clinical Criteria for Xultophy[®]

Clinical criteria that must be documented for approval of a PA request for Xultophy® are **all** of the following:

- The member has type 2 diabetes mellitus.
- The member is 18 years of age or older.
- The member does not currently have or have a history of pancreatitis.
- The member does not currently have or have a history of gastroparesis.
- The member's target HbA1c treatment goal has been provided.
- The member's current HbA1c (measured within the past three months) has been provided.
- The member is not taking any meal-time insulin.
- The member has used Tresiba[®] concurrently with Victoza[®] for at least three consecutive months and reached their target HbA1c treatment goal. Both of the following dose requirements must be met:
 - ✓ A Tresiba[®] dose must be less than or equal to 50 units taken once daily.
 - ✓ A Victoza[®] dose must be less than or equal to 1.8 mcg taken once daily.
- PA requests for Xultophy[®] will only be considered for once daily dosing. PA requests for twice daily dosing will be denied.

A copy of the member's diabetes management medical records must be provided to demonstrate the member meets the clinical criteria listed above.

Hypoglycemics, Insulin — Long-Acting

PA requests for non-preferred hypoglycemics, insulin long-acting drugs must be completed and signed by the prescriber. PA requests for non-preferred hypoglycemics, insulin — long-acting drugs must be submitted using the Prior Authorization/Preferred Drug List (PA/PDL) for Hypoglycemics, Insulin — Long-Acting form, F-01749 (07/2016), and the PA/RF.

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

ForwardHealth has revised the clinical criteria for hypoglycemics, insulin — long-acting drugs.

Clinical Criteria for Non-Preferred Hypoglycemics, Insulin — Long-Acting Drugs

Clinical criteria that must be documented for approval of a PA request for a non-preferred hypoglycemics, insulin — long-acting drug are **all** of the following:

- The member has diabetes.
- The member is unable to use Lantus[®] due to **one** of the following:
 - ✓ The member has used Lantus[®] for at least six consecutive months and was unable to obtain adequate fasting glucose control.
 - ✓ The member has used Lantus[®] and experienced continued episodes of hypoglycemia.
- The member is unable to use Levemir[®] due to **one** of the following:
 - ✓ The member has used Levemir[®] for at least six consecutive months and was unable to obtain adequate fasting glucose control.
 - ✓ The member has used Levemir[®] and experienced continued episodes of hypoglycemia.
- The member's diabetes treatment regimen was adjusted to optimize glycemic control or reduce hypoglycemia and the member was compliant with their diabetes treatment regimen and blood glucose monitoring schedule. (Insulin regimen adjustment options should include basal dose escalation, splitting the daily basal

dose, adjusting the basal dosing time, and the addition or dose escalation of meal-time insulin.)

Note: Members who are using greater than or equal to 80 units per day of Lantus[®] or Levemir[®] are not required to attempt both products.

In addition to meeting the above clinical criteria, the following must be documented:

- The member's current diabetes treatment regimen
- The member's previous diabetes treatment regimen(s)
- The member's proposed diabetes treatment regimen to include the non-preferred long-acting insulin (initial PA request only)
- The glycemic treatment goals the prescriber has established for the member, such as HbA1c and fasting blood glucose (FBG)

The following will **not** be considered as criteria to support the need for a non-preferred hypoglycemics, insulin — longacting drug:

- Non-adherence to previous diabetes treatment regimen
- Member or prescriber preference for the use of a nonpreferred long-acting insulin
- Member or prescriber preference for a smaller injection volume

If clinical criteria for a non-preferred hypoglycemics, insulin — long-acting drug are met, initial PA requests may be approved for up to a maximum of 183 days. Medical records must be submitted to support the need for a non-preferred long-acting insulin.

Renewal PA requests may be approved for up to a maximum of 365 days. A copy of the member's diabetes management medical records must be submitted demonstrating an improvement in the member's glycemic control. Examples include a decrease in HbA1c, improved FBG, and decreased hypoglycemia.

Lipotropics, Fibric Acids

Effective for DOS on and after **July 1, 2017,** generic fenofibric acid and generic fenofibrate tablets will become preferred drugs in the lipotropics, fibric acids drug class.

Brand name TriCor[®] and Trilipix[®] will remain preferred drugs for DOS through July 31, 2017, in order to allow for a one-month transition period.

Effective for DOS on and after **August 1, 2017,** brand name TriCor[®] and Trilipix[®] will require brand medically necessary (BMN) PA.

Members should transition to generic fenofibric acid or generic fenofibrate tablets unless it is medically necessary for a member to continue to use brand name TriCor® or Trilipix®. If brand name TriCor® or Trilipix® is medically necessary for a member, the pharmacy provider should work with the prescriber to complete and sign a Prior Authorization/Brand Medically Necessary Attachment (PA/BMNA) form, F-11083 (04/2017); the pharmacy provider should then submit a request for BMN PA for the member to continue taking brand name TriCor® or Trilipix®.

Effective for DOS on and after **August 1, 2017,** ForwardHealth will no longer apply a generic copayment to claims submitted for brand name TriCor[®].

Lipotropics, Omega-3 Acids

Effective for DOS on and after **July 1, 2017,** generic omega-3 acid ethyl esters will become a preferred drug requiring clinical PA in the lipotropics, omega-3 acids drug class. Brand name Lovaza[®] will remain a preferred drug requiring clinical PA for DOS through July 31, 2017, in order to allow for a one-month transition period.

Effective for DOS on and after **August 1, 2017,** brand name Lovaza[®] will require BMN PA.

Members should transition to generic omega-3 acid ethyl esters unless it is medically necessary for a member to continue to use brand name Lovaza[®]. If brand name Lovaza[®] is medically necessary for a member, the pharmacy provider should work with the prescriber to complete and sign a PA/BMNA form. In addition to completing the PA/BMNA form, the prescriber is also required to complete the Prior Authorization Drug Attachment for Lipotropics, Omega-3 Acids form, F-00162 (07/2017), for a BMN PA request for brand name Lovaza[®]. For approval of a BMN PA request, the member must meet both the clinical criteria for BMN drugs and the clinical criteria for non-preferred omega-3 acids. The pharmacy provider should then submit a request for BMN PA for the member to continue taking brand name Lovaza[®].

Note: BMN PA requests for Lovaza[®] may **not** be requested through the Drug Authorization and Policy Override Center (DAPO) and must be submitted by the pharmacy provider, not by prescribers or their designees.

For more information about BMN PA requests, providers should refer to the following topics in the Brand Medically Necessary Drugs and Brand Before Generic Drugs chapter of the Prior Authorization section of the Pharmacy service area of the Online Handbook:

- Titration (topic #2012)
- Brand Medically Necessary Drugs: A Prescriber's Responsibilities (topic #2016)
- Brand Medically Necessary Drugs: A Pharmacy Provider's Responsibilities (topic #2017)

Revised Prior Authorization Drug Attachment for Lipotropics, Omega-3 Acids Form

ForwardHealth has revised the Prior Authorization Drug Attachment for Lipotropics, Omega-3 Acids form. The previous version will be removed from the Forms page of the Portal and placed on the Pharmacy-Related Forms and Completion Instructions archive page linked under the Archives section of the Pharmacy Resources page of the Portal. PA requests submitted on and after July 1, 2017, must be submitted on the revised form or the PA request will be returned to the provider.

PA requests that have already been approved will be honored until they expire or until the approved days' supply is used up.

Clinical PA is required for all omega-3 acids in the lipotropics, omega-3 acids drug class, including preferred omega-3 acids. PA requests for omega-3 acids in the lipotropics, omega-3 acids drug class must be submitted by prescribers or their designees, **not** pharmacy providers. PA requests for omega-3 acids for BadgerCare Plus, Medicaid, and SeniorCare members should be submitted using the Prior Authorization Drug Attachment for Lipotropics, Omega-3 Acids form.

PA requests for omega-3 acids in the lipotropics, omega-3 acids drug class may be submitted using the DAPO Center, on the Portal, by fax, or by mail (but **not** using the STAT-PA system).

PA Requests Submitted by Fax or Mail

If a prescriber or their designee chooses to submit a PA request for an omega-3 acid in the lipotropics, omega-3 acids drug class by fax or mail, the following must be completed and submitted to ForwardHealth:

- The PA/RF
- The Prior Authorization Drug Attachment for Lipotropics, Omega-3 Acids form
- Supporting documentation, as appropriate

The Prior Authorization Fax Cover Sheet is available for providers submitting the forms and documentation by fax.

ForwardHealth has revised the clinical criteria for lipotropics, omega-3 acids.

Clinical Criteria for Preferred Omega-3 Acids

Clinical criteria for approval of a PA request for a preferred omega-3 acid for members who are **not** currently taking a preferred omega-3 acid are **all** of the following:

- The member is 18 years of age or older.
- The member does not have an allergy or sensitivity to fish.
- **One** of the following is true:
 - ✓ The member currently has a triglyceride level of 500 mg/dL or greater.
 - ✓ The member currently has a triglyceride level below 500 mg/dL and both of the following are true:
 - The member has had a triglyceride level of 500 mg/dL or greater in the past.
 - The member has a current triglyceride level between 200 and 499 mg/dL while taking a fibrate or niacin. (If a member's triglyceride

level is below 200 mg/dL, the PA request will be denied.)

Clinical criteria for approval of a PA request for a preferred omega-3 acid for members who are currently taking a preferred omega-3 acid are **all** of the following:

- The member is 18 years of age or older.
- The member does not have an allergy or sensitivity to fish.
- The member's current triglyceride level has decreased by at least 20 percent from the baseline level.
- The member has had a triglyceride level of 500 mg/dL or greater in the past.

Clinical Criteria for Non-Preferred Omega-3 Acids

Clinical criteria for approval of a PA request for a nonpreferred omega-3 acid for members who are **not** currently taking a non-preferred omega-3 acid are **all** of the following:

- The member is 18 years of age or older.
- The member does not have an allergy or sensitivity to fish.
- In the past year, the member has taken the maximum dose of a preferred omega-3 acid for **at least four** consecutive months and **one** of the following is true:
 - ✓ The member failed to achieve at least a 30 percent decrease in triglyceride level from the baseline level.
 - ✓ The member's triglyceride level remained at 500 mg/dL or greater.
- **One** of the following is true:
 - ✓ The member currently has a triglyceride level of 500 mg/dL or greater.
 - ✓ The member currently has a triglyceride level below 500 mg/dL and both of the following are true:
 - The member has had a triglyceride level of 500 mg/dL or greater in the past.
 - The member has a current triglyceride level between 200 and 499 mg/dL while taking a fibrate or niacin. (If a member's triglyceride level is below 200 mg/dL, the PA request will be denied.)

Clinical criteria for approval of a PA request for a nonpreferred omega-3 acid for members who are currently taking a non-preferred omega-3 acid are **all** of the following:

- The member is 18 years of age or older.
- The member does not have an allergy or sensitivity to fish.
- The member's current triglyceride level has decreased by at least 20 percent from the baseline level.
- The member has had a triglyceride level of 500 mg/dL or greater in the past.

Approved PA Requests for Omega-3 Acids

PA requests for omega-3 acids may be initially approved for up to 122 days. Renewal PA requests may be approved for up to a maximum of 365 days. For an **initial renewal** PA request to be approved, the member's triglyceride levels must decrease by **at least** 20 percent from the baseline triglyceride level. For **subsequent renewal** PA requests to be approved, the member must continue to maintain the improved triglyceride level.

Lipid panels, including triglyceride levels, within the previous three months are required for each yearly renewal PA request thereafter.

Lipotropics, Other

Rosuvastatin will become a preferred drug in the lipotropics, other drug class and will no longer be classified as a brand before generic (BBG) drug requiring PA.

Crestor[®] will remain a non-preferred drug in the lipotropics, other drug class. Effective for DOS on and after **August 1**, **2017**, Crestor[®] will require BMN PA. Brand name Crestor[®] will remain a non-preferred drug for DOS through July 31, 2017, in order to allow for a one-month transition period.

Certain brand name drugs will be preferred over their generic equivalents. Brand name Zetia[®] will remain a preferred drug (in addition to other preferred drugs) in the lipotropics, other drug class. ForwardHealth will automatically apply a generic copayment to claims submitted for brand name Zetia[®].

Ezetimibe tablet will remain a non-preferred drug and will be classified as a BBG drug requiring PA.

For more information and clinical criteria for BBG PA requests, providers may refer to the following topics in the Brand Medically Necessary Drugs and Brand Before Generic Drugs chapter of the Prior Authorization section of the Pharmacy service area of the Online Handbook:

- An Introduction to Brand Medically Necessary Drugs and Brand Before Generic Drugs (topic #20078)
- Brand Before Generic Drugs (topic #20077)

For more information about BMN drugs, providers may refer to the Brand Medically Necessary Drugs and Brand Before Generic Drugs section of the Prior Authorization chapter of the Pharmacy service area of the Online Handbook.

Lipotropics, PCSK9 Inhibitors

Clinical PA is required for all lipotropics, proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors.

PA requests for lipotropics, PCSK9 inhibitors must be completed and signed by the prescriber. PA requests for lipotropics, PCSK9 inhibitors should be submitted using Section VI (Clinical Information for Drugs with Specific Criteria Addressed in the ForwardHealth Online Handbook) of the PA/DGA form and the PA/RF. Clinical documentation supporting the use of a lipotropics, PCSK9 inhibitor must also be submitted with the PA request.

PA requests for lipotropics, PCSK9 inhibitors may be submitted on the Portal, by fax, or by mail (but **not** using the STAT-PA system).

PA requests that have already been approved will be honored until they expire or until the approved days' supply is used up.

ForwardHealth has revised the clinical criteria for lipotropics, PCSK9 inhibitors.

Clinical Criteria for Lipotropics, PCSK9 Inhibitors (Praluent[®] and Repatha[®])

PCSK9 inhibitors are Food and Drug Administration (FDA)-approved as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH). Clinical criteria that must be documented for approval of an initial PA request for lipotropics, PCSK9 inhibitors for members who are 18 years of age or older and have HeFH are **all** of the following:

- The member has been diagnosed by a specialist in cardiology or lipid management.
- Clinical documentation supports a definitive diagnosis of HeFH using either World Health Organization criteria (Dutch Lipid Clinic Network clinical criteria with a score greater than 8) or Simon Broome diagnostic criteria.
- The member must currently be taking a statin and must have attempted to maximize the treatment dose. The member must have taken the maximally tolerated dose of a statin combined with 10 mg/day of ezetimibe, for **at least three** consecutive months with failure to reach a low-density lipoprotein (LDL) level of 100 mg/dL or less. (*Note:* The member must continue to take the maximally tolerated dose of a statin during treatment with the PCSK9 inhibitor.)

For members 13 years of age or older, Repatha® is FDAapproved as an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) for the treatment of members with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL cholesterol. Clinical criteria that must be documented for approval of an initial PA request for Repatha® for members who are 13 years of age or older and have HoFH are **one** of the following:

- The member has genetic confirmation of **two** of the following mutant alleles at the LDL receptor:
 - ✓ Apolipoprotein B
 - ✓ PCSK9
 - ✓ Autosomal recessive hypercholesterolemia adaptor protein gene locus
- The member has an untreated low-density lipoprotein cholesterol (LDL-C) greater than 500 mg/dL or a total treated LDL-C greater than or equal to 300 mg/dL and one of the following:
 - ✓ Cutaneous tendinous xanthoma(s) before 10 years of age

 ✓ Untreated LDL-C levels of greater than or equal to 190 mg/dL in both parents

In addition to **one** of the above clinical criteria for the treatment of members with HoFH, the member must currently be taking lipid-lowering medication and must have attempted to maximize the treatment regimen. The member must have taken the maximally tolerated regimen of lipid-lowering medications for **at least three** continuous months with failure to reach an LDL level of 130 mg/dL or less.

Note: The member must continue to take the maximally tolerated regimen of lipid-lowering medications during treatment with the PCSK9 inhibitor.

PCSK9 inhibitors are FDA-approved as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with clinical atherosclerotic cardiovascular disease who require additional lowering of LDL cholesterol. Clinical criteria that must be documented for approval of an initial PA request for lipotropics, PCSK9 inhibitors for members who have clinical atherosclerotic cardiovascular disease as evidenced by the presence of **one** of the following:

- The member has coronary artery disease, which is supported by a history of myocardial infarction (heart attack), coronary revascularization, or 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

In addition to **one** of the above clinical criteria for clinical atherosclerotic cardiovascular disease, the member must currently be taking a statin and must have attempted to maximize the treatment dose. The member must have taken the maximally tolerated dose of a statin combined with 10 mg/day of ezetimibe, for **at least three** continuous months with failure to reach an LDL level of 70 mg/dL or less.

Note: The member must continue to take the maximally tolerated dose of a statin during treatment with the PCSK9 inhibitor.

If the member is not able to use high-intensity statin therapy due to significant skeletal muscle symptoms thought to be related to treatment, the maximally tolerated statin regimen must be established. The maximally tolerated statin regimen must be established through trials with **at least three** different statins (with one regimen containing pravastatin, fluvastatin, or rosuvastatin) and must include the following documentation:

- Non-statin causes of significant skeletal muscle-related symptoms (e.g., hypothyroidism, vitamin D deficiency, recent exercise) were ruled out.
- Skeletal muscle-related symptoms resolved after dose reduction or discontinuation of a statin.
- Skeletal muscle-related symptoms recurred after rechallenged with the original statin at a lower dose or trial of an alternative statin.
- Drug-drug interactions that can increase systemic statin exposure or exacerbate medication-related side effects must have been considered and amended.

In circumstances where it is not recommended that lipidlowering treatment include high-intensity statin therapy, such as advanced age (75 years of age or older) or other safety concerns per FDA labeling, moderate or low-intensity statin regimens may suffice.

If the member's statin therapy dosing was limited by a rise in transaminases greater than three times the upper limit of normal, liver function testing (against a timeline of statin dosing) should accompany the PA request to support how the maximally tolerated statin dose was established.

If clinical criteria for lipotropics, PCSK9 inhibitors are met, initial PA requests may be approved for up to a maximum of 120 days. Renewal PA requests may be approved for up to 183 days.

Renewal PA requests for members who have HeFH or clinically evident cardiovascular disease (i.e., coronary artery disease, non-hemorrhagic stroke, or symptomatic peripheral arterial disease) must meet the clinical criteria for initial PA requests for lipotropics, PCSK9 inhibitors and demonstrate evidence of LDL reduction of at least 30 percent to 50 percent from pre-treatment baseline or a decrease to 100 mg/dL or less. Members must also continue to take the maximally tolerated dose of a statin during treatment with the PCSK9 inhibitor.

Note: 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.

Migraine Agents, Injectable

Effective for DOS on and after **July 1, 2017**, generic sumatriptan injectable will become a preferred drug in the migraine agents, injectable drug class. Brand name Imitrex[®] injection will remain a preferred drug for DOS through July 31, 2017, in order to allow for a one-month transition period.

Effective for DOS on and after **August 1, 2017,** brand name Imitrex[®] injection will require BMN PA.

Members should transition to generic sumatriptan injectable unless it is medically necessary for a member to continue to use brand name Imitrex® injection. If brand name Imitrex® injection is medically necessary for a member, the pharmacy provider should work with the prescriber to complete and sign a PA/BMNA form. In addition to completing the PA/BMNA form, the prescriber is also required to complete the Prior Authorization/Preferred Drug List (PA/PDL) for Migraine Agents, Injectable form, F-00622 (06/12), for a BMN PA request for brand name Imitrex® injection. For approval of a BMN PA request the member must meet both the clinical criteria for BMN drugs and the clinical criteria for non-preferred migraine agents, injectable drugs. The pharmacy provider should then submit a request for BMN PA for the member to continue taking brand name Imitrex® injection.

Effective for DOS on and after **August 1, 2017,** ForwardHealth will no longer apply a generic copayment to claims submitted for brand name Imitrex[®] injection.

Migraine Agents, Other

Effective for DOS on and after **July 1, 2017**, generic sumatriptan nasal spray will become a preferred drug in the migraine agents, other drug class. Brand name Imitrex[®] nasal spray will remain a preferred drug for DOS through July 31, 2017, in order to allow for a one-month transition period.

Effective for DOS on and after **August 1, 2017,** brand name Imitrex[®] nasal spray will require BMN PA.

Members should transition to generic sumatriptan nasal spray unless it is medically necessary for a member to continue to use brand name Imitrex® nasal spray. If brand name Imitrex[®] nasal spray is medically necessary for a member, the pharmacy provider should work with the prescriber to complete and sign a PA/BMNA form. In addition to completing the PA/BMNA form, the prescriber is also required to complete the Prior Authorization/Preferred Drug List (PA/PDL) for Migraine Agents, Other form, F-00280 (07/13), for a BMN PA request for brand name Imitrex® nasal spray. For approval of a BMN PA request the member must meet both the clinical criteria for BMN drugs and the clinical criteria for nonpreferred migraine agents, other drugs. The pharmacy provider should then submit a request for BMN PA for the member to continue taking brand name Imitrex® nasal spray.

Effective for DOS on and after **August 1, 2017,** ForwardHealth will no longer apply a generic copayment to claims submitted for brand name Imitrex[®] nasal spray.

Multiple Sclerosis Agents, Immunomodulators

Zinbryta[®] will become a non-preferred drug in the multiple sclerosis (MS) agents, immunomodulators drug class.

Revised Prior Authorization/Preferred Drug List for Multiple Sclerosis Agents, Immunomodulators Form

ForwardHealth has revised the Prior

Authorization/Preferred Drug List (PA/PDL) for Multiple Sclerosis (MS) Agents, Immunomodulators form, F-00805 (07/2017). The previous version will be removed from the Forms page of the Portal and placed on the PharmacyRelated Forms and Completion Instructions archive page linked under the Archives section of the Pharmacy Resources page of the Portal. PA requests submitted on and after July 1, 2017, must be submitted on the revised form or the PA request will be returned to the provider.

PA requests that have already been approved will be honored until they expire or until the approved days' supply is used up.

ForwardHealth has revised the clinical criteria for MS agents, immunomodulators to include clinical criteria for Zinbryta[®].

Clinical Criteria for Members Currently Being Treated with Zinbryta[®]

Clinical criteria for approval of a PA request for Zinbryta[®] for members currently being treated with Zinbryta[®] are **all** of the following:

- The member and prescriber are following established monitoring guidelines outlined in the FDA-approved product labeling.
- The member has been adherent with the Zinbryta[®] 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 (i.e., the member has been granted eligibility for ForwardHealth within the past month) and has taken Zinbryta® continuously for the last 30 days or longer and had a measurable therapeutic response. (*Note:* Medical records must be provided to demonstrate that the member meets this criterion.)
- The member had an approved PA request for Zinbryta[®] issued by ForwardHealth that recently expired, and the member has taken Zinbryta[®] 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 request review.

Clinical Criteria for Members Not Currently Being Treated with Zinbryta[®]

Clinical criteria for approval of a PA request for Zinbryta[®] for members not currently being treated with Zinbryta[®] are that the member must experience an unsatisfactory therapeutic response or a clinically significant adverse drug reaction to **at least two** of the following preferred agents:

- Aubagio[®]
- Copaxone[®]
- Gilenya[®]
- Preferred MS interferons

PA requests must include detailed documentation regarding why the member has previously discontinued at least two preferred MS immunomodulators agents listed above.

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

The following will **not** be considered as criteria to support the need for Zinbryta[®]:

- Non-adherence to previous MS treatment
- Member or prescriber preference for the use of Zinbryta[®]
- Member or prescriber preference for a less frequent dosing schedule

Opioid Dependency Agents

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

Zubsolv[®] will become a preferred drug requiring clinical PA in the opioid dependency agents — buprenorphine drug class.

Revised Prior Authorization/Preferred Drug List for Opioid Dependency Agents — Buprenorphine Form

ForwardHealth has revised the Prior Authorization/Preferred Drug List (PA/PDL) for Opioid Dependency Agents — Buprenorphine form, F-00081 (07/2017). The previous version will be removed from the Forms page of the Portal and placed on the Pharmacy-Related Forms and Completion Instructions archive page linked under the Archives section of the Pharmacy Resources page of the Portal. PA requests submitted on and after July 1, 2017, must be submitted on the revised form or the PA request will be returned to the provider.

PA requests that have already been approved will be honored until they expire or until the approved days' supply is used up.

Drugs in the opioid dependency agents — buprenorphine drug class **are** diagnosis restricted. Providers may refer to the Diagnosis Restricted Drugs data table on the Pharmacy Resources page of the Providers area of the Portal for the most current list of allowable diagnosis codes.

For more information about drugs in the opioid dependency agents — buprenorphine drug class, providers may refer to the Opioid Dependency Agents topic (topic #8917) in the Preferred Drug List chapter of the Prior Authorization section of the Pharmacy service area of the Online Handbook.

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

Submitting PA Requests for Opioid Dependency Agents — Buprenorphine

PA requests for buprenorphine tablets, Suboxone[®] film, and Zubsolv[®] for BadgerCare Plus, Medicaid, and SeniorCare members may be submitted using the STAT-PA system, on the ForwardHealth 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 preferred Suboxone[®] film and Zubsolv[®] submitted by a narcotic treatment service provider (provider type 52) as the billing provider may be approved for up to a maximum of 365 days. PA requests for preferred Suboxone[®] film and Zubsolv[®] submitted by other allowable provider types as the billing provider may be approved for up to a maximum of 183 days.

The following drugs in the opioid dependency agents buprenorphine drug class are available through an expedited emergency supply request, which may be granted for up to a 14-day supply:

- Buprenorphine tablets (pregnant women only)
- Suboxone[®] film
- Zubsolv®

For more information about expedited emergency supply request drugs, providers may refer to the Emergency Medication Dispensing topic (topic #1399) in the Covered Services and Requirements chapter of the Covered and Noncovered Services section of the Pharmacy service area of the Online Handbook.

ForwardHealth has revised the clinical criteria for opioid dependency agents — buprenorphine.

Clinical Criteria for Suboxone[®] Film and Zubsolv[®]

Suboxone[®] film and Zubsolv[®] are preferred drugs that require clinical PA.

Clinical criteria for approval of a PA request for Suboxone[®] film or Zubsolv[®] are **all** of the following:

- The member has a diagnosis of opioid type dependence.
- The member is 16 years of age or older.
- The drug is being prescribed by a physician who has obtained a Drug Addiction Treatment Act of 2000 (DATA 2000) waiver allowing them to prescribe buprenorphine-based agents for opioid dependency treatment.

- The prescriber has indicated that they have read the educational brochure titled Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Prescribers, which is provided through the Buprenorphine-containing Transmucosal products for Opioid Dependence (BTOD) Risk Evaluation and Mitigation Strategies (REMS) program.
- The prescriber has communicated the key messages to the member about the risks of accidental overdose, misuse, and abuse while taking products covered under the BTOD REMS program.
- The member is not taking other opioids, tramadol, or carisoprodol.
- The prescriber has indicated whether or not the member has been receiving BTOD treatment for more than two years.
- For members who have been receiving BTOD treatment for more than two years, the prescriber has indicated whether or not the member is being maintained on a daily dose of 12 mg or less of a BTOD.
- The prescriber has indicated if the member is taking any benzodiazepines.
- For members who are taking benzodiazepines, the prescriber of BTOD has indicated if they are also the prescriber of the benzodiazepine(s).
- The prescriber has indicated that they have read the attestation statement on the PA request form and that they agree to follow guidelines set forth by the United States Department of Health and Human Services (HHS) Federation of State Medical Boards Model Policy Guidelines for Opioid Addiction Treatment.

Clinical Criteria for Buprenorphine Tablets

Buprenorphine tablets are a non-preferred drug in the opioid dependency agents — buprenorphine drug class.

Clinical criteria for approval of a PA request for buprenorphine tablets are **all** of the following:

- The member has a diagnosis of opioid type dependence.
- The member is 16 years of age or older.
- The drug is being prescribed by a physician who has obtained a DATA 2000 waiver allowing them to prescribe buprenorphine-based agents for opioid dependency treatment.

- The prescriber has indicated that they have read the educational brochure titled Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Prescribers, which is provided through the BTOD REMS program.
- The prescriber has communicated the key messages to the member about the risks of accidental overdose, misuse, and abuse while taking products covered under the BTOD REMS program.
- The member is not taking other opioids, tramadol, or carisoprodol.
- The prescriber has indicated whether or not the member has been receiving BTOD treatment for more than two years.
- For members who have been receiving BTOD treatment for more than two years, the prescriber has indicated whether or not the member is being maintained on a daily dose of 12 mg or less of a BTOD.
- The prescriber has indicated if the member is taking any benzodiazepines.
- For members who are taking benzodiazepines, the prescriber of BTOD has indicated if they are also the prescriber of the benzodiazepine(s).
- The prescriber has indicated that they have read the attestation statement on the PA request form and that they agree to follow guidelines set forth by the HHS Federation of State Medical Boards Model Policy Guidelines for Opioid Addiction Treatment.
- The member is pregnant and the prescriber has indicated the member's expected delivery date.
- The prescriber discussed with the member that methadone maintenance is the standard of care for opioid addiction treatment in pregnant women.
- The prescriber informed the member about the limited safety data for the support of buprenorphine use in pregnant women.

Clinical Criteria for Non-Preferred Buprenorphine-Naloxone Drugs

Clinical criteria for approval of a PA request for nonpreferred buprenorphine-naloxone drugs are **all** of the following:

- The member has a diagnosis of opioid type dependence.
- The member is 16 years of age or older.

- The drug is being prescribed by a physician who has obtained a DATA 2000 waiver allowing them to prescribe buprenorphine-based agents for opioid dependency treatment.
- The prescriber has indicated that they have read the educational brochure titled Office-Based Buprenorphine Therapy for Opioid Dependence: Important Information for Prescribers, which is provided through the BTOD REMS program.
- The prescriber has communicated the key messages to the member about the risks of accidental overdose, misuse, and abuse while taking products covered under the BTOD REMS program.
- The member is not taking other opioids, tramadol, or carisoprodol.
- The prescriber has indicated whether or not the member has been receiving BTOD treatment for more than two years.
- For members who have been receiving BTOD treatment for more than two years, the prescriber has indicated whether or not the member is being maintained on a daily dose of 12 mg or less of a BTOD.
- The prescriber has indicated if the member is taking any benzodiazepines.
- For members who are taking benzodiazepines, the prescriber of BTOD has indicated if they are also the prescriber of the benzodiazepine(s).
- The prescriber has indicated that they have read the attestation statement on the PA request form and that they agree to follow guidelines set forth by the HHS Federation of State Medical Boards — Model Policy Guidelines for Opioid Addiction Treatment.
- The prescriber has submitted detailed clinical justification for prescribing a non-preferred buprenorphine-naloxone drug instead of both Suboxone[®] film and Zubsolv[®], including clinical information explaining why the member cannot use both Suboxone[®] film and Zubsolv[®] and explaining why it is medically necessary that the member receive a non-preferred buprenorphine-naloxone drug instead of Suboxone[®] film and Zubsolv[®].

Stimulants

Vyvanse[®] for the Treatment of Binge Eating Disorder

The use of Vyvanse[®] for the treatment of binge eating disorder (BED) requires clinical PA.

PA requests for Vyvanse[®] for the treatment of BED should be submitted using Section VI (Clinical Information for Drugs with Specific Criteria Addressed in the ForwardHealth Online Handbook) of the PA/DGA form and the PA/RF.

PA requests for Vyvanse[®] for the treatment of BED may be submitted on the Portal, by fax, or by mail (but **not** using the STAT-PA system).

ForwardHealth has revised the clinical criteria for Vyvanse[®] for the treatment of BED.

Clinical Criteria for Vyvanse[®] for the Treatment of BED

Clinical criteria that must be documented for approval of a PA request for Vyvanse[®] for the treatment of BED are **all** of the following:

- The member is 18 years of age or older.
- The member has experienced at least three binge days per week for the last two weeks.
- The member is participating in at least one weekly intervention, including, but not limited to the following:
 - ✓ Psychotherapy (individual or group)
 - \checkmark Nutritional counseling
 - ✓ Monitored exercise program (*Note*: The name and telephone number of the individual monitoring the intervention[s] must be included on the PA request form.)
- The member is not currently taking an anti-obesity drug.
- The member is not currently taking any other drug in the stimulants or stimulants related agents drug classes.
- The member does not have a history of drug abuse or drug diversion.

PA requests should also include clinical documentation of the diagnostic work-up for BED, as well as all past and current BED treatments that have been attempted (both pharmacologic and non-pharmacologic).

If clinical criteria for Vyvanse[®] for the treatment of BED are met, PA requests will be approved for up to a maximum of 183 days.

Once the member has completed 183 days of Vyvanse[®] for the treatment of BED, the member must wait six months before PA can be requested for a second trial.

ForwardHealth allows only two approvals for Vyvanse[®] for the treatment of BED during a member's lifetime. Additional PA requests will not be approved. ForwardHealth will return additional PA requests to the provider as noncovered services. Members do not have appeal rights for noncovered services.

Pharmacy Policy Changes

Changes to Prospective Drug Utilization Review Alerts

Pharmacy providers will no longer be exempt from responding to prospective Drug Utilization Review (DUR) alerts (except for late refill and three-month supply) if a member is in a group home, assisted living, or nursing home. Providers will be required to respond to all prospective DUR alerts for members in a group home, assisted living, or nursing home, with the exception of three-month supply and late refill.

For more information about prospective DUR alerts, providers may refer to the Prospective Drug Utilization Review System topic (topic #1977) of the Drug Utilization Review chapter of the Claims section of the Pharmacy service area of the Online Handbook.

Copayment for Brand Name Drugs Preferred Over Generic Drugs

ForwardHealth generally applies a generic copayment to a brand name drug when a drug that previously required BMN 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.

For drugs determined to be included in this policy, ForwardHealth will automatically apply the generic copayment 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 copayment deduction.

The following table includes the most current list of drugs for which this policy applies. Drugs shown in bold letters are drugs that have been added to this list. This list is available on the Preferred Drug List Quick Reference on the Pharmacy Resources page of the Providers area of the Portal. Providers are encouraged to review the list closely to identify future changes.

Drug Class	Drug Name	Effective Date
Acne Agents, Topical	Differin®	01/01/2012
	cream	
	Retin-A [®]	07/01/2016
Anticonvulsants	Tegretol®	01/01/2016
	suspension	
	Tegretol®	01/01/2016
	tablet	
	Tegretol [®] XR	04/06/2016
	100 mg	
	Tegretol [®] XR	01/01/2012
	200 mg	
	Tegretol [®] XR	01/01/2012
	400 mg	
Antihypertensives,	Catapres-TTS®	01/01/2014
Sympatholytics		
Glucocorticoids,	Pulmicort	01/01/2016
Inhaled	Respules®	
Immunomodulators,	Aldara®	01/01/2014
Topical		
Lipotropics, Fibric	TriCor [®] *	07/01/2015
Acids		

Drug Class	Drug Name	Effective Date
Lipotropics, Other	Zetia®	07/01/2017
Migraine Agents,	Imitrex [®]	07/01/2012
Injectable	Injection*	
Migraine Agents,	Imitrex [®] Nasal	07/01/2012
Other	Spray*	
Ophthalmics,	TobraDex®	01/01/2012
Antibiotic-Steroid	suspension	
Combinations		
Ophthalmics,	Alphagan® P	01/01/2012
Glaucoma — Other	0.15%	
Proton Pump	Nexium®	07/01/2016
Inhibitors		
Stimulants	Adderall XR®	01/01/2012

* Effective for DOS on and after August 1, 2017, TriCor[®], Imitrex[®] Injection, and Imitrex[®] Nasal Spray will require BMN PA and will be removed from the Brand Name Drugs with Generic Copay table on the Preferred Drug List Quick Reference.

Expedited Emergency Supply

As a result of changes made during the July 2017 PDL review, the Expedited Emergency Supply Request Drugs data table on the Pharmacy Resources page of the Providers area of the Portal has been updated. The Emergency Medication Dispensing topic (topic #1399) of the Covered Services and Requirements chapter of the Covered and Noncovered Services section of the Pharmacy service area of the Online Handbook includes more information about dispensing an emergency supply of medication.

For More Information

Providers should refer to the Pharmacy service area of the Online Handbook on the Portal for more information about PDL policies.

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.

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, 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, DHS.

For questions, call Provider Services at 800-947-9627 or visit our website at *www.forwardhealth.wi.gov/.* P-1250

This *Update* was issued on 06/16/2017 and information contained in this *Update* was incorporated into the Online Handbook on 07/05/2017.

ATTACHMENT 1 Changes to Pharmacy Prior Authorization Forms and Completion Instructions

The table below lists the pharmacy prior authorization forms and completion instructions that are new or that have been revised, renamed, or discontinued as a result of the July 2017 Preferred Drug List review or as a result of other pharmacy policy changes. Providers should refer to the Forms page of the ForwardHealth Portal at *www.forwardhealth.wi.gov/* for current copies of these forms and completion instructions. Unless otherwise noted, all form changes listed are effective July 1, 2017. The old versions of these forms and completion instructions will be moved to the Pharmacy-Related Forms and Completion Instructions archive page that is linked under the Archives section on the Pharmacy Resources page of the Portal. Additional information regarding changes to clinical criteria or submission options is noted under the applicable drug classes in this *ForwardHealth Update*.

Form Name	Form Number	Revised or Discontinued	Effective Date
Prior Authorization Drug Attachment for Hepatitis C Agents	F-01247	Revised	07/01/2017
Completion Instructions	F-01247A	Revised	07/01/2017
Prior Authorization Drug Attachment for Hepatitis C Agents Renewal	F-01248	Discontinued	12/01/2017
Completion Instructions	F-01248A	Discontinued	12/01/2017
Prior Authorization Drug Attachment for Lipotropics, Omega-3 Acids	F-00162	Revised	07/01/2017
Completion Instructions	F-00162A	Revised	07/01/2017
Prior Authorization/Preferred Drug List (PA/PDL) for Antiemetics, Cannabinoids	F-00194	Revised	07/01/2017
Completion Instructions	F-00194A	Revised	07/01/2017
Prior Authorization/Preferred Drug List (PA/PDL) for Glucagon-Like Peptide (GLP-1) Agents	F-00238	Revised	07/01/2017
Completion Instructions	F-00238A	Revised	07/01/2017
Prior Authorization/Preferred Drug List (PA/PDL) for Growth Hormone Drugs	F-11092	Revised	07/01/2017
Completion Instructions	F-11092A	Revised	07/01/2017
Prior Authorization/Preferred Drug List (PA/PDL) for Multiple Sclerosis (MS) Agents, Immunomodulators	F-00805	Revised	07/01/2017
Completion Instructions	F-00805A	Revised	07/01/2017
Prior Authorization/Preferred Drug List (PA/PDL) for Opioid Dependency Agents — Buprenorphine	F-00081	Revised	07/01/2017
Completion Instructions	F-00081A	Revised	07/01/2017

ATTACHMENT 2 Changes to the Preferred or Non-Preferred Status of Drugs on the Preferred Drug List

The following table lists drugs that have had a change in their preferred or non-preferred status as a result of the July 2017 Preferred Drug List review. The updated statuses are effective July 1, 2017. Drugs that have not been previously reviewed by the Wisconsin Medicaid Pharmacy PA Advisory Committee are marked with an asterisk (*). The complete Preferred Drug List Quick Reference can be referenced on the Pharmacy Resources page of the Providers area of the ForwardHealth Portal at *wnw.forwardhealth.wi.gov/*.

Drug Class	Drug Name	Status Effective July 1, 2017
Acne Agents, Topical	Aczone [®] Gel w/pump*	Non-Preferred
	adapalene gel pump*	Non-Preferred
	clindamycin/benzoyl peroxide	Non-Preferred
	(BenzaClin®) w/pump*	
	clindamycin/tretinoin*	Non-Preferred
	sulfacetamide sodium/sulfur	Non-Preferred
Analgesics, Opioids Long-Acting	Embeda® ER	Preferred
	oxycodone ER*	Non-Preferred
	tramadol ER tablets (Ultram [®] ER)	Preferred
	Xtampza® ER*	Non-Preferred
Analgesics, Opioids Short-Acting	Capital [®] w/ codeine	Non-Preferred
	codeine	Non-Preferred
	Norco®	Non-Preferred
Angiotensin Modulators, ACE	Epaned®*	Non-Preferred
Inhibitors	Qbrelis [™] solution*	Non-Preferred
Angiotensin Modulators, ARBs and	olmesartan*	Non-Preferred
DRIs	olmesartan HCTZ*	Non-Preferred
Angiotensin Modulators,	olmesartan/amlodipine*	Non-Preferred
Combination	olmesartan/amlodipine/HCTZ*	Non-Preferred
	Byvalson [™] *	Non-Preferred
Antibiotics, GI	tinidazole	Preferred
	Xifaxan®	Preferred
Antibiotics, Macrolides/Ketolides	erythromycin granules*	Preferred
Antibiotics, Tetracyclines	doxycycline hyclate tablet DR*	Non-Preferred
Antibiotics, Vaginal	Clindesse®	Preferred
Antiemetics	aprepitant capsule*	Non-Preferred
	aprepitant pack*	Non-Preferred
	Emend® powder packet*	Non-Preferred
	granisetron	Preferred

Drug Class	Drug Name	Status Effective July 1, 2017
Antiemetics, Cannabinoids	dronabinol	Non-Preferred
Antivirals, Influenza	oseltamivir capsule*	Non-Preferred
Bladder Relaxant Preparations	darifenacin ER*	Non-Preferred
BPH Agents, Alpha Reductase	dutasteride	Preferred
Inhibitors		
GI Motility, Chronic	Relistor [®] *	Non-Preferred
	Viberzi®	Non-Preferred
	Xifaxan [®] 550 mg	Preferred
Growth Hormone	Genotropin [®]	Preferred
	Nutropin AQ [®]	Non-Preferred
Hepatitis B Agents	Vemlidy [®] *	Non-Preferred
Hypoglycemics, Alpha-glucosidase	miglitol*	Non-Preferred
Inhibitors	0	
Hypoglycemics, DPP-4 Inhibitors	alogliptin*	Non-Preferred
	alogliptin/metformin*	Non-Preferred
	alogliptin/pioglitazone*	Non-Preferred
	Jentadueto [®] XR*	Non-Preferred
Hypoglycemics, GLP-1	Adlyxin®*	Non-Preferred
	Soliqua [™] *	Non-Preferred
	Tanzeum®	Non-Preferred
	Victoza®	Preferred
	Xultophy®*	Non-Preferred
Hypoglycemics, Insulin	Basaglar®*	Non-Preferred
	NovoLog®	Preferred
	NovoLog [®] mix	Preferred
Hypoglycemics, Other	Farxiga®	Preferred
,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,,	Invokamet [®]	Non-Preferred
	Invokamet® XR*	Non-Preferred
Lipotropics, Bile Acid Sequestrants	Welchol®	Preferred
Lipotropics, Fibric Acids	fenofibrate capsule (Antara®)*	Non-Preferred
	fenofibrate capsule (Lipofen®)*	Non-Preferred
	fenofibrate capsule (Lofibra®)*	Non-Preferred
	fenofibrate tablet (Fenoglide®)*	Non-Preferred
	fenofibrate tablet (TriCor®)	Preferred
	fenofibric acid tablet (Fibricor®)	Non-Preferred
	fenofibric acid capsule (Trilipix®)	Preferred
Lipotropics, Omega-3 Acids	omega-3 acid ethyl esters	Preferred
Lipotropics, Other	rosuvastatin*	Preferred
Lipotropics, PCSK9 Inhibitors	Repatha [®] Pushtronex [™] *	Non-Preferred
Migraine Agents, Other	Onzetra [®] *	Non-Preferred
	sumatriptan nasal spray	Preferred

Drug Class	Drug Name	Status Effective July 1, 2017
	sumatriptan injectable	Preferred
Multiple Sclerosis Agents,	Zinbryta®*	Non-Preferred
Immunomodulators		
Opioid Dependency Agents	Zubsolv®	Preferred
Platelet Aggregation Inhibitors	aspirin/dipyridamole*	Non-Preferred
	Brilinta®	Preferred
	Yosprala [®] *	Non-Preferred
Pulmonary Arterial Hypertension	Adcirca®	Preferred
	Uptravi®*	Non-Preferred
Ulcerative Colitis Agents	mesalamine*	Non-Preferred

* Drug was not previously reviewed. For more information, refer to the Changes to the Preferred or Non-Preferred Status of Drugs on the Preferred Drug List section of this *ForwardHealth Update*.