STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Service
Prior Authorization Criteria

Liptropics, Others (Non-Statins)
Fatty Acids Sub-class
(Lovaza, Omega-3 acid ethyl esters, Vascepa)
Effective 07/01/2019

Old Sub-Class Criteria:

These agents shall only be authorized when the patient has an initial triglyceride level ≥ 500 mg/dL and has had inadequate response or intolerance to trials of BOTH a nicotinic acid and a fibrate, unless otherwise contraindicated.

New Sub-Class Criteria:

These agents are recommended when the patient has an initial triglyceride level ≥ 500 mg/dL.

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Prior Authorization Criteria

Continuous Glucose Monitors
(Freestyle Libre & Dexcom)
Effective 05/24/2019

Prior Authorization Request Form

The WV Medicaid DUR Board strongly recommends that a diabetic educator provide instruction and assistance whenever a continuous glucose monitors has been prescribed.

Pediatric patients (< 18 years of age) diagnosed with Type I Diabetes shall receive a prior authorization with no further restrictions beyond those included in the manufacturers label.

All other prior authorization requests for the covered CGMs listed on this document may be approved if the following criteria are met:

0. Patient must be diagnosed with Type I or Type II Diabetes; **AND**
1. Patient must meet all age restrictions stated in the manufacturer's label; **AND**
2. Patient must have been compliant on their current antidiabetic regimen for at least the last 6 months and this regimen must include multiple daily injections of insulin (requiring at least 3 injections per day); **AND**
3. Documentation (i.e. a glucose log) must be submitted indicating a glucose self-testing frequency of at least 4 times per day during the 3 months prior to the request.

AND at least one of the following:

a. Documented history of recurring hypoglycemia; **OR**
b. Wide fluctuations in pre-meal blood glucose, history of severe glycemic excursions, or experiencing "Dawn" phenomenon with fasting blood glucose exceeding 200 mg/dL; **OR**
c. Patient is currently using insulin pump therapy while continuing to need frequent dosage adjustments or experiencing recurring episodes of severe hypoglycemia (50 mg/dl).

References

1.) ADA Standards of Medical Care in Diabetes - 2019 (Diabetes Care Vol 42, Supplement 1, January 2019) - http://care.diabetesjournals.org/content/suppl/2018/12/17/42.Supplement_1.DC1
2.) 2019 Summary of Revisions: Standards of Medical Care in Diabetes (Diabetes Care Vol 42, Supplement 1, January 2019) - http://care.diabetesjournals.org/content/42/Supplement_1/S4
3.) 2019 AACE Comprehensive Type 2 Diabetes Management Algorithm (Executive Summary) - https://journals.aace.com/doi/pdf/10.4158/CS-2018-0535
4.) Freestyle Libre and Dexcom G6 websites reviewed 5/8/2019

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Prior Authorization Criteria

Omnipod® Insulin Management System
Effective 05/24/2019

Prior Authorization Request Form

The Omnipod® Insulin Management System is a compact, waterproof, tubeless wearable device that provides up to 72 hours of non-stop insulin delivery. The system comes with a Freestyle blood glucose meter which is built into the Personal Diabetes Manager (PDM) that communicates wirelessly to the pod. The PDM is a separate unit, is NOT waterproof and must be within 5 feet of the pod to communicate with it. ***The pods themselves are not cross-compatible between the original Omnipod system and the Omnipod DASH system. The Omnipod is NOT a continuous glucose monitor.***

Prior authorization requests for the Omnipod insulin management system may be approved if the following criteria are met:

1. Patient must be diagnosed with Type I or Type II Diabetes; **AND**
2. Product must be prescribed by (or in documented consultation with) an endocrinologist; **AND**
3. Documentation must be submitted indicating that the patient has received diabetic education; **AND**
4. Patient must meet all age restrictions stated in the manufacturer's label; **AND**
5. Patient must have been compliant on their current antidiabetic regimen for at least the last 6 months and this regimen must include multiple daily injections of insulin (requiring at least 3 injections per day); **AND**
6. Documentation (i.e. a glucose log) must be submitted indicating a glucose self-testing frequency of at least 4 times per day during the 3 months prior to the request.

   AND at least one of the following criteria must also be met:
   a. Documented history of recurring hypoglycemia; **OR**
   b. Wide fluctuations in pre-meal blood glucose, history of severe glycemic excursions or experiencing "Dawn" phenomenon with fasting blood glucose exceeding 200 mg/dL; **OR**
   c. Prior use of an insulin pump with documented frequency of glucose self-testing of at least 4 times per day in the month immediately prior to the request.

Initial approval of the Omnipod system will be for 6 months. Additional therapy shall be approved with documentation of satisfactory patient response (including current HbA1C).

References

1.) ADA Standards of Medical Care in Diabetes - 2019 (Diabetes Care Vol 42, Supplement 1, January 2019) - http://care.diabetesjournals.org/content/suppl/2018/12/17/42.Supplement_1.DC1
2.) 2019 Summary of Revisions: Standards of Medical Care in Diabetes (Diabetes Care Vol 42, Supplement 1, January 2019) - http://care.diabetesjournals.org/content/42/Supplement_1/S4
3.) 2019 AACE Comprehensive Type 2 Diabetes Management Algorithm (Executive Summary) - https://journals.aace.com/doi/pdf/10.4158/CS-2018-0535
4.) Omnipod Website - https://www.myomnipod.com/healthcareproviders

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Prior Authorization Criteria

PCSK9 INHIBITORS
PRALUENT®(alirocumab), REPATHA® (evolocumab)
Effective 5/24/2019

Prior Authorization Request Form

REPATHA *is a PCSK9 (proprotein convertase subtilisin kexin type 9) inhibitor antibody indicated:*

- *to reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease.*
- *as an adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol (LDL-C).*
- *as an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) in patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C.*

PRALUENT *is a PCSK9 (proprotein convertase subtilisin kexin type 9) inhibitor antibody indicated:*

- *to reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease.*
- *as adjunct to diet, alone or in combination with other lipid-lowering therapies (e.g., statins, ezetimibe), for the treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol LDL-C.*

CRITERIA FOR APPROVAL

1) Must be prescribed by or in consultation with a cardiologist, lipid specialist, or endocrinologist; **AND**

2) Patient must meet all age and indication restrictions imposed by the current FDA-approved label; **AND**

3) Documentation must be submitted indicating that the patient failed to reach an LDL<70 mg/dL after 8-week trials each of **atorvastatin 40 - 80 mg** and **rosuvastatin 20 - 40 mg AND** at least one of these trials must include concurrent therapy with ezetimibe.

4) Should the patient be unable to tolerate 8 weeks at the recommended dosing for high-intensity statin therapy, the patient will be required to trial at least one other statin taken at the maximally tolerated dose for at least 8 weeks.

CRITERIA FOR CONTINUATION

Initial approval is for 90 days and documentation of efficacy must be supported by at least a 40% LDL-C reduction from pre-treatment level.

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PCSK9 INHIBITOR MONOTHERAPY DUE TO STATIN INTOLERANCE

WV Medicaid recognizes that there are patients with hyperlipidemia who require aggressive lipid-lowering therapy but who may not be able to safely tolerate a high-intensity statin or other lipid-lowering therapy.

Approval of off-label use of any PCSK9 inhibitor requires documentation that the patient has previously failed to tolerate at least three different statins OR has experienced a potentially life-threatening adverse effect such as rhabdomyolysis while taking a statin.

Patient statements that they have experienced muscle cramps/spasms or "myopathy" is NOT sufficient for approval as monotherapy without verifiable pharmacy claims.

REFERENCES

1) Repatha package insert revised 2/2019
2) Praulent package insert revised 4/2019
3) Lexi-Comp Clinical Application reviewed 5/02/2019
4) AACE 2017 Guidelines: American Association of Clinical Endocrinologists and American College of Endocrinology Guidelines for Management of Dyslipidemia and Prevention of Cardiovascular Disease. Endocrine Practice Vol 23 (Suppl 2) April 2017.
5) *UpToDate* clinical article: Management of low density lipoprotein cholesterol (LDL-C) in secondary prevention of cardiovascular disease (last update 7-25-2017)
6) Evolocumab and Clinical Outcomes in Patients with Cardiovascular Disease; N Engl J Med 2017; 376:1713-1722
7) Stone, N. J., Robinson, J., Lichtenstein, A. H., et al. 2013 ACC/AHA Guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: A report of the American College of Cardiology/American Heart Association Task Force on practice guidelines. *Circulation* 2013. Retrieved from: http://circ.ahajournals.org.
8) Goldberg, A. C., Hopkins, P. N., Toth, P. P., et al. Familial hypercholesterolemia: Screening, diagnosis and management of pediatric and adult patients. Clinical guidance from the National Lipid Association Expert Panel on Familial Hypercholesterolemia. *J. of Clinical Lipidology* 2011 Volume 5, Number 3S.
9) Treating Statin Intolerant Patients. Marcello Arca and Giovanni Pigna. Diabetes Metab Syndr Obes. 2011; 4: 155–166.

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Prior Authorization Criteria

Qbrexza® (glycopyrronium - topical)

Effective 05/24/2019

Prior Authorization Request Form

QBREXZA *is an anticholinergic indicated for topical treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older.*
Qbrexza is applied topically once every 24 hours to clean dry skin on the underarm areas only; it is not for use on other body areas.

Prior authorization requests for Qbrexza may be approved if the following criteria are met:

1) Diagnosis of primary axillary hyperhidrosis;
2) Prescribed by or in consultation with a dermatologist;
3) Patient must meet the minimum age restriction stated in the FDA-approved label;
4) Documented failure of a 3-month trial of topical aluminum chloride unless contraindicated or clinically significant adverse effects are experienced;
5) Dose does not exceed a single cloth per day.

Initial approvals are for 3 months. Additional authorization for up to 12 months at a time may be granted with documentation of efficacy and patient compliance.

REFERENCES

1) Qbrexza package insert 06/2018
2) Lexi-Comp Clinical Application 04/22/2019
3) UpToDate Articles accessed 04/22/19: Primary Focal Hyperhidrosis

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Prior Authorization Criteria

SPRAVATO™ (esketamine – nasal spray)

Effective 05/24/2019

Prior Authorization Request Form

SPRAVATO™ *is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults.*

Prior authorization requests for Spravato may be approved if the following criteria are met:

6) Diagnosis of treatment resistant depression (TRD) by an identified psychiatrist; **AND**
7) Prescribed by a REMS-certified provider; **AND**
8) Age must be appropriate to the FDA-approved label; **AND**
9) Progress notes are required as documentation of the patient's diagnosis of treatment-resistant Major Depressive Disorder and must include screening to rule out Bipolar Disorder as well as all previous therapies failed; **AND**
10) The patient's baseline depression symptoms must be measured and documented using an objective clinical rating scale such as (but not limited to) the PHQ-9, Clinically Useful Depression Outcome Scale, Quick Inventory of Depressive Symptomatology-Self Report 16 Item, MADRS, or HAM-D; **AND**
11) Patient has failed to achieve a satisfactory response after attempting a minimum of THREE separate therapeutic trials for MDD. These trials must include antidepressants from at least two (2) different drug classes as well as at least one trial using augmentation therapy; **AND**
12) All medications must be taken compliantly for at least **8 weeks** based on pharmacy fill history; **AND**
13) Spravato must be used in combination with an oral antidepressant.

Approvals will be for 90 days at a time.

CONTINUATION OF THERAPY CRITERIA

1) Patient's claims history must indicate concurrent use of an oral antidepressant; **AND**
2) Patient must show demonstrable improvement over baseline as measured by the same scale used for the initial approval.

REFERENCES

4) Spravato package insert 03/2019
5) Lexi-Comp Clinical Application 05/17/2019
6) UpToDate Articles accessed 05/17/19: Treatment resistant Depression

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Prior Authorization Criteria

HEREDITARY ANGIOEDEMA AGENTS
Cinryze® & Haegarda® (human C1-inhibitor)
Takhzyro® (lanadeluemab)
Effective 05/24/2019

Prior Authorization Request Form

CINRYZE and HAEGARDA *are plasma-derived concentrates of C1 esterase inhibitor (human) (C1-INH) indicated for routine prophylaxis to prevent Hereditary Angioedema Attacks (HAE).*
TAKHZYRO *is a plasma kallikrein inhibitor (monoclonal antibody) indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE).*

CRITERIA FOR APPROVAL

14) The diagnosis of hereditary angioedema (HAE) must be clinically established by, or in consultation with, an allergist or immunologist; **AND**
15) The patient must meet the individual age restrictions outlined in the FDA-approved label for the requested agent; **AND**
16) Diagnosis of HAE must be documented and based on evidence of low C4 level AND one of the following:
    a. A low C1 inhibitor (C1-INH) antigenic level; **OR**
    b. A normal C1-INH antigenic level and a low C1-INH functional level;

    AND

17) The member has a history of more than one moderate to severe attack per month (i.e. swelling of the face, throat, or abdomen); **AND**
18) Baseline frequency of HAE attacks must be documented; **AND**
19) The member is not concurrently taking an angiotensin converting enzyme (ACE) inhibitor or estrogen replacement therapy or any other medication known to cause potentially cause angioedema; **AND**
20) The recipient has had an insufficient response or contraindication to therapy with a 17α – alkylated androgen (e.g. danazol, stanozolol, oxandrolone, methyltestosterone). **This requirement is waived for growing children and for pregnant or lactating females.**

Initial approvals are for 6 months.

CONTINUATION OF THERAPY CRITERIA

Medical records documenting a decrease of at least 50% in the frequency of attacks and significant improvement in severity and duration of attacks must be provided.

REFERENCES

7) Cinryze package insert 06/2018
8) Haegarda package insert 10/2017
9) Takhzyro package insert 11/2018
10) Lexi-Comp Clinical Application 11/12/2017
11) UpToDate Articles accessed 05/03/19: Hereditary Angioedema and Pathogenesis; Hereditary Angioedema- General Care and Long-term Prophylaxis
12) US Hereditary Angioedema Association Medical Advisory Board 2013 Recommendations for the Management of Hereditary Angioedema Due to C1 Inhibitor Deficiency; J ALLERGY CLIN IMMUNOL: IN PRACTICE VOLUME 1, NUMBER

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Prior Authorization Criteria

XIFAXAN® (rifaximin)

Prior Authorization Request Form

Xifaxan® (rifaximin) is a rifamycin antibacterial indicated for:

I) Treatment of travelers' diarrhea (TD) caused by noninvasive strains of *Escherichia coli* in adult and pediatric patients 12 years of age and older.
II) Reduction in risk of overt hepatic encephalopathy (HE) recurrence in adults.
III) Treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults.

Indication –specific Criteria for Approval

I) **Traveler's diarrhea** (caused by non-invasive strains of *Escherichia coli*)

1. Request must be for Xifaxan 200 mg tablets; **AND**
2. Patient must be between twelve (12) and eighteen (18) years of age; **OR**
3. Patients over eighteen (18) years of age must have had a previous trial of ciprofloxacin.

II) **Hepatic encephalopathy**

1. Request must be for Xifaxan 550 mg tablets; **AND**
2. Patient must be eighteen (18) years of age or older; **AND**
3. History of treatment with lactulose. *If lactulose has been discontinued, documentation must be included indicating lack of efficacy or the occurrence of an adverse effect.*

III) **Irritable bowel syndrome with diarrhea (IBS-D)**

1) Request must be for Xifaxan 550 mg tablets; **AND**
2) Patient must be eighteen (18) years of age or older; **AND**
3) History of failure, contraindication or intolerance to **one** of the following:
   a. Antispasmodic (for example: dicyclomine, hyoscyamine)
   b. Tricyclic antidepressant (for example: amitriptyline)

All other requests will be approved on a case-by-case basis.

References

10) Lexi-Comp Clinical Application 05/24/2019
11) UpToDate article: Treatment of Irritable Bowel Syndrome in Adults (updated May 23,2019)
12) Xifaxan package insert (Rev 5-2015)
4) American College of Gastroenterology Monograph on the Management of Irritable Bowel Syndrome and Chronic Idiopathic Constipation. *Am J Gastroenterol* 2014; 109:S2 – S26; doi: 10.1038/ajg.2014.187. (http://gi.org/wp-content/uploads/2014/08/IBS_CIC_Monograph_AJG_Aug_2014.pdf)
5) *Am Fam Physician.* 2009 Jun 15;79(12):1108-1117. http://www.aafp.org/afp/2009/0615/p1108.html
6) http://www.cdc.gov/Ncidod/dbmd/diseaseinfo/travelersdiarrhea_g.htm
7) http://www.aasld.org/sites/default/files/guideline_documents/hepaticencephenhanced.pdf
8) http://pharmpractice.ku.edu/journal-club-digest/rifaximin-use-treatment-hepatic-encephalopathy
9) Rifaximin treatment in hepatic encephalopathy. N Engl J Med. 2010 Mar 25;362(12):1071-81
10) https://www.gastro.org/guidelines/ibd-and-bowel-disorders/pharmacological-management-of-irritable-bowel-syndrome-guideline-patient-companion