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

Office of Pharmacy Service
Prior Authorization Criteria

NON-SEDATING ANTIHISTAMINES
(Cetirizine, Loratadine, Fexofenadine)
Effective 1/01/2018

Prior Authorization Request Form

CRITERIA FOR APPROVAL

- WV Medicaid shall cover generic **cetirizine, loratadine, and fexofenadine** without the requirement of a prior-authorization.

- All other non-sedating antihistamines shall require 14-day trials of all three of the above agents unless contraindicated or age restricted.

STATE OF WEST VIRGINIA
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Office of Pharmacy Service
Prior Authorization Criteria

PCSK-9 INHIBITORS
PRALUENT®(alirocumab), REPATHA® (evolocumab)
Effective 1/01/2018

Prior Authorization Request Form

- ***REPATHA®*** *is a PCSK9 (Proprotein Convertase Subtilisin Kexin Type 9) inhibitor antibody indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of LDL-cholesterol (LDL-C).*
  Repatha is also indicated as an adjunct to diet and other LDL-lowering therapies 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 as adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of LDL-cholesterol (LDL-C).*

CRITERIA FOR APPROVAL

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

2) Patient age must match the FDA approved indication for the requested PCSK-9 inhibitor:
   a. Patient must be 13 years or older for HoFH **OR**
   b. 18 years or older for HeFH and ASCVD
   AND

3) The patient must have a documented diagnosis of familial hypercholesterolemia (supported by genetic testing) **OR** a documented diagnosis of ASCVD[1];
   AND

4) Documentation must be submitted indicating that the patient has failed to reach an LDL<70 mg/dL after 8-week trials of **both** atorvastatin 40 to 80 mg and rosuvastatin 20 to 40 mg (prescribed at the maximally tolerated dose) **AND** at least one of these trials must include a concurrent trial of ezetimibe. **In both trials, documentation must clearly indicate an attempt was made to maximize the statin dose** and patient adherence to all statin/ezetimibe trials must be evidenced by consistent pharmacy claims.

5) Should the patient be unable to tolerate the recommended dosing for high-intensity statin therapy, the patient will be required to trial at least **two (2)** other lipid-lowering agents with a statin prescribed at the maximally tolerated dose, unless doing so would be unlikely to achieve the goal LDL.

[1]Diagnosis of ASCVD is defined as one of the following: acute coronary syndrome, or a history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin.

CRITERIA FOR CONTINUATION

1) Documentation of efficacy indicated by at least a 40% LDL-C reduction from pre-treatment level; **AND**

2) Documentation that the member has been adherent to concurrent treatment with statin and PCSK9 inhibitor as demonstrated by consistent pharmacy claims. Note: Ezetimibe and other lipid lowering agents may be discontinued at the discretion of the clinician once the patient has been established on the PCSK9 inhibitor.

(OFF-LABEL USE): PCSK9 INHIBITOR MONOTHERAPY DUE TO STATIN INTOLERANCE

Off-label use of the PCSK9 Inhibitors is approvable **only** on appeal to the Medical Director.

The PCSK9 inhibitors are not FDA-approved for use in the absence of concurrent statin therapy, however WV Medicaid recognizes that there are patients who require aggressive lipid-lowering therapy but who may not be able to safely tolerate a high-intensity statin.

Approval of off-label use of any PCSK9 inhibitor requires documentation that the patient has previously experienced rhabdomyolysis while on a statin OR that the prescriber has personally tested the patient for a physiological statin intolerance. Verification of intolerance requires laboratory findings indicating significant elevation in creatine kinase levels (typically > 10x the upper normal limit). **Simple documentation that the patient had muscle cramps/spasms or "myopathy" is NOT sufficient for approval as monotherapy.**

The following is an example of an acceptable strategy for proving statin intolerance:

A minimum of three statins must be trialed, two of which must be high-intensity statins (atorvastatin to a goal of 40-80 mg or rosuvastatin to a goal of 20-40 mg).

High intensity statin #1→ Patient experiencing adverse effects→ If appropriate, discontinue statin and allow a 2-week washout period→ Attempt to re-initiate the same statin at a lower dose and titrate upward as tolerated. Verification of physical intolerance or toxicity require laboratory findings indicating significant elevation in creatine kinase levels (typically > 10x the upper normal limit).

If failure to tolerate high-intensity statin #1, then switch to high-intensity statin #2 and proceed in a similar fashion. Should the patient fail the second high-intensity statin, the 3rd trial should involve titration of a different statin to the highest dose tolerated. Should the 3rd trial fail, then the patient may be approved for PCSK9 therapy off-label therapy. NOTE: Approval of any PCSK9 therapy is contingent on the patient not being able to reach their goal LDL with the addition of either ezetimibe or a bile acid sequestrant to any current statin therapy tolerated.

REFERENCES

1) Repatha package insert revised 9/2015
2) Praulent package insert revised 7/2015
3) Lexi-Comp Clinical Application reviewed 8/22/2017
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.

STATE OF WEST VIRGINIA
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BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Service
Prior Authorization Criteria

CINRYZE® & HAEGARDA®
(human C1-inhibitor)
Effective 1/01/2018

Prior Authorization Request Form

CINRYZE *and* ***HAEGARDA*** *are plasma-derived concentrates of C1 esterase inhibitor (human) (C1-INH) indicated for routine prophylaxis to prevent Herediatry Angioedema Attacks (HAE) in adolescent and adult patients.*

CRITERIA FOR APPROVAL

1) The diagnosis of hereditary angioedema (HAE) has been clinically established by, or in consultation with, an allergist or immunologist; **AND**
2) Patient must be 12 years or older; **AND**
3) Diagnosis of HAE is documented 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
4) 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**
5) Baseline frequency of HAE attacks must be documented; **AND**
6) The member is not concurrently taking an angiotensin converting enzyme (ACE) inhibitor or estrogen replacement therapy; **AND**
7) 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.**

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

1) Cinryze package insert 12/2016
2) Haegarda package insert rev 06/2017
3) Lexi-Comp Clinical Application 11/12/2017
4) UpToDate Articles accessed 11/12/17: Hereditary Angioedema and Pathogenesis; Hereditary Angioedema- General Care and Long-term Prophylaxis
5) 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 5

STATE OF WEST VIRGINIA
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BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Service
Prior Authorization Criteria

DUPIXENT® (dupilumab)
Effective 1/01/2018

Prior Authorization Request Form

DUPIXENT *is an interleukin-4 receptor alpha antagonist indicated for the treatment of adult patients with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. DUPIXENT can be used with or without topical corticosteroids.*

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

1. Prescribed by or in consultation with an allergist, immunologist or dermatologist; **AND**

2. Documented diagnosis of moderate to severe Atopic Dermatitis (AD). Documentation must include the affected BSA, areas of involvement and severity of symptoms; **AND**

3. Patient is at least 18 years old; **AND**

4. Affected body surface area is greater than or equal to 10%; **AND**

5. Patient has failed to find relief of symptoms after a minimum of 6-week trials of all agents from the following list in the last 12 months:

    a. Medium to High potency topical corticosteroid*
    b. Elidel
    c. Eucrisa
    d. Tacrolimus

*Requirement for topical corticosteroid therapy will be excluded for patients with sensitive areas of involvement such as the face, skin folds or genitals.

Initial approval of Dupixent will be for 60 days. Additional therapy shall be approved with documentation of satisfactory patient response (including current affected BSA and severity of symptoms).

References

1.) https://www.aad.org/practicecenter/quality/clinical-guidelines/atopic-dermatitis/diagnosis-and-assessment/disease-severity-recommendations
2.) https://www.ecu.edu/cs-dhs/fammed/upload/Atopic-Dermatitis-Guidelines.pdf
3.) LexiComp monograph and P&T formulary review for dupliumab (accessed 11/03/2017)
4.) Dupixent package insert revision 3/2017

v2017.4a – BMT updated 10/04/2017
DUR Board Approval:

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

Office of Pharmacy Service
Prior Authorization Criteria

EMFLAZA™ (deflazacort)
Effective 1/01/2018

Prior Authorization Request Form

EMFLAZA *is a corticosteroid indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 5 years of age and older.*

Prior authorization requests for Emflaza are only available on appeal to the medical director and require the patient to satisfy the following criteria to be considered for approval:

6. Diagnosis of Duchenne muscular dystrophy (DMD); **AND**

7. Patient ≥ 5 years old; **AND**

8. Patient must have a documented history of at least 12-months continuous therapy with prednisone; **AND**

9. Documentation must be submitted indicating that the patient has experienced significant adverse effects associated with prednisone therapy. Documentation must include a detailed description of the adverse effect; as the side effect profiles are similar between deflazacort and prednisone, prior authorization shall only be granted for those patients experiencing side effects where deflazacort shows an improved profile.

References

5.) Griggs RC, Miller JP, Greenberg CR, et al. Efficacy and safety of deflazacort vs prednisone and placebo for Duchenne muscular dystrophy. *Neurology*. 2016;87(20):2123-2131
6.) Lexi-Comp drug monograph for deflazacort (Reviewed 8/22/2017)
7.) Efficacy and safety of deflazacort vs prednisone and placebo for Duchenne muscular dystrophy. Neurology. 2016 Nov 15; 87(20): 2123–2131.
8.) UpToDate article: Treatment of Duchenne and Becker muscular dystrophy. Updated July 18, 2017.

STATE OF WEST VIRGINIA
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BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Service
Prior Authorization Criteria

HUMIRA® (adalimumab) and ENBREL® (etanercept)
Effective 1/01/2018

Prior Authorization Request Form

Prior authorization requests for Humira and Enbrel may be approved for their FDA approved indications provided the following criteria are met. Diagnoses must accompany all requests.

- Patient is eighteen (18) years of age or older (see below if diagnosed with juvenile idiopathic arthritis or pediatric Crohn's Disease); **AND**
- Initial treatment plan is done in consultation with an appropriate specialist (such as a dermatologist, gastroenterologist or rheumatologist); **AND**
- Negative tuberculin skin test before initiation of therapy; **AND**

THE FOLLOWING INDICATION-SPECIFIC CRITERIA MUST ALSO BE SATISFIED:

- **Ankylosing spondylitis:** must include documentation indicating ninety (90) day treatment history with NSAIDs (unless contraindicated).

- **Psoriasis** must have:
  1. Diagnosis of moderate to severe psoriasis; **AND**
  2. Prior treatment with a potent topical corticosteroid plus calcipotriol; **AND**
  3. Prior treatment with a Vitamin D analogue; **AND**
  4. Prior ninety (90) day treatment history with a disease-modifying agent (DMARD) such as methotrexate, cyclosporine, acitretin, etc.

- **Psoriatic arthritis:** must have a documented ninety (90) day history of NSAID therapy as well as ninety (90) day trials of at least two DMARDs.

- **Rheumatoid arthritis:** must have documented ninety (90) day trials of at least two DMARDs.

- **Juvenile idiopathic arthritis**: Prior authorization for Humira and Enbrel may be granted if the patient is two (2) years of age or older and has failed a ninety (90) day course of therapy with methotrexate.

- **Crohn's Disease:** Humira is approvable for moderate to severe Crohn's disease. *Enbrel is not indicated for treatment of Crohn's disease and will not be approved.*

- ***Pediatric Crohn's disease*** **(moderate to severe):** For patients 6 years of age and older, prior authorization requests for Humira are approvable with documentation of an inadequate response to a 14-day trial of corticosteroids or an immunomodulator such as azathioprine, 6-mercaptopurine, or methotrexate.

- **Ulcerative Colitis:** Humira is approvable following failure or clinically significant adverse effects to a thirty (30) day course of aminosalicylates (e.g. sulfasalazine, mesalamine) requiring treatment for two (2) or more exacerbations using corticosteroids, such as prednisone. *Enbrel is not indicated for treatment of UC and will not be approved.*

- **Hidradenitis suppurativa:** Humira may be approved in patients 18 years of age or older who satisfy the following additional criteria:
    1. Has severe disease (Hurley stage III); **OR**
    2. Has moderate disease (Hurley state II) despite treatment with an oral formulary tetracycline (i.e., doxycycline) OR topical clindamycin.

- **Uveitis:** Humira may be approved in patients diagnosed with non-infectious uveitis who are at least 18 years of age and who have failed to respond adequately to corticosteroid therapy, or in whom corticosteroid therapy is inappropriate.

References

10) Lexi-Comp drug monographs for Humira and Enbrel (7/11/2016)
11) Humira Package Insert (7/2016)
12) Enbrel Package Insert
13) 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis
14) The 2012 BSR and BHPR guideline for the treatment of psoriatic arthritis with biologics
15) American College of Rheumatology/Spondylitis Association of America/Spondyloarhtritis Research and Treatment Network 2015 Recommendations for the Treatment of Anykylosing Spondylitis and Noradiographic Axial Spondyloarthritis
16) Crofford *Arthritis Research & Therapy* 2013, 15(Suppl 3):S2
17) J Braun *et al*. 2010 update of the ASAS/EULAR recommendations for the management of anykylosing spondylitis. Ann Rheum Dis 2011; 70:896-904
18) Scottish Intercollegiate Guidelines Network (SIGN). Diagnosis and management of psoriasis and psoriatic arthritis in adults. A national clinical guideline. Edinburgh (Scotland); Scottish Intercollegiate (SIGN), 2010 Oct (SIGN publication, no. 121 (217 references)
19) G Lichtenstein, S Hanauer *et al.* Management of Crohn's Disease in Adults. Am J Gastroenterol advance online publication, 6 January 2009
20) EDF Guideline for Hidradenitis Suppurativa / Acne Inversa (HS) - S1 Guideline – 2016-2017 (file:///C:/Users/E033601/Downloads/Guideline-on-Hidradenitis-suppurativa-S1.pdf)

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

Office of Pharmacy Service
Prior Authorization Criteria

JUXTAPID® (lomitapide)
Effective 1/01/2018

Prior Authorization Request Form

JUXTAPID *is a microsomal triglyceride transfer protein inhibitor indicated as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH)*

CRITERIA FOR APPROVAL

1) Diagnosis of Homozygous familial hypercholesteremia (HoFH); **AND**
2) Prescriber must be enrolled in the Juxtapid REMS program; **AND**
3) Patient has had a minimum 8-week trial of Repatha, used in combination with other lipid-lowering therapies; **AND**
4) Patient is currently receiving other lipid-lowering therapies (low-fat diet, apheresis, and lipid lowering agents including HMG-CoA inhibitors at the maximum tolerable dose); **AND**
5) Measurement of ALT, AST, alkaline phosphatase and bilirubin before initiation of therapy and before each dose increase or every month, whichever comes first during the first twelve (12) months of therapy. After the first year, all levels must be measured every three (3) months or before each dose increase, whichever comes first; **AND**
6) Negative pregnancy test prior to starting therapy, if at risk; **AND**
7) Capable of complying with effective contraceptive measures if at risk; **AND**
8) No concomitant use of strong CYP3E4 inhibitors (such as boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, medefradil, nedazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin or voriconazole)
9) Patient must take daily supplements of vitamins containing 400 international units vitamin E and at least 200 mg linoleic acid, 210 mg ALA, 110 mg EPA, and 80 mg DHA while receiving Juxtapid.

REFERENCES

1) Lexicomp monograph on Juxtapid reviewed 11/9/2017
2) Package Insert for Juxtapid (rev 8/2017)
3) UpToDate Monograph: Familial hypercholesterolemia in adults: Treatment

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

Office of Pharmacy Service
Prior Authorization Criteria

KYNAMRO® (mipomersen)
Effective 1/01/2018

Prior Authorization Request Form

KYNAMRO *is an oligonucleotide inhibitor of apolipoprotein B-100 synthesis indicated as an adjunct to lipid-lowering medications and diet to reduce low density lipoprotein-cholesterol (LDL-C), aploliproprotein B (apo B), total cholesterol (TC), and non-high density lipoprotein-cholesterol (non-HDL-C) in patients with with homozygous familial hypercholesterolemia (HoFH).*

CRITERIA FOR APPROVAL

10) Diagnosis of Homozygous familial hypercholesteremia (HoFH); **AND**

11) Prescriber must be enrolled in the Kynamro REMS program; **AND**

12) Patient has had a minimum 8-week trial of Repatha, used in combination with other lipid-lowering therapies; **AND**

13) Patient is currently receiving other lipid-lowering therapies (low-fat diet, apheresis, and lipid lowering agents including HMG-CoA inhibitors at the maximum tolerable dose); **AND**

14) Measurement of ALT, AST, alkaline phosphatase and bilirubin before initiation of therapy and every month during the first twelve (12) months of therapy. After the first year, all levels must be measured every three (3) months. Lipid levels (total cholesterol [C], LDL-C, HDL-C, triglycerides) should be monitored and documented at least every 3 months for the first year.

REFERENCES

4) Lexicomp monograph on Kynamro reviewed 11/12/2017
5) Package Insert for Kynamro (rev 5/2016)
6) UpToDate Monograph: Familial hypercholesterolemia in adults: Treatment

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