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

Office of Pharmacy Service
Prior Authorization Criteria

As posted on PDL

Lyrica will be authorized only if the following criteria are met:

1. Diagnosis of seizure disorders or neuropathic pain associated with a spinal cord injury **or**
2. Diagnosis of fibromyalgia, postherpetic neuralgia, or diabetic neuropathy AND a history of a 90-day trial of duloxetine at the generally accepted maximum therapeutic dose of 60 mg/day AND a 90-day trial of gabapentin at a therapeutic dose range between 900 mg and 2,400 mg per day for ninety (90) days within the previous twenty-four (24) month period or an intolerance due to a potential adverse drug-drug interaction, drug-disease interaction, or intolerable side effect (In cases of renal impairment, doses may be adjusted based on the degree of impairment.)

Gralise will be authorized if the following criteria are met:

1. Diagnosis of post herpetic neuralgia **and**
2. Trial of a tricyclic antidepressant for a least thirty (30) days **and**
3. 90-day trial of gabapentin immediate release formulation (positive response without adequate duration) **and**
4. Request is for once daily dosing with 1800 mg maximum daily dosage.

Savella will only be authorized for a diagnosis of fibromyalgia after a 90-day trial of one preferred agent.

Topical Antifungal/Steroid Combinations: Non-preferred agents require fourteen (14) day trials of all unique preferred agents in the same subclass before they will be approved, unless one (1) of the exceptions on the PA form is present. If a non-preferred shampoo is requested, a fourteen (14) day trial of one (1) preferred product (i.e. ketoconazole shampoo) is required.

Trulance is indicated for CIC and IBS-C and requires a thirty (30) day trial of Amitiza.

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Office of Pharmacy Service
Prior Authorization Criteria

OFEV® (Nintedanib)
Effective 03/05/2018

Prior Authorization Request Form

OFEV is a kinase inhibitor indicated for the treatment of idiopathic pulmonary fibrosis (IPF).

Criteria for Approval

1) Diagnosis of idiopathic pulmonary fibrosis (IPF); **AND**
2) Must be prescribed by or in conjunction with a pulmonologist; **AND**
3) Patient must be eighteen (18) years of age or older; **AND**
4) Patient must be enrolled in a smoking cessation program (or must indicate that they do not smoke); **AND**
5) Liver function tests (ALT, AST, and bilirubin) should be conducted prior to the initiation of therapy (documentation required), at regular intervals for the first three (3) months and periodically thereafter. Initial lab results must be submitted with prior authorization request; **AND**
6) Patient must not be pregnant.

Note:

- Patient will be denied coverage if they have previously been treated with Ofev and experienced greater than five (5) times the upper normal limit of ALT and/or AST.

References

1) Ofev package insert 1/2018
2) Lexi-Comp Clinical Application 2/16/2018

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Office of Pharmacy Service
Prior Authorization Criteria

HUMIRA® (adalimumab) and ENBREL® (etanercept)
Effective 03/05/2018
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*; **AND**
  3. Prior treatment with a vitamin D analog (such as calcipotriol)*;
  4. Prior ninety (90) day treatment history with a disease-modifying agent (DMARD) such as methotrexate, cyclosporine, acitretin, etc.

  *Please note: clinical studies have indicated that using a topical corticosteroid in combination with a vitamin D analog is more effective than using either agent separately.

- **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

3) Lexi-Comp drug monographs for Humira and Enbrel (7/11/2016)
4) Humira Package Insert (7/2016)
5) Enbrel Package Insert
6) 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis
7) The 2012 BSR and BHPR guideline for the treatment of psoriatic arthritis with biologics
8) 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
9) Crofford *Arthritis Research & Therapy* 2013, 15(Suppl 3):S2
10) J Braun *et al*. 2010 update of the ASAS/EULAR recommendations for the management of anykylosing spondylitis. Ann Rheum Dis 2011; 70:896-904
11) 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)
12) G Lichtenstein, S Hanauer *et al.* Management of Crohn's Disease in Adults. Am J Gastroenterol advance online publication, 6 January 2009
13) EDF Guideline for Hidradenitis Suppurativa / Acne Inversa (HS) - S1 Guideline – 2016-2017 (file:///C:/Users/E033601/Downloads/Guideline-on-Hidradenitis-suppurativa-S1.pdf)

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Office of Pharmacy Service
Prior Authorization Criteria

PCSK-9 INHIBITORS
PRALUENT®(alirocumab), REPATHA® (evolocumab)
Effective 03/05/2018

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 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).*

****** FOR ALL indications, WV MEDICAID requires the PCSK-9 Inhibitors to be used in combination with an optimized regimen of lipid-lowering therapy (e.g., high-intensity statin) unless there is a clinically demonstrated intolerance to statin therapy (see below for details on monotherapy).***

CRITERIA FOR APPROVAL

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

2) Prior authorization request must be for an FDA-approved indication (as listed above) and clinical documentation supporting the diagnosis must be submitted with the request; **AND**

3) 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.

4) 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.

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.

PCSK-9 INHIBITOR MONOTHERAPY DUE TO STATIN INTOLERANCE

PCSK-9 inhibitor monotherapy is approvable **only** on appeal to the BMS Medical Director.

Approval of monotherapy with 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

14) Repatha package insert revised 12/2017
15) Praulent package insert revised 7/2015
16) Lexi-Comp Clinical Application reviewed 02/19/2018
17) 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.
18) *UpToDate* clinical article: Management of low density lipoprotein cholesterol (LDL-C) in secondary prevention of cardiovascular disease (last update 7-25-2017)
19) Sabatine et al. Evolocumab and Clinical Outcomes in Patients with Cardiovascular Disease; N Engl J Med 2017; 376:1713-1722
20) 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.
21) 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.
22) Treating Statin Intolerant Patients. Marcello Arca and Giovanni Pigna. Diabetes Metab Syndr Obes. 2011; 4: 155–166.

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Office of Pharmacy Service
Prior Authorization Criteria

Synagis® (palivizumab)
Effective 03/05/2018

Prior Authorization Request Form

Palivizumab (Synagis) is a respiratory syncytial virus (RSV) F protein inhibitor monoclonal antibody indicated for the prevention of serious lower respiratory tract disease caused by RSV in children at high risk of RSV disease.

LENGTH OF AUTHORIZATION

- Authorization shall be for a maximum of five (5) doses during the current RSV season (five monthly doses of 15 mg/kg IM).
- Prior authorizations will be granted for a dose sufficient to provide 15 mg/kg based upon the patient's initial weight at the time of request. Prior authorizations will NOT be adjusted to account for weight gain during the RSV season.
- In infants and children less than 24 months already on prophylaxis and eligible, one post-op dose can be approved after cardiac bypass or after extracorporeal membrane oxygenation (ECMO).

RSV SEASON

- Generally considered to run from November to April. WV Medicaid will provide coverage for qualifying prescriptions until March 31st. A maximum of five (5) doses during RSV season provides six (6) months of RSV prophylaxis.

- Only a maximum of five (5) doses will be approved during RSV season. If prophylaxis is initiated later in the RSV season, the infant or child will receive less than five (5) doses. For example, if prophylaxis is initiated in January, the 3rd and final dose, will be administered in March. For eligible infants born during RSV season, fewer than five (5) monthly doses may be needed.

**** See the following pages for full approval and denial conditions ****

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APPROVAL CRITERIA - Palivizumab will be approved in the following scenarios

Infant/Child Age at Start of RSV Season	Criteria
≤12 months (1st year of life)	▪ GA <29 wks, 0 d (otherwise healthy) ▪ CLD of prematurity (GA <32 wks, 0 d requiring >21% supplemental O_2 x first 28 d after birth) ▪ Anatomic pulmonary abnormalities, or neuromuscular disorder, or congenital anomaly that impairs the ability to clear secretions ▪ Profoundly immunocompromised ▪ CF with CLD and/or nutritional compromise ▪ CHD (hemodynamically *significant*) with *acyanotic* HD on CHF medications and who will require cardiac surgery or who have moderate to severe PH. For *cyanotic* heart defects consult a pediatric cardiologist
>12 months to ≤ 24 months (2nd year of life)	▪ CLD of prematurity (GA <32 wks, 0 d and >21% O_2 x first 28 d after birth) and medical support (chronic systemic steroids, diuretic therapy, or supplemental O_2) within 6 months before start of 2nd RSV season ▪ CF with severe lung disease* or weight for length <10th percentile ▪ Cardiac transplant during RSV season ▪ Already on prophylaxis and eligible: give post-op dose after cardiac bypass or after ECMO ▪ Profoundly immunocompromised

GA=gestational age; wks=weeks; d=day; CLD=chronic lung disease; CHD=congenital heart disease; O_2=oxygen; HD=heart disease; CHF=congestive heart failure; PH=pulmonary hypertension; CF=cystic fibrosis; ECMO=extracorporeal membrane oxygenation

* Examples of severe lung disease: previous hospitalization for pulmonary exacerbation in the 1st year of life, abnormalities on chest radiography [chest X-ray], or chest computed tomography [chest CT] that persist when stable

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DENIAL CRITERIA – Palivizumab will NOT be approved in the following scenarios

Infant/Child Age at Start of RSV Season	Deny
>12 months to ≤ 24 months (2nd year of life)	▪ Based on prematurity alone ▪ CLD without medical support (chronic systemic steroids, diuretic therapy, or supplemental O_2) ▪ CHD ▪ Otherwise healthy children in 2nd year of life
Any age	▪ Breakthrough RSV hospitalization** ▪ Hemodynamically *insignificant* CHD*** ▪ CHD lesions corrected by surgery (unless on CHF meds) ▪ CHD and mild cardiomyopathy not on medical therapy ▪ CHD in 2nd year of life
No specific age defined	▪ GA ≥29 wks, 0 d (otherwise healthy) ▪ Asthma prevention ▪ Reduce wheezing episodes ▪ Down Syndrome ▪ CF (otherwise healthy) ▪ Healthcare-associated RSV disease****

** If any infant or child is receiving palivizumab prophylaxis and experiences a breakthrough RSV hospitalization, discontinue palivizumab, because the likelihood of a second RSV hospitalization in the same season is extremely low.

*** Examples of hemodynamically *insignificant* CHD: secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, patent ductus arteriosus.

**** No rigorous data exist to support palivizumab use in controlling outbreaks of health care-associated disease; palivizumab use is not recommended for this purpose.

REFERENCES

1 American Academy of Pediatrics. Position Statement. Updated guidance for palivizumab prophylaxis among Infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. Pediatrics 2014; 134;415. DOI: 10.1542/peds.2014-1665. Available at: http://pediatrics.aappublications.org/content/134/2/415.full.pdf+html?sid=c5cf7568-4302-4ccd-9c71-ea785e33e241. Accessed August 6, 2014.

2. American Academy of Pediatrics. Technical Report. Updated guidance for palivizumab prophylaxis among Infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. DOI: 10.1542/peds.2014-1666. Available at: http://pediatrics.aappublications.org/content/early/2014/07/23/peds.2014-1666. Accessed July 29, 2014.

3. Synagis [package insert]. Gaithersburg, MD; MedImmune; March 2014.

4. Clinical criteria recommendations from Magellan Medicaid Administration, Inc.; August 2014.