ANTIHEMOPHILIA FACTOR AGENTS[CL]

CLASS PA CRITERIA: All agents will require prior-authorization, and non-preferred agents require medical reasoning explaining why the need cannot be met using a preferred product.

All currently established regimens shall be grandfathered with documentation of adherence to therapy.

FACTOR IXa/IX

HEMLIBRA (emicizumab-kxwh) (Non-Preferred) - - Hemlibra shall be approved without further restriction for patients with Hemophilia A with documented presence of Factor VIII inhibitors.

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

Office of Pharmacy Service
Prior Authorization Criteria

Cytokine & CAM antagonist criteria
Effective 11/21/2019
Prior Authorization Request Form

Prior Authorization for any agent in this class requires the following criteria to be met. Additional criteria may be required for specific indications; off-label requests require an appeal:

- **Diagnoses Must Accompany All Requests**
- Patient must meet the minimum age recommended by the manufacturer for the FDA-approved indication; **AND**
- Initial treatment plan must be done by, or in consultation with an appropriate specialist (such as a dermatologist, gastroenterologist or rheumatologist); **AND**
- A negative tuberculin skin test must be submitted prior to initiation of therapy.
- Off-label use must be appealed to the Medical Director and be accompanied with a letter from the prescriber detailing the clinical rationale for the request.
- *DMARD refers to a non-biologic disease-modifying anti-rheumatic drug and includes such agents as methotrexate (MTX), sulfasalazine, leflunomide, and cyclosporine among other agents).*

THE FOLLOWING INDICATION-SPECIFIC CRITERIA MUST ALSO BE SATISFIED:

- **Ankylosing spondylitis, Plaque Psoriasis and Psoriatic Arthritis:**
  - **Plaque psoriasis**: Preferred agents require evidence of failure after at least 90 days of topical therapy* with two different agents classified as an emollient, corticosteroid, topical retinoid or vitamin D analog. A 90-day trial of one DMARD (or a systemic retinoid such as acitretin) is also required.
    **Topical therapy requirement is waived for moderate-to-severe disease affecting at least 5% of the BSA or crucial body areas such as the hands, feet, face, neck, genitals/groin, or intertriginous areas.*
  - **Psoriatic Arthritis:** Preferred agents require a 90-day trial of one DMARD.
  - **Ankylosing Spondylitis:** Preferred agents require failure of two 30-day trials of NSAIDs.
  - Note: Cosentyx may be authorized only after a 90-day trial of either Humira or Enbrel.
  - Non-preferred agents require 90-day trials of Enbrel, Humira and Cosentyx.
- **Rheumatoid arthritis:**
  - Humira and Enbrel each require a 90-day trial a DMARD.
  - Non-preferred agents require 90-day trials each of one DMARD, and Enbrel and Humira.
- **Juvenile idiopathic arthritis:**
  - Humira and Enbrel each require a 90-day trial of a DMARD.
  - Non-preferred agents require 90-day trials each of one DMARD, and Enbrel and Humira.

- **Crohn's Disease (Adult and Pediatric):**
  - Humira may be authorized upon demonstration of an inadequate response to at least one 14-day trial of corticosteroids or an immunomodulator such as azathioprine, 6-mercaptopurine, or methotrexate.
  - In addition to the above criteria, non-preferred agents require a 90-day trial of Humira.

- **Ulcerative Colitis:**
  - Humira may be authorized upon demonstration of an inadequate response to at least a thirty (30) day course of aminosalicylates (e.g. sulfasalazine, mesalamine) requiring treatment for two (2) or more exacerbations using corticosteroids, such as prednisone.
  - In addition to the above criteria, non-preferred agents require a 90-day trial of Humira.

- **Hidradenitis suppurativa:**
  - Humira may be authorized with documentation indicating that the patient has severe disease (Hurley stage III) OR moderate disease (Hurley state II) despite treatment with an oral formulary tetracycline (i.e., doxycycline) OR topical clindamycin.

- **Uveitis:**
  - Humira may be authorized for a diagnosis of non-infectious uveitis and failure to respond to an appropriate trial of oral/topical corticosteroid therapy, unless contraindicated.

Table 1 FDA-approved indications – *(Preferred agents highlighted).* ***Current on 2/22/2019***

		Ankylosing Spondylitis	Plaque Psoriasis	Psoriatic Arthritis	Polyarticular JIA	Rheumatoid Arthritis	Crohn's Disease	Pediatric Crohn's Disease	Ulcerative Colitis	Hidradenitis Suppurativa	Uveitis	Cytokine Release Syndrome	Giant Cell arteritis	Systemic JIA	Periodic Fever Syndromes	Mechanism of Action
Humira	adalinumab	☑	☑	☑	☑ ≥ 2 y	☑	☑ ≥ 6 y	☑	☑	☑ ≥ 12 y	☑ ≥ 2 y					Anti-TNF
Ebrel	etanercept	☑	☑ ≥ 4 y	☑	☑ ≥ 2 y	☑										Anti-TNF
Cosentyx	secukinumab	☑	☑	☑												Anti-IL-17A
Cimzia	certolizumab pegol	☑	☑	☑		☑	☑									Anti-TNF
Remicade	infliximab	☑	☑	☑		☑	☑		☑							Anti-TNF
Renflexis	infliximab	☑	☑	☑		☑	☑		☑							Anti-TNF
Simponi	golimumab	☑	☑	☑					☑							Anti-TNF
Actemra	tocilizumab				☑	☑						☑	☑	☑		Anti-IL-6
Entyvio	vedolizumab						☑		☑							Select. adhesion mol. inhib.
Ilaris	canakinumab													☑	☑	IL-1 Beta Inhibitor
Kevzara	sarilumab					☑										Anti-IL-6
Orencia	abatacept			☑	☑	☑										Select. T-Cell costim. blocker
Otezla	apremilast		☑	☑												PDE-4 Enzyme Inhibitor
Siliq	brodalumab		☑													Anti-IL-17A
Stelara	ustekinumab		☑	☑			☑									Anti-IL-12/23
Taltz	ixekizumab		☑	☑												Anti-IL-17A
Tremfya	guselkumab		☑													Anti-IL-23
Xeljanz	tofacitinib			☑		☑			☑							JAK inhibitor

REFERENCES

1) Lexi-Comp drug monographs for all drugs listed reviewed on 2-22-2019
2) Package Inserts reviewed on 2-22-2019
3) 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis
4) The 2012 BSR and BHPR guideline for the treatment of psoriatic arthritis with biologics
5) 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
6) Crofford *Arthritis Research & Therapy* 2013, 15(Suppl 3):S2
7) J Braun *et al*. 2010 update of the ASAS/EULAR recommendations for the management of anykylosing spondylitis. Ann Rheum Dis 2011; 70:896-904
8) 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)
9) G Lichtenstein, S Hanauer *et al.* Management of Crohn's Disease in Adults. Am J Gastroenterol advance online publication, 6 January 2009
10) EDF Guideline for Hidradenitis Suppurativa / Acne Inversa (HS) - S1 Guideline – 2016-2017

Table 1.2 Drugs by Indication - *(Alternate view - Preferred agents highlighted). **Current on 2/22/2019***

	Humira	Ebrel	Cosentyx	Cimzia	Remicade	Renflexis	Simponi	Actemra	Entyvio	Ilaris	Kevzara	Orencia	Otezla	Siliq	Stelara	Taltz	Tremfya	Xeljanz
Ankylosing Spondylitis	☑	☑	☑	☑	☑	☑	☑	☑	☑									
Plaque Psoriasis	☑	☑ ≥ 4 y	☑	☑	☑	☑	☑						☑	☑	☑	☑	☑	
Psoriatic Arthritis	☑	☑	☑	☑	☑	☑	☑					☑	☑		☑	☑		☑
Polyarticular JIA	☑ ≥ 2 y	☑ ≥ 2 y						☑				☑						
Rheumatoid Arthritis	☑	☑		☑	☑	☑		☑			☑	☑						☑
Crohn's Disease	☑ ≥ 6 y			☑	☑	☑			☑						☑			
Pediatric Crohn's Disease	☑																	
Ulcerative Colitis	☑				☑	☑	☑		☑									☑
Hidradentis Suppurativa	☑ ≥ 12																	
Uveitis	☑ ≥ 2 y																	
Cytokine Release Syndrome								☑										
Giant Cell arteritis								☑										
Systemic JIA								☑	☑									
Periodic Fever Syndromes									☑									

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

Office of Pharmacy Service
Prior Authorization Criteria

CGRP Receptor Antagonists

Aimovig® (erunumab-aooe)
Emgality™ (galcanezumab-gnlm)
Ajovy™ (fremanezumab-vfrm)
Effective 1/01/2020

Prior Authorization Request Form

AIMOVIG, EMGALITY and AJOVY are calcitonin gene-related peptide receptor antagonists indicated for the preventive treatment of migraine in adults.

- **Emgality 300 mg/3 mL requires review by the Medical Director and is available only on appeal.**
- **Ajovy is a non-preferred agent and requires a 90-day trial of both Aimovig and Emgality.**

Prior authorization requests for Aimovig or Emgality 120mg/mL may be approved if the following criteria are met.

1. The patient is within the age range as recommended by the FDA label; **AND**

2. Prescriber is a specialist or has consulted a specialist such as neurologist; **AND**

3. Patient is experiencing at least 4 migraine days per month requiring acute pharmacological management; **AND**

4. Patient has failed to achieve therapeutic goals after using an agent from at least TWO of the following three classes of preventative medications. Individual trials may be waived when evidence is presented indicating a direct contraindication exists due to a clinically significant allergy, drug interaction or adverse effect. **To qualify as a trial, each agent must be dosed within the listed range for at least 90 consecutive days. Agents may be used alone or in combination, however at least one of these preventative trials must have taken place in the last 12 months.**
    - **Beta Blockers** – metoprolol (50 – 200 mg daily), propranolol (40-160 mg daily), timolol (10-30 mg daily), nadolol (20-240 mg daily), atenolol (25-100 mg daily)
    - **Antidepressants** – amitriptyline (20-50 mg qHS), venlafaxine (75-150 mg daily)
    - **Anticonvulsants** – valproate (500-1500 mg daily), topiramate (100 mg daily)

    For agents not listed above, a prophylactic trial may be satisfactory only when the request is accompanied by documentation referencing clinical trials that support the agent's efficacy in migraine prevention.

Initial prior authorization approval will be for 3 months. Additional therapy may be approved only with clinical documentation showing a 50% reduction in either the number of headache days per month or the overall symptom severity (as measured by MIDAS or HIT-6) compared to baseline.

References

1.) Aimovig Package Insert (5/2018)
2.) Emgality Package Insert (9/2018)
3.) Ajovy Package Insert (9/2018)
4.) UpToDate (Chronic Migraine) – Aug 10, 2018
5.) LexiComp monograph on Aimovig (reviewed 8/22/2018)
6.) ICER Calcitonin Gene-Related Peptide (CGRP) Inhibitors as Preventative Treatments for Patients with Episodic or Chronic Migraine: Effectiveness and Value (April 11, 2018)
7.) Blocking CGRP in migraine patients – a review of pros and cons (Deen et al. The Journal of Headache and Pain (2017) 18:96)
8.) Preventative treatment in migraine and the new US guidelines. Neuropsychiatr Dis Treat. 2013; 9: 709-720.
9.) American Academy of Neurology 2012 Update: Pharmacologic Treatment for Episodic Migraine Prevention in Adults

West J Med. 2000 Nov; 173(5): 341–345. Migraine prophylaxis in adult patients

STATE OF WEST VIRGINIA
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Office of Pharmacy Service
Prior Authorization Criteria

Testosterone Injection

Effective 11/20/2019

Prior Authorization Request Form

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

1. Patient must be male; **AND**

2. Patient has two (2) morning pre-treatment total testosterone levels below the lower limit of the normal total testosterone reference range of the individual laboratory used (please attach lab results); **AND**

3. Patient has primary hypogonadism or hypogonadotropic hypogonadism caused by gonadotropin (GnRH) or luteinizing hormone-releasing hormone (LHRH) deficiency, or pituitary-hypothalamic injury from tumors, trauma, or radiation; **OR**

4. Patient has primary hypogonadism (congenital or acquired) caused by testicular failure due to one of the following:
    a) Cryptorchidism
    b) Bilateral torsion
    c) Orchitis
    d) Vanishing testes syndrome
    e) Orchiectomy
    f) Klinefelter's syndrome
    g) Chemotherapy
    h) Toxic damage from alcohol or heavy metals

Requests for erectile dysfunction, infertility, and age-related hypogonadism will not be approved without one of the above etiologies being specified.

If criteria for coverage are met, initial authorization will be given for 3 months. **Requests for continuation of therapy will require the following:**

1. An updated total testosterone level (Please attach lab result); **AND**
2. Documentation the patient has not experienced a hematocrit > 54% or an increase in PSA > 1.4ng/mL in the past 12 months.

References

10.) Lexi-Comp drug monograph for testosterone (Reviewed 8/14/2017)
11.) Merck Manual – guidance on Male Hypogonadism
12.) US Pharmacist: Testosterone Replacement Therapy: Controversy and Recent Trends. *US Pharm.* 2019;44(8):17-23.

STATE OF WEST VIRGINIA
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ANTIPSYCHOTICS, ATYPICAL

CLASS PA CRITERIA: All antipsychotic agents require prior authorization for children up to eighteen (18) years of age. All PA requests for antipsychotics for children 6 years of age and younger will be reviewed by Medicaid's consultant psychiatrist.

Non-preferred agents require thirty (30) day trials of two (2) preferred agents, including the generic formulation of the requested agent (if available), before they will be approved unless one (1) of the exceptions on the PA form is present. All trials must be at the maximum recommended dose for the diagnosis provided before they would be considered a failure unless an adverse reaction is documented necessitating a change in therapy.

Patients shall be grandfathered onto their existing therapy, provided the requested agent is being used according to the manufacturer label. Continuation of therapy for an off-label indication or non-standard dosage may be granted a thirty (30) day prior-authorization while the Medical Director reviews the request.

SINGLE INGREDIENT

LATUDA (lurasidone) (Non-Preferred) -- LATUDA will be be authorized for the indication of <u>bipolar depression</u> with documentation of the diagnosis. All other indications require class criteria to be followed.

STATE OF WEST VIRGINIA
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Office of Pharmacy Service
Prior Authorization Criteria

Orilissa® (elagolix)

Effective 1/01/2020

Prior Authorization Request Form

Orilissa is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the management of moderate to severe pain associated with endometriosis.

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

0. The patient must be within the age range as recommended by the FDA label; **AND**

1. Patient must not be pregnant; **AND**

2. Patient has failed to achieve significant symptomatic relief with NSAID therapy (please provide documentation); **AND**

3. Patient has failed a 90-day trial with one agent from each of the following categories (unless contraindicated):
    a. GnRH agonist
    b. Extended-cycle combined oral contraceptive **OR** progestin therapy

***Initial prior authorization will be for 90 days.**
Continuation of coverage requires clinically significant improvement in symptoms as compared to that seen using previous therapy.

References

13.) Orilissa Package Insert (7/2018)
14.) LexiComp monograph on Orilissa (reviewed 9/17/2018)
15.) UpToDate article on Endometriosis: Treatment of pelvic pain (reviewed 11/18/2019)
16.) ACOG updates guideline on diagnosis and treatment of endometriosis. Am Fam Physician. 2011 Jan 1;83(1):84-85
17.) Institute for Clinical and Economic Review Final Report Highlights Limitations in Evidence on Long-term Safety and Effectiveness of Elagolix for Endometriosis, Discusses Options for Insurance Coverage Criteria. August 3, 2018

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MULTIPLE SCLEROSIS AGENTS[CL]

CLASS PA CRITERIA: All agents require a prior authorization and documented diagnosis of multiple sclerosis. Preferred oral agents require a ninety (90) day trial of any preferred injectable agent. Non-preferred agents require ninety (90) day trials of each chemically unique preferred agent (in the same sub-class) before they will be approved, unless one (1) of the exceptions on the PA form is present.

Change to Class Criteria. New criteria listed above.

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Office of Pharmacy Service
Prior Authorization Criteria

PCSK9 INHIBITORS
PRALUENT®(alirocumab), REPATHA® (evolocumab)
Effective 11/21/2019

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 an 8-week trial of either **atorvastatin 40 - 80 mg + ezetimibe** OR **rosuvastatin 20 - 40 mg + ezetimibe.** Note: If the patient failed to tolerate the first statin/ezetimibe combination, then they must be trialed on the second combination for 8-weeks or until intolerance occurs.

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.

REFERENCES

11) Repatha package insert revised 2/2019
12) Praulent package insert revised 4/2019
13) Lexi-Comp Clinical Application reviewed 5/02/2019
14) 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.
15) *UpToDate* clinical article: Management of low density lipoprotein cholesterol (LDL-C) in secondary prevention of cardiovascular disease (last update 7-25-2017)
16) Evolocumab and Clinical Outcomes in Patients with Cardiovascular Disease; N Engl J Med 2017; 376:1713-1722
17) 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.
18) 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.
19) Treating Statin Intolerant Patients. Marcello Arca and Giovanni Pigna. Diabetes Metab Syndr Obes. 2011; 4: 155–166.

LEUKOTRIENE MODIFIERS

CLASS PA CRITERIA: Non-preferred agents require a twelve (12) week trial of a preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.

CHOLESTEROL ABSORPTION INHIBITORS

Zetia (Preferred) and generic Ezetimibe (Non-Preferred) - will be authorized with prior use of a HMG-CoA reductase inhibitor within the previous six (6) months.

IRRITABLE BOWEL SYNDROME/SHORT BOWEL SYNDROME/SELECTED GI AGENTS CL

CLASS PA CRITERIA: All agents are approvable only for patients age eighteen (18) and older. See below for additional sub-class criteria.

CONSTIPATION

LINZESS (linaclotide) (Preferred) - - All agents require documentation of the current diagnosis and evidence that the patient has failed to find relief with dietary modification and a fourteen (14) day trial of an osmotic laxative.

The following indication-specific criteria also apply:

Linzess is indicated for CIC and IBS-C

IRRITABLE BOWEL SYNDROME/SHORT BOWEL SYNDROME/SELECTED GI AGENTS CL

CLASS PA CRITERIA: All agents are approvable only for patients age eighteen (18) and older. See below for additional sub-class criteria.

CONSTIPATION

MOTEGRITY (prucalopride) (Non-Preferred) - - All agents require documentation of the current diagnosis and evidence that the patient has failed to find relief with dietary modification and a fourteen (14) day trial of an osmotic laxative.

The following indication-specific criteria also apply:

Motegrity is indicated for CIC and requires a 30-day trial of both Amitiza and Linzess.

OPHTHALMICS, ANTI-INFLAMMATORIES- IMMUNOMODULATORS CL

CLASS PA CRITERIA: All agents require a prior authorization. All agents must meet the following prior-authorization criteria:

1.) Patient must be sixteen (16) years of age or greater; **AND**
2.) Prior Authorization must be requested by an ophthalmologist or optometrist; **AND**
3.) Clinically diagnosed tear deficiency due to ocular inflammation in patients with keratoconjunctivitis sicca or dry eye syndrome (also known as dry eye); **AND**
4.) Patient must have a functioning lacrimal gland; **AND**
5.) Patient using artificial tears at least four (4) times a day over the last thirty (30) days; **AND**

Patient must not have an active ocular infection

Non-preferred agents also require a 60-day trial of the preferred agent(s).

Change in class criteria, new criteria is listed above.

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OPHTHALMICS, GLAUCOMA AGENTS

CLASS PA CRITERIA: All agents are approvable only for patients age eighteen (18) and older. See below for additional sub-class criteria.

RHO-KINASE INHIBITORS

Prior Authorization criteria was removed, as both agents are no Preferred.

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

Office of Pharmacy Service
Prior Authorization Criteria

Fasenra® (benralizumab)
Effective 11/21/2019

Prior Authorization Request Form

FASENRA is an interleukin-5 receptor alpha-directed cytolytic monoclonal antibody (IgG1, kappa) indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

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

TREATMENT OF EOSINOPHILIC ASTHMA:

1. Must be prescribed by or in consultation with an allergist, immunologist or pulmonologist; **AND**

2. The patient must be within the age range as recommended by the FDA label and indication; **AND**

3. Patient must have documented adherence to a therapeutic regimen consisting of a LABA + high dose ICS therapy in the last 90 days; **AND**

4. Documentation must be supplied indicating **one** of the following:
    a. A positive sputum test for eosinophilic phenotype asthma with sputum eosinophil level ≥ 3% **OR**
    b. Asthma with eosinophilic phenotype with blood eosinophil count greater than or equal to 300 cells/mcL in the past 12 months
    c. **OR** claims data that reflect a continual reliance on oral corticosteroid therapy in the last 90 days.

Initial approval of Fasenra for asthma will be for 90 days. Additional therapy shall be approvable with documentation of satisfactory patient response and compliance on inhaled therapy.

References

18.) Fasenra Package Insert (10/2019)
19.) LexiComp monograph review (11/18/2019)
20.) UpToDate literature review on the treatment of severe asthma in adolescents and adults (11/07/2018)

STATE OF WEST VIRGINIA
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Office of Pharmacy Service
Prior Authorization Criteria

TRIKAFTA®
(elexacaftor, tezacaftor, and ivacaftor tablets)

Prior Authorization Request Form

Effective 11/21/2019

TRIKAFTA is a combination of ivacaftor, a CFTR potentiator, tezacaftor, and elexacaftor indicated for the treatment of cystic fibrosis (CF) in patients aged 12 years and older who have at least one F508del mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one F508del mutation.

Criteria for Approval

4) Individual is 12 years or older; **AND**
5) Patient must have a confirmed diagnosis of Cystic Fibrosis; **AND**
6) Patient must be determined to have at least one ***F508del*** mutation in the CFTR gene as confirmed by an FDA-approved CF mutation test; **AND**
7) Patient must have a documented baseline AST, ALT and FEV_1 (forced expiratory volume in one second) presented with the prior authorization request; **AND**
8) Patients under the age of 18 years must have undergone a baseline ophthalmic examination to monitor for lens opacities/cataracts.

Prior authorizations will be for every 6 months in the first year, followed thereafter by an annual prior authorization.

Criteria for Continuation of Therapy

1) Patients under the age of 18 years must have follow up ophthalmic examinations at least annually (documentation required); **AND**
2) Patient must have LFTs/bilirubin monitored every 6 months for the first year of treatment and annually thereafter (documentation required); **AND**
3) Serum ALT or AST < 5 times the upper limit of normal (ULN); **OR**
4) Serum ALT or AST < 3 times the ULN with bilirubin < 2 times the ULN.

References

20) Trikafta package insert revised 10/2019
21) Lexi-Comp Clinical Application 11/15/2019