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

Office of Pharmacy Service
Prior Authorization Criteria

ANORO ELLIPTA®
(umeclidinium-vilanterol inhalation powder)

ANORO ELLIPTA is a combination of umeclidinium, a long-acting anticholinerigic, and vilanterol, a long-acting beta 2-adrenergic agonist (LABA). Anoro Ellipta is indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD). *Anoro Ellipta is not indicated for the treatment of asthma.*

Criteria for Approval

1) Patient must be ≥18 years of age; **AND**
2) Patient must have had a diagnosis of COPD; **AND**
3) Patient must have had a 30 day trial of a LABA or a combination drug containing a LABA; **AND**
4) Patient must have had a **concurrent** 30 day trial with a long-acting anticholinergic;
5) Prior-authorization will be denied for patients with a sole diagnosis of asthma.

References

1) 2014 GOLD guidelines: (http://www.goldcopd.org/uploads/users/files/GOLD_Report_2014_Jan23.pdf)
2) Anoro Ellipta package insert 05/2014
3) Lexi-Comp Clinical Application September 2014
4) *Detail-Document;* Pharmacist's Letter 2014; 30(4):300403

Version 6 Reviewed and Approved by
Drug Utilization Review Board
November 19th, 2014 (BMT)

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

Office of Pharmacy Service
Prior Authorization Criteria

EVZIO®
(naloxone auto-injection)

Evzio is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. Evzio is intended for immediate administration as emergency therapy in settings where opioids may be present. Evzio is not a substitute for emergency medical care.

Evzio will be authorized for 1 year at a quantity limit of 4 per claim (two boxes - 1.6 ml) if the following criteria have been met:

1.) Prescriber must complete the Opioid Overdose Risk Assessment Checklist Form and submit for documentation. The link below is for the form:
http://evzio.com/pdfs/Evzio-Opioid-Overdose-Risk-Assessment-Checklist.pdf

AND

2.) Patient must be receiving addiction counseling services if the diagnosis is substance abuse, dependence and/or addiction; such as psychosocial therapy from a Substance Abuse provider. Documentation provided must include provider name, type of provider, and provider phone number.

AND

3.) The medication is to be administered outside of a healthcare facility (such as a personal residence or school)

References

5) Lexi-Comp drug monograph for Evzio (Nov. 10th, 2014)
6) www.Evzio.com
7) Evzio package insert (rev 4/2014)

Version 2 Reviewed and Approved by
Drug Utilization Review Board
November 19th, 2014 (BMT)

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

Office of Pharmacy Service
Prior Authorization Criteria

HUMIRA® (adalimumab) and ENBREL® (etanercept)

Humira and Enbrel will be granted prior authorization for the listed indications if the specified criteria are satisfied. Diagnoses must accompany all requests.

1. Patient is 18 years of age or older (see below if diagnosed with juvenile idiopathic arthritis); **and**

2. Initial treatment plan is done in consultation with an appropriate specialist (such as a dermatologist, gastroenterologist or rheumatologist).

3. Negative tuberculin skin test before initiation of therapy; **and**

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

5. **Psoriasis** must have:
    i. Diagnosis of moderate to severe psoriasis (≥10% of the body affected); **and**
    ii. Prior treatment with a potent topical corticosteroid plus calcipotriol; **and**
    iii. Prior treatment with a Vitamin D analogue; **and**
    iv. Prior treatment with phototherapy; **and**
    v. Prior 90-day treatment history with a disease-modifying agent (DMARD) such as methotrexate, cyclosporine, acitretin, etc.

6. **Psoriatic arthritis** or **rheumatoid arthritis:** must have a documented 90-day history of NSAID therapy as well as 90 day trials of at least two DMARDs.

7. **Juvenile idiopathic arthritis**: Prior authorization may be granted for Humira if the patient is 4 years or older; Enbrel may be granted a PA if the patient is 2 years of age or older. In either case, the patient must have tried and failed a 90 day course of therapy with methotrexate.

8. **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.*

9. **Ulcerative Colitis:** Humira is approvable following failure or clinically significant adverse effects to a 30 day course of aminosalicylates (e.g. sulfasalazine,

mesalamine) requiring treatment for 2 or more exacerbations using corticosteroids, such as prednisone. *Enbrel is not indicated for treatment of UC and will not be approved.*

References

8) Lexi-Comp drug monographs for Humira and Enbrel (Nov. 4th, 2014)
9) Humira Package Insert (5/2014)
10) Enbrel Package Insert
11) J Braun *et al*. 2010 update of the ASAS/EULAR recommendations for the management of anykylosing spondylitis. Ann Rheum Dis 2011; 70:896-904
12) 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)
13) G Lichtenstein, S Hanauer *et al.* Management of Crohn's Disease in Adults. Am J Gastroenterol advance online publication, 6 January 2009

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

Prior Authorization Criteria
HARVONI® (ledipasvir/sofosbuvir) for Hepatitis C (HCV)

Harvoni is a two-drug fixed-dose combination product containing 90 mg ledipasvir and 400 mg sofosbuvir. Harvoni is indicated for the treatment of adult patients diagnosed with hepatitis C genotype 1.

Criteria for Approval

1) Patient must be eighteen (18) years of age or older; **AND**
2) Harvoni must be prescribed by, or in conjunction with, a board certified gastroenterologist, hepatologist or infectious disease physician; **AND**
3) Patient must be diagnosed with Hepatitis C Genotype 1; **AND**
4) Patient must have a documented diagnosis of cirrhosis or a fibrosis level ≥ F3 (see below under Diagnostic/Disease Severity Evidence)
5) Patient must be sofosbuvir (including Harvoni) treatment naïve; **AND**
6) Patient must **NOT** be co-infected with HIV; **AND**
7) Patient must **NOT** be awaiting liver transplant (Harvoni is not indicated in this population); **AND**
8) Patient has abstained from the use of illicit drugs and alcohol for a minimum of six (6) months, as indicated by the patient's signature on the Patient Consent form; **AND**
9) Patient must be vaccinated against Hepatitis A and Hepatitis B; **AND**
10) Patient must agree to complete the full regimen and the patient and the provider must agree that an SVR12 and SVR24 will be collected and submitted to WV Medicaid to verify therapy success;

Duration of Approval

- Initial approval is for 8 weeks and requires submission of the starting HCV RNA level.
- Continued coverage after week 8 depends upon receipt of an HCV RNA level at treatment week 4 (TW4), documentation of patient compliance, continued abstinence and an HCV RNA < 25 IU/ml.
- See Table 1 for a list of approved Hep C regimens and the duration of coverage.

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Table 1. Accepted Regimens and Treatment Duration for HCV Combination Therapy in HCV Mono-Infected and HCV/HIV-1 Co-Infected Patients

Diagnosis	Approved Regimen	Duration
Genotype 1 - Treatment Naive - HCV RNA <6 mil IU/ml without cirrhosis	Harvoni	8 weeks
Genotype 1 - Treatment Naive - HCV RNA >6 mil IU/ml	Harvoni	12 weeks
Genotype 1 - Treatment Experienced[1] without cirrhosis	Harvoni	12 weeks
Genotype 1 - Treatment Experienced[1] with cirrhosis	Sovaldi + peginterferon alfa + ribavirin	12 weeks
Genotype 1 – Treatment experienced with cirrhosis and Interferon Ineligible[2]	Sovaldi + Olysio	12 weeks
Genotype 1 - HIV Co-Infection	Sovaldi + peginterferon alfa + ribavirin	12 weeks
Genotype 1 - HIV - Interferon Ineligible[2]	Sovaldi + ribavirin	24 weeks
Genotype 2	Sovaldi + ribavirin	12 weeks
Genotype 3	Sovaldi + peginterferon alfa + ribavirin	12 weeks
Genotype 3 - Interferon Ineligible[2]	Sovaldi + ribavirin	24 weeks
Genotype 4	Sovaldi + peginterferon alfa + ribavirin	12 weeks
Genotype 4 - Interferon Ineligible[2]	Sovaldi + ribavirin	24 weeks

[1]**TREATMENT EXPERIENCED** patients are defined as those who have failed a previous regimen containing peginterferon alfa + ribavirin or an HCV protease inhibitor + peginterferon alfa + ribavirin. Patients previously treated with a sofosbuvir-containing regimen will not be covered except at the discretion of the Medical Director of the Bureau of Medical Services.

[2]**INTERFERON-INELIGIBILITY** is defined under “CRITERIA FOR DENIAL”

ALL OTHER REGIMEN REQUESTS WILL BE CONSIDERED ON A CASE-BY-CASE BASIS

STATE OF WEST VIRGINIA
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Diagnostic/Disease Severity Evidence (must be attached to request)

1) Cirrhosis may be substantiated either through biopsy or the presence of **at least two** of the following clinical features:
    a. Cirrhotic features on imaging
    b. Ascites
    c. Esophageal varices
    d. Reversed AST:ALT ratio (> 1), thrombocytopenia (< 130,000 platelets/μL), and coagulopathy (INR > 2)
2) Fibrosis level of F3 (indicating bridging fibrosis) must be substantiated via biopsy or other accepted method (e.g. FibroSure Assay)

Criteria for Denial

1) Prescription for any other HCV anti-viral medication.
2) Patient has HIV co-infection.
3) Diagnosis for any genotype other than GT 1.
4) Patient is awaiting liver transplant.
5) Patient is post-liver transplant (safety and efficacy have not been established).
6) Patient is not sofosbuvir naïve.
7) Patient has not abstained from the use of illicit drugs and/or alcohol for at least six (6) months prior to the start of treatment, as evidenced by an accepted laboratory screening test.
8) Patient is receiving concomitant hepatitis protease inhibitor therapy (e.g. telaprevir (Incivek), boceprevir (Victrelis).
9) Patient has decompensated cirrhosis (defined as a Child-Pugh score greater than 6 [class B or C]).
10) Patient has severe renal impairment (eGFR < 30 mL/min/1.73m2) or end stage renal disease (ESRD) requiring hemodialysis.
11) Patient is taking a concomitant medication that has a significant clinical interaction with sofosbuvir:
    a. tipranavir/ritonavir
    b. rifampin, rifabutin, rifapentine
    c. carbamazepine, phenytoin, phenobarbital, oxcarbazepine
    d. St. John’s wort

Additional Considerations

1) Sofosbuvir is a nucleotide analog NS5B polymerase inhibitor.
2) Ledipasvir is an inhibitor of the hepatitis C virus NS5A protein.
3) Coverage shall be for one course of therapy in a lifetime. Exceptions may be considered on a case-by-case basis.
4) Lost or stolen medication replacement request will not be authorized.

References

1) Harvoni [package insert]. Foster City, CA; Gilead, October 2014.
2) Sovaldi [package insert]. Foster City, CA; Gilead, December 2013.
3) FDA Antiviral Drugs Advisory Committee Meeting, October 25, 2013; Background Package for NDA 204671 sofosbuvir (GS-7977).
4) Lawitz E, Mangia A, Wyles D, et al. Sofosbuvir for previously untreated chronic hepatitis C infection. *N Engl J Med*. 2013; 368:1878-87. doi: 10.1056/NEJMoa1214853. Available at: http://www.nejm.org/doi/pdf/10.1056/NEJMoa1214853. Accessed January 2, 2014.
5) Jacobson IM, Gordon SC, Kowdley KV, et al. Sofosbuvir for hepatitis C genotype 2 or 3 in patients without treatment options. *N Engl J Med.* 2013;368:1867-77. doi: 10.1056/NEJMoa1214854. Available at: http://www.nejm.org/doi/pdf/10.1056/NEJMoa1214854. Accessed January 2, 2014.
6) American Association for the Study of Liver Diseases Infectious Diseases Society of America: Recommendations for testing, managing and treating hepatitis C. Available at: http://www.hcvguidelines.org/. Accessed February 18, 2014.
7) Poynard T, Ratziu V, Benmanov Y, DiMartino V, Bedossa P, Opolon P. Fibrosis in patients with hepatitis c: detection and significance. *Semin Liver Dis*. 2000;20(1). Retrieved from www.medscape.com. Accessed February 26, 2014.

Version 3 Reviewed and Approved by
Drug Utilization Review Board
November 19th, 2014 (BMT)

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

Office of Pharmacy Service
Prior Authorization Criteria

GRASTEK®, ORALAIR®, RAGWITEK®

Three allergen extracts for sublingual administration as immunotherapy for allergic rhinitis have been approved by the FDA:

1.) Grastek (timothy grass pollen allergen extract)
2.) Ragwitek (short ragweed pollen allergen extract)
3.) Oralair (5 grass pollen allergen extract)

Grastek Criteria for Approval

6) Patient must be 5 to 65 years of age for Grastek approval.
7) PA requests will be granted only between Dec. 1st and Feb 1st of the following year. The duration of the PA, if authorized, will be no longer than 10 months.
8) Diagnosis must be confirmed by a positive skin test or *in vitro* testing for pollen-specific IgE antibodies for timothy grass or cross-reactive grass pollens. Results should be submitted along with request for approval.
9) Patient must have concurrent auto-injectable epinephrine prescription
10) Patient must NOT currently be receiving subcutaneous allergen immunotherapy.
11) Initial treatment must be administered in the prescriber's office and the patient should be under supervision for 30 minutes. Note: Pediatric patients should be supervised by an adult after all subsequent doses.

Oralair Criteria for Approval

1) Patient must be 10 to 65 years of age for Oralair approval
2) PA requests will be granted only between Dec. 1st and Feb 1st of the following year. The duration of the PA, if authorized, will be no longer than 10 months.
3) Diagnosis must be confirmed by a positive skin test to grass pollen from the Pooideae subfamily of grasses (this includes, but is not limited to sweet vernal, Kentucky blue grass, Timothy grass, orchard, or perennial rye grass) OR positive in vitro test (blood test for allergen-specific IgE antibodies) for a grass in the Pooideae subfamily of grasses. Results should be submitted along with request for approval
4) Patient must have concurrent auto-injectable epinephrine prescription
5) Patient must NOT currently be receiving subcutaneous allergen immunotherapy.
6) Initial treatment must be administered in the prescriber's office and the patient should be under supervision for 30 minutes. Note: Pediatric patients should be supervised by an adult after all subsequent doses.

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Ragwitek Criteria for Approval

1.) Patient must be 18 to 65 years of age for Ragwitek approval.
2.) PA requests will be granted only between Dec. 1st and Feb 1st of the following year. The duration of the PA, if authorized, will be no longer than 10 months.
3.) Diagnosis must be confirmed by either a positive skin test response to short ragweed pollen OR positive in vitro test for short ragweed pollen (blood test for allergen-specific IgE antibodies). Results should be submitted along with request for approval.
4.) Patient must have concurrent auto-injectable epinephrine prescription
5.) Patient must NOT currently be receiving subcutaneous allergen immunotherapy.
6.) Initial treatment must be administered in the prescriber's office and the patient should be under supervision for 30 minutes.

References

14) Lexi-Comp drug monographs for Grastek, Oralair and Ragwitek (Oct 31, 2014)
15) Package inserts for Grastek (06/2014) and Ragwitek (06/2014)
16) The Allergy and Asthma Foundation of America®
17) The American Academy of Allergy Asthma & Immunology
18) http://www.allergyescape.com/pollen-allergy.html

Version 2 Reviewed and Edits requested – add start date of PA
Drug Utilization Review Board
November 19th, 2014 (BMT)

Version 2.2 Nov. 21st, 2014 (BMT)

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

Office of Pharmacy Service
Prior Authorization Criteria

HYQVIA®

(Human Immune Globulin 10% infusion)

HyQvia is a subcutaneous immune globulin (IG) infusion 10% (human) with recombinant human hyaluronidase indicated for the treatment of Primary Immundeficiency (PI) in adults. HyQvia contains recombinant human hyaluronidase which increases dispersion and absorption of the immune globulin allowing a full therapeutic dose in one subcutaneous infusion site.

Prior Authorization Criteria

1.) Patient must be 18 years of age or older; **AND**
2.) Diagnosis of primary humoral immunodeficiency, which includes, but is not limited to congenital agammaglobulinemia, common variable immunodeficiency (CVID), X-linked agammaglobulinemia, congenital agammaglobulinemia Wiskott-Aldrich syndrome, and severe combined immunodeficiencies; **AND**
3.) The initial dose of HyQvia should be administered in a healthcare setting capable of monitoring for and treating hypersensitivity reactions. All subsequent doses may be administered at home or in a home care setting.

Any indication not otherwise specified shall be reviewed for prior-authorization on a case-by-case basis with the assumption that all supporting evidence has been submitted along with the request for coverage.

References

19) Lexi-Comp drug monograph for HyQvia (Nov. 10th, 2014)
20) www.HyQvia.com
21) HyQvia package insert (rev 9/2014)

Version 4 Reviewed and Approved by
Drug Utilization Review Board
November 19th, 2014 (BMT)

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

Office of Pharmacy Service
Prior Authorization Criteria

RESTASIS®
(cyclosporine ophthalmic emulsion 0.05%)

Restasis is an ophthalmic immunomodulator approved to increase tear production in patients whose tear production is presumed to be suppressed due to ocular inflammation associated with keratoconjunctivitis sicca.

Restasis will be authorized for 1 year if the following criteria have been met:

1.) Patient must be 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 4 times a day over the last 30 days; **AND**

6.) Patient must not have an active ocular infection

References

22) Lexi-Comp drug monograph for Restasis (Nov. 10th, 2014)
23) www.Restasis.com
24) Restasis package insert (rev 6/2013)

Version 4 Reviewed and Approved by
Drug Utilization Review Board
November 19th, 2014 (BMT)