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

Office of Pharmacy Service
Prior Authorization Criteria

Nucala® (mepolizumab)
Effective 10/01/2019

Prior Authorization Request Form

NUCALA is an interleukin-5 (IL-5) antagonist monoclonal antibody (IgG1 kappa) indicated for:
- Add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.
- The treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

Prior authorization requests for Nucala 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 Nucala for asthma will be for 90 days. Additional therapy shall be approvable with documentation of satisfactory patient response and compliance on inhaled therapy.

TREATMENT OF EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS (EGPA):

1. Patient must have a documented diagnosis of EPGA (also known as Churg-Strauss Syndrome) with the patient meeting at least 4 of the following diagnostic criteria:
    a. Asthma
    b. Eosinophilia of > 10% in peripheral blood
    c. Paranasal sinusitis
    d. Pulmonary infiltrates, sometimes transient

e. Histologic evidence of vasculitis with extravascular eosinophils
f. Multiple mononeuropathy or polyneuropathy

AND

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

3. Patient has failed to achieve remission of symptoms following at least a 90-day course of systemic glucocorticoid therapy equivalent to (or greater than) 7.5 mg/day of oral prednisone PLUS immunosuppressive therapy such as, but not restricted to, cyclophosphamide, methotrexate or azathioprine (unless contraindicated) *

   * If the provider feels that immunosuppressive therapy is contraindicated, they must document the reason for this.

Initial approval of Nucala for EGPA will be for 90 days. Additional therapy shall be approvable with documentation of satisfactory patient response.

References

1.) Nucala Package Insert (06/2019)
2.) LexiComp monograph review (09/06/2019)
3.) UpToDate review: Treatment and prognosis of eosinophilic granulomatosis with polyangiitis (Churg-Strauss) – Last updated 11/29/2018
4.) UpToDate literature review on the treatment of severe asthma in adolescents and adults (11/07/2018)
5.) American College of Rheumatology – Arthritis and Rheumatism, Vol. 33, No. 8 (August 1990) The American College of Rheumatology 1990 Criteria for the Classification of Churg-Strauss Syndrome (Allergic Granulomatosis and Angiitis)

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

Office of Pharmacy Service
Prior Authorization Criteria

Palynziq® (pegvaliase-pqpz)

Effective 10/01/2019

Prior Authorization Request Form

Palynziq is a phenylalanine-metabolizing enzyme indicated to reduce blood phenylalanine concentrations in adult patients with phenylketonuria who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management.

Criteria for Approval

1) Diagnosis of phenylketonuria; **AND**
2) The patient must be within the age range recommended by the FDA label and indication; **AND**
3) Patient has been prescribed an epinephrine autoinjector (as recommended by the manufacturers label in case of anaphylaxis); **AND**
4) Documentation is submitted indicating that the patient is currently adhering to a Phe-restricted diet, and has failed to reduce PHE levels below 600 µmol/L after a minimum 60-day trial of Kuvan with at least 30 days of therapy at a dose of ≥ 20 mg/kg/day (unless a contraindication/intolerance to Kuvan is documented); **AND**
5) Palynziq will **not** be authorized for concurrent use with Kuvan.

NOTE: Prescriber must submit the patient's current weight and phenylalanine levels at initiation of therapy. Initial prior authorization will be for 6 months.

Reauthorization Criteria

- Patient must have experienced at least a 20% reduction in Phe after 6 months of therapy.
- The maximum approvable dose is 40 mg/day.
- Patient must continue to adhere to therapy as well as a Phe-restricted diet.

References

1) Lexi-Comp Clinical Application 09/20/2019
2) Palynziq [package insert]. 05/2018
3) Vockley J, Andersson HC, Antshel KM, et al. "Phenylalanine Hydroxylase Deficiency: Diagnosis and Management Guideline" *ACMG Practice Guideline.* 2014. Accessed 4/20/2015.

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

Office of Pharmacy Service
Prior Authorization Criteria

DUPIXENT® (dupilumab)
Effective 10/01/2019

Prior Authorization Request Form

DUPIXENT *is an interleukin-4 receptor alpha antagonist indicated:*

I. For the treatment of patients aged 12 years and older 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.

II. As an add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma.

III. As an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP).

I. For the Indication of Atopic Dermatitis, prior authorization requests may be approved if the following criteria are met:

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

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

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

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

9. Patient has failed to find relief of symptoms after a minimum of 30-day 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 for atopic dermatitis will be for 90 days. Additional therapy shall be approvable with documentation of satisfactory patient response (including current affected BSA and severity of symptoms).

II. For the indication of Asthma, prior authorization requests may be approved if the following criteria are met:

10. Prescribed by or in consultation with an allergist, immunologist or pulmonologist; **AND**

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

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

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

III. For the indication of Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP), prior authorization requests may be approved if the following criteria are met:

14. Member must have a diagnosis of CRSwNP which has been inadequately controlled after at least 3-months of therapy with any intranasal steroid. If the member has not trialed Xhance intranasal steroid, then they must also fail 3-months of therapy with that product; **AND**

15. The patient must be within the approved age range according to the FDA label and indication; **AND**

16. Dupixent is only approvable as add-on therapy for CRSwNP.

Continuation of coverage requires documentation of reduction/elimination of nasal polyps AND patient adherence to therapy (including the original agent Dupixent was supplementing).

References

6.) LexiComp monograph for dupliumab (accessed 09/09/2019)
7.) Dupixent package insert revision 06/2019
8.) GINA: Difficult-to-treat and Severe Asthma in adolescents and adults patients. V2.0 April 2019 (www.ginasthma.org)
9.) UpToDate literature review on the treatment of severe asthma in adolescents and adults (11/07/2018)
10.) UpToDate literature review on the treatment of atopic dermatitis (11/2018)
11.) https://www.aad.org/practicecenter/quality/clinical-guidelines/atopic-dermatitis/diagnosis-and-assessment/disease-severity-recommendations
12.) https://www.ecu.edu/cs-dhs/fammed/upload/Atopic-Dermatitis-Guidelines.pdf
13.) https://journal.chestnet.org/article/S0012-3692(11)60278-X/pdf (Point: Is Measuring Sputum Eosinophils Useful in the Management of Sever Asthma? Yes) Chest/139/6/June,2011 p 1271-1273.
14.) https://journal.chestnet.org/article/S0012-3692(11)60279-1/pdf (Counterpoint: Is Measuring Sputum Eosinophils Useful in the Management of Severe Asthma? No, Not for the Vast Majority of Patients) Chest/139/6/June,2011 p 1273-1275.

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

Office of Pharmacy Service
Prior Authorization Criteria

Diclegis® (doxylamine and pyroxidine)
Effective 10/01/2019

Prior Authorization Request Form

DICLEGIS is a fixed dose combination drug product of doxylamine succinate, an antihistamine, and pyridoxine hydrochloride, a Vitamin B6 analog, indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management.

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

0. Diagnosis of nausea and vomiting associated with pregnancy; **AND**

1. Failure of conservative therapy for nausea and vomiting* (please document all previous therapies);
   *An algorithm containing recommended alternative management strategies for nausea and vomiting of pregnancy (NVP) may be found at the end of this document.
   AND

2. Failure of a seven (7) day trial of combination therapy consisting of doxylamine 12.5 mg taken twice daily with pyridoxine 25 mg taken qid. Although available OTC, Medicaid provides coverage for both of these products, therefore this trial must be verifiable by review of pharmacy claims or purchase history.

Initial approval of Diclegis will be for seven (7) days at a dose of up to four (4) tablets daily.

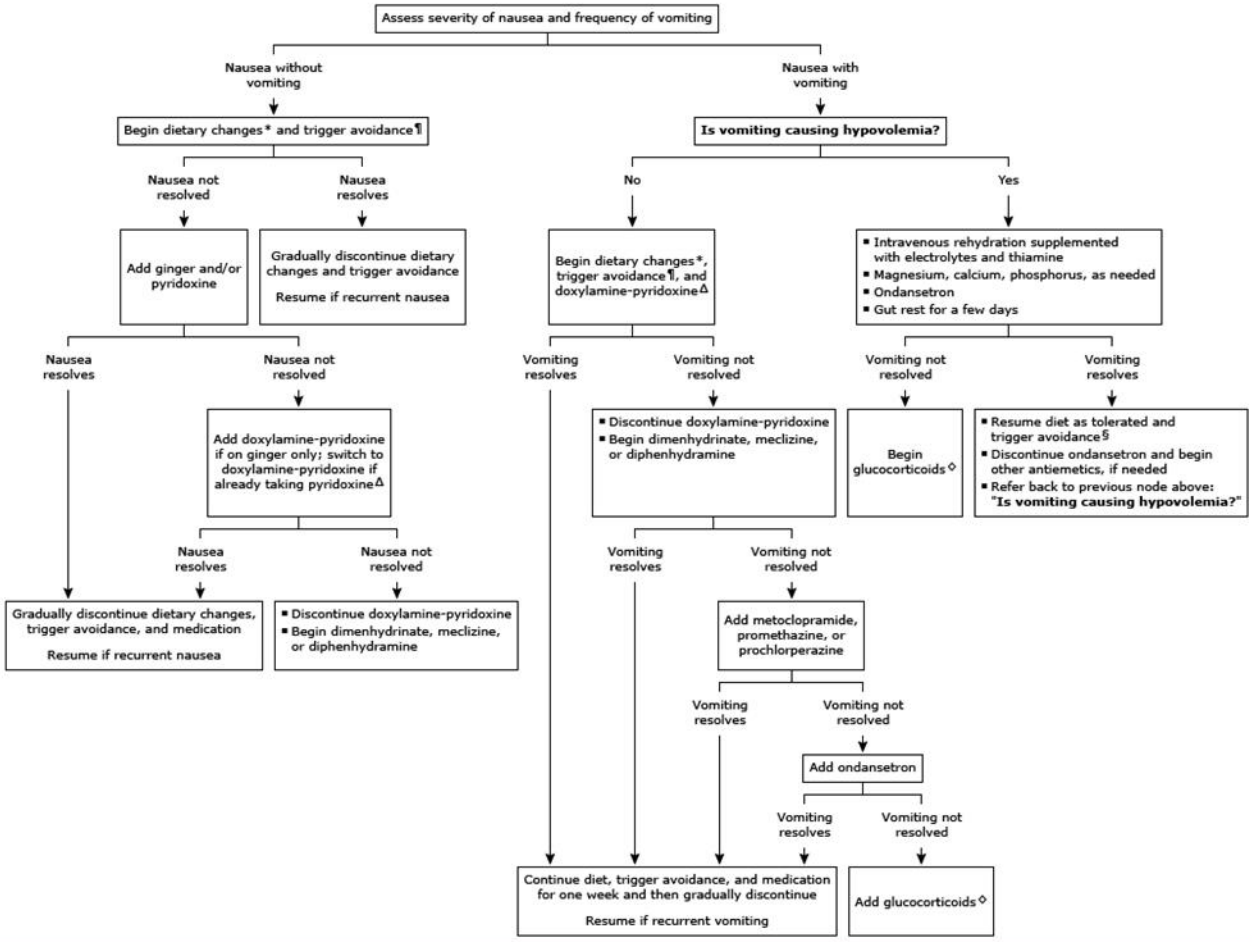
Additional therapy shall only be authorized with documentation that the member has experienced satisfactory efficacy within the initial approval period. Clinical studies have shown that efficacy of Diclegis should be assessable in most patients within 4 days, therefore extensions will not be granted if the patient has not experienced relief within the initial prior authorization period.

References

15.) https://www.ncbi.nlm.nih.gov/pubmed/27881103
16.) UptoDate – Treatment and Outcome of Nausea and Vomiting in Pregancy (9/06/2019)
17.) Diclegis Package Insert (6/2018)
18.) LexiComp monograph on Diclegis (reviewed 9/06/2019)

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

Management algorithm for treatment of nausea and vomiting of pregnancy (NVP)



Women with mild symptoms may benefit from acupuncture, acupressure, or hypnosis. Women with heartburn/acid reflux may benefit from acid-reducing medications as adjunctive therapy anytime during the course of illness. Antacids containing aluminum or calcium are preferred. Preferred H2 blockers are ranitidine or cimetidine. There is less experience using proton pump inhibitors (eg, lansoprazole or esomeprazole).

* Eat small amounts of food every one to two hours to avoid an empty or full stomach. It can be helpful to eliminate spicy, odorous, high-fat, acidic, and very sweet foods, and substitute protein-dominant, salty, low-fat, bland, and/or dry foods. Fluids should be consumed at least 30 minutes before or after solid food to minimize the effect of a full stomach. Fluids are better tolerated if cold, clear, and carbonated or sour. Avoid lying down after eating.

¶ Examples of some triggers include stuffy rooms, odors, heat, humidity, noise, visual or physical motion, and gastric irritants (eg, coffee, iron supplements).

Δ Doxylamine succinate 10 mg and pyridoxine 10 mg may be given separately or as a combination pill. We begin with 20 mg of each drug at bedtime. If ineffective, we give an additional 10 mg of each drug in the morning and in the afternoon.

◇ We generally treat refractory cases with a short course of glucocorticoids but may begin with chlorpromazine in selected patients, such as those in whom the side effects of glucocorticoids may be more serious.

§ We usually begin with a diet consisting of bananas, rice, applesauce, and toast (BRAT diet) and then advance as tolerated to usual diet suggested for women with nausea and vomiting of pregnancy.

UpToDate®

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

Patient-Provider Agreement – Hepatitis C

I, _____, have been counseled by my healthcare provider on the following:

☐ The importance of not drinking alcohol or using illicit drugs during and after my treatment for Hepatitis C and that I may be required to submit to a drug screen at the discretion of my healthcare provider.

☐ How to avoid being re-infected with Hepatitis C during and after my treatment.

☐ (**Male**) The importance of using a barrier method of birth control and encouraging my partner to also use birth control.

☐ (**Female**) The importance of using two forms of birth control (one of which must be a barrier method) while being treated. I agree to have pregnancy tests as ordered by my healthcare provider. I also understand that I must tell my healthcare provider if I do become pregnant.

☐ I agree to complete the entire course of treatment, as well as all associated laboratory tests during and after treatment, as ordered by my healthcare provider.

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☐ **(Prescriber)** I understand that an SVR12 is required to verify treatment success and that failure to provide these results to Medicaid may result in disqualification of my patient from future coverage.

☐ **(Prescriber)** I have confirmed to the best of my ability that my patient has not abused alcohol or illicit drugs (excluding marijuana) for at least the past **three (3) months**.

X _____ _____
Patient Signature Date

X _____ _____
Prescriber Signature Date

Ver2019.3b

V2019.3a – BMT updated 09/27/2019
DUR Board Approval: 09/25/2019

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

Office of Pharmacy Service
Prior Authorization Criteria

Xhance® (*fluticasone propionate 93 mg nasal spray*)
Effective 10/01/2019

Prior Authorization Request Form

XHANCE (fluticasone propionate 93 mg nasal spray) is a corticosteroid indicated for the treatment of nasal polyps in patients 18 years of age or older. This product is packaged with an Exhalation Delivery System designed for administration deep into the nasal passages.

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

3. Patient must meet all age and indication restrictions listed in the FDA label; **AND**

4. Member must have a diagnosis of nasal polyps which have been inadequately controlled after at least 3-months of therapy with any intranasal steroid.

Initial approval shall be for 90 days and continuation of coverage shall require documentation of reduction/elimination of nasal polyps and patient adherence to therapy.

References

19.) LexiComp monograph on Xhance (accessed 9/12/2019)
20.) Xhance package insert (revised: 09/2017)
21.) UpToDate review on the Clinical presentation, diagnosis, and treatment of nasal obstruction (updated 7/29/2019)