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

Office of Pharmacy Services
Prior Authorization Criteria
DUPIXENT® (dupilumab)
Effective 1/1/2023

Prior Authorization Request Form

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

I. For the treatment of adult and pediatric patients ≥6 months of age 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).
IV. For the treatment of adult and pediatric patients ≥12 years of age, weighing ≥40 kg, with eosinophilic esophagitis.
V. For the treatment of adult patients with Prurigo Nodularis.

I. For the Indication of Atopic Dermatitis, prior authorization requests 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. The patient must be within the age range as recommended by the FDA label and indication; **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 30-day trials of two agents from the following list in the last 12 months:

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

*Trial of medium to high potency topical steroid is required unless the affected area involves sensitive areas such as the face, skin folds or genitals. However, a trial of two other agents among the list above, are still required prior to Dupixent approval.

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:

1. 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 150 cells/mcL within the past 6 weeks or blood eosinophil count greater than or equal to 300 cells/mcL in the past 12 months; **OR**
    c. 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:

1. Must be prescribed by or in consultation with, an ENT, allergist, or other suitable specialist; **AND**

2. Member must have a diagnosis of CRSwNP which has been inadequately controlled after at least 3-months of therapy with any intranasal steroid; **AND**

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

4. 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).

IV. For the indication of Eosinophilic Esophagitis, prior authorization requests may be approved if the following criteria are met:

1. Prescribed by or in consultation with an allergist, immunologist, pulmonologist, or gastroenterologist; **AND**
2. The patient must be within the age range as recommended by the FDA label and indication; **AND**
3. The patient has an eosinophilic count ≥15 eosinophils per high-power microscopy field (eos/hpf); **AND**
4. The patient has symptoms of dysphagia or prior history of esophageal dilation; **AND**
5. The patient has had a 90-day trial resulting in an inadequate response to topical/systemic glucocorticoids, unless contraindicated.

Initial approval of Dupixent for Eosinophilic Esophagitis will be for 90 days. Additional therapy shall be approvable with documentation showing that the member has achieved a significant reduction in dysphagia symptoms since treatment initiation.

V. For the indication of Prurigo Nodularis, prior authorization requests may be approved if the following criteria are met:

1. Prescribed by or in consultation with a dermatologist, allergist, or immunologist; **AND**
2. The patient must be within the age range as recommended by the FDA label and indication; **AND**
3. Patient has a Worst Itch Numeric Rating Scale (WI-NRS) score of ≥7 on a scale of 0 to 10; **AND**
4. The patient has at least 20 nodular lesions; **AND**
5. The patient has had a trial resulting in an inadequate response/treatment failure to a super potent topical corticosteroid or an intralesional corticosteroid, unless contraindicated.

Initial approval of Dupixent for Prurigo Nodularis will be for 90 days. Additional therapy shall be approvable with documentation of satisfactory patient response and compliance on therapy.

References:

1.) LexiComp monograph for dupliumab (accessed 09/09/2019), 3/21, 11/21, 11/22
2.) Dupixent package insert revision 06/2019, 3/21, 11/21, 11/22
3.) GINA: Difficult-to-treat and Severe Asthma in adolescents and adults patients. V2.0 April 2019 (www.ginasthma.org)
4.) UpToDate literature review on the treatment of severe asthma in adolescents and adults (11/07/2018)
5.) UpToDate literature review on the treatment of atopic dermatitis (11/2018)
6.) https://www.aad.org/practicecenter/quality/clinical-guidelines/atopic-dermatitis/diagnosis-and-assessment/disease-severity-recommendations
7.) https://www.ecu.edu/cs-dhs/fammed/upload/Atopic-Dermatitis-Guidelines.pdf
8.) 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.
9.) 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.
10.) UpToDate literature review on Chronic rhinosinusitis: Management (11/2021)
11.) UpToDate literature review on the treatment of eosinophilic esophagitis (EoE) (11/2022)
12.) UpToDate literature review Prurigo Nodularis (11/2022)