Utilization Management Policy Name: Dupixent - NC Standard

Restricted Product(s):

- Dupixent® (dupilumab) injection

FDA Approved Use:

- For the treatment of patients aged 6 months 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.
- For treatment as an add-on maintenance treatment in patients with moderate-to-severe asthma aged 6 years and older with an eosinophilic phenotype or with an oral corticosteroid dependent asthma.
    - Limitations of Use: Not for the relief of acute bronchospasm or status asthmaticus.
- For add-on maintenance treatment in adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP).
- For the treatment of adult and pediatric patients 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis (EoE).
- For the treatment of adult patients with prurigo nodularis (PN).
- For add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.
    - Limitations of Use: Not for the relief of acute bronchospasm.

Criteria for Approval of Restricted Product(s):

Initial Coverage Criteria:

1. ONE of the following:
    a. The patient has a diagnosis of **moderate to severe atopic dermatitis**; **AND**
        i. The patient is 6 months of age or older; **AND**
        ii. The patient has tried and failed or has a clinical intolerance/contraindication to a moderate to high potency topical corticosteroid in the last 6 months **(medical record documentation required)**; **AND**
        iii. The patient has tried and failed or has a clinical intolerance/contraindication to a topical calcineurin inhibitor in the last 6 months **(medical record documentation required)**; **AND**
        iv. The patient has Body Surface Area (BSA) involvement of at least 10% OR the patient has involvement of the palms, soles, head and neck, or genitalia, causing disruption in normal daily activities and/or employment **(medical record documentation required)**; **OR**

b. The patient has a diagnosis of **moderate to severe asthma**; **AND**
    i. The patient is 6 years of age or older; **AND**
    ii. One of the following:
        1. The patient has an eosinophilic phenotype; **AND**
            a. The patient has blood eosinophil counts greater than or equal to 150 cells/microliter **(medical record documentation required); OR**
        2. The patient has oral corticosteroid dependent asthma; **AND**
            a. The patient has been on and adherent to an oral corticosteroid regimen for the last 6 months; **AND**
    iii. The patient has been on and currently treated with maximally tolerated conventional therapies which include:
        1. An inhaled corticosteroid regimen in the past 12 months **(medical record documentation required)**; **OR**
            a. The patient has a clinical intolerance/contraindication to ALL inhaled corticosteroids **(medical record documentation required)**; **AND**
        2. A regimen containing either a long-acting beta agonist, leukotriene receptor antagonist, theophylline, or zileuton for the last 6 months **(medical record documentation required)**; **OR**
            a. The patient has a clinical intolerance/contraindication to ALL of the following; long-acting beta agonist, leukotriene receptor antagonist, theophylline, or zileuton **(medical record documentation required)**; **AND**
    iv. The patient has had either of the following:
        1. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months: **OR**
        2. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months; **OR**

c. The patient has a diagnosis of **chronic rhinosinusitis with nasal polyposis**; **AND**
    i. The patient is 12 years of age or older; **AND**
    ii. The patient has had symptoms consistent with chronic rhinosinusitis (CRS) for at least 12 consecutive weeks; **AND**
    iii. ONE of the following**:**
        1. The patient has tried and failed or has a clinical intolerance/contraindication to Xhance **(medical record documentation required)**; **OR**
        2. The patient has tried and failed or has a clinical intolerance/contraindication to oral systemic corticosteroids within the previous 6 months **(medical record documentation required)**; **AND**
    iv. The patient has had prior sinonasal surgery for nasal polyps **(medical record documentation required)**; **OR**
        1. The patient is not a candidate for sinonasal surgery **(medical record documentation required); AND**
    v. The patient will not be using Dupixent in combination with Xhance; **AND**

vi. The patient is currently being treated with an over-the-counter intranasal steroid; **OR**
    1. The patient has a clinical intolerance/contraindication to ALL intranasal steroids **(medical record documentation required)**; **OR**

d. The patient has a diagnosis of **eosinophilic esophagitis; AND**
    i. The patient is at least 1 year of age or older and weighing at least 15 kg; **AND**
    ii. The patient has chronic symptoms of esophageal dysfunction (i.e., two or more episodes of dysphagia per week); **AND**
    iii. The patient has tried and failed proton pump inhibitor and was unable to achieve adequate control of symptoms with guideline recommended therapy or has a clinical intolerance/contraindication to a proton pump inhibitor **(medical record documentation required)**; **AND**
    iv. The patient has tried and failed or has a clinical intolerance/contraindication to swallowed inhaled respiratory glucocorticoid and was unable to achieve adequate control of symptoms with guideline recommended therapy **(medical record documentation required)**; **OR**

e. The patient has a diagnosis of **prurigo nodularis (PN); AND**
    i. The patient is 18 years of age or older; **AND**
    ii. The patient has been diagnosed with PN for at least 3 months, **AND**
    iii. The patient has severe or very severe itch (WI-NRS score ≥ 7) reported within the past week **(medical record documentation required)**; **AND**
    iv. The patient has at least 20 PN lesions in total on both legs and/or both arms and/or trunk **(medical record documentation required)**; **AND**
    v. The patient has tried and failed or has a clinical intolerance/contraindication to moderate to high potency topical corticosteroid in the last 6 months **(medical record documentation required)**; **OR**
f. The patient has a diagnosis of **chronic obstructive pulmonary disease (COPD)**; **AND**
    i. The patient is 18 years of age or older; **AND**
    ii. The patient has an eosinophilic phenotype COPD and has blood eosinophil count greater than or equal to 300 cells/microliter **(medical record documentation required)**; **AND**
    iii. The patient has symptoms of chronic bronchitis including productive cough for at least 3 months in the past year; **AND**
    iv. The patient has a post-bronchodilator FEV1/ forced vital capacity [FVC] ratio <0.70 and post-bronchodilator FEV1 % predicted >30% and ≤70% **(medical record documentation required)**; **AND**
    v. The patient is currently receiving maintenance triple therapy which include ALL of the following:
        1. An inhaled corticosteroid (ICS) regimen for the past 12 months **(medical record documentation required)**; **OR**

a. The patient has a clinical intolerance/contraindication to ALL inhaled corticosteroids (ICS) **(medical record documentation required)**; **AND**

2. A regimen containing a long-acting beta agonist (LABA) for the last 6 months **(medical record documentation required); OR**
    a. The patient has a clinical intolerance/contraindication to ALL long-acting beta agonist (LABA) **(medical record documentation required); AND**
3. A regimen containing a long-acting muscarinic antagonist (LAMA) for the last 6 months **(medical record documentation required); OR**
    a. The patient has a clinical intolerance/contraindication to ALL long-acting muscarinic antagonist (LAMA) **(medical record documentation required)**; **AND**

vi. The patient has had 2 moderate or 1 severe chronic obstructive pulmonary disease (COPD) exacerbation despite receiving maintenance triple therapy in the previous year (i.e., requiring systemic corticosteroids and/or antibiotics, hospitalization, or over 24 hours in an emergency department or urgent care facility) **(medical record documentation required)**; **AND**

2. The patient will not be using Dupixent in combination with another biologic immunomodulator for the same indication; **AND**
3. The provider is aware that if approved, any previous authorizations through Blue Cross NC for biologic agents used for the same indication as the requested agent will be terminated; **AND**
4. The patient will not be using Dupixent in combination with Opzelura; **AND**
5. If Dupixent 300 mg weekly is requested:
    a. The patient has a diagnosis of eosinophilic esophagitis**; AND**
6. The patient is being managed by or in consultation with a specialist in the area of the patient's diagnosis (e.g., dermatologist, allergist, pulmonologist, or otolaryngologist); **AND**
7. For formularies that exclude (non-formulary) the requested medication, Non-formulary Exception Criteria applies.

Duration of Approval: 365 days (1 year)

Continuation Coverage Criteria

1. The patient has been previously approved with Blue Cross and Blue Shield of North Carolina (Blue Cross NC) or would have met initial criteria for approval upon the start of therapy; **AND**
2. The therapy has been effective for the patient through improvements in disease severity (i.e., body surface area involvement, WI-NRS score, normal daily activities, asthma exacerbations, pre-bronchodilator FEV, oral corticosteroid reduction etc.); **AND**
3. The patient will not be using Dupixent in combination with another biologic immunomodulator for the same indication; **AND**

4. The provider is aware that if approved, any previous authorizations through Blue Cross NC for biologic agents used for the same indication as the requested agent will be terminated; **AND**
5. The patient will not be using Dupixent in combination with Opzelura; **AND**
6. If Dupixent 300 mg weekly is requested:
    a. The patient has a diagnosis of eosinophilic esophagitis**; AND**
7. For patients with **asthma**:
    a. The patient has been on and adherent to an inhaled corticosteroid regimen since starting Dupixent **(medical record documentation required)**; **AND**
    b. The patient has been on and currently treated with a maximally tolerated regimen containing either a long-acting beta agonist, leukotriene receptor antagonist, theophylline, or zileuton since starting Dupixent **(medical record documentation required)**; **AND**
    c. For patients with oral corticosteroid dependent asthma, the patient has been on and currently treated with an oral corticosteroid regimen and was able to achieve at least a corticosteroid dose reduction **(medical record documentation required)**; **AND**

8. For patients with **chronic rhinosinusitis with nasal polyposis**:
    a. The patient has been on and adherent to an over-the-counter intranasal steroid since starting Dupixent **(medical record documentation required)**; **OR**
    b. The patient has a clinical intolerance/contraindication to ALL intranasal steroids **(medical record documentation required)**.
9. For patient with chronic obstructive pulmonary disease (COPD):
    a. The patient has been on and adherent to maintenance triple therapy regimen since starting Dupixent **(medical record documentation required); OR**
        i. The patient has a clinical intolerance/contraindication to inhaled corticosteroid (ICS), long-acting beta agonist (LABA) **OR** long-acting muscarinic antagonist (LAMA) **(medical record documentation required).**

Duration of Approval: 365 days (1 year)

Quantity Limitations: quantity limitations apply to brand and associated generic products.

Medication	Quantity

Dupixent (dupilumab) 100 mg / 0.67 mL prefilled syringe	2 syringes (1.34 mL) in the **first 28 days of therapy**
Dupixent (dupilumab) 200 mg / 1.14 mL prefilled syringe or pen-injector	4 syringes/pens (4.56 mL) in the **first 28 days of therapy**
Dupixent (dupilumab) 300 mg / 2 mL prefilled syringe or pen-injector	4 syringes/pens (8 mL) in the **first 28 days of therapy**
Dupixent (dupilumab) 100 mg / 0.67 mL prefilled syringe	2 syringes (1.34 mL) every 28 days **for maintenance therapy**
Dupixent (dupilumab) 200 mg / 1.14 mL prefilled syringe or pen-injector	2 syringes/pens (2.28 mL) every 28 days **for maintenance therapy**
Dupixent (dupilumab) 300 mg / 2 mL prefilled syringe or pen-injector	2 syringes/pens (4 mL) every 28 days **for maintenance therapy**

Quantity Limit Exception Criteria:

1. If the requested medication is Dupixent for the diagnosis of eosinophilic esophagitis:
    a. The request is for maintenance dosing of 300 mg every week (four 300 mg injections every 28 days); **OR**
2. If Dupixent 200mg every 4 weeks is requested (two 200 mg injections every 56 days):
    a. The request is for atopic dermatitis in patients aged 6 months to 5 years old weighing 5kg to < 15kg; **OR**
3. If Dupixent 300mg every 4 weeks is requested (two 300 mg injections every 56 days):
    a. The request is for atopic dermatitis in patients aged 6 months to 17 years old weighing 15kg to < 30kg; **OR**
    b. The request is for asthma in patients aged 6 years to 11 years old weighing 15kg to < 30kg; **OR**
4. The quantity (dose) requested is for documented titration purposes at the initiation of therapy (authorization for a 90-day titration period); **AND**
5. The prescribed dose cannot be achieved using a lesser quantity of a higher strength; **AND**
6. The quantity (dose) requested does not exceed the maximum FDA labeled dose, when specified, or to the safest studied dose per the manufacturer's product insert; **OR**
7. If the quantity (dose) requested exceeds the maximum FDA labeled dose, when specified, or to the safest studied dose per the manufacturer's product insert, then the prescriber must submit documentation in support of therapy with a higher dose for the intended diagnosis (submitted documentation may include medical records OR fax form which reflects medical record documentation that shows the length of time the requested dose has been used, and what other medications and doses have been tried and failed).

Duration of Approval: 365 days (1 year)

References: all information referenced is from FDA package insert unless otherwise noted below.

Policy Implementation/Update Information: Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q2 annually.

October 2024: Criteria change: Updated indication for CRSwNP for ages 12-17 and added indication of add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.
February 2024: Criteria change: Updated indication for eosinophilic esophagitis to include adult and pediatric patients 1 year and older, weighing at least 15 kg, and removed 6-month requirement for trial and failure of proton pump inhibitors and swallowed inhaled respiratory glucocorticoid for eosinophilic esophagitis as recommended by guidelines. Updated quantity limit section to allow for increase quantity for atopic dermatitis and asthma patients with dosing frequency of every 4 weeks.
October 2023: Criteria change: Require medical record documentation for BSA involvement in moderate to severe atopic dermatitis. Require symptoms of chronic rhinosinusitis must be consistent for at least 12 weeks with CRS with nasal polyposis.
January 2023: Criteria update: Extended initial duration of approval to 365 days (1 year).
October 2022: Criteria change: Added new indication for prurigo nodularis (PN). Clarified dosing and quantity limit exception criteria for eosinophilic esophagitis.
August 2022: Criteria update: Added new indication for eosinophilic esophagitis. Updated age to 6 months of age and older for moderate-to-severe atopic dermatitis.
April 2022 v2: Criteria update: Updated chronic rhinosinusitis with nasal polyposis indication to allow tried/failed Xhance OR oral systemic corticosteroids
April 2022: Criteria change: Added medication cannot take in combination with Opzelura.
January 2022: Criteria update: Added clause if patient is not a surgery candidate
November 2021: Criteria update: Updated age to 6 years of age and older for moderate to severe asthma. Added new 100mg syringe to policy.
October 2021: Criteria update: If approved, any authorizations for biologic agents used for the same indication as Dupixent will be terminated.
July 2021: Criteria update: Added new 200mg /1.14 mL pen injector to policy.
July 2021: Criteria change: Trial and failure of Xhance and prior surgery required for nasal polyposis indication. Removed requirement of nasal saline irrigation.
March 2021: Criteria change: Require medical record documentation for all trial and failure requirements.
Jan 2021: Criteria change: Addition of requirement that the patient will not be using the requested agent in combination with another biologic immunomodulator for the same indication.
July 2020: Criteria update: Added new 300mg/2mL pen injector to policy.
June 2020: Criteria update: Updated age to 6 years of age and older for moderate-to-severe atopic dermatitis.
January 2020: Criteria Change: Addition of criteria for chronic rhinosinusitis with nasal polyposis.

October 2019: Criteria Change: Phototherapy removed as a prerequisite therapy; Eosinophil counts reduced from 300 cells/microliter to150 cells/microliter; patient asthma exacerbations changed from “two” to “frequent” with the inclusion of 2 steroid burst or hospitalization; Adherence requirements no longer defined by criteria; continuation criteria updated to remove the percent reduction in oral steroid use.
April 2019: Criteria modification – updated age of approval for Atopic Dermatitis
November 2018: Added new indication asthma and strength 200mg/1.14mL to policy
April 2017: Original utilization management criteria issued.