# Commercial/Healthcare Exchange PA Criteria

***Effective: November 7th, 2018***

***Prior Authorization:*** Dupixent (dupilumab injection)

***Products Affected:*** Dupixent (dupilumab injection) prefilled syringe 200mg/1.14mL and 300mg/2mL

***Covered Uses:***

1. Atopic Dermatitis
2. Asthma
3. Chronic Rhinosinusitis with Nasal Polyposis

***Exclusion Criteria:***

1. Treatment naïve patients
2. Relief of acute bronchospasm or status asthmaticus

***Required Medical Information:***

1. Diagnosis
2. Previous therapies tried with dates of treatment [documentation required]
3. Percentage of body surface area (BSA) affected
4. Physician chart notes

***Age Restrictions:***

Atopic dermatitis: Patient must be 6 years of age and older.
Asthma: Patient must be 12 years of age and older
CRSwNP: Patient must be 18 years of age and older

***Prescriber Restrictions:*** Dupixent must be prescribed in consultation with an Allergist, Immunologist, Dermatologist, Pulmonologist, or Otolaryngologist

***Coverage Duration:*** Initiation – 16 weeks; Continuation – 1 year

***Other Criteria:***

1. **Atopic Dermatitis – moderate to severe**
   A) Initiation – Approve for 16 weeks if the patient meets all the following criteria (a, b, c, and d):
      a. Patient has atopic dermatitis involvement estimated to be ≥ 10% of the body surface area (BSA); AND
      b. Patient meets all of the following (i, ii, and iii):
         i. Patient has used at least one medium-, medium-high, high-, and/or super-high-potency prescription topical corticosteroid; AND
         ii. This topical corticosteroid was applied daily for at least 30 consecutive days; AND
         iii. Inadequate efficacy was demonstrated with this topical corticosteroid therapy, according to the prescribing physician; AND
      c. In the past 6 months, the patient has tried tacrolimus ointment; AND
      d. Patient meets both of the following (i and ii):

i. In the past 6 months, the patient has tried at least one of the following systemic agents: oral corticosteroid, intramuscular corticosteroid, oral cyclosporine, oral azathioprine, oral methotrexate, or oral mycophenolate mofetil; AND
ii. Inadequate efficacy was demonstrated with systemic therapy, according to the prescribing physician.

B) Continuation – Approve for 1 year if the patient meets the following criteria (a, b, and c):
a. The patient has responded to Dupixent therapy as determined by the prescribing physician (e.g., marked improvements in erythema, induration/papulation/edema, excoriations, and lichenification; reduced pruritus; decreased requirement for other topical or systemic therapies; reduced body surface area (BSA) affected with atopic dermatitis; or other responses observed) [documentation required].

2. **Asthma – moderate to severe**
A) Initiation – Approve for 16 weeks if the patient meets all of the following criteria (a, b, c, and d)
a. Patient is diagnosed with moderate to severe asthma with an eosinophilic phenotype **OR** with oral corticosteroid dependent asthma; AND
b. Dupixent must be used for add-on maintenance treatment in patients regularly receiving BOTH of the following:
i. High-dose inhaled corticosteroids; AND
ii. An additional controller medication(e.g., long-acting beta agonist, etc.); AND
c. Patient must have ONE of the following:
i. Two or more exacerbations in the previous year; OR
ii. Require daily oral corticosteroids ( for at least 3 days in addition to the regular maintenance therapy defined above)
d. Patient is not on concurrent treatment with another Interleukin-inhibitor

B) Continuation – Approve for 1 year when the following criteria are met. Treatment has resulted in clinical benefit, defined as one or more of the following:
a. Decreased use of systemic corticosteroids; OR
b. Increase in Forced Expiratory Volume (FEV1) from pretreatment baseline; OR
c. Decreased use of inhaled corticosteroid use for at least 3 days; OR
d. Decrease in hospitalizations; OR
e. Decrease in ER visits; OR
f. Decrease in unscheduled visits to healthcare provider

3. **Chronic rhinosinusitis with nasal polyposis**
A) Initiation – Approve for 16 weeks if the patient meets all of the following criteria (a and b):
a. Patient has a diagnosis of Chronic rhinosinusitis with nasal polyposis for at least 12 weeks; AND
b. Patient has had an adequate trial of intranasal steroids without adequate control of symptoms
B) Continuation - Approve for 1 year if the patient meets all of the following criteria:
a. Treatment has resulted in clinical benefit, defined by **both** of the following:
i. Decreased use of systemic or intranasal corticosteroids; AND
ii. The patient has responded to Dupixent therapy as determined by the prescribing physician

***References:***

1. Dupixent [prescribing information]. Bridgewater, NJ: Sanofi Aventis; July 2017.

***Policy Revision history***

| Rev # | Type of Change | Summary of Change | Sections Affected | Date |
|---|---|---|---|---|
| 4 | Policy update | Atopic dermatitis age updated to 6 years of age or older<br><br>Removed exclusion criteria:1. Dupixent has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval in the following circumstances. 2. Pediatric patients, and 3. Not for use in combination with other biologics | Age restrictions<br><br>Exclusion Criteria | 6/10/2020 |
| 3 | Policy Update | Added new indication CRSwNP to match FDA Label | Covered Uses, Age Restrictions, Prescriber Restrictions, Other Criteria | 6/28/2019 |
| 2 | Policy Revision | Updated Age range to match FDA Label | All | 3/15/19 |
| 1 | New Policy | Updated Policy, new template, new indication | All | 11/7/18 |