curative

Dupixent Prior Authorization

Drug(s) Applied:	**Dupixent** (dupilumab)

Criteria:
Drug(s) Applied will be approved when the requested medication is being used for an FDA approved indication and all of the following criteria are met:

I. Initial Therapy Criteria
- **A. Atopic dermatitis (AD)** as indicated by chart notes within past 180 days
  1. Patient is 6 months of age or older **and**
  2. Patient has ONE of the following:
     a) At least 10% body surface area involvement **or**
     b) Involvement of body sites that are difficult to treat with prolonged topical corticosteroid therapy (e.g., hands, feet, face, neck, scalp, genitals/groin, skin folds) **or**
     c) Eczema Area and Severity Index (EASI) score of greater than or equal to 16 **or**
     d) Investigator Global Assessment (IGA) score of greater than or equal to 3 **and**
  3. Patient has tried and had an inadequate response after a minimum of 3 months with an oral systemic immunosuppressant (e.g., methotrexate, azathioprine, mycophenolate mofetil, cyclosporine) for the treatment of AD or patient has an intolerance to ALL oral systemic immunosuppressants **or**
  4. ALL of the following:
     a) Patient has tried and had an inadequate response to a mid-potency or stronger topical steroid used for a minimum of 4 weeks or has an intolerance to a mid-potency or stronger topical steroid **and**
     b) Patient has tried and had an inadequate response to a topical calcineurin inhibitor (e.g., pimecrolimus or tacrolimus) used for a minimum of 6 weeks or has an intolerance to a topical calcineurin inhibitor **and**
     c) Patient has tried and had an inadequate response to Eucrisa or Zoryve 0.15% used for a minimum of 4 weeks or has an intolerance to a topical phosphodiesterase-4 inhibitor **and**
  5. If patient is 12 years of age or older and weighs 40 kg or more then patient has tried and had an inadequate response to Ebglyss used for a minimum of 3 months or has an intolerance or contraindication to Ebglyss **and**

6. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**
7. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., dermatology, allergy and immunology)

Approval Duration: 6 months

B. Moderate-to-severe asthma as indicated by chart notes within past 180 days

1. Patient is 6 years of age or older **and**
2. ONE of the following:
    a) Patient has eosinophilic type asthma and ONE of the following:
        (1) Baseline (prior to therapy with the requested agent) blood eosinophilic count of 150 cells/microliter or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **or**
        (2) Fraction of exhaled nitric oxide (FeNO) of 20 parts per billion or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **or**
        (3) Sputum eosinophils 2% or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **or**
    b) Patient has oral corticosteroid dependent type asthma **and**
3. Patient has a history of uncontrolled asthma while on asthma controller therapy as demonstrated by ONE of the following:
    a) Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months **or**
    b) Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months **or**
    c) Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered **or**
    d) Patient has baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted **and**
4. ONE of the following:
    a) Patient is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 consecutive months **or**
    b) Patient has an intolerance or FDA labeled contraindication to ALL inhaled corticosteroids **and**

5. ONE of the following:
    a) Patient is currently being treated for at least 3 consecutive months with a maximally tolerated long-acting beta-2 agonist (LABA) **or**
    b) Patient has an intolerance or FDA labeled contraindication to ALL inhaled LABAs **and**
6. ONE of the following:
    a) Patient has tried and had an inadequate response after a minimum of 3 consecutive months with a long-acting muscarinic antagonist (LAMA) **or**
    b) Patient has an intolerance to therapy with LAMAs **or**
    c) Patient has an FDA labeled contraindication to LAMAs **and**
7. ONE of the following:
    a) Patient is currently being treated for at least 3 consecutive months with ONE of the following:
        (1) Leukotriene receptor antagonist (LTRA) **or**
        (2) Oral corticosteroids (OCS) **or**
    b) Patient has an intolerance or hypersensitivity to therapy with LTRA or OCS **or**
    c) Patient has an FDA labeled contraindication to ALL LTRA and OCS **and**
8. For severe eosinophilic asthma, ONE of the following:
    a) Patient has tried for a minimum duration of 4 consecutive months and has an inadequate response to Nucala (mepolizumab), **or**
    b) Patient has an intolerance or contraindication to Nucala (mepolizumab) **and**
9. Patient will continue asthma controller therapy (e.g., ICS, ICS/LABA, LTRA, LAMA) in combination with the requested agent **and**
10. Requested drug is not being used for the relief of acute bronchospasm or status asthmaticus **and**
11. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**
12. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., pulmonology, allergy and immunology)

Approval Duration: 6 months

C. Chronic rhinosinusitis with nasal polyposis (CRSwNP) as indicated by chart notes within past 180 days

1. Patient is at least 12 years of age **and**
2. Patient has at least TWO of the following symptoms consistent with chronic rhinosinusitis (CRS) for at least 12 consecutive weeks:
    a) Nasal discharge (rhinorrhea or post-nasal drainage)
    b) Nasal obstruction or congestion
    c) Loss or decreased sense of smell (hyposmia)
    d) Facial pressure or pain **and**
3. Diagnosis was confirmed by either anterior rhinoscopy or endoscopy, or computed tomography (CT) of the sinuses **and**
4. Patient had an inadequate response to sinonasal surgery or is NOT a candidate for sinonasal surgery **or**
5. ONE of the following:
    a) Patient has tried and had an inadequate response to at least 2 intranasal corticosteroids (e.g., fluticasone, mometasone, Sinuva) after at least a 4-week duration of therapy **or**
    b) Patient has an intolerance or FDA labeled contraindication to at least 2 intranasal corticosteroids **and**
6. ONE of the following:
    a) Patient has tried for a minimum duration of 4 consecutive months and has had an inadequate response to Nucala (mepolizumab) **or**
    b) Patient has an intolerance or contraindication to Nucala **or**
    c) Patient is less than 18 years of age **and**
7. Patient is currently treated with standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) **and**
8. Patient will continue standard nasal polyp maintenance therapy in combination with the requested agent **and**
9. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**
10. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., allergy, otolaryngology)

Approval Duration: 6 months

D. Eosinophilic esophagitis (EoE) as indicated by chart notes within past 180 days

1. Patient is aged 1 year or older **and**
2. Patient is at least 15 kg **and**

3. Diagnosis confirmed by ALL of the following:
    a) Chronic symptoms of esophageal dysfunction **and**
    b) Greater than or equal to 15 eosinophils per high-power field on esophageal biopsy **and**
    c) Other causes that may be responsible for or contributing to symptoms and esophageal eosinophilia have been ruled out **and**
4. ONE of the following:
    a) Patient has tried and had an inadequate response to ONE proton pump inhibitor (PPI) used in the treatment of EoE **or**
    b) Patient has an intolerance or hypersensitivity to PPI therapy used in the treatment of EoE **and**
5. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**
6. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., allergy, gastroenterology)

Approval Duration: 6 months

E. Prurigo nodularis (PN) as indicated by chart notes within past 180 days

1. Patient is 18 years of age or older **and**
2. Patient has ALL of the following features associated with PN:
    a) Presence of firm, nodular lesions **and**
    b) Pruritus that has lasted for at least 6 weeks **and**
    c) History and/or signs of repeated scratching, picking, or rubbing **and**
3. Patient has tried and had an inadequate response after a minimum of 3 months with an oral systemic immunosuppressant (e.g., methotrexate, azathioprine, mycophenolate mofetil, cyclosporine) for the treatment of AD or patient has an intolerance or hypersensitivity to ALL oral systemic immunosuppressants **or**
4. ALL of the following
    a) Patient has tried and had an inadequate response to at least a mid-potency or stronger topical steroid used for a minimum of 2 weeks or patient has an intolerance to therapy with at least a mid-potency or stronger topical steroid **and**
    b) Patient has tried and had an inadequate response to a topical calcineurin inhibitor (e.g., pimecrolimus or tacrolimus) used for a minimum of 4 weeks or has an intolerance to a topical calcineurin inhibitor **and**

5. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**
6. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., allergy and immunology)

Approval Duration: 6 months

F. Chronic obstructive pulmonary disease (COPD), refractory as indicated by chart notes within past 180 days

1. Patient is 18 years of age or older **and**
2. Patient has at least a 12 month history of uncontrolled COPD while on COPD controller therapy as demonstrated by ALL of the following:
    a) At least 2 moderate (requiring treatment with either systemic corticosteroids and/or antibiotics) or 1 severe (requiring hospitalization) COPD exacerbation within the past 12 months **and**
    b) Blood eosinophil count of at least at least 300 cells/uL in the past 12 months **and**
    c) Patient has post-bronchodilator FEV1/FVC ratio <0.7 **and**
    d) Patient has post-bronchodilator FEV1 of 20% to 80% predicted **and**
    e) Patient has chronic bronchitis **and**
3. BOTH of the following:
    a) Patient is currently treated with a maximally tolerated inhaled triple therapy for COPD (inhaled corticosteroid (ICS) + long-acting beta-2 agonist (LABA) + long-acting muscarinic antagonist (LAMA)) for at least 3 consecutive months **and**
    b) Chart notes and/or prescriber do not provide documentation of discontinuation of COPD controller therapy (e.g. ICS + LABA + LAMA) in combination with the requested agent **and**
4. ONE of the following:
    a) Patient has tried for a minimum duration of 3 consecutive months and has had an inadequate response to Nucala (mepolizumab) **or**
    b) Patient has an intolerance or contraindication to Nucala **and**
5. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested

(e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**

6. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., allergy, immunology, pulmonology)

Approval Duration: 6 months

G. Urticaria, chronic spontaneous as indicated by chart notes within past 180 days

1. Patient is 12 years of age or older **and**
2. Patient has urticaria for > 6 weeks, with symptoms present > 3 days per week despite daily non-sedating H1 antihistamine therapy (i.e., cetirizine, desloratadine, fexofenadine, levocetirizine, and loratadine) with doses that have been titrated up to a maximum of four times the standard FDA-approved dose **and**
3. Patient has tried and had an inadequate response to a leukotriene receptor antagonist (i.e., montelukast) for a minimum of 4 weeks or has an intolerance, hypersensitivity, or serious neuropsychiatric risk or event preventing use of a leukotriene receptor antagonist **and**
4. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**
5. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., dermatology)

Approval Duration: 6 months

H. Bullous pemphigoid (BP) as indicated by chart notes within past 180 days

1. Patient is 18 years of age or older **and**
2. Diagnosis of bullous pemphigoid confirmed by skin biopsy or serologic study **and**
3. Chart notes and/or prescriber do not provide documentation that the patient's BP is drug-induced (i.e., not due to a reaction from medications known to cause BP, such as DPP4 inhibitors, PD-1/PD-L1 checkpoint inhibitors, loop diuretics, sulfasalazine, spironolactone, thiazides, beta-blockers, NSAIDs, and several antibiotics) **and**
4. Patient has tried and had an inadequate response after a minimum of 3 months with an oral systemic immunosuppressant (e.g., methotrexate, azathioprine, mycophenolate mofetil, cyclosporine) for the treatment of bullous pemphigoid or

patient has an intolerance to ALL oral systemic immunosuppressants **or**

5. Patient has tried and had an inadequate response to TWO of the following:
    a) High-potency topical steroid (e.g., clobetasol, betamethasone dipropionate, halobetasol) used for a minimum of 4 weeks or has an intolerance to high-potency topical steroids
    b) Oral corticosteroid (e.g., prednisone, prednisolone, dexamethasone) used for a minimum of 4 weeks or has an intolerance to oral corticosteroids
    c) Tetracycline antibiotic (e.g., doxycycline, minocycline) used for a minimum of 4 weeks or has an intolerance to tetracycline antibiotics
    d) Dapsone used for a minimum of 4 weeks or has an intolerance to dapsone **and**
6. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**
7. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., dermatology)

Approval Duration: 6 months

II. Continued Therapy Criteria

A. Atopic dermatitis (AD) as indicated by chart notes within past 12 months

1. Chart notes indicate patient has been treated with the requested agent and is a continuation of therapy (starting on samples is not approvable) **and**
2. Patient's **baseline** was ONE of the following:
    a) At least 10% body surface area involvement **or**
    b) Involvement of body sites that are difficult to treat with prolonged topical corticosteroid therapy (e.g., hands, feet, face, neck, scalp, genitals/groin, skin folds) **or**
    c) Eczema Area and Severity Index (EASI) score of greater than or equal to 16 **or**
    d) Investigator Global Assessment (IGA) score of greater than or equal to 3 **and**
3. Documented clinical benefit since starting the requested agent (i.e., reduction or stabilization from baseline) of at least ONE of the following:
    a) Affected body surface area **or**
    b) Flares **or**

c) Pruritis, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification **or**
d) Decrease in the Eczema Area and Severity Index (EASI) score **or**
e) Decrease in the Investigator Global Assessment (IGA) score **and**

4. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required])

Approval Duration: 12 months

B. Moderate-to-severe asthma as indicated by chart notes within past 12 months

1. Chart notes indicate patient has been treated with the requested agent and is a continuation of therapy (starting on samples is not approvable) **and**
2. Patient meets BOTH of the below at **baseline**:
   a) ONE of the following:
      (1) Patient has eosinophilic type asthma AND ONE of the following:
         (a) Blood eosinophilic count of 150 cells/microliter or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **or**
         (b) FeNO of 20 parts per billion or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **or**
         (c) Sputum eosinophils 2% or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **or**
      (2) Patient has oral corticosteroid dependent type asthma **and**
   b) Patient has a history of uncontrolled asthma while on asthma controller therapy as demonstrated by ONE 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**
      (3) Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered **or**
      (4) Patient has baseline (prior to therapy with the requested agent) FEV1 that is less than 80% of predicted **and**
3. Documented clinical benefit since starting the requested agent (i.e.,

improvements or stabilization from baseline) as indicated by at least ONE of the following:

a) Increase in percent predicted Forced Expiratory Volume (FEV1) **or**
b) Decrease in the dose of inhaled corticosteroids required to control the patient's asthma **or**
c) Decrease in need for treatment with systemic corticosteroids due to exacerbations of asthma **or**
d) Decrease in number of hospitalizations, need for mechanical ventilation, or visits to urgent care or emergency room due to exacerbations of asthma **and**

4. Patient continues to be treated with and has greater than or equal to 80% adherence to with asthma controller therapy [e.g., inhaled corticosteroids, ICS/long-acting beta-2 agonist (LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA)] **and**
5. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required])

Approval Duration: 12 months

C. Chronic rhinosinusitis with nasal polyposis (CRSwNP) as indicated by chart notes within past 12 months

1. Patient meets the initial therapy criteria above **and**
2. Documented clinical benefit since starting the requested agent (i.e., reduction in serum free IgE) **and**
3. Patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with the requested agent **and**
4. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required])

Approval Duration: 12 months

D. Eosinophilic esophagitis (EoE) as indicated by chart notes within past 12 months

1. Patient meets the initial therapy criteria above **and**
2. Documented clinical benefit since starting the requested agent (i.e., histologic response threshold of <15 eosinophils per high power field) **and**
3. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required])

Approval Duration: 12 months

E. Prurigo nodularis (PN) as indicated by chart notes within past 12 months

1. Patient meets the initial therapy criteria above **and**
2. Documented clinical benefit since starting the requested agent (i.e., reduction in lesions, less pruritus, less scratching, picking, or rubbing) **and**
3. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required])

Approval Duration: 12 months

F. Chronic obstructive pulmonary disease (COPD), refractory as indicated by chart notes within past 12 months

1. Patient meets the initial therapy criteria above **and**
2. Documented clinical benefit since starting the requested agent (i.e., reduction of moderate or severe COPD exacerbations) **and**
3. Patient continues to be treated with and has greater than or equal to 80% adherence to maximally tolerated inhaled triple therapy for COPD (inhaled corticosteroid (ICS) + long-acting beta-2 agonist (LABA) + long-acting muscarinic antagonist (LAMA)) (provider attestation) **and**
4. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required])

Approval Duration: 12 months

G. **Urticaria, chronic spontaneous** as indicated by chart notes within past 12 months
    1. Patient meets the initial therapy criteria above **and**
    2. Documented clinical benefit since starting the requested agent (i.e., reduction in swelling, less raised patches) **and**
    3. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required])

    Approval Duration: 12 months

H. **Bullous pemphigoid** as indicated by chart notes within past 12 months
    1. Patient meets the initial therapy criteria above **and**
    2. Documented clinical benefit since starting the requested agent (i.e., reduction in exacerbations, reduction in blisters, decreased pruritus, increased lesion healing) **and**
    3. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required])

    Approval Duration: 12 months

Policy Owned by: Curative PBM team