**STANDARD COMMERCIAL DRUG FORMULARY**
**PRIOR AUTHORIZATION GUIDELINES**

**DUPILUMAB**

| Generic | Brand | HICL | GCN | Medi-Span | Exception/Other |
|---|---|---|---|---|---|
| DUPILUMAB | DUPIXENT | 44180 | | GPI-10 (9027302000) | |

## GUIDELINES FOR USE

## INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis and meet **ALL** of the following criteria?
   - The patient is 6 months of age or older
   - Therapy is prescribed by or in consultation with a dermatologist, allergist, or immunologist
   - The patient has TWO of the following: intractable pruritus, cracking and oozing/bleeding of affected skin, impaired activities of daily living
   - Dupixent will NOT be used concurrently with other systemic biologics (e.g., Adbry [tralokinumab-ldrm]) or any JAK inhibitors (e.g., Rinvoq [upadacitinib], topical Opzelura [ruxolitinib], Cibinqo [abrocitinib]) for the treatment of atopic dermatitis

   If yes, continue to #2.
   If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   - The patient was previously stable on another biologic (e.g., Adbry [tralokinumab-ldrm]) and switching to the requested drug
   - The patient has atopic dermatitis involving at least 10% of body surface area (BSA)
   - The patient's atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas

   If yes, continue to #3.
   If no, do not approve.
   **DENIAL TEXT:** See the initial denial text at the end of the guideline.

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## DUPILUMAB

**INITIAL CRITERIA (CONTINUED)**

3. Does the patient have a trial of or contraindication to **ONE** of the following?
   - Topical corticosteroid (e.g., hydrocortisone, clobetasol, halobetasol propionate)
   - Topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]
   - Topical PDE-4 inhibitor [e.g., Eucrisa (crisaborole)]
   - Topical JAK inhibitor [e.g., Opzelura (ruxolitinib)]
   - Phototherapy

   If yes, **enter TWO approvals by GPID or GPI-14 for the requested strength for a total of 6 months as follows:**
   - **FIRST APPROVAL: Approve with an end date of 1 month as follows:**
     - **200mg/1.14mL: #4.56mL.**
     - **300mg/2mL: #8mL.**
   - **SECOND APPROVAL: Approve for 5 months as follows (enter a start date of 1 week after the end of the first approval):**
     - **200mg/1.14mL: #2.28mL per 28 days.**
     - **300mg/2mL: #4mL per 28 days.**

   If no, do not approve.
   **DENIAL TEXT:** See the initial denial text at the end of the guideline.

4. Does the patient have a diagnosis of moderate to severe asthma with an eosinophilic phenotype **AND** meet the following criterion?
   - The patient has a documented blood eosinophil level of 150 to 1500 cells/mcL within the past 12 months

   If yes, continue to #6.
   If no, continue to #5.

5. Does the patient have a diagnosis of moderate to severe oral corticosteroid-dependent asthma?

   If yes, continue to #6.
   If no, continue to #9.

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**INITIAL CRITERIA (CONTINUED)**

6. Does the patient meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a physician specializing in pulmonary or allergy medicine
   - The patient is on concurrent treatment with medium, high-dose, or maximally tolerated inhaled corticosteroid (ICS) [e.g., triamcinolone acetonide, beclomethasone, mometasone, budesonide, etc.] AND at least one other maintenance medication (e.g., long-acting inhaled beta2-agonist [e.g., salmeterol, formoterol, etc.], long-acting muscarinic antagonist [e.g., aclidinium bromide, ipratropium, tiotropium, umeclidinium, etc.], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast, zileuton, etc.], theophylline)
   - Dupixent will NOT be used concurrently with Xolair (omalizumab) or an anti-IL5 biologic (e.g., Nucala [mepolizumab], Cinqair [reslizumab], Fasenra [benralizumab]) when these are used for the treatment of asthma

   If yes, continue to #7.
   If no, do not approve.
   **DENIAL TEXT:** See the initial denial text at the end of the guideline.

7. Does the patient meet **ONE** of the following criteria?
   - The patient experienced at least ONE asthma exacerbation requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months OR at least ONE serious exacerbation requiring hospitalization or emergency room visit within the past 12 months
   - The patient has poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks:
     - Daytime asthma symptoms more than twice per week
     - Any night waking due to asthma
     - Short-acting inhaled beta2-agonist (SABA; e.g., albuterol) reliever for symptoms more than twice per week
     - Any activity limitation due to asthma

   If yes, continue to #8.
   If no, do not approve.
   **DENIAL TEXT:** See the initial denial text at the end of the guideline.

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**INITIAL CRITERIA (CONTINUED)**

8. Is the request for the 100 mg/0.67mL strength?

   If yes**, approve 100 mg/0.67mL by GPID or GPI-14 for 4 months with a quantity limit of #1.34mL per 28 days.**

   If no, **enter TWO approvals by GPID or GPI-14 for the requested strength for a total of 4 months as follows:**
   - **FIRST APPROVAL: Approve with an end date of 1 month as follows:**
     - **200mg/1.14mL: #4.56mL.**
     - **300mg/2mL: #8mL.**
   - **SECOND APPROVAL: Approve for 3 months as follows (enter a start date of 1 week after the end of the first approval):**
     - **200mg/1.14mL: #2.28mL per 28 days.**
     - **300mg/2mL: #4mL per 28 days.**

9. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an otolaryngologist, allergist, or immunologist
   - There is documentation of evidence of nasal polyps by direct examination, endoscopy, or sinus CT scan
   - The patient has inadequately controlled disease as determined by ONE of the following:
     - Use of systemic steroids in the past 2 years
     - Endoscopic sinus surgery
   - Dupixent will be used as add-on maintenance treatment (i.e., in conjunction with maintenance intranasal steroids)
   - The patient had a previous 90-day trial of ONE intranasal corticosteroid

   If yes, **approve 300mg/2mL for 6 months by GPID or GPI-14 with a quantity limit of #4mL per 28 days.**

   If no, continue to #10.

10. Does the patient have a diagnosis of eosinophilic esophagitis (EoE) and meet **ONE** of the following criteria?
    - The patient is 18 years of age or older
    - The patient is 12 to 17 years of age AND weighs at least 40kg

    If yes, continue to #11.
    If no, continue to #12.

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## DUPILUMAB

**INITIAL CRITERIA (CONTINUED)**

11. Does the patient meet **ALL** of the following criteria?
    - Therapy is prescribed by or in consultation with a gastroenterologist, allergist, or immunologist
    - The patient's diagnosis is confirmed by an esophagogastroduodenoscopy (EGD) with biopsy
    - The patient had a trial of or contraindication to dietary therapy
    - The patient had a trial of or contraindication to a proton pump inhibitor (e.g., omeprazole, lansoprazole, pantoprazole)

    If yes, **approve 300mg/2mL for 6 months by GPID or GPI-14 with a quantity limit of #8mL per 28 days.**

    If no, do not approve.
    **DENIAL TEXT:** See the initial denial text at the end of the guideline.

12. Does the patient have a diagnosis of prurigo nodularis (PN) and meet **ALL** of the following criteria?
    - The patient is 18 years of age or older
    - Therapy is prescribed by or in consultation with a dermatologist, immunologist or allergist
    - The patient has chronic pruritis (i.e., itch lasting longer than 6 weeks), presence of multiple pruriginous lesions (localized or general), and a history or sign of a prolonged scratching behavior
    - The patient had a trial of or contraindication to ONE of the following: topical capsaicin, topical ketamine/amitriptyline/lidocaine, gabapentinoids (e.g., gabapentin, pregabalin), antidepressants (SNRI, SSRI, TCA), k-/mu-opioid receptor antagonists (e.g., naltrexone, butorphanol), thalidomide, topical corticosteroids, topical calcineurin inhibitors, topical calcipotriol, intralesional corticosteroids, phototherapy, methotrexate, cyclosporine, azathioprine

    If yes, **enter TWO approvals by GPID or GPI-14 for the requested strength for a total of 6 months as follows:**
    - **FIRST APPROVAL: Approve with an end date of 1 month as follows:**
      - **300mg/2mL: #8mL**
    - **SECOND APPROVAL: Approve for 5 months as follows (enter a start date of 1 week after the end of the first approval):**
      - **300mg/2mL: #4mL per 28 days.**

    If no, do not approve.
    **DENIAL TEXT:** See the initial denial text at the end of the guideline.

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## DUPILUMAB

### INITIAL CRITERIA (CONTINUED)

**INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **DUPILUMAB (Dupixent)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe atopic dermatitis (a type of skin condition)
   2. Moderate to severe asthma
   3. Chronic rhinosinusitis with nasal polyposis (a type of long-term nasal condition)
   4. Eosinophilic esophagitis (a type of immune system disorder)
   5. Prurigo nodularis (a type of skin condition)

B. **If you have moderate to severe atopic dermatitis, approval also requires:**
   1. You are 6 months of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (a type of skin doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
   3. You have TWO of the following: intractable pruritus (severe itching), cracking and oozing/bleeding of affected skin, impaired activities of daily living
   4. You had a trial of or contraindication (harmful for) to ONE of the following: topical corticosteroid (such as hydrocortisone, clobetasol, halobetasol propionate), topical calcineurin inhibitor [Elidel (pimecrolimus), Protopic (tacrolimus)], topical PDE-4 inhibitor [Eucrisa (crisaborole)], topical JAK inhibitor [Opzelura (ruxolitinib)], phototherapy (light therapy)
   5. You will NOT use Dupixent concurrently (at the same time) with other systemic biologics (such as Adbry [tralokinumab-ldrm]) or any JAK inhibitors (such as Rinvoq [upadacitinib], topical Opzelura [ruxolitinib], Cibinqo [abrocitinib]) for the treatment of atopic dermatitis
   6. You meet ONE of the following:
      a. You were previously stable on another biologic (such as Adbry [tralokinumab-ldrm]) and switching to the requested drug
      b. You have atopic dermatitis involving at least 10 percent of body surface area (BSA)
      c. Your atopic dermatitis is affecting the face, head, neck, hands, feet, groin, or intertriginous areas (between skin folds)

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## DUPILUMAB

**INITIAL CRITERIA (CONTINUED)**

C. **If you have moderate to severe asthma, approval also requires:**
1. You are 6 years of age or older
2. Therapy is prescribed by or in consultation with a doctor specializing in pulmonary (lung/breathing) or allergy medicine
3. You have an eosinophilic phenotype asthma (type of adult inflammatory asthma) with a documented blood eosinophil level of 150 to 1500 cells/mcL within the past 12 months OR you have oral corticosteroid-dependent asthma
4. You are being treated at the same time with medium, high-dose, or maximally tolerated inhaled corticosteroid [such as triamcinolone acetonide, beclomethasone, mometasone, budesonide] AND at least one other maintenance medication such as long-acting inhaled beta2-agonist (such as salmeterol, formoterol), long-acting muscarinic antagonist (such as aclidinium bromide, ipratropium, umeclidinium, tiotropium), a leukotriene receptor antagonist (such as montelukast, zafirlukast, zileuton), or theophylline
5. You will NOT use Dupixent concurrently (at the same time) with Xolair (omalizumab) or an anti-IL5 biologic (such as Nucala [mepolizumab], Cinqair [reslizumab], Fasenra [benralizumab]) when these are used for the treatment of asthma
6. You meet ONE of the following:
   a. You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months OR at least ONE serious exacerbation requiring hospitalization or emergency room (ER) visit within the past 12 months
   b. You have poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks:
      i. Daytime asthma symptoms more than twice per week
      ii. Any night waking due to asthma
      iii. Use of short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
      iv. Any activity limitation due to asthma

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**INITIAL CRITERIA (CONTINUED)**

D. **If you have chronic rhinosinusitis with nasal polyposis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an otolaryngologist (ear, nose, throat doctor), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
   3. There is documentation of evidence of nasal polyps (non-cancerous growths) by direct examination, endoscopy (using a small camera) or sinus CT scan
   4. You have inadequately controlled disease as determined by ONE of the following:
      a. Use of systemic steroids in the past 2 years
      b. Endoscopic sinus surgery (using a small camera to help in surgery)
   5. Dupixent will be used as add-on maintenance treatment (in conjunction with maintenance intranasal steroids)
   6. You had a previous 90-day trial of ONE intranasal corticosteroid

E. **If you have eosinophilic esophagitis, approval also requires:**
   1. You meet ONE of the following:
      a. You are 18 years of age or older
      b. You are 12 to 17 years of age AND weigh at least 40 kilograms
   2. Therapy is prescribed by or in consultation with a gastroenterologist (doctor who treats digestive conditions), allergist (a type of allergy doctor), or immunologist (a type of immune system doctor)
   3. Your diagnosis is confirmed by an esophagogastroduodenoscopy (EGD) with biopsy (a test that looks at the lining of your food pipe, stomach, and small intestine)
   4. You had a trial of or contraindication (harmful for) to dietary therapy
   5. You had a trial of or contraindication (harmful for) to a proton pump inhibitor (such as omeprazole, lansoprazole, pantoprazole)

F. **If you have prurigo nodularis, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with a dermatologist (skin doctor), immunologist (type of immune system doctor), or allergist
   3. You have chronic pruritis (itch lasting longer than 6 weeks), presence of multiple pruriginous lesions (wounds), and a history or sign of a prolonged scratching behavior
   4. You had a trial of or contraindication (harmful for) to ONE of the following: topical capsaicin, topical ketamine/amitriptyline/lidocaine, gabapentinoids (e.g., gabapentin, pregabalin), antidepressants (serotonin-norepinephrine reuptake inhibitor [SNRI], selective serotonin reuptake inhibitor [SSRI], tricyclic antidepressant [TCA]), k-/mu-opioid receptor antagonists (e.g., naltrexone, butorphanol), thalidomide, topical corticosteroids, topical calcineurin inhibitors, topical calcipotriol, intralesional corticosteroids, phototherapy, methotrexate, cyclosporine, azathioprine

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## DUPILUMAB

### INITIAL CRITERIA (CONTINUED)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

### RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis and meet **ALL** of the following criteria?
   - The patient has shown improvement while on therapy
   - Dupixent will NOT be used concurrently with other systemic biologics (e.g., Adbry [tralokinumab-ldrm]) or any JAK inhibitors (e.g., Rinvoq [upadacitinib], topical Opzelura [ruxolitinib], Cibinqo [abrocitinib]) for the treatment of atopic dermatitis

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **200mg/1.14mL: #2.28mL per 28 days.**
   - **300mg/2mL: #4mL per 28 days.**

   If no, continue to #2.

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## DUPILUMAB

**RENEWAL CRITERIA (CONTINUED)**

2. Does the patient have a diagnosis of moderate to severe asthma and meet **ALL** of the following criteria?
   - The patient continues to use an inhaled corticosteroid (ICS) AND at least one other maintenance medication (e.g., long-acting inhaled beta2-agonist [such as salmeterol, formoterol, etc.], long-acting muscarinic antagonist [such as aclidinium bromide, ipratropium, tiotropium, umeclidinium, etc.], a leukotriene receptor antagonist [such as montelukast, zafirlukast, zileuton, etc.], theophylline)
   - The patient has shown a clinical response as evidenced by ONE of the following:
     - Reduction in asthma exacerbation from baseline
     - Decreased utilization of rescue medications
     - Increase in percent predicted FEV1 from pretreatment baseline
     - Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)
   - Dupixent will NOT be used concurrently with Xolair (omalizumab) or an anti-IL5 biologic (e.g., Nucala [mepolizumab], Cinqair [reslizumab], Fasenra [benralizumab]) when these are used for the treatment of asthma

   If yes, **approve for 12 months by GPID or GPI-14 for the requested strength as follows:**
   - **100mg/0.67mL: #1.34mL per 28 days.**
   - **200mg/1.14mL: #2.28mL per 28 days.**
   - **300mg/2mL: #4mL per 28 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) **AND** meet the following criterion?
   - The patient has shown clinical benefit compared to baseline (e.g., improvements in nasal congestion, sense of smell or size of polyps)

   If yes, **approve 300mg/2mL for 12 months by GPID or GPI-14 with a quantity limit of #4mL per 28 days.**

   If no, continue to #4.

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## DUPILUMAB

### RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of eosinophilic esophagitis (EoE) **AND** meet the following criterion?
   - The patient has shown improvement while on therapy (e.g., symptom improvement or achieving histological remission defined as peak esophageal intraepithelial eosinophil count of less than or equal to 6 eos/hpf)

   If yes, **approve 300mg/2mL for 12 months by GPID or GPI-14 with a quantity limit of #8mL per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of prurigo nodularis **AND** meet the following criterion?
   - The patient has had prurigo nodularis improvement (reduction) of pruritis or pruriginous lesions

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #4mL per 28 days.**
   If no, do not approve.
   **RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

   Our guideline named **DUPILUMAB (Dupixent)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Moderate to severe atopic dermatitis (a type of skin condition)
      2. Moderate to severe asthma
      3. Chronic rhinosinusitis with nasal polyposis (inflammation of nasal and sinus ways with small growths in the nose)
      4. Eosinophilic esophagitis (a type of immune system disorder)
      5. Prurigo nodularis (a type of skin condition)
   B. **If you have moderate to severe atopic dermatitis, renewal also requires:**
      1. You have shown improvement while on therapy
      2. You will NOT use Dupixent concurrently (at the same time) with other systemic biologics (such as Adbry [tralokinumab-ldrm]) or any JAK inhibitors (such as Rinvoq [upadacitinib], topical Opzelura [ruxolitinib], Cibinqo [abrocitinib]) for the treatment of atopic dermatitis

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## DUPILUMAB

### RENEWAL CRITERIA (CONTINUED)

C. **If you have moderate to severe asthma, renewal also requires:**
   1. You will continue to use an inhaled corticosteroid (ICS) AND at least one other maintenance medication (e.g., long-acting inhaled beta2-agonist [such as salmeterol, formoterol, etc.], long-acting muscarinic antagonist [such as aclidinium bromide, ipratropium, tiotropium, umeclidinium, etc.], a leukotriene receptor antagonist [such as montelukast, zafirlukast, zileuton, etc.], theophylline)
   2. You have shown a clinical response as evidenced by ONE of the following:
      a. Reduction in asthma exacerbation (worsening of symptoms) from baseline
      b. Decreased use of rescue medications
      c. Increase in percent predicted FEV1 (amount of air you can forcefully exhale) from pretreatment baseline
      d. Reduction in severity or frequency of asthma-related symptoms such as less wheezing, shortness of breath, coughing, etc.
   3. You will NOT use Dupixent concurrently (at the same time) with Xolair (omalizumab) or an anti-IL5 biologic (such as Nucala [mepolizumab], Cinqair [reslizumab], Fasenra [benralizumab]) when these are used for the treatment of asthma

D. **If you have chronic rhinosinusitis with nasal polyposis, renewal also requires:**
   1. You have shown a clinical benefit compared to baseline (such as improvements in nasal congestion, sense of smell or size of polyps)

E. **If you have eosinophilic esophagitis, renewal also requires**:
   1. You have shown improvement while on therapy (such as symptom improvement or achieving histological remission defined as peak esophageal intraepithelial eosinophil count of less than or equal to 6 eos/hpf [a type of test that evaluates disease status])

F. **If you have prurigo nodularis, renewal also requires:**
   1. You have had prurigo nodularis improvement or reduction of pruritis (itching) or pruriginous lesions (wounds)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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## DUPILUMAB

### RATIONALE

For further information, refer to the Prescribing Information and/or Drug Monograph for Dupixent.

### REFERENCES


- Dupixent [Prescribing Information]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; September 2022.


| Library | Commercial | NSA |
|---|---|---|
| Yes | Yes | No |

Part D Effective: N/A
Commercial Effective: 07/01/23

Created: 01/17
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P&T Approval: 04/23