DUPILUMAB

Generic	Brand	HICL	GCN	Exception/Other
DUPILUMAB	DUPIXENT	44180		

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 meets at least **ONE** of the following for disease severity:
     - Atopic dermatitis involving at least 10% of body surface area (BSA) **OR**
     - Atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas
   - The patient has at least **TWO** of the following:
     - Intractable pruritus
     - Cracking and oozing/bleeding of affected skin
     - Impaired activities of daily living
   - Therapy is prescribed by or given in consultation with a dermatologist or allergist/immunologist
   - The patient had inadequate response or contraindication to **ONE** of the following: topical corticosteroids, topical calcineurin inhibitors [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)], topical PDE-4 inhibitors [e.g., Eucrisa (crisaborole)], or phototherapy

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

2. Is the patient between 12 and 17 years of age?

   If yes, **please enter TWO approvals by GPID with a quantity limit based on the patient's weight as follows:**
   - **FIRST APPROVAL:**
     - **If weight is less than 60kg: Approve 1 fill for a quantity of #4.56mL (#4 200mg/1.14mL syringes, GPID 45522) with an end date of 1 month.**
     - **If weight is 60kg or more: Approve 1 fill for a quantity of #8mL (#4 300mg/2mL syringes, GPID 43222) with an end date of 1 month.**
   - **SECOND APPROVAL:**
     - **If weight is less than 60kg: Approve for 5 months with a quantity limit of #2.28mL (#2 200mg/1.14mL syringes, GPID 45522) per 28 days (enter a start date one day after the end of the first approval).**
     - **If weight is 60kg or more: Approve for 5 months with a quantity limit of #4mL (#2 300mg/2mL syringes, GPID 43222) per 28 days (enter a start date one day after the end of the first approval).**

   APPROVAL TEXT: See initial approval text on the next page.

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

APPROVAL TEXT: Renewal requires that the patient has experienced or maintained improvement in at least two of the following: intractable pruritus,cracking and oozing/bleeding of affected skin, impaired activities of daily living.

If no, continue to #3.

3. Is the patient 18 years of age or older?

   If yes, **please enter TWO approvals by GPID as follows:**
   - **FIRST APPROVAL: Approve 1 fill for a quantity of #8mL (#4 300mg/2mL syringes, GPID 43222) with an end date of 1 month.**
   - **SECOND APPROVAL: Approve for 5 months with a quantity limit of #4mL (#2 300mg/2mL syringes, GPID 43222) per 28 days (enter a start date one day after the end of the first approval).**

   APPROVAL TEXT: Renewal requires that the patient has experienced or maintained improvement in at least two of the following: intractable pruritus, cracking and oozing/bleeding of affected skin, impaired activities of daily living.

   If no, do not approve.
   DENIALTEXT: 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 at least 150 cells/mcL within the past 6 weeks

   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 #7.

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

6. Does the patient meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient had a prior therapy with a medium, high-dose, or maximally tolerated inhaled corticosteroid (ICS) AND at least one other maintenance medication (e.g., long-acting inhaled beta2-agonist, long-acting muscarinic antagonist, a leukotriene receptor antagonist, theophylline)
   - The patient has experienced at least **ONE** asthma exacerbation within the past 12 months (exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days)
   - Dupixent will be used as an add-on maintenance treatment
   - The patient is not being concurrently treated with Xolair or an anti-IL5 asthma biologic (e.g., Nucala, Cinqair, Fasenra)
   - Dupixent is prescribed by or given in consultation with a physician specializing in pulmonary or allergy medicine

   If yes, **please enter TWO approvals by GPID for the requested medication as follows:**
   - **FIRST APPROVAL: approve 1 fill for a quantity of #8mL (#4 300mg/2mL syringes, GPID 43222) OR #4.56mL (#4 200mg/1.14mL syringes, GPID 45522) with an end date of 1 month.**
   - **SECOND APPROVAL: approve for 11 months with a quantity limit of #4mL (#2 300mg/2mL syringes, GPID 43222) OR #2.28mL (#2 200mg/1.14mL syringes, GPID 45522) per 28 days (enter a start date one day after the end of the first approval).**

   APPROVAL TEXT: Renewal requires ALL of the following: i) the patient will continue to use inhaled corticosteroid (ICS) or ICS-containing combination inhalers, ii) the patient has shown a clinical response as evidenced by one of the following: a) reduction in asthma exacerbation from baseline, b) decreased utilization of rescue medications, c) increase in percent predicted FEV1 from pretreatment baseline, or d) reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.).

   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)

7. 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
   - 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)
   - Dupixent is prescribed by or given in consultation with an otolaryngologist or allergist/immunologist

   If yes, **approve for 6 months by GPID (43222) with a quantity limit of #4mL (#2 300mg/2mL syringes) per 28 days.**
   APPROVAL TEXT: Renewal requires physician attestation of clinical benefit compared to baseline (e.g., improvements in nasal congestion, sense of smell or size of polyps).

   If no, do not approve.
   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 a diagnosis of moderate to severe atopic dermatitis (condition of red, itchy skin), moderate to severe asthma OR chronic rhinosinusitis with nasal polyposis (inflammation of nasal and sinus ways with small growths in the nose)
   B. **If you have moderate to severe atopic dermatitis, approval also requires:**
      1. You meet at least one of the following for disease severity:
         a. Atopic dermatitis involving at least 10% of body surface area (BSA)
         b. Atopic dermatitis affecting the face, head, neck, hands, feet, groin, or intertriginous areas (between skin folds, the hands, feet, etc)
      2. You have at least two (2) of the following:
         a. Intractable pruritus (severe itching)
         b. Cracking and oozing/bleeding of affected skin
         c. Impaired activities of daily living

   (Initial denial text continued on next page)

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DUPILUMAB

INITIAL CRITERIA (CONTINUED)

3. Therapy is prescribed by or recommended by a dermatologist (skin doctor) or allergist/immunologist (allergy doctor)
4. You are 12 years of age or older
5. You had an inadequate response or contraindication to (a medical reason why you cannot use) ONE of the following: topical corticosteroids, topical calcineurin inhibitors [Elidel (pimecrolimus), Protopic (tacrolimus)], topical PDE-4 inhibitors [Eucrisa (crisaborole)], or phototherapy (light therapy)

C. **If you have moderate to severe asthma, approval also requires:**
1. You have an eosinophilic phenotype asthma (type of adult inflammatory asthma) with a documented blood eosinophil level of at least 150 cells/mcL within the past 6 weeks **OR** oral corticosteroid-dependent asthma
2. You are 12 years of age or older
3. You had prior therapy with medium, high-dose, or maximally tolerated inhaled corticosteroid AND at least one other maintenance medication such as long-acting inhaled beta2-agonist (salmeterol, formoterol), long-acting muscarinic antagonist (tiotropium), a leukotriene receptor antagonist (montelukast), theophylline
4. You have experienced at least ONE asthma exacerbations within the past 12 months (exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days)
5. Dupixent will be used as an add-on maintenance treatment
6. You are not being concurrently treated with Xolair or an anti-IL5 asthma biologic such as Nucala, Cinqair, Fasenra
7. Dupixent is prescribed by or given in consultation with a physician specializing in pulmonary (lung/breathing) or allergy medicine

D. **If you have chronic rhinosinusitis with nasal polyposis, approval also requires:**
1. You are 18 years of age or older
2. Documentation of evidence of nasal polyps (non-cancerous growths) by direct examination, endoscopy (using a small camera) or sinus CT scan
3. 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)
4. Dupixent will be used as add-on maintenance treatment (in conjunction with maintenance intranasal steroids)
5. Dupixent is prescribed by or given in consultation with an otolaryngologist (ear nose throat doctor) or allergist/immunologist

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

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe atopic dermatitis **AND** meet the following criterion?
   - The patient has experienced or maintained improvement in at least two of the following: intractable pruritus, cracking and oozing/bleeding of affected skin, impaired activities of daily living

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

2. Is the patient between 12 and 17 years of age?

   If yes, **approve for 12 months by GPID with a quantity limit based on the patient's weight, as follows:**
   - **If weight is less than 60kg: Approve with a quantity limit of #2.28mL (#2 200mg/1.14mL syringes, GPID 45522) per 28 days.**
   - **If weight is 60kg or more: Approve with a quantity limit of #4mL (#2 300mg/2mL syringes, GPID 43222) per 28 days.**

   If no, continue to #3.

3. Is the patient 18 years of age or older?

   If yes, **approve for 12 months by GPID (43222) with a quantity limit of #4mL (#2 300mg/2mL syringes) per 28 days.**
   If no, do not approve.
   DENIALTEXT: See the renewal denial text at the end of the guideline.

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DUPILUMAB

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of moderate to severe asthma and meet **ALL** of the following criteria?
   - The patient will continue to use inhaled corticosteroid (ICS) or ICS-containing combination inhalers
   - 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.)

   If yes, **approve for 12 months by GPID for the requested medication with a quantity limit of #4mL (#2 300mg/2mL syringes, GPID 43222) OR #2.28mL (#2 200mg/1.14mL syringes, GPID 45522) per 28 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) and meet the following criterion?
   - Physician attestation of clinical benefit compared to baseline (e.g., improvements in nasal congestion, sense of smell or size of polyps)

   If yes, **approve for 12 months by GPID (43222) with a quantity limit of #4mL (#2 300mg/2mL syringes) per 28 days.**
   If no, do not approve.
   DENIALTEXT: See the renewal denial text at the end of the guideline.

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DUPILUMAB

RENEWAL CRITERIA (CONTINUED)

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 approval:

A. You have a diagnosis of moderate to severe atopic dermatitis (condition of red, itchy skin), moderate to severe asthma OR chronic rhinosinusitis with nasal polyposis (inflammation of nasal and sinus ways with small growths in the nose)
B. **If you have moderate to severe atopic dermatitis, approval also requires:**
    1. You have experienced or maintained improvement in at least two of the following:
        a. Intractable pruritus (severe itching)
        b. Cracking and oozing/bleeding of affected skin
        c. Impaired activities of daily living
    2. You are 12 years of age or older
C. **If you have moderate to severe asthma, approval also requires:**
    1. You will continue to use inhaled corticosteroid (ICS) or ICS-containing combination inhalers
    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 utilization 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.
D. **If you have chronic rhinosinusitis with nasal polyposis, approval also requires:**
    1. Physician attestation of clinical benefit compared to baseline (such as improvements in nasal congestion, sense of smell or size of polyps)

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. June 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/01/20
Created: 01/17
Client Approval: 01/20
P&T Approval: 10/19