HARVARD PILGRIM HEALTH CARE
RECOMMENDED MEDICATION REQUEST GUIDELINES

DUPILUMAB (DUPIXENT)

Generic	Brand	HICL	GCN	Exception/Other
DUPILUMAB	DUPIXENT	44180		

If the caller wishes to initiate a request then a MRF must be completed. This drug requires a written request for prior authorization. All requests for high-impact medications require review by a pharmacist prior to final approval.

GUIDELINES FOR USE

INITIAL CRITERIA (FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a patient with the diagnosis of moderate to severe atopic dermatitis and does the request meet **ALL** of the following criteria?
   - Patient is 12 years of age or older
   - Prescribed by, or in consultation with, a specialist (e.g., dermatologist, allergist or immunologist)
   - Patient's condition meets **at least one** of the following conditions:
     - Body Surface Area (BSA) of at least 10%
     - Eczema Area and Severity Index (EASI) score of at least 16
     - Investigator's Global Assessment/Physician Global Assessment (IGA/PGA) score of at least 3
   - Previous trial with **at least two** of the following therapies:
     - Phototherapy
     - Medium-to-high potency topical corticosteroids
     - Tacrolimus (Protopic) 0.1% ointment
     - Crisaborole (Eucrisa)
     - Oral systemic therapies (e.g. cyclosporine, azathioprine, methotrexate)

     If yes, continue to #3.
     If no, continue to #2.

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DUPILUMAB (DUPIXENT)

INITIAL CRITERIA (CONTINUED)

2. Is the request for a patient with the diagnosis of moderate to severe asthma and does the request meet **ALL** of the following criteria?
   - Diagnosis of eosinophilic phenotype or with corticosteroid dependent asthma as determined by one of the following:
     - An eosinophilic phenotype, i.e. documented blood eosinophil level of at least 150 cells/mcL within the past 6 months
     - Oral corticosteroid-dependent asthma, i.e. chronic corticosteroid use for at least 6 months
     - Current treatment with an alternative biologic indicated for moderate to severe allergic or eosinophilic asthma, i.e., Cinqair, Fasenra, Nucala, Xolair
   - Patient is 12 years of age or older
   - Prescribed by, or in consultation with, a specialist (e.g., pulmonologist, allergist or immunologist)
   - Patient is currently maintained on a maximally tolerated inhaled corticosteroid plus at least one other maintenance medication (e.g., long-acting inhaled beta2-agonist, long-acting muscarinic antagonist, a leukotriene receptor antagonist)
   - Patient will not be concurrently treated with an alternative biologic for asthma (e.g., Nucala, Cinqair, Fasenra, Xolair)

   If yes, continue to #3.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT (diagnosis of atopic dermatitis): Per your health plan's DUPILUMAB (DUPIXENT) guideline, this medication is only covered for members with the diagnosis of moderate to severe atopic dermatitis who meet all of the following conditions:
   - 12 years of age or older
   - Prescribed by, or in consultation with, a specialist (e.g., dermatologist, allergist or immunologist)
   - Skin condition meets **at least one** of the following conditions:
     - Body Surface Area (BSA) of at least 10%
     - Eczema Area and Severity Index (EASI) score of at least 16
     - Investigator's Global Assessment /Physician Global Assessment (IGA/PGA) score of at least 3
   - Previous trial with **at least two** of the following therapies:
     - Phototherapy
     - Medium-to-high potency topical corticosteroids
     - Tacrolimus (Protopic) 0.1% ointment
     - Crisaborole (Eucrisa)
     - Oral systemic therapies (e.g. cyclosporine, azathioprine, methotrexate

   Your provider did not indicate that you **[are at least 12 years of age / have seen a specialist / affected body surface area is at least 10 % / previously tried at least two alternative therapies]** and therefore your request was not approved.
   (Initial denial text continued on next page)

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DUPILUMAB (DUPIXENT)

INITIAL CRITERIA (CONTINUED)

DENIAL TEXT (diagnosis of asthma): Per your health plan's DUPILUMAB (DUPIXENT) guideline, this medication is only covered for members with the diagnosis of moderate to severe asthma who meet all of the following conditions:

- Diagnosis of eosinophilic phenotype or with corticosteroid dependent asthma determine by one of the following conditions:
  - An eosinophilic phenotype, i.e. documented blood eosinophil level of at least 150 cells/mcL within the past 6 months
  - Oral corticosteroid-dependent asthma, i.e. chronic corticosteroid use for at least 6 months
  - Current treatment with an alternative biologic indicated for moderate to severe allergic or eosinophilic asthma, i.e., Cinqair, Fasenra, Nucala, Xolair
- 12 years of age or older
- Prescribed by, or in consultation with, a specialist (e.g., pulmonologist, allergist or immunologist)
- Currently maintained on a maximally tolerated inhaled corticosteroid plus at least one other maintenance medication (e.g., long-acting inhaled beta2-agonist, long-acting muscarinic antagonist, a leukotriene receptor antagonist)
- Not concurrently treated with an alternative biologic for asthma (e.g., Nucala, Cinqair, Fasenra, Xolair)

Your provider did not indicate that you **[meet the conditions for eosinophilic phenotype or with corticosteroid dependent asthma / are at least 12 years of age / have seen a specialist / adherent on a maximally tolerated inhaled corticosteroid plus at least one other maintenance medication / will not be concurrently treated with an alternative biologic for asthma]** and therefore your request was not approved.

DENIAL TEXT (diagnosis not met): Per your health plan's DUPILUMAB (DUPIXENT) guideline, this medication is only covered for members with the diagnosis of moderate to severe atopic dermatitis or with the diagnosis of moderate to severe eosinophilic phenotype or corticosteroid dependent asthma. Your provider did not indicate that you have one of these conditions and therefore your request was not approved.

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DUPILUMAB (DUPIXENT)

INITIAL CRITERIA (CONTINUED)

3. **Please approve by HICL as follows:**
   - **For atopic dermatitis, please approve for 6 months.**
   - **For asthma, please approve for 12 months.**

   Dupixent is hard-coded with a quantity of two syringes per 28 days.
   - 200 mg per 1.14 ml strength: 2.28 mls
   - 300 mg per 2 ml strength: 4 mls

   For members starting therapy, please enter two PAs as follows:
   - **First PA:**
     - **If the request is for the 300 mg strength: Approve 8 mLs (four 300 mg/2ml syringes) for the first month; fill count 1.** (**NOTE:** Please enter F in the restriction field with a Max Quantity of 8.)
     - **If the request is for the 200mg strength: Approve 4.6 mLs (four 200 mg/1.14 ml syringes) for the first month; fill count 1.** (**NOTE:** Please enter F in the restriction field with a Max Quantity of 4.6.)
   - **Second PA: Approve for 5 months with a fill count = 5 if for atopic dermatitis or for 11 months with a fill count = 11 if for asthma.** (**NOTE:** Please enter a start date 3 weeks after the initial PA.)
     Please use status code #056 and the approval text provided.

     Atopic Dermatitis:
     APPROVAL TEXT (new starts; atopic dermatitis): Your request for Dupixent 300 mg syringes has been approved for a 6-month period with a quantity of four syringes for the first month, and then two syringes per 28 days for the remaining 5 months.

     APPROVAL TEXT (continuing therapy without a loading dose; atopic dermatitis): Your request for Dupixent 300 mg syringes has been approved for a 6-month period with a quantity of two syringes per 28 days.

     Asthma:
     APPROVAL TEXT (new starts; asthma): Your request for Dupixent **[200 mg or 300 mg]** syringes has been approved for a 12-month period with a quantity of four syringes for the first month, and then two syringes per 28 days for the remaining 11 months.

     APPROVAL TEXT (continuing therapy without a loading dose; asthma): Your request for Dupixent **[200 mg or 300 mg]** syringes has been approved for a 12-month period with a quantity of two syringes per 28 days.

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DUPILUMAB (DUPIXENT)

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the request meet ALL of the following criteria?
   - Diagnosis of moderate to severe atopic dermatitis or moderate to severe asthma
   - Prescribed by, or in consultation with, a specialist, (e.g., allergist, immunologist, dermatologist, or pulmonologist)
   - Patient has shown improvement with therapy

   If yes, **approve by HICL for 12 months up to 13 fills.** Please use status code #056. (Dupixent is hard-coded with a quantity of two syringes per 28 days.)
   APPROVAL TEXT: Your request for Dupixent **[200 mg or 300 mg]** syringes has been approved for two syringes per 28 days for a 12-month period.

   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's DUPILUMAB (DUPIXENT) guideline, this medication is only covered for members who meet all of the following criteria:
   - Diagnosis of moderate to severe atopic dermatitis or moderate to severe asthma
   - Prescribed by, or in consultation with, a specialist, (e.g., allergist, immunologist, dermatologist, or pulmonologist)
   - You have shown improvement with therapy

   Your provider did not indicate that you **[have one of the covered diagnoses/have been seen by a specialist/have shown improvement with therapy]** and therefore your request was not approved.

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DUPILUMAB (DUPIXENT)

RATIONALE
To promote the appropriate use of Dupixent based on FDA-approved indication and preferred first- and second-line courses of therapy.

FDA APPROVED INDICATIONS
Dupixent is an interleukin-4 receptor alpha antagonist indicated for:
- Treatment of adult patients 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.
- As an add-on maintenance treatment in patients with moderate-to-severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma.

DOSAGE:
The recommended dose is an initial dose of:
- 400 mg (two 200 mg subcutaneous injections in different injection sites), followed by 200 mg every other week or
- 600 mg (two 300 mg subcutaneous injections in different injection sites), followed by 300 mg given subcutaneously every other week.

Dupixent is available in a package of two pre-filled syringes, with needle shield, in 200 mg/1.14 mL and 300 mg/2 mL strengths.

REFERENCES

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