Dupixent

Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-866-249-6155**. If you have questions regarding the prior authorization, please contact CVS Caremark at **1-866-814-5506.** For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

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Patient's Name: _____ Date: _____
Patient's ID: _____ Patient's Date of Birth: _____
Physician's Name: _____
Specialty: _____ NPI#: _____
Physician Office Telephone: _____ Physician Office Fax: _____
Request Initiated For: _____

1. What is the dose being prescribed?

   A) Initial dose (i.e., loading dose): _____ mg

   B) Maintenance dose (i.e., continuation of therapy): _____ mg every other week

2. What is the diagnosis?
   - ❑ Atopic dermatitis, moderate-to-severe
   - ❑ Asthma
   - ❑ Chronic rhinosinusitis with nasal polyposis
   - ❑ Other _____

3. What is the ICD-10 code? _____

4. Is the patient currently receiving Dupixent? ❑ Yes ❑ No

Complete the following section based on the patient's diagnosis, if applicable.

Section A: Atopic Dermatitis

5. Is the request for continuation of therapy with Dupixent? ❑ Yes ❑ No *If No, skip to #8*

6. Is the patient currently receiving Dupixent through samples or a manufacturer's patient assistance program? *If Yes or Unknown, skip to #8* ❑ Yes ❑ No ❑ Unknown

7. Has the patient achieved or maintained positive clinical response as evidenced by low disease activity (i.e., clear or almost clear skin), or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting) since starting treatment with Dupixent? ❑ Yes ❑ No *No further questions.*

8. What is the percentage of body surface area (BSA) affected prior to initiation of Dupixent? _____% *If greater than or equal to 10% of BSA, skip to #10.*

9. Are crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) affected? ❑ Yes ❑ No

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10. To which topical therapies, if any, has the patient had an inadequate treatment response in the past 180 days? ***ACTION REQUIRED: If Yes, please attach supporting chart note(s) or medical record showing drug name, dosage form and strength.***
    - ❑ Topical corticosteroid
    - ❑ Topical calcineurin inhibitor (e.g., Elidel, Protopic), *no further questions*
    - ❑ Both a topical corticosteroid and a topical calcineurin inhibitor, *no further questions*
    - ❑ None of the above, *skip to #12*

11. What is the potency of the highest-potency topical corticosteroid the patient has tried in the past 180 days?
    - ❑ Low potency
    - ❑ Medium potency
    - ❑ High potency, *no further questions*
    - ❑ Very high potency, *no further questions*

12. Is the use of high-potency topical corticosteroids and topical calcineurin inhibitors not advisable for the patient (e.g., due to contraindications or prior intolerances)? ❑ Yes ❑ No

Section B: Asthma

13. The preferred products for your patient's health plan are Nucala and Xolair. Can the patient's treatment be switched to a preferred product? ***If Yes, please call 1-866-814-5506 to have the updated form faxed to your office OR you may complete the PA electronically (ePA). You may sign up online via CoverMyMeds at: www.covermymeds.com/epa/caremark/ or call 1-866-452-5017.***
    ❑ Yes - Nucala ❑ Yes - Xolair ❑ No - Continue request for Dupixent

14. Is this request for continuation of therapy with the requested product? ❑ Yes ❑ No *If No, skip to #16*

15. Is the patient currently receiving the requested product through samples or a manufacturer's patient assistance program? If unknown, answer Yes. ❑ Yes ❑ No *If No, skip to #20*

16. What is the patient's eosinophil count? _____ cells per micro liter
    If less than 150 cells per microliter, skip to #18.

17. Does the patient have a documented inadequate response or intolerable adverse event to treatment with Nucala? ***ACTION REQUIRED: If Yes, attach supporting chart note(s).*** ❑ Yes ❑ No *If No, complete this form in its entirety and State Step Therapy section.*

18. What is the patient's pretreatment serum IgE level? _____ IU/mL *If less than 30 IU/mL, skip to #20*

19. Does the patient have a documented inadequate response or intolerable adverse event to treatment with Xolair? ***ACTION REQUIRED: If Yes, attach supporting chart note(s).*** ❑ Yes ❑ No *If No, complete this form in its entirety and State Step Therapy section.*

20. Will the patient receive Dupixent as monotherapy (i.e., without any other asthma medications such as inhaled corticosteroids)? ❑ Yes ❑ No

21. Will the patient receive Dupixent concomitantly with other biologics indicated for asthma (e.g., Cinqair, Fasenra, Nucala or Xolair)? ❑ Yes ❑ No

22. Is the request for continuation of therapy with Dupixent? ❑ Yes ❑ No *If No, skip to #28*

23. Is the patient currently receiving Dupixent through samples or a manufacturer's patient assistance program? *If Yes or Unknown, skip to #25* ❑ Yes ❑ No ❑ Unknown

24. Has asthma control improved on Dupixent treatment, as demonstrated by at least one of the following? *Indicate below and no further questions.*
    - ❑ A reduction in the frequency and/or severity of symptoms and exacerbations
    - ❑ A reduction in the daily maintenance oral corticosteroid dose
    - ❑ None of the above

25. Prior to Dupixent therapy, what was the patient's baseline (e.g., before significant oral steroid use) blood eosinophil count in cells per microliter? ***ACTION REQUIRED: Please attach supporting chart note(s) or medical record with the patient's baseline blood eosinophil count.*** _____ cells per microliter
    ❑ Unknown *If less than 150 cells per microliter or unknown, skip to #27*

26. Prior to receiving Dupixent, did the patient have inadequate asthma control (e.g. hospitalization or emergency medical care visit within the past year) despite current treatment with both of the following medications at optimized doses? ❑ Yes ❑ No *No further questions.*
    A) Inhaled corticosteroid
    B) Additional controller (long acting beta$_2$-agonist, leukotriene modifier, or sustained-release theophylline)

27. Prior to receiving Dupixent, did the patient have inadequate asthma control (e.g. hospitalization or emergency medical care visit within the past year) despite concomitant treatment with all of the following medications at optimized doses? ***ACTION REQUIRED: If 'Yes', please attach supporting chart note(s) or medical record showing patient's oral glucocorticoid use history, including drug, dose, frequency and duration and skip to #31.***
    ❑ Yes ❑ No
    A) High-dose inhaled corticosteroid
    B) Additional controller (long acting beta$_2$-agonist, leukotriene modifier, or sustained-release theophylline)
    C) Oral glucocorticoids (at least 5 mg per day of prednisone/prednisolone or equivalent)

28. What is the patient's baseline (e.g., before significant oral steroid use) blood eosinophil count in cells per microliter? ***ACTION REQUIRED: Please attach supporting chart note(s) or medical record with the patient's baseline blood eosinophil count.*** _____ cells per microliter ❑ Unknown *If less than 150 cells per microliter or unknown, skip to #30*

29. Does the patient have inadequate asthma control (e.g. hospitalization or emergency medical care visit within the past year) despite current treatment with both of the following medications at optimized doses:
    ❑ Yes ❑ No *No further questions.*
    A) Inhaled corticosteroid
    B) Additional controller (long acting beta$_2$-agonist, leukotriene modifier, or sustained-release theophylline)

30. Does the patient have inadequate asthma control (e.g. hospitalization or emergency medical care visit within the past year) despite concomitant treatment with all of the following medications at optimized doses?
    ACTION REQUIRED: If Yes, please attach supporting chart note(s) or medical record showing patient's oral glucocorticoid use history, including drug, dose, frequency and duration. ❑ Yes ❑ No
    A) High-dose inhaled corticosteroid
    B) Additional controller (long acting beta$_2$-agonist, leukotriene modifier, or sustained-release theophylline)
    C) Oral glucocorticoids (at least 5 mg per day of prednisone/prednisolone or equivalent)

31. Has the patient received treatment with the inhaled corticosteroid and additional controller for at least the previous 3 months? ❑ Yes ❑ No

32. Has the patient received treatment with oral glucocorticoids for most days during the previous 6 months (e.g. 50% of days, 3 steroid bursts in the previous 6 months)? ❑ Yes ❑ No

<u>Section C: Chronic Rhinosinusitis with Nasal Polyposis</u>

33. Is the request for continuation of therapy with Dupixent? ❑ Yes ❑ No *If No, skip to #36*

34. Is the patient currently receiving Dupixent through samples or a manufacturer's patient assistance program? *If Yes or Unknown, skip to #36* ❑ Yes ❑ No ❑ Unknown

35. Has the patient achieved or maintained positive clinical response as evidenced by improvement in signs and symptoms of CRSwNP (e.g., improvement in nasal congestion, nasal polyp size, loss of smell, anterior or posterior rhinorrhea, sinonasal inflammation, hyposmia and/or facial pressure or pain or reduction in corticosteroid use)? ❑ Yes ❑ No *No further questions.*

36. Are intranasal corticosteroids contraindicated or not tolerated? ❑ Yes ❑ No

37. Does the patient have bilateral nasal polyposis and chronic symptoms of sinusitis? ❑ Yes ❑ No

38. Has the patient had intranasal corticosteroid treatment for at least 2 months? ❑ Yes ❑ No

39. Has the patient had prior sino-nasal surgery? *If Yes, skip to #42* ❑ Yes ❑ No

40. Has the patient had an inadequate response with systemic corticosteroids within the last two years? *If Yes, skip to #42* ❑ Yes ❑ No

41. Are systemic corticosteroids contraindicated or not tolerated? ❑ Yes ❑ No

42. Has the patient had a bilateral nasal endoscopy or anterior rhinoscopy showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril? ***ACTION REQUIRED: If Yes, please attach supporting chart note(s) or medical record showing endoscopy or rhinoscopy details (e.g., polyps location, size).*** ❑ Yes ❑ No

43. Does the patient have nasal obstruction? ❑ Yes ❑ No

44. Does the patient have rhinorrhea (anterior/posterior) or reduction or loss of smell? ❑ Yes ❑ No

45. Will the patient be using a daily intranasal corticosteroid while being treated with Dupixent? ❑ Yes ❑ No

State Step Therapy

1. Is the requested drug being used for an FDA-approved indication or an indication supported in the compendia of current literature (examples: AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)? ❑ Yes ❑ No

2. Does the prescribed quantity fall within the manufacturer's published dosing guidelines or within dosing guidelines found in the compendia of current literature (examples: package insert, AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)? ❑ Yes ❑ No

3. Does the patient reside in Maryland? ❑ Yes ❑ No *If No, skip to #7*

4. Is the alternate drug (Nucala and Xolair) FDA-approved for the medical condition being treated? ❑ Yes ❑ No *If No, please specify:* _____

5. Has the prescriber provided proof, documented in the patient's chart notes, indicating that the requested drug was ordered for the patient in the past 180 days? ❑ Yes ❑ No *If No, skip to #7*

6. Has the prescriber provided proof, documented in the patient chart notes, that in their opinion the requested drug is effective for the patient's condition? ❑ Yes ❑ No *No further questions*

7. Are any of the following conditions met for the alternate drug (Nucala and Xolair)?
   ❑ The alternate drug is contraindicated
   ❑ The alternate drug is likely to cause an adverse reaction, physical or mental harm
   ❑ The alternate drug is expected to be ineffective
   ❑ The alternate drug was previously tried or a drug in the same class or with the same action was previously tried and was stopped due to ineffectiveness or an adverse event
   ❑ The alternate drug is not in the patient's best interest
   ❑ The alternate drug was tried while covered by the current or the previous health benefit plan
   ❑ None of the above
   If Yes, please specify: _____

8. Is the patient stable or currently receiving a positive therapeutic outcome with the requested drug and a change in the prescription drug is expected to be ineffective or cause harm to the patient? ❑ Yes ❑ No

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

X_____

Prescriber or Authorized Signature **Date (mm/dd/yy)**

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