oscar

Clinical Guideline

Guideline Number: PG026, Ver. 1

Dupixent (dupilumab)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Oscar may delegate utilization management decisions of certain services to third-party delegates who may develop and adopt their own clinical criteria.

The clinical guidelines are applicable to all commercial plans. Services are subject to the terms, conditions, limitations of a member's plan contracts, state laws, and federal laws. Please reference the member's plan contracts (e.g., Certificate/Evidence of Coverage, Summary/Schedule of Benefits) or contact Oscar at 855-672-2755 to confirm coverage and benefit conditions.

Summary

Dupixent (dupilumab) is an interleukin-4 receptor alpha agonist indicated for the following conditions:

Atopic dermatitis, moderate to severe

- Dupilumab is indicated as treatment of patients aged 6 years and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupilumab can be used with or without topical corticosteroids.

Asthma, moderate to severe

- Dupilumab is indicated 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.

Chronic rhinosinusitis with nasal polyposis (CRSwNP)

- Dupilumab is indicated as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis.

Limitation of Use: Dupixent is not indicated for the relief of acute bronchospasm or asthma exacerbation.

Medical Necessity Criteria for Initial Authorization

Oscar covers Dupixent when ALL of the following criteria are met for each indication:

Atopic dermatitis, moderate to severe

1. Member is at least 6 years age; ***and***
2. The prescriber is a specialist in dermatology, allergy or immunology; ***and***
3. The member's affected body surface area (BSA) before treatment is equal to or greater than 10%), OR member's affected BSA is less than 10% but involves sensitive body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected; ***and***
4. Member has had an inadequate treatment response to ALL of the following topical therapies for at least 8 weeks each in the past 365 days, unless the use of any of the topical therapies is not advisable for the member (e.g., due to documented contraindications or prior intolerances):
    a. At least two (2) topical corticosteroid (TCS) from medium potency (group III to IV) classes to higher potencies (groups I to II) classes (e.g., betamethasone valerate 0.1% cream or ointment, betamethasone dipropionate augmented 0.05% ointment),
    b. Tacrolimus ointment,
    c. Crisaborole (requires prior treatment with a medium or higher potency TCS within the past 180 days); ***and***
5. Member has had an inadequate treatment response to at least ONE of the following systemic immunosuppressive therapies for at least 8 weeks in the past 365 days, unless the use these systemic therapies is not advisable for the member (e.g., due to documented contraindications or prior intolerances): azathioprine, cyclosporine, methotrexate, or mycophenolate.

If the member meets the criteria listed above, dupilumab will be approved for atopic dermatitis for 4 months initially. See below for reauthorization criteria.

Asthma, moderate to severe

1. Member is at least 12 years of age; ***and***
2. Member meets one of the following criteria (a or b):
    a. Documentation of history with 2 or more exacerbations (hospitalization, emergency department visit, exacerbations requiring systemic corticosteroids burst), despite current treatment with ALL of the following medications at optimized doses*, unless the member is intolerant or has a contraindication to all of these medications:
        i. High-dose inhaled corticosteroid
        ii. Additional controller (long acting beta2-agonist, leukotriene modifier, or sustained-release theophylline)
        iii. Oral glucocorticoids (at least 5 mg per day of prednisone/prednisolone or equivalent); ***or***

    (*Members should be receiving treatment with inhaled corticosteroid and additional controller for at least the previous 3 months, and oral glucocorticoids for most days during the previous 6 months [e.g. 50% of days, 3 steroid bursts in the previous 6 months])
    b. Documentation of baseline blood eosinophil count of at least 150 cells per microliter and 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 for at least 3 months, unless the member is intolerant or has a contraindication to all of these medications:
    i. High-dose inhaled corticosteroid
    ii. Additional controller (long acting beta2-agonist, leukotriene modifier, or sustained-release theophylline); ***and***
3. Documentation of member's pre-treatment FEV1 and Asthma Control Questionnaire (ACQ); ***and***
4. Member will not use Dupixent as monotherapy; ***and***
5. Documentation that member is currently smoke-free and does not currently smoke; ***and***
6. Member will not use Dupixent concomitantly with other biologics (e.g., Cinqair, Fasenra, Nucala or Xolair).

If the member meets the criteria listed above, dupilumab will be approved for asthma for 6 months initially. See below for reauthorization criteria.

Chronic rhinosinusitis with nasal polyposis (CRSwNP)

1. Member is at least 18 years of age; ***and***
2. Member has bilateral nasal polyposis and chronic symptoms of sinusitis despite intranasal corticosteroid treatment for at least 2 months unless contraindicated or not tolerated; ***and***
3. The member has CRSwNP despite one of the following:
    a. Prior sino-nasal surgery; ***or***
    b. Prior treatment with systemic corticosteroids within the last two years was ineffective, unless contraindicated or not tolerated; ***and***
4. Member has a bilateral nasal endoscopy or anterior rhinoscopy showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril; ***and***
5. Member has nasal obstruction plus one additional symptom:
    a. Rhinorrhea (anterior/posterior); ***or***
    b. Reduction or loss of smell; ***and***
6. Member's current treatment plan includes using a daily intranasal corticosteroid while being treated with dupilumab, unless contraindicated or not tolerated.

If the member meets the criteria listed above, dupilumab will be approved for CRSwNP for 6 months initially. See below for reauthorization criteria.

Medical Necessity Criteria for Reauthorization

All prior authorization renewals will be reviewed for the following indications to determine if continuation of therapy is medically necessary. Prior Authorization may be extended based on the diagnosis, documentation of the response to therapy, and pharmacy claims record.

Atopic dermatitis, moderate to severe

Authorization of 12 months may be provided for members 6 years of age or older who achieve or maintain positive clinical response with dupilumab therapy for moderate-to-severe atopic dermatitis as evidenced by low disease activity (e.g., a reduction in BSA%), or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting).

Asthma, moderate to severe

Authorization of 12 months may be provided for members 12 years of age or older when all of the following criteria are met:

1. Asthma control has improved on dupilumab treatment as demonstrated by at least one of the following:
    a. A reduction in the frequency and/or severity of symptoms and exacerbations
    b. A reduction in the daily maintenance oral corticosteroid dose; ***and***
2. Documentation of member's most current FEV1 and ACQ; ***and***
3. Member will not use dupilumab as monotherapy; ***and***
4. Member remains smoke-free and does not currently smoke; ***and***
5. Member will not use dupilumab concomitantly with other biologics (e.g., Cinqair, Fasenra, Nucala or Xolair).

Chronic rhinosinusitis with nasal polyposis (CRSwNP)

Authorization of 12 months may be provided for members 18 years of age or older who achieve or maintain positive clinical response to dupilumab therapy 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), with consistent use of intranasal corticosteroids while being treated with dupilumab.

Experimental or Investigational / Not Medically Necessary

The safety and efficacy of this medication in patients younger than the approved age for each indication has not been established. Therefore, it is not a covered medication for those under the approved age of use. Dupilumab for any other indication is *not covered* by Oscar as it is considered experimental, investigational, or unproven.

Applicable Billing Codes (HCPCS/CPT Codes)

Dupixent (dupilumab)	
CPT/HCPCS Codes covered if criteria are met:	
Code	*Description*
C9399, J3590	Unclassified biologics
ICD-10 codes covered if criteria are met:	
Code	*Description*
J33.0 - J 33.9	Nasal polyp
J45.40 - J45.42	Moderate persistent asthma
J45.50 - J45.52	Severe persistent asthma
L20.0	Besnier's prurigo

L20.81	Atopic neurodermatitis
L20.82	Flexural eczema
L20.84	Intrinsic (allergic) eczema
L20.89	Other atopic dermatitis
L20.9	Atopic dermatitis, unspecified

References

1. Dupixent [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; 5/2020.
2. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: Section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014;71:116-32. (Including potencies of topical corticosteroids).
3. Simpson EL., Bieber T, Guttman-Yassky E, et al. Two phase 3 trials of dupilumab versus placebo in atopic dermatitis. N Engl J Med. 2016;375:2335-2348.
4. Castro M, Corren J, Pavord ID, et al. Dupilumab efficacy and safety in moderate-to-severe uncontrolled Asthma. N Engl J Med. 2018;378(26):2486-2496.
5. Rabe KF, Nair P, Brusselle G, et al. Efficacy and safety of dupilumab in glucocorticoid-dependent severe asthma. N Engl J Med. 2018;378(26):2475-2485.
6. Bachert C, Han JK, Desrosiers M, et al. Efficacy and safety of dupilumab in patients with severe chronic rhinosinusitis with nasal polyps (LIBERTY NP SINUS-24 and LIBERTY NP SINUS-52): results from two multicentre, randomised, double-blind, placebo-controlled, parallel-group phase 3 trials. Lancet. 2019;394(10209):1638.

Clinical Guideline Revision / History Information

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Reviewed/Revised: