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Policy Number: C21777-A

Dupixent (dupilumab)

PRODUCTS AFFECTED

Dupixent (dupilumab)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Moderate to severe Atopic Dermatitis, Moderate-to-severe asthma with an eosinophilic phenotype or with oral corticosteroid dependent, Nasal polyposis, Eosinophilic esophagitis, Prurigo nodularis, Chronic Obstructive Pulmonary Disease

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory

generic and that generic drugs will be dispensed whenever available.

A. MODERATE TO SEVERE ATOPIC DERMATITIS:
1. Documented diagnosis of moderate to severe chronic atopic dermatitis (eczema)
AND
2. Documentation of inadequate response, serious side effects, or contraindication to ONE of the following: medium to high potency topical corticosteroids or preferred/formulary topical calcineurin inhibitor (tacrolimus, pimecrolimus)

B. MODERATE TO SEVERE ASTHMA:
1. Documented diagnosis of moderate to severe asthma
AND
2. Documentation member has eosinophilic phenotype or predominantly eosinophil-driven disease with blood eosinophil counts ≥150 cells/microliter at initiation of therapy (within 6 weeks of request) or ≥300 cells/microliter in the prior 12 months OR member requires chronic maintenance oral corticosteroid treatment [DOCUMENTATION REQUIRED]
AND
3. Documentation member has experienced exacerbation(s) or hospitalization(s), within the last 12 months as evidenced by any of the following:
    i. ONE or more exacerbations requiring treatment with systemic corticosteroid (intramuscular, intravenous, or oral) despite the use of high-dose inhaled corticosteroids in the past 12 months
    OR
    ii. One or more exacerbation requiring hospitalization in the past 12 months
    OR
    iii. Any prior intubation for an asthma exacerbation
AND
4. Member is currently being treated with ONE of the following regimens or there is contraindication or intolerance to all medications within the regimenMedium or High dose ICS-LABA combination product AND one additional asthma controller medication (LAMA, LTRA, low dose azithromycin), preferably a LAMA per GINA 2024 guideline
OR
a. Medium or High dose ICS-LABA combination product AND oral corticosteroids [see Appendix for product classes]

C. NASAL POLYPOSIS:
1. Documented diagnosis of chronic rhinosinusitis with nasal polyposis
AND
2. Documentation the member has experienced an inadequate response (after 2 consistent months of use) or serious side effects to ONE of the following medications unless contraindicated: intranasal corticosteroids
AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal (e.g., nasal congestion, loss of smell, sino-nasal symptoms) [DOCUMENTATION REQUIRED]

D. EOSINOPHILIC ESOPHAGITIS:
1. Documented diagnosis of eosinophilic esophagitis (EoE)
AND
2. Documentation of inadequate response, (or labeled contraindication) to ONE of the following: proton-pump inhibitor, and topical glucocorticoids (fluticasone or budesonide)
AND

3. Member weighs at least 15 kg

E. PRURIGO NODULARIS:
1. Documented diagnosis of prurigo nodularis

F. CHRONIC OBSTRUCTIVE PULMONARY DISEASE:
1. Documented diagnosis of chronic obstructive pulmonary disease (COPD)
   AND
2. Documentation member has eosinophilic phenotype or predominantly eosinophil-driven disease with blood eosinophil count ≥ 300 cellls/mcL [DOCUMENTATION REQUIRED]
   AND
3. Member had inadequate response, intolerable adverse effects, or contraindication to a regimen of at least 3 months of triple therapy that includes a long-acting muscarinic antagonist (LAMA), long- acting beta agonist (LABA), and inhaled corticosteroid (ICS)
   Note: trial of double therapy (LABA plus LAMA) permitted if ICS is contraindicated
   AND
4. Documentation that Dupixent (dupilumab) is NOT being used as monotherapy for COPD (must be prescribed as add-on maintenance to be used in combination with other medications for long-term control of COPD)
   AND
5. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal (e.g., baseline symptomatology [dyspnea, wheezing, cough, sputum], exacerbations, etc.)

CONTINUATION OF THERAPY:

A. FOR ALL INDICATIONS:
1. (a) MODERATE TO SEVERE ASTHMA: Documentation of clinical improvement as evidenced by improvement in lung function (increase in percent predicted FEV1 or PEF) from pre-treatment baseline, or decreased utilization of rescue medication, or decreased frequency of exacerbations (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroids), or decreased frequency of unscheduled clinic or urgent care or emergency department visits, or reduction in reported symptoms (chest tightness, coughing, shortness of breath, nocturnal wakening, wheezing, sustained improvement in Asthma Control Text scores), or decreased or stopped oral treatments including oral corticosteroids and other add on medication if applicable, or reduced ICS-LABA dose to at least moderate
   OR
   (b) MODERATE TO SEVERE ATOPIC DERMATITIS: Member has responded to Dupixent therapy as determined by the prescribing physician (e.g., marked improvements in erythema, induration/ papulation/edema, excoriations, and lichenification; reduced pruritus; decreased requirement for other topical or systemic therapies; reduced body surface area (BSA) affected with atopic dermatitis; or other responses observed
   OR
   (c) NASAL POLYPOSIS: Documentation of significant reduction in nasal congestion, loss of smell or sino-nasal symptoms reported at initial authorization
   OR
   (d) EOSINOPHILIC ESOPHAGITIS: Documentation of positive clinical response as demonstrated by low EoE disease activity and/or improvements in the condition's signs and symptoms
   OR
   (e) PRURIGO NODULARIS: Documentation of positive clinical response as demonstrated by an improvement in itching
   OR
   (f) COPD: Documentation of positive clinical response as demonstrated by improvement in symptoms (e.g., dyspnea, wheezing, cough, sputum), or decreased severity or frequency of exacerbations

AND

2. Documentation Dupixent (dupilumab) will not be used as monotherapy for asthma or nasal polyps or COPD

DURATION OF APPROVAL:
Initial authorization: 12 months, Continuation of therapy: 12 months

PRESCRIBER REQUIREMENTS:
MODERATE TO SEVERE ATOPIC DERMATITIS: Prescribed by or in consultation with an allergist, immunologist, or dermatologist.
MODERATE TO SEVERE ASTHMA: Prescribed by, or in consultation with, a board-certified asthma specialist (allergist, immunologist, pulmonologist) or physician experienced in the management of asthma.
NASAL POLYPOSIS: Prescribed by or in consultation with an Otolaryngologist, or Allergist/Immunologist
EOSINOPHILIC ESOPHAGITIS: Prescribed by or in consultation with a gastroenterologist or physician experienced in the management of eosinophilic esophagitis
PRURIGO NODULARIS: Prescribed by or in consultation with a dermatologist or physician experienced in the management of prurigo nodularis
COPD: Prescribed by or in consultation with an allergist/immunologist or pulmonologist
[If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
ATOPIC DERMATITIS: 6 months of age and older
MODERATE TO SEVERE ASTHMA: 6 years of age and older
NASAL POLYPOSIS: 12 years of age and older
EOSINOPHILIC ESOPHAGITIS: 1 year of age and older
PRURIGO NODULARIS, COPD: 18 years of age and older

QUANTITY:
ATOPIC DERMATITIS:
Adults: 600mg (2x300mg) followed by 300mg every 2 weeks
Pediatrics (6 months to 5 years of age):
5kg to <15kg: 200mg every 4 weeks
15kg to <30kg: 300mg every 4 weeks

Pediatrics (6 years to 17 years of age):
15 to <30kg: 600mg (2x300mg) followed by 300mg every 4 weeks
30 to <60kg: 400mg (2x200mg) followed by 200mg every 2 weeks
60kg or greater: 600 mg (2x300mg) followed by 300 mg every 2 weeks

MODERATE TO SEVERE ASTHMA:
Adults and Pediatrics 12 years and older: 400mg (2x200mg) followed by 200mg every 2 weeks OR 600mg (2x300mg) followed by 300mg every 2 weeks

Pediatrics 6 to 11 years of age:
15kg to < 30kg: 300mg every 4 weeks 30kg or greater: 200mg every 2 weeks
NOTE: For pediatric patients 6 to 11 years of age with asthma and co-morbid moderate-to-severe AD, follow the recommended dosage for AD which includes an initial loading dose.

NASAL POLYPOSIS: 300 mg given every 2 weeks.

EOSINOPHILIC ESOPHAGITIS:
15 to <30kg: 200mg every 2 weeks
30 to <40kg: 300mg every 2 weeks

40kg or greater: 300 mg given 2 weeks

PRURIGO NODULARIS: 600 mg (2x300mg), followed by 300 mg given every 2 weeks

COPD: 300 mg given every 2 weeks

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous

DRUG CLASS:
Atopic Dermatitis - Monoclonal Antibodies

FDA-APPROVED USES:
Dupixent is indicated:

- for the treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe atopic dermatitis (AD) 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 of adult and pediatric patients aged 6 years and older with moderate- to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma.
- as an add-on maintenance treatment in adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP)
- for the treatment of adult and pediatric patients aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis (EoE)
- for the treatment of adult patients with prurigo nodularis
- as an add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype

Limitation of Use: Not for the relief of acute bronchospasm or status asthmaticus

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
Asthma Control Questionnaire (ACQ): A validated, patient-centered tool for evaluating asthma control developed using expert opinion and originally contained seven items; however, a five-item version (ACQ- 5) has been validated for use in clinical trials and epidemiological surveys. The ACQ score has been shown to correlate with a measure of control based on the GINA/NIH criteria. The ACQ assesses 7 items, which include asking patients to recall their experiences in the previous week and to respond to questions about nighttime waking, symptoms on waking, activity limitations, shortness of breath, wheezing, required use of short-acting b2-agonists for rescue, and FEV1 percent predicted before bronchodilator on a 7-pointscale. All of these items are equally weighted, and the ACQ score is the mean of the 7 items and ranges from 0 (totally controlled) to 6 (severely uncontrolled). The final score is generated by averaging the total scores for the 7 items. Higher scores indicate worse asthma control.[9] May be accessed via: https://www.qoltech.co.uk/questionnaires.htm
Asthma Control Test (ACT): The ACT contains 5 questions that are related to the frequency of both asthma symptoms and required rescue medication use during the previous 4 weeks. The scores in the ACT range from 5 (worse control) to 25 (total control).[10]May be accessed via: https://www.asthma.com/additional-

resources/asthma-control-test.html https://www.memphischildrens.org/Asthma_Control-12-and-older.pdf

LONG-ACTING BETA2-AGONIST
- salmeterol xinafoate Serevent Diskus

MAST CELL STABILIZER
- cromolyn sodium

STEROID + LONG-ACTING BETA2-AGONIST
- budesonide/ formoterol fumarate dihydrate Symbicort 80mcg/4.5mcg, 160mcg/4.5mcg MDI
- fluticasone furoate/ vilanterol Breo Ellipta 100mcg/25mcg, 200mcg/25mcg DPI
- fluticasone propionate/ salmeterol Advair Diskus 100mcg/50mcg, 250mcg/50mcg, 500mcg/50mcg DPI, Advair HFA 45mcg/21mcg, 115mcg/21mcg, 230mcg/21mcg MDI, AirDuo Digihaler/RespiClick 55mcg/14mcg, 113mcg/14mcg, 232mcg/14mcg DPI, Wixela Inhub 100mcg/50mcg,250mcg/50mcg,500mcg/50mcg DPI
- mometasone furoate/formoterol fumarate dihydrate Dulera 50mcg/5mcg, 100mcg/5mcg, 200mcg/5mcg MDI

ANTICHOLINERGIC
- tiotropium bromide monohydrate Spiriva Respimat 1.25mcg, 2.5mcg soln

STEROID
- beclomethasone diproprionate Qvar Redihaler 40mcg, 80mcg MDI
- budesonide Pulmicort Flexhaler 90mcg, 180mcg DPI
- ciclesonide Alvesco 80mcg, 160mcg MDA
- fluticasone furoate Arnuity Ellipta 50mcg, 100mcg, 200mcg DPI
- fluticasone propionate ArmonAir Digihaler 55mcg, 113mcg, 232mcg DPI, Flovent Diskus 50mcg, 100mcg,250mcg DPI, Flovent HFA 44mcg, 110mcg, 220mcg MDI
- mometasone furoate Asmanex HFA 50mcg, 100mcg, 200mcg MDI, Asmanex Twisthaler 110mcg, 220mcgDPI

STEROID + ANTICHOLINERGIC + LONG-ACTING BETA2-AGONIST
- fluticasone + umeclidinium + vilanterol Trelegy Ellipta 100/62.5/25mcg, 200/62.5/25mcg DPI
- budesonide + glycopyrrolate + formoterol Breztri Aerosphere MDI 160/9/4.8 mcg

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Dupixent is indicated for the treatment of adult patients with moderate to severe atopic dermatitis (AD) whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent is a human monoclonal antibody that binds to the interleukin- 4receptoralpha (IL-4Rα) subunit shared by the interleukin (IL)-4 and IL-13 receptor complexes, thereby inhibiting IL-4 and IL-13 signaling. This inhibition limits IL-4 and IL-13 cytokine-induced responses, including the release of proinflammatory cytokines, chemokines, and IgE. Following a one-time loading dose of 600 mg (administered as two 300 mg subcutaneous [SC] injections), the recommended dose of Dupixent is 300 mg SC once every other week (QOW). Dupixent may be administered by the patient or caregiver following appropriate training.

Chronic Rhinosinusitis with Nasal Polyposis

The chronic rhinosinusitis with nasal polyposis (CRSwNP) development program included two randomized, double-blind, parallel-group, multicenter, placebo-controlled studies (CSNP Trial 1 and CSNP Trial 2) in 724subjects aged 18 years and older on background intranasal corticosteroids (INCS). These studies included subjects with CRSwNP despite prior sino-nasal surgery or treatment with, or who were ineligible to receive or were intolerant to, systemic corticosteroids in the past 2 years. Patients with chronic rhinosinusitis without nasal polyposis were not included in these trials. Rescue with systemic

corticosteroids or surgery was allowed during the studies at the investigator's discretion.

In CSNP Trial 1, a total of 276 subjects were randomized to receive either 300 mg DUPIXENT (N=143) or placebo (N=133) every other week for 24 weeks. In CSNP Trial 2, 448 subjects were randomized to receive either 300 mg DUPIXENT (N=150) every other week for 52 weeks, 300 mg DUPIXENT (N=145) every other week until week 24 followed by 300 mg DUPIXENT every 4 weeks until week 52, or placebo (N=153). All subjects had evidence of sinus opacification on the Lund Mackay (LMK) sinus CT scan and 73% to 90% of subjects had opacification of all sinuses. Subjects were stratified based on their histories of prior surgery and co- morbid asthma/nonsteroidal anti- inflammatory drug exacerbated respiratory disease (NSAID- ERD). A total of 63% of subjects reported previous sinus surgery, with a mean number of 2.0 prior surgeries, 74% used systemic corticosteroids in the previous 2 years with a mean number of 1.6 systemic corticosteroid courses in the previous 2 years, 59% had co-morbid asthma, and 28% had NSAID-ERD. The co-primary efficacy endpoints were change from baseline to Week 24 in bilateral endoscopic nasal polyps score (NPS; 0-8 scale) as graded by central blinded readers, and change from baseline to Week 24 in nasal congestion/obstruction score averaged over 28 days (NC; 0-3 scale), as determined by subjects using a daily diary. For NPS, polyps on each side of the nose were graded on a categorical scale (0=no polyps; 1=small polyps in the middle meatus not reaching below the inferior border of the middle turbinate; 2=polyps reaching below the lower border of the middle turbinate; 3=large polyps reaching the lower border of the inferior turbinate or polyps medial to the middle turbinate; 4=large polyps causing complete obstruction of the inferior nasal cavity). The total score was the sum of the right and left scores. Nasal congestion was rated daily by the subjects on a 0 to 3 categorical severity scale (0=no symptoms; 1=mild symptoms; 2=moderate symptoms; 3=severe symptoms).

In both studies, key secondary endpoints at Week 24 included change from baseline in: LMK sinus CT scan score, daily loss of smell, and 22-item sino-nasal outcome test (SNOT-22). The LMK sinus CT scan score evaluated the opacification of each sinus using a 0 to 2 scale (0=normal; 1=partial opacification; 2=total opacification) deriving a maximum score of 12 per side and a total maximum score of 24 (higher scores indicate more opacification). Loss of smell was scored reflectively by the patient every morning on a 0-3 scale (0=no symptoms, 1=mild symptoms, 2=moderate symptoms, 3=severe symptoms). SNOT- 22 includes 22 items assessing symptoms and symptom impact associated with CRSwNP with each item scored from 0 (no problem) to 5 (problem as bad as it can be) with a global score ranging from 0 to 110. SNOT-22 had a 2-week recall period. In the pooled efficacy results, the reduction in the proportion of subjects rescued with systemic corticosteroids and/or sino-nasal surgery (up to Week 52) were evaluated. At Week 52, the LS mean difference for nasal congestion in the DUPIXENT group versus placebo was -
0.98 (95% CI -1.17, -0.79). In both studies, significant improvements in nasal congestion were observed as early as the first assessment at Week 4. The LS mean difference for nasal congestion at Week 4 in the DUPIXENT group versus placebo was -0.41 (95% CI: -0.52, -0.30) in CSNP Trial 1and -0.37 (95% CI: -0.46, -0.27) in CSNP Trial 2. A significant decrease in the LMK sinus CT scan score was observed. The LS mean difference for LMK sinus CT scan score at Week 24 in the DUPIXENT group versus placebo was -7.44 (95% CI: -8.35, -6.53) in CSNP Trial 1 and -5.13 (95% CI: -5.80, -4.46) in CSNP Trial 2 At Week52, in CSNP Trial 2 the LS mean difference for LMK sinus CT scan score in the DUPIXENT group versus placebo was -6.94 (95% CI: -7.87, -6.01). Dupilumab significantly improved the loss of smell compared to placebo. The LS mean difference for loss of smell at Week 24 in the DUPIXENT group versus placebo was -1.12 (95% CI: -1.31, -0.93) in CSNP Trial 1 and -0.98 (95% CI: - 1.15, -0.81) in CSNP Trial 2. At Week 52, the LS mean difference for loss of smell in the DUPIXENT group versus placebo was -1.10 (95% CI 1.31, -0.89). In both studies, significant improvements in daily loss of smell severity were observed as early as the first assessment at Week 4. Dupilumab significantly decreased sino-nasal symptoms as measured bySNOT-22 compared to placebo. The LS mean difference for SNOT-22 at Week 24 in the DUPIXENT group versus placebo was -21.12 (95% CI: -25.17, -17.06) in CSNP Trial 1 and -17.36 (95% CI: - 20.87, -13.85) in CSNP Trial 2. At Week 52, the LS mean difference in the DUPIXENT group versus placebo was -20.96 (95% CI -25.03, -16.89). In the pre- specified multiplicity-adjusted pooled analysis of two studies, treatment with DUPIXENT resulted in significant reduction of systemic corticosteroid use and need for sino-nasal surgery versus placebo (HR of 0.24; 95% CI: 0.17, 0.35) (see Figure 9). The proportion of subjects who required systemic corticosteroids was reduced by 74% (HR of 0.26; 95% CI: 0.18, 0.38). The total number of systemic corticosteroid courses per year was reduced by 75% (RR of 0.25; 95% CI: 0.17, 0.37). The proportion of subjects who required surgery was reduced by 83% (HR of 0.17; 95% CI: 0.07, 0.46).

Drug and Biologic Coverage Criteria

Chronic Obstructive Pulmonary Disease (COPD)

Dupixent is approved for us in adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype. Efficacy and safety were evaluated in two randomized, double-blind, multicenter, parallel-group, placebo-controlled trials (BOREAS [NCT03930732] and NOTUS [NCT04456673]) of 52 weeks duration. The two trials enrolled a total of 1874 adult subjects with COPD. Both trials enrolled subjects with a diagnosis of COPD with moderate to severe airflow limitation and a minimum blood eosinophil count of 300 cells/mcL at screening. Trial enrollment required an exacerbation history of at least 2 moderate or 1 severe exacerbation in the previous year despite receiving maintenance triple therapy consisting of a long-acting muscarinic antagonist (LAMA), long- acting beta agonist (LABA), and inhaled corticosteroid (ICS), and symptoms of chronic productive cough for at least 3 months in the past year. In both trials, subjects were randomized to receive DUPIXENT 300 mg subcutaneously every two weeks (Q2W) or placebo in addition to their background maintenance therapy for 52 weeks. The primary endpoint for BOREAS and NOTUS trials was the annualized rate of moderate or severe COPD exacerbations during the 52-week treatment period. In both trials, DUPIXENT demonstrated a significant reduction in the annualized rate of moderate or severe COPD exacerbations compared to placebo when added to background maintenance therapy [BOREAS rate ratio vs placebo 0.71 (95% CI 0.58, 0.86), NOTUS rate ratio vs placebo 0.66 (95% CI 0.54, 0.82)]. Treatment with Dupixent also decreased time to first exacerbation when compared with placebo in BOREAS (HR: 0.80; 95% CI: 0.66, 0.98) and NOTUS (HR: 0.71; 95% CI: 0.57, 0.89).

The 2024 GOLD guidelines mention dupilumab as a drug with potential to reduce exacerbations that requires confirmation in further studies.

The 2025 GOLD guidelines list dupilumab as treatment for patients treated with LABA+LAMA+ICS who still have exacerbations, with eosinophils 300 cellls/mcL or greater, and with symptoms of chronic bronchitis.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Dupixent (dupilumab) are considered experimental/investigational and therefore will follow the Molina Healthcare, Inc. off-label policy. Contraindications to Dupixent (dupilumab) include: Known hypersensitivity to dupilumab or any of its excipients, avoid use of live vaccines with Dupixent.

Exclusions/Discontinuation:

Do not use Dupixent concurrently with other monoclonal antibodies: Xolair (omalizumab), Cinqair (reslizumab), Nucala (mepolizumab), Fasenra (benralizumab), or Tezspire (tezepelumab).

OTHER SPECIAL CONSIDERATIONS:

If a weekly dose is missed, administer the dose as soon as possible, and start a new weekly schedule from the date of the last administered dose. If an every other week dose is missed, administer the injection within 7 days from the missed dose and then resume the patient's original schedule. If the missed dose is not administered within 7 days, wait until the next dose on the original schedule. If an every 4 week dose is missed, administer the injection within 7 days from the missed dose and then resume the patient's original schedule. If the missed dose is not administered within 7 days, administer the dose, starting a new schedule based on this date.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Dupixent SOAJ 200MG/1.14ML prefilled pen
Dupixent SOAJ 300MG/2ML prefilled pen
Dupixent SOSY 100MG/0.67ML prefilled syringe
Dupixent SOSY 200MG/1.14ML prefilled syringe
Dupixent SOSY 300MG/2ML prefilled syringe

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION-Notable Revisions: Diagnosis Required Medical Information Continuation of Therapy Prescriber Requirements Age Restrictions Quantity FDA-Approved Uses Appendix Background References	Q3 2025
Q2 2022 Established tracking in new format	Historical changes on file