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Policy Number: C11152-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:
Atopic Dermatitis, Moderate to severe, moderate-to-severe asthma with an eosinophilic phenotype or with oral corticosteroid dependent, Nasal polyposis, Eosinophilic esophagitis, Prurigo nodularis

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.

A. MODERATE TO SEVERE ATOPIC DERMATITIS:
1. Documented diagnosis of moderate to severe chronic atopic dermatitis (eczema)
   AND
2. (a) Member has atopic dermatitis involvement estimated to be ≥ 10% of the body surface area (BSA) according to the prescribing physician; AND meets all of the following criteria:

i. Member has used at least TWO of the following: a medium potency prescription topical corticosteroid, a medium-high potency prescription topical corticosteroid, a high potency prescription topical corticosteroid, OR a super high- potency prescription topical corticosteroid;
AND
ii. Each topical corticosteroid was applied daily for at least 14 consecutive days;
AND
iii. Inadequate efficacy was demonstrated with this topical corticosteroid therapy, according to the prescribing physician
AND
iv. FOR MEMBERS 12 YEARS OF AGE AND OLDER: Documentation of inadequate response, serious side effects, contraindication, or clinical rationale of inappropriateness to ONE of the following: trial (6 weeks) of preferred/formulary topical calcineurin inhibitor (tacrolimus, pimecrolimus) OR trial (4 weeks) of crisaborole (Eucrisa) OR trial (8 weeks) of Opzelura (ruxolitinib)
OR
FOR MEMBERS <12 YEARS OF AGE: Documentation of inadequate response, serious side effects, contraindication, or clinical rationale of inappropriateness to a trial (4 weeks) of crisaborole (Eucrisa)

OR

(b) Member has atopic dermatitis involvement estimated to be < 10% of the BSA according to the prescribing physician and meets ALL of the following criteria:

i. Member has atopic dermatitis affecting ONLY the following areas: face, eyes/eyelids, skinfolds, and/or genitalia.
AND
ii. Documentation of inadequate response, serious side effects, contraindication, or clinical rationale of inappropriateness to BOTH of the following (when age appropriate): trial (6 weeks) of tacrolimus ointment (Protopic, generics) AND trial (8 weeks) of Opzelura (ruxolitinib)

AND

3. Documentation of prescriber baseline assessment of disease activity (e.g., erythema, induration/papulation/edema, excoriations, lichenification, pruritis, BSA affected, topical requirement, etc.)
AND
4. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Dupixent (dupilumab) include: Known hypersensitivity to Dupixent or any of its excipients, and use of live vaccines with Dupixent]

B. MODERATE TO SEVERE ASTHMA

1. Documented diagnosis of moderate to severe asthma and prescriber has ruled out COPD, acute bronchospasm, or status asthmaticus
AND
2. (a) Documentation of 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
(b) Member has experienced exacerbation(s) or hospitalization(s), within the last 12 months documented by any of the following:

i. TWO (2) 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. Two-fold increase or greater in the dose of systemic corticosteroid treatment for asthma exacerbations
OR

iii. Asthma worsens upon tapering of oral corticosteroid therapy
OR
iv. Mechanical ventilation in the past 12 months
OR
v. Poor symptom control indicated by Asthma Control Questionnaire (ACQ) score consistently greater than 1.5 or Asthma Control Test (ACT) score consistently less than 20
OR
vi. Forced expiratory volume in 1 second (FEV1) < 80% predicted OR FEV1/forced vital capacity (FVC) < 0.80

AND

3. Symptoms inadequately controlled (as documented in criteria above) after an adherent regimen of at least 3 months of the following COMBINATION THERAPY or labeled contraindication or clinical intolerance to the agent(s): 1) High-dose inhaled corticosteroid (or maximally tolerated dose) AND ONE (1) ADDITIONAL ASTHMA CONTROLLER MEDICATION (Long-acting beta- agonists, Leukotriene Receptor Antagonists, inhaled long- acting muscarinic antagonist, Theophylline)- See Appendix
AND
4. Dupixent (dupilumab) will not be used as monotherapy for asthma or concurrently with other monoclonal antibodies typically used to treat asthma: Xolair (omalizumab), Cinqair (reslizumab), Nucala (mepolizumab) or Fasenra (benralizumab), Tezspire (tezepelumab)
AND
5. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Dupixent (dupilumab) include: Known hypersensitivity to Dupixent or any of its excipients, and use of live vaccines with Dupixent]

C. NASAL POLYPOSIS:
1. Member is diagnosed with chronic rhinosinusitis with nasal polyposis
AND
2. Member has a history of sino-nasal surgery or is not eligible for surgery
AND
3. Member has experienced an inadequate response (after 3 consistent months of use) or intolerance to one of the following medications unless contraindicated: preferred formulary intranasal steroids OR preferred formulary oral corticosteroids
AND
4. Member is concurrently receiving treatment with one of the following agents: Intranasal steroids, Oral corticosteroids, Nasal saline irrigations or Antibiotics
AND
5. Prescriber attests that Dupixent (dupilumab) will not be used as monotherapy
AND
6. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Dupixent (dupilumab) include: Known hypersensitivity to Dupixent or any of its excipients, and use of live vaccines with Dupixent]

D. EOSINOPHILIC ESOPHAGITIS:
1. Documented diagnosis of eosinophilic esophagitis (EoE)
AND
2. Prescriber attests member has tried and failed elimination diet therapy for a minimum of 6 weeks
AND
3. Documentation of trial and failure (or labeled contraindication) to BOTH of the following: proton-pump inhibitor and topical glucocorticoids (fluticasone or budesonide)
AND
4. Member weights at least 40kg

AND

5. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Dupixent (dupilumab) include: Known hypersensitivity to Dupixent or any of its excipients, and use of live vaccines with Dupixent]

E. PRURIGO NODULARIS:

1. Documented diagnosis of prurigo nodularis
   AND
2. Documentation that member has widespread disease (greater than or equal to 20 nodular lesions) or has failed to respond to topical or intralesional corticosteroids (minimum of a 6 week trial)
   AND
3. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Dupixent (dupilumab) include: Known hypersensitivity to Dupixent or any of its excipients, and use of live vaccines with Dupixent]

CONTINUATION OF THERAPY:

A. FOR ALL INDICATIONS:

1. Adherence to therapy at least 85% of the time as verified by Prescriber and member's medication fill history (review Rx history for compliance)
   AND
2. (a) MODERATE TO SEVERE ASTHMA: Documentation of significant reduction in corticosteroid dosage or asthma exacerbations
   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
   AND
3. Dupixent (dupilumab) will not be used as monotherapy for asthma or nasal polyps or concurrently with other monoclonal antibodies typically used to treat asthma: Xolair (omalizumab), Cinqair (reslizumab), Nucala (mepolizumab) or Fasenra (benralizumab), Tezspire (tezepelumab)
   AND
4. Prescriber attests or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity

DURATION OF APPROVAL:

Initial authorization: 6 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
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 experience in the management of prurigo nodularis
[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
MODERATETO SEVERE ASTHMA: 6 years of age and older
NASAL POLYPOSIS: 18 years of age and older
EOSINOPHILIC ESOPHAGITIS:12 years of age and older
PRURIGO NODULARIS: 18 years of age and older

QUANTITY:
ATOPIC DERMATITIS:
Adults: 600mg (2x300mg) followed by 300mg every 14 days
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:
Initial dose in 12 years of age and older: 2 syringes [400 (2x200mg) or 600mg (2x300) total] per 14 days; then, 2 syringes (200mg or 300mg) per 28 days – administered every other week.
Initial dose in 6-11 years of age: 15kg to less than 30kg: 100mg every other week or 300mg every 4 weeks, ≥ 30kg 200mg every other week

NASAL POLYPOSIS: 300 mg given every other week.

EOSINOPHILIC ESOPHAGITIS: 300 mg given every week

PRURIGO NODULARIS: initial dose of 600 mg (2x300mg), followed by 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 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 patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP)
- for the treatment of adult and pediatric patients aged 12 years and older, weighing at least 40 kg, with eosinophilic esophagitis (EoE)
- for the treatment of adult patients with prurigo nodularis

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/5mcgMDI

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

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).

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 Dupixent or any of its excipients, and use of live vaccines with Dupixent.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

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

REFERENCES

1. Dupixent (dupilumab) [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals; October 2022
2. 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(24):2335-2348.
3. Schneider L, Tilles S, Lio P, et al. Atopic dermatitis: a practice parameter update 2012. JAllergy Clin Immunol.2013;131:295-299.
4. Sidbury R, et al. Guidelines of care for the management of atopic dermatitis Section 3. Management and treatment with phototherapy and systemic agents. J Am Acad Dermatol. 2014;71(2): 327-349.
5. 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(1):116-132.
6. Wenzel S, Ford L, Pearlman D, et al. Dupilumab in persistent asthma with elevated eosinophil levels.N Engl J Med. 2013;368(26):2455- 2466.
7. Wenzel S, Castro M, Corren J, et al. Dupilumab efficacy and safety in adults with uncontrolled persistent asthma despite use of medium-to-high-dose inhaled corticosteroids plus a long- acting beta-2 agonist: a randomized double-blind placebo controlled pivotal phase 2b dose- ranging trial. Lancet.2016;388:31-44.
8. US National Institutes of Health. In: ClinicalTrials.gov [Internet]. Bethesda(MD): National Library of Medicine (US). 2000- [cited 2016 Nov 16]. Available from: https://www.clinicaltrials.gov/ct2/results?term=dupilumab&Search=Search. Search term: dupilumab.
9. Bachert C, Mannent L, Naclerio RM, et al. Effect of subcutaneous dupilumab on nasal polyp burden in patients with chronic sinusitis and nasal polyposis: a randomized clinical trial. JAMA. 2016;315(5):469-479
10. Juniper EF, O'Byrne PM, Guyatt GH, et al. Development and validation of a questionnaire to measure asthma control. Eur Respir J 1999; 14: 902–907.
11. Nathan RA, Sorkness CA, Kosinski M, et al. Development of the asthma control test: a survey for assessing asthma control. J Allergy Clin Immunol 2004; 113:59–65.
12. Furuta GT, Katzka DA. Eosinophilic Esophagitis. N Engl J Med. 2015 Oct 22;373(17):1640-8. doi: 10.1056/NEJMra1502863. PMID: 26488694; PMCID: PMC4905697.

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION-Notable Revisions: Diagnosis Required Medical Information Continuation of Therapy Duration of Approval Quantity Available Dosage Forms References	Q2 2023
REVISION-Notable Revisions: Required Medical Information Continuation of Therapy Prescriber Requirements Age Restrictions Quantity FDA-Approved Uses	Q4 2022
REVISION-Notable Revisions: Required Medical Information Prescriber Requirements Quantity FDA Approved Uses Appendix	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file