Effective Date: 01/14/2022
Last Approval/Version: 04/2025
Next Review Date: 04/2026
Policy Number: C22067-A

Dupixent (dupilumab), IL Medicaid Only

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 along with state and federal requirements, benefits 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.

A. Moderate to Severe Asthma:
    1. Provider attestation that member has a diagnosis of moderate to severe asthma with ONE of the following:
        a. Eosinophils greater than or equal to 150 cells/microliter with at least one (1) exacerbation requiring an oral corticosteroid burst, ER visit, hospitalization or office visit
        OR

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b. Member is oral corticosteroid dependent
OR
c. Member has a baseline forced expiratory volume (FEV1) that is less than 80% predicted for adults or less than 90% for adolescents

AND

2. Member has had a trial and failure of ONE of the following:
   a. Leukotriene modifier
   OR
   b. Medium to high (or maximally tolerated) inhaled corticosteroid (ICS) plus an additional controller medication
   OR
   c. Maximally tolerated ICS/long-acting beta agonist (LABA) combination

B. Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP):
   1. Provider attestation that member has a confirmed diagnosis of CRSwNP
   AND
   2. Documentation that member's CRSwNP has been inadequately controlled by medical therapy with two (2) of the following:
   Note to reviewer: Prior nasal surgery should be taken into consideration.
      a. Intranasal Corticosteroids
      Note to reviewer: Look back for up to one year for intranasal corticosteroid use.
      OR
      b. Systemic corticosteroids or member has a contraindication or intolerance to systemic corticosteroids
      OR
      c. Nasal nebulized solution of budesonide

C. Atopic Dermatitis (AD):
   1. Prescriber attestation to a diagnosis of moderate to severe AD
   AND
   2. Documentation that member has had a trial and inadequate response to a medium to high potency topical corticosteroid AND one (1) of the following:
      a. Generic immunosuppressant
      OR
      b. Topical calcineurin inhibitor
      OR
      c. Phototherapy
      OR
      d. Phosphodiesterase-4 inhibitor (PDE-4)
      Note to reviewer: Look back for up to one year for topical corticosteroid use and up to two years for additional agent.

D. Eosinophilic Esophagitis (EoE):
   1. Member is at least 1 year of age and weighs at least 15 kg
   AND
   2. Documentation of a diagnosis of EoE confirmed by endoscopic esophageal biopsy showing the presence of eosinophils (greater than or equal to 15 eosinophils per high-power field)
   AND
   3. Documentation that members has had a trial and inadequate response to a generic proton pump inhibitor (esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole) for a minimum of 8 weeks
   Note to reviewer: Look back for up to one year for proton pump inhibitor use.
   AND

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4. Documentation that the member has a failure, intolerance or contraindication to topical glucocorticoids (fluticasone using MDI without a spacer or budesonide administered as an oral slurry)

E. Prurigo Nodularis:
   1. Prescriber attestation to a diagnosis of prurigo nodularis
      AND
   2. Documentation that member has had a trial and inadequate response to one (1) of the following:
      a. Topical corticosteroid
         OR
      b. intralesional corticosteroid
      Note to reviewer: Look back for up to one year for topical corticosteroid use and up to two years for additional agent.
      AND
   3. Prescriber attests (or the clinical reviewer has found) that the member is not having any FDA labeled contraindications that haven't been addressed within the documentation submitted for review

F. Chronic Obstructive Pulmonary Disease (COPD):
   1. Documented diagnosis of chronic obstructive pulmonary disease
      AND
   2. Documentation member has eosinophilic phenotype or predominantly eosinophil-driven disease with blood eosinophil count ≥ 300 cells/mcL [DOCUMENTATION REQUIRED]
      AND
   3. Documentation member has experienced exacerbation(s) or hospitalizations, within the last 12 months as evidenced by either of the following:
      i. Two or more moderate exacerbations that meet three of the following AND no evidence of acidosis:
         a. Dyspnea VAS ≥ 5
         b. Respiratory rate ≥ 24 breaths/min
         c. Heart rate ≥ 95 beats/min
         d. Resting SaO2 < 92% (on room air) and/or change > 3%
         e. CRP ≥ 10 mg/L
         OR
      ii. One or more severe exacerbation that meet three of the following AND there is evidence of new onset or worsening hypercapnia and acidosis:
         a. Dyspnea VAS ≥ 5
         b. Respiratory rate ≥ 24 breaths/min
         c. Heart rate ≥ 95 beats/min
         d. Resting SaO2 < 92% (on room air) and/or change > 3%
         e. CRP ≥ 10 mg/L
      AND
   4. Symptoms are inadequately controlled (as documented in criteria above) after an adherent 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)
      AND
   5. 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

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6. 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. ALL INDICATIONS:

1. Prescriber attestation of positive response to therapy

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

PRESCRIBER REQUIREMENTS:
Asthma: Prescribed by or in consultation with a pulmonologist, allergist, or immunologist
Chronic Rhinosinusitis with Nasal Polyposis: Prescribed by or in consultation with, an allergist, pulmonologist, or otolaryngologist (ENT)
Atopic dermatitis: None
Eosinophilic esophagitis: Prescribed by or in consultation with a gastroenterologist, immunologist, allergist
Prurigo nodularis: Prescribed by or in consultation with an allergist or dermatologist
COPD: Prescribed by or in consultation with an allergist/immunologist or pulmonologist

AGE RESTRICTIONS:
Atopic Dermatitis: Age 6 months of age and older
Moderate to Severe Asthma: Age 6 years of age and older
Eosinophilic Esophagitis: 1 year of age and older
Nasal Polyposis: Age 12 years or age and older
Prurigo Nodularis and COPD: Age 18 years or age and older

QUANTITY: See Illinois Medicaid Drug Formulary or use maximum quantity per FDA label

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:
Monoclonal Antibody

FDA-APPROVED USES:
DUPIXENT (dupilumab): is an interleukin-4 receptor alpha antagonist indicated:

- For the treatment of 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 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 1 year and older, weighing at least 15kg, with eosinophilic esophagitis (EoE).
- for the treatment of adult patients with prurigo nodularis (PN).
- as an add-on maintenance treatment of adult patients with inadequately controlled chronic

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obstructive pulmonary disease (COPD) and an eosinophilic phenotype

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

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Dupixent (dupilumab) are considered experimental/investigational and therefore, will follow Molina's off- label policy. Contraindications to Dupixent (dupilumab) include known hypersensitivity to dupilumab or any of its excipients. Avoid use of live vaccines with Dupixent.

OTHER SPECIAL CONSIDERATIONS:
None

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	N/A

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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REFERENCES

1. Illinois HFS Drugs with Stipulated PA Language per Contract for MCOs 03.01.2025.
2. Illinois Medicaid Preferred Drug List; Effective March 13, 2025.
3. Dupixent (dupilumab) [prescribing information], Tarrytown, NY: Regeneron Pharmaceuticals, Inc., September 2024.

SUMMARY OF REVIEW/REVISIONS	DATE
ANNUAL REVIEW- Notable revisions: Required Medical Information Drug Information Diagnosis Prescriber Requirements Age Restrictions Contraindications/Exclusion/Discontinuation Available Dosage Forms References	04/2025
ANNUAL REVIEW- Notable revisions: Required Medical Information Drug Information FDA-Approved Uses Available Dosage Forms References	04/2024
ANNUAL REVIEW- No coverage criteria changes with this annual review.	04/2023

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