CareSource Rx Innovations

PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Dupixent (dupilumab)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Dupixent was originally approved by the FDA in 2017 for the treatment of moderate to severe atopic dermatitis. Since then, it has also been granted approvals for the treatment of moderate to severe asthma, chronic rhinosinusitis with nasal polyposis, and eosinophilic esophagitis. It is administered by subcutaneous injection.
Dupixent is an interleukin (IL) - 4 receptor alpha antagonist monoclonal antibody. It inhibits the signaling of IL-4 and IL-13 to help combat cytokine-induced inflammatory responses.

Dupixent (dupilumab) will be considered for coverage when the following criteria are met:

Atopic Dermatitis

For **initial** authorization:

1. Member must be 6 months of age or older; AND
2. Medication must be prescribed by a dermatologist, allergist, or immunologist; AND
3. Member has a documented diagnosis of moderate-to-severe atopic dermatitis; AND
4. Member's atopic dermatitis involves 10% or more of the body surface area (BSA) OR involves highly visible or functional areas (e.g., neck, face, genitals, palms) and is significantly impairing quality of life; AND
5. Member has a documented trial and failure of, intolerance, or contraindication to at least one medium to high potency topical corticosteroid for at least 4 weeks. Note: a topical calcineurin inhibitor (e.g., tacrolimus, pimecrolimus) or Eucrisa may also be acceptable.
6. Member has documented trial and failure of, intolerance, or contraindication to one of the following:
   a) At least 8 weeks of phototherapy treatment (i.e., UV-A, UV-B, a combination of both, psoralen plus UV-A (PUVA), or UV-B1 (narrow-band UV-B));
   b) At least 12 weeks of one oral immunomodulatory agent (e.g., cyclosporine, methotrexate, azathioprine).
7. **Dosage allowed/Quantity limit:**
   Adults: Initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every other week.
   Pediatrics 6-17 years:

Body Weight	Initial Loading Dose	Subsequent Doses
15 to less than 30 kg	600 mg (two 300 mg injections)	300 mg every 4 weeks (Q4W)
30 to less than 60 kg	400 mg (two 200 mg injections)	200 mg every other week (Q2W)
60 kg or more	600 mg (two 300 mg injections)	300 mg every other week (Q2W)

Pediatrics 6 months to 5 years:

Body Weight	Initial[a] and Subsequent Dosage
5 to less than 15 kg	200 mg (one 200 mg injection) every 4 weeks (Q4W)
15 to less than 30 kg	300 mg (one 300 mg injection) every 4 weeks (Q4W)

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes demonstrate improvement of signs and symptoms such as fewer flares, less itching/erythema, improved quality of life, etc.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Asthma

For **initial** authorization:

1. Member must be 6 years of age or older; AND
2. Medication must be prescribed by or in consultation with a pulmonologist, immunologist or allergist; AND
3. Member has **one** of the following:
   a) Severe eosinophilic asthma including:
      i) Blood eosinophil count of at least 150 cells/μL; AND
      ii) At least two documented severe asthma exacerbations requiring oral corticosteroids (OCS), or at least one requiring hospitalization, within last year; OR
   b) Oral corticosteroid (OCS) dependent asthma; AND
4. Member's asthma has been inadequately controlled after 3 months of conventional treatment on medium to high doses of inhaled corticosteroids (ICS) and long acting beta 2-agonists (LABA); AND
5. Medication is being used as the add-on maintenance treatment to conventional therapies for asthma (i.e., ICS, LABA, etc.); AND
6. Medication is not used in conjunction with any other biologic therapy for asthma.
7. **Dosage allowed/Quantity limit:**
   Adults and adolescents 12 years of age and older:

Initial Loading Dose	Subsequent Dose
400 mg (two 200 mg injections)	200 mg every 2 weeks (Q2W)
or	
600 mg (two 300 mg injections)	300 mg every 2 weeks (Q2W)
Dosage for patients with oral corticosteroid-dependent asthma or with co-morbid moderate-to-severe atopic dermatitis or adults with co-morbid chronic rhinosinusitis with nasal polyposis	
600 mg (two 300 mg injections)	300 mg every 2 weeks (Q2W)

Pediatric age 6-11 years:

Body Weight	Initial[a] and Subsequent Doses
15 to less than 30 kg	100 mg every other week (Q2W) or 300 mg every four weeks (Q4W)
≥30 kg	200 mg every other week (Q2W)

*No loading dose for this age group

If all the above requirements are met, the medication will be approved for 16 weeks.

For **reauthorization**:
1. Medication is not being used as monotherapy for asthma; AND
2. Chart notes have been provided that show the member has demonstrated improvement during 16 weeks of medication therapy:
   a) Decreased frequency of emergency department visits or hospitalizations due to asthma exacerbations; OR
   b) Increase in percent predicted FEV1 from pretreatment baseline; OR
   c) Improved functional ability (i.e., decreased effect of asthma on ability to exercise, function in school or at work, or quality of sleep); OR
   d) Decreased utilization of rescue medications or oral corticosteroids.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

For **initial** authorization:
1. Member is 18 years old or older; AND
2. Medication must be prescribed by or in consultation with an allergist, immunologist, or otorhinolaryngologist (ENT); AND
3. Member has a diagnosis of severe CRSwNP with at least two of the following symptoms for 12 weeks or more:
   a) Nasal blockage/obstruction/congestion;
   b) Nasal discharge;
   c) Facial pain/pressure;
   d) Reduction in smell; AND
4. Chart notes must show documentation of bilateral nasal polyps by direct examination, endoscopy, or sinus CT scan; AND
5. Member has symptoms of chronic rhinosinusitis after at least a 4-week trial with an intranasal corticosteroid (e.g., mometasone, fluticasone) in combination with nasal saline irrigation AND ALL of the following:
   a) Prior sinonasal surgery;
   b) Systemic corticosteroids (unless not tolerated or contraindicated); AND

6. Medication is used as an add-on maintenance treatment in combination with intranasal corticosteroid, unless not tolerated or contraindicated; AND
7. Member does not have ANY of the following:
   a) Nasal polyp removal surgery within the past 6 months.
   b) Combination use with Xolair or Nucala;
   c) Allergic Fungal rhinosinusitis (AFRS)
8. **Dosage allowed/Quantity limit:** 300 mg every other week. (2 pens/syringes per 28 days)

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Medication is to be used as add-on maintenance therapy in combination with intranasal corticosteroids, unless not tolerated or contraindicated; AND
2. Chart notes have been provided showing improvement of nasal congestion/obstruction symptoms, and/or reduced nasal polyp size.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Eosinophilic Esophagitis (EOE)

For **initial** authorization:
1. Member is at least 12 years of age (and weighs at least 40 kg); AND
2. Medication is prescribed by or in consultation with an allergist, immunologist, otorhinolaryngologist (ENT), or gastroenterologist; AND
3. Member has a diagnosis of EOE confirmed by endoscopy with esophageal biopsy showing ≥15 intraepithelial eosinophils per high-power field (eos/hpf); AND
4. Member has symptoms of dysphagia; AND
5. Trial and failure of at least 2 of the following established 1st line options:
   a) High dose proton pump inhibitor (PPI) for at least 8 and optimally 12 weeks
   b) Topical (swallowed) corticosteroid therapy (i.e., budesonide or fluticasone) for 12 weeks
   c) Dietary modifications.
6. **Dosage allowed/Quantity limit:** 300 mg every week. (4 pens/syringes per 28 days)

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes have been provided documenting at least one of the following:
   a) Histological remission (peak esophageal intraepithelial eosinophil count ≤6 eos/hpf)
   b) Improvement of dysphagia symptom frequency or severity

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Dupixent (dupilumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
06/12/2017	New policy for Dupixent created.
05/22/2019	New indication of Moderate-to-Severe Persistent Asthma added. For Atopic Dermatitis: age requirements expanded (covered for 12 years old members and older); topical corticosteroids use required for at least 3 months; clarification on

	tanning beds for UV exposure entered; step therapy for topical calcineurin inhibitors revised.
10/14/2019	New diagnosis of Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP) was added.
06/05/2020	Age lowered to 6 years old for atopic dermatitis and pediatric dosing table added.
01/12/2021	Persistent Asthma: eosinophil count was updated to be consistent with guidelines; exacerbation number was updated to be consistent with guidelines (2 requiring OCS or 1 requiring hospitalization in the last year); ICS + LTRA treatment removed; requirements despite adherence to therapy removed (i.e. intubation, urgent care visit or hospital admin); changed from not to be used with Nucala, Cinqair, or Fasenra to not to be used with any other asthma biologic. CRSwNP: removed documentation of severity/amount of polyposis; removed "use in the past 2 years" for systemic steroid. Specified 4 weeks of trial for intranasal steroid and added that it must be used with nasal saline. Specified that Dupixent must be used as add-on treatment with intranasal steroid for initial and reauth. Removed list of symptoms of sinusitis. Removed Hep B & C requirement. Specified what improvement looks like for reauth. Reduced the list of exclusion to only ask that member does not have AFRS. Atopic Dermatitis: removed EASI score requirement. Added diagnosis of AD. Added that AD involvement that significantly affects QoL also qualifies for moderate to severe. Reduced topical trials to just one trial of steroid for 4 weeks. Made Eucrisa and TCI optional if member cannot use steroid. Reduced phototherapy trial to 8 weeks. Changed from phototherapy and immunosuppressant to phototherapy OR immunosuppressant. Removed requirement of combination with another biologic. Updated reauth to require specific signs and symptoms of AD improvements. Increased reauth length to 12 months. Updated references.
11/16/2021	Transferred to new template. For asthma, amended minimum age from 12 years to 6 years per recent label update and added dosing information for the new age group.
06/14/2022	Updated min age for atopic dermatitis from 6 years to 6 months and added dosing. Added new indication for diagnosis of EOE.

References:

1. Dupixent [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.: June 2022.
2. Atopic dermatitis clinical guideline (2017). In American Academy of Dermatology. Retrieved from https://www.aad.org/practicecenter/quality/clinical-guidelines/atopic-dermatitis.
3. Eichenfield LF, Tom WL, Chamlin SL et al. Guidelines of care for the management of atopic dermatitis: section 1. Diagnosis and assessment of atopic dermatitis. J Am Acad Dermatol. 2014; 70(1):338-51.
4. 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.
5. Sidbury R, Davis DM, Cohen DE, 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 Aug;71(2):327-49.
6. Deleanu D, Nedelea I. Biological therapies for atopic dermatitis: An update. *Exp Ther Med*. 2019;17(2):1061-1067.
7. Eichenfield LF, Boguniewicz M, Simpson EL, et al. Translating Atopic Dermatitis Management Guidelines Into Practice for Primary Care Providers. *Pediatrics*. 2015;136(3):554-565.
8. Wong ITY, Tsuyuki RT, Cresswell-Melville A, Doiron P, Drucker AM. Guidelines for the management of atopic dermatitis (eczema) for pharmacists. *Can Pharm J (Ott)*. 2017;150(5):285-297.
9. Boguniewicz M, Alexis AF, Beck LA, et al. Expert Perspectives on Management of Moderate-to-Severe Atopic Dermatitis: A Multidisciplinary Consensus Addressing Current and Emerging Therapies. *J Allergy Clin Immunol Pract.* 2017;5(6):1519-1531.
10. Patrizi A, Raone B, Ravaioli GM. Management of atopic dermatitis: safety and efficacy of phototherapy. *Clin Cosmet Investig Dermatol*. 2015;8:511-520.

11. Thaçi D, L Simpson E, Deleuran M, et al. Efficacy and safety of dupilumab monotherapy in adults with moderate-to-severe atopic dermatitis: a pooled analysis of two phase 3 randomized trials (LIBERTY AD SOLO 1 and LIBERTY AD SOLO 2). *J Dermatol Sci*. 2019;94(2):266-275.
12. Simpson EL, Akinlade B, Ardeleanu M. Two Phase 3 Trials of Dupilumab versus Placebo in Atopic Dermatitis. *N Engl J Med*. 2017;376(11):1090-1091.
13. IPD Analytics. New Drug Approval. Dupixent (dupilumab). Available at: http://www.ipdanalytics.com.
14. Difficult-To-Treat & Severe Asthma in Adolescent and Adult Patients: Diagnosis and Management. Global Initiative For Asthma (GINA); Apr. 2019. Available at: https://ginasthma.org/wp-content/uploads/2018/11/GINA-SA-FINAL-wms.pdf
15. 2020 Focused Updates To The Asthma Management Guidelines. National Institute of Health; Dec 2020. Available at: https://www.nhlbi.nih.gov/health-topics/asthma-management-guidelines-2020-updates
16. Stevens WW, Schleimer RP, Kern RC. Chronic Rhinosinusitis with Nasal Polyps. *J Allergy Clin Immunol Pract*. 2016;4(4):565-572. doi:10.1016/j.jaip.2016.04.012.
17. Peters AT, Spector S, Hsu J, et al. Diagnosis and management of rhinosinusitis: a practice parameter update. *Ann Allergy Asthma Immunol*. 2014;113(4):347-85. DOI: 10.1016/j.anai.2014.07.025.
18. Sedaghat AR. Chronic rhinosinusitis. *Am Fam Physician*. 2017;96(8):500.506.
19. 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 [published correction appears in Lancet. 2019 Nov 2;394(10209):1618]. *Lancet*. 2019;394(10209):1638-1650. doi:10.1016/S0140-6736(19)31881-1.
20. Laidlaw TM, Buchheit KM. Biologics in chronic rhinosinusitis with nasal polyposis. *Ann Allergy Asthma Immunol*. 2020;124(4):326-332. doi:10.1016/j.anai.2019.12.001.
21. Orlandi RR, Kingdom TT, Hwang PH, et al. International consensus statement of allergy and rhinology: rhinosinusitis. *Int Forum Allergy Rhinol*. 2016 Feb;6 Suppl 1:S22-209. doi: 10.1002/alr.21695.
22. Fokkens WJ, Lund V, Bachert C, et al. EUFOREA consensus on biologics for CRSwNP with or without asthma. *Allergy*. 2019 Dec;74(12):2312-2319. doi: 10.1111/all.13875.
23. Hirano I, Chan ES, Rank MA, et al. AGA institute and the joint task force on allergy-immunology practice parameters clinical guidelines for the management of eosinophilic esophagitis. *Ann Allergy Asthma Immunol*. 2020;124(5):416-423. doi:10.1016/j.anai.2020.03.020
24. Johnston DT. Examining unmet needs in the management of eosinophilic esophagitis. *Am J Manag Care*. 2021;27(17 Suppl):S311-S318. doi:10.37765/ajmc.2021.88756
25. Hirano I, Dellon ES, Hamilton JD, et al. Efficacy of Dupilumab in a Phase 2 Randomized Trial of Adults With Active Eosinophilic Esophagitis. *Gastroenterology*. 2020;158(1):111-122.e10. doi:10.1053/j.gastro.2019.09.042
26. Feo-Ortega S, Lucendo AJ. Evidence-based treatments for eosinophilic esophagitis: insights for the clinician. *Therap Adv Gastroenterol*. 2022;15:17562848211068665. Published 2022 Jan 19. doi:10.1177/17562848211068665
27. Muir A, Falk GW. Eosinophilic Esophagitis: A Review. *JAMA*. 2021;326(13):1310-1318. doi:10.1001/jama.2021.14920
28. Dhar A, Haboubi HN, Attwood SE, et al. British Society of Gastroenterology (BSG) and British Society of Paediatric Gastroenterology, Hepatology and Nutrition (BSPGHAN) joint consensus guidelines on the diagnosis and management of eosinophilic oesophagitis in children and adults. *Gut*. 2022;71(8):1459-1487. doi:10.1136/gutjnl-2022-327326

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