Dupixent (dupilumab)-Dossier

Maryland Prescription Drug Affordability Board

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MARYLAND
Prescription Drug Affordability Board

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Cost Review Study Dossier - Dupixent (dupilumab)

Introduction

To the extent practicable, and in compliance with COMAR 14.01.04.05B, staff has assembled the data and analyses specified by Health-General Article §21-2C-09(b), Annotated Code of Maryland, and the regulations for consideration by the Board in conducting its cost review study.

Section 1: Background

The table below displays a list of all possible NDC-11 codes associated with Dupixent (proprietary name) and dupilumab (non-proprietary name).[1] The NDC-11 codes were identified by staff through searching the RxNorm database.[2]

Table 1. Dupixent NDC List

National Drug Code	Proprietary Name	Non-Proprietary Name	Dosage-Strength
00024-5911-00	Dupixent	Dupilumab	100 MG/0.67ML
00024-5911-01	Dupixent	Dupilumab	150 MG/ML
00024-5911-02	Dupixent	Dupilumab	100 MG/0.67ML
00024-5911-20	Dupixent	Dupilumab	100 MG/0.67ML
00024-5914-00	Dupixent	Dupilumab	150 MG/ML
00024-5914-01	Dupixent	Dupilumab	300 MG/2ML
00024-5914-02	Dupixent	Dupilumab	300 MG/2ML
00024-5914-20	Dupixent	Dupilumab	150 MG/ML
00024-5915-00	Dupixent	Dupilumab	300 MG/2ML
00024-5915-01	Dupixent	Dupilumab	300 MG/2ML
00024-5915-02	Dupixent	Dupilumab	300 MG/2ML
00024-5915-20	Dupixent	Dupilumab	300 MG/2ML
00024-5916-01	Dupixent	Dupilumab	300 MG/2ML
00024-5918-00	Dupixent	Dupilumab	175 MG/ML
00024-5918-01	Dupixent	Dupilumab	200 MG/1.14ML
00024-5918-02	Dupixent	Dupilumab	200 MG/1.14ML
00024-5918-20	Dupixent	Dupilumab	175 MG/ML
00024-5919-00	Dupixent	Dupilumab	200 MG/1.14ML
00024-5919-01	Dupixent	Dupilumab	200 MG/1.14ML
00024-5919-02	Dupixent	Dupilumab	200 MG/1.14ML
00024-5919-20	Dupixent	Dupilumab	200 MG/1.14ML

[1] The standard practice in published literature is to refer to drugs by the name of the molecule rather than the brand name of the drug. Staff has retained that convention. As a result, when discussing literature, Dupixent is referred to as dupilumab.

[2] https://www.nlm.nih.gov/research/umls/rxnorm/index.html. This list contains NDCs for products that are discontinued, and products that are not sold commercially—such as sample product NDCs, NDCs owned by repackagers and relabelers, and NDCs that contain only the active ingredient. In the interest of completeness, these NDCs are included in the dossier.

Section 2: Clinical Information

Factor 2.1: Clinical information, including FDA indications and doses and information concerning standard medical practice.

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(i)
Methodology: Literature review
Data Sources: U.S. Food & Drug Administration (FDA) labels and clinical guidelines

Summary of Clinical Information

Table 2a. Dupixent® (dupilumab): FDA approved indications and associated dosing regimen(s)[3]

Indication	*Dosing Regimen(s)*	*Estimated Annual Use*
Atopic dermatitis • Moderate to severe • Inadequately controlled on or not advisable for topical prescription therapies • May be used with or without topical corticosteroids	**Route: subcutaneous injection for all indications** **Adults** 600mg (300mg syringe x 2) loading dose, then 300mg every 2 weeks **Pediatrics** **6 months to 5 years** **Initial & maintenance dosing** • 5 to <15 kg: 200mg every 4 weeks • 15kg to <30kg: 300mg every 4 weeks **6 years & older** • 15kg to <30kg: 600mg loading dose, then 300mg every 4 weeks • 30kg to <60kg: 400mg loading dose, then 200mg every 2 weeks • ≥60kg: 600mg loading dose, then 300mg every 2 weeks	**Available dosage forms & strengths** Single-dose pre-filled syringe w/ needle shield OR single-dose pre-filled pen • 300mg/2mL (150mg/mL) • 200mg/1.14mL (175mg/mL) **Adult annual use:** 1 loading dose (300mg x2) + 25 doses of 300mg = 27 doses of 300mg **Pediatric annual use:** **6 months to 5 years:** • 5 to <15kg: 13 doses of 200mg • 15 to <30kg: 13 doses of 300mg **6 years & older** • 15kg to <30kg: 14 doses of 300mg • 30kg to <60kg: 27 doses of 200mg

[3] Dupixent. Tarrytown (NY): Regeneron Pharmaceuticals Inc.; 2025 Jun. Package Insert. NDC 0024-5914-00.

		• ≥60kg: 27 doses of 300mg
Asthma • Add-on maintenance treatment • Moderate to severe • Characterized by eosinophilic phenotype or with oral corticosteroid dependent asthma • Not for the relief of acute bronchospasm or status asthmaticus	**Adults and pediatric patients ≥12 years of age** • 400mg loading dose, then 200mg every 2 weeks OR • 600mg loading dose, then 300mg every 2 weeks Oral corticosteroid dependent asthma or co-morbid moderate-to-severe atopic dermatitis or adults with co-morbid chronic rhinosinusitis with nasal polyps • 600mg loading dose, then 300mg every 2 weeks **Pediatric patients 6 to 11 years of age** **Initial & maintenance dosing** • 15kg to <30kg: 300mg every 4 weeks • ≥30kg: 200mg every 2 weeks Asthma and co-morbid moderate-to-severe atopic dermatitis, follow recommended pediatric dosing for atopic dermatitis, which includes a separate initial loading dose	**Adults and pediatric patients ≥12 years of age** • 27 doses of either 200mg or 300mg **Pediatric patients 6 to 11 years of age** • 15kg to <30kg: 13 doses of 300mg • ≥30kg: 26 doses of 200mg
Chronic rhinosinusitis with nasal polyps (CRSwNP) • Add-on maintenance treatment • Inadequately controlled chronic rhinosinusitis with nasal polyps	**Adults and pediatric patients ≥12 years of age** • 300mg every 2 weeks	26 doses of 300mg
Eosinophilic esophagitis	**Adults and pediatric patients ≥1 year of age & weight ≥15kg**	• 15kg to <30kg: 26 doses of 200mg

	• 15kg to <30kg: 200mg every 2 weeks • 30kg to <40kg: 300mg every 2 weeks • ≥40kg: 300mg every week	• 30kg to <40kg: 26 doses of 300mg • ≥40kg: 52 doses of 300mg
Prurigo nodularis	**Adults** • 600mg loading dose, then 300mg every 2 weeks	• 27 doses of 300mg
Chronic Obstructive Pulmonary Disease (COPD) • Add-on maintenance treatment • Inadequately controlled chronic obstructive pulmonary disease and an eosinophilic phenotype	**Adults** • 300mg every 2 weeks	• 26 doses of 300mg
Chronic spontaneous urticaria • Remain symptomatic despite H1 antihistamine treatment • Not indicated for other forms of urticaria	**Adults** • 600mg loading dose, then 300mg every 2 weeks **Pediatric patients 12 to 17 years of age** • 30kg to <60kg: 400mg loading dose, then 200mg every 2 weeks • ≥60kg: 600mg loading dose, then 300mg every 2 weeks	**Adults** • 27 doses of 300mg **Pediatric patients 12 to 17 years of age** • 30kg to <60kg: 27 doses of 200mg • ≥60kg: 27 doses of 300mg
Bullous pemphigoid	**Adults** • 600mg loading dose, then 300mg every 2 weeks • Use in combination with tapering course of oral corticosteroids, then continue Dupixent as monotherapy	• 27 doses of 300mg

Pharmacologic Class

Interleukin-4 (IL-4) receptor-α antagonist

Dupixent is a fully human immunoglobulin G subclass 4 (IgG4) monoclonal antibody which binds to IL-4 receptor-α blocking the binding of cytokines IL-4 and IL-13, thereby preventing further downward inflammatory signaling. IL-4 and IL-13 drive key features of Type 2 inflammation, including IgE, mucus production, eosinophil recruitment, and fractional exhaled nitric oxide (FeNO). Type 2 inflammation occurs in a substantial subset of moderate to severe asthma. This inflammatory pathway is also a significant driver of atopic dermatitis, chronic rhinosinusitis with nasal polyps and allergic rhinitis. Notably, Dupixent neutralizes targeted cytokines without inhibiting immune cells, avoiding general immunosuppression.[4]

Standard Medical Practice Recommendations

Dupixent® (dupilumab) Place in Therapy for Atopic Dermatitis

Atopic dermatitis (AD) is a chronic inflammatory skin condition causing intense pruritus (itching) in most individuals with the disease. Pruritus is difficult to control and is frequently the most burdensome symptom, additional symptoms are skin lesions and appearance, skin pain, and sleep disturbances.[5]

Treatment mainstays of AD are topical treatments including bland moisturizers, topical corticosteroids, topical calcineurin inhibitors, and topical phosphodiesterase 4 inhibitors. When escalation is needed for moderate to severe AD refractory to topical treatments, systemic therapy is added. Systemic treatment preference recommendations vary depending upon the guideline utilized, however options with strong or conditional recommendation in favor of use include biologics of Dupixent or tralokinumab, small molecule immunosuppressants of JAK inhibitors (abrocitinib, baricitinib or upadacitinib), cyclosporine, mycophenolate, or methotrexate and phototherapy.[6,7]

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[4] Ameer OZ, Mansour GK, Al-Amoudi RS, Abu-Owaimer FM. Exploring dupilumab for asthma: from mechanistic insights to clinical outcomes, safety, and cost-effectiveness. Front Pharmacol. 2025 Aug 6;16:1631321. doi: 10.3389/fphar.2025.1631321. PMID: 40843371; PMCID: PMC12364877.

[5] Atopic dermatitis (eczema) guidelines: 2023 American Academy of Allergy, Asthma and Immunology/American College of Allergy, Asthma and Immunology Joint Task Force on Practice Parameters GRADE– and Institute of Medicine–based recommendations. Chu, Derek K. et al. Annals of Allergy, Asthma & Immunology, Volume 132, Issue 3, 274 - 312

[6] Joint Task Force on Practice Parameters GRADE– and Institute of Medicine–based recommendations. Chu, Derek K. et al. Annals of Allergy, Asthma & Immunology, Volume 132, Issue 3, 274 - 312

[7] Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. Davis, Dawn M.R. et al. Journal of the American Academy of Dermatology, Volume 90, Issue 2, e43 - e56

Clinical use in AD Key Takeaway: Dupixent is appropriate for moderate to severe AD refractory to topical therapies or when topical therapies are not advisable in individual patients. Dupixent is one option of many second line agents available; clinicians tend to prefer Dupixent or other biologics due to efficacy with minimal associated side effects (as compared to broader immunosuppressive therapies with more potential toxicity and monitoring requirements).[8,9]

Dupixent® (dupilumab) Place in Therapy for Chronic Obstructive Pulmonary Disease (COPD)

Chronic obstructive pulmonary disease (COPD) is a heterogeneous lung condition represented by chronic respiratory symptoms including cough, dyspnea, sputum production, and/or exacerbations, resulting from abnormalities of the airways and/or alveoli that causes persistent, usually progressive airflow obstruction.

COPD treatment mainstays are inhaled long-acting beta agonists (LABA), inhaled long-acting antimuscarinics (LAMA) and inhaled corticosteroids (ICS). These agents are recommended to be used in combination based on a patient's history of dyspnea (shortness of breath) and exacerbations (events of dyspnea and/or cough and sputum that worsen over <14 days) and blood eosinophil count.

In patients with continued symptoms and/or exacerbations of COPD on ICS+LAMA+LABA, additional therapy may be considered based on specific factors. For those individuals who are no longer smoking, azithromycin may be considered. For individuals with a forced expiratory volume in 1 second (FEV1) <50%, chronic bronchitis and a history of a severe exacerbation, roflumilast may be considered. For individuals with an eosinophil count ≥300 cells/μL and chronic bronchitis, Dupixent may be considered.

Clinical use in COPD Key Takeaway: Dupixent in COPD is considered an add-on therapy to standard therapy of ICS + LABA + LAMA in patients who also have chronic bronchitis, a history of 2 or more moderate exacerbations or 1 or more severe exacerbations in the prior year and an eosinophil count ≥300 cells/μL.[10]

[8] Dupixent. Tarrytown (NY): Regeneron Pharmaceuticals Inc.; 2025 Jun. Package Insert. NDC 0024-5914-00.
[9] Atopic dermatitis (eczema) guidelines: 2023 American Academy of Allergy, Asthma and Immunology/American College of Allergy, Asthma and Immunology Joint Task Force on Practice Parameters GRADE– and Institute of Medicine–based recommendations Chu, Derek K. et al. Annals of Allergy, Asthma & Immunology, Volume 132, Issue 3, 274 - 312
[10] Venkatesan P. GOLD COPD report: 2025 update. Lancet Respir Med. 2025 Jan;13(1):e7-e8. doi: 10.1016/S2213-2600(24)00413-2. Epub 2024 Dec 5. PMID: 39647487.

Dupixent ® (dupilumab) Place in Therapy for Asthma

Asthma is a heterogeneous disease of the airways, usually with chronic airway inflammation and variable expiratory airflow limitations. Respiratory symptoms, including wheezing, shortness of breath, cough and chest tightness, vary over time and in intensity.

After optimization of existing therapy (ICS + LABA), including assessment of adherence and correct inhaler technique, treatment of modifiable risk factors and comorbidities, add-on therapy may be considered. Add-on therapy options include LAMA, leukotriene receptor antagonists (LTRA), low-dose azithromycin in adults and biologic agents. Biologic agent classes for severe asthma include anti-IgE (omalizumab), anti-IL5/anti-IL5R (benralizumab, mepolizumab, reslizumab), anti-IL4Rα (Dupixent) and anti-TSLP (tezepelumab). Generally, non-biologic therapies are recommended prior to initiation of biologic agents, except for oral corticosteroids (OCS) recommended as last line option. In clinical practice, OCS are used more frequently than guidelines recommend due to efficacy and ease of access. Biologic agent use is driven by targeting the same patient population as derived benefit in clinical trials. These patient populations differ amongst biologic agents, thereby limiting the ability to determine superiority. In practice, matching individual patient factors such as exacerbation history, eosinophil count, IgE serum levels and affordability (insurance coverage criteria) decide biologic agent use. Due to the complexity of treatment options for specific patient populations, referral to an asthma specialist and specialized testing is strongly advised.[11]

Clinical use in Asthma Key Takeaway: Dupixent may be considered as add-on therapy for severe eosinophilic or Type 2 asthma uncontrolled on high-dose ICS-LABA OR requiring maintenance oral corticosteroids. Dupixent should be avoided in patients with current or past blood eosinophils >/= 1500/mL.[12]

Dupixent® (dupilumab) Place in Therapy for CRSwNP

Chronic rhinosinusitis with nasal polyps is an inflammatory disease of the nasal mucosa and sinuses that lasts at least 12 weeks. Nasal polyps are present, distinguishing it from chronic rhinosinusitis without nasal polyps. Symptoms include loss of smell, nasal obstruction, thick nasal drainage, and facial pressure. These symptoms negatively affect quality of life though reduced sleep, productivity, and exercise. Many individuals with CRSwNP have asthma due to

[11] Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2024. Updated May 2024. Available from: www.ginasthma.org
[12] Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2024. Updated May 2024. Available from: www.ginasthma.org

shared underlying inflammatory pathways; therefore, treatment options are generally overlapping for both diseases.[13]

Current guidelines for the management of CRSwNP conditionally recommend biologic therapy, including Dupixent, omalizumab, or mepolizumab, as one option to be considered amongst intranasal corticosteroids, surgery, saline rinse, antibiotics, and aspirin therapy after desensitization [specially for individuals with aspirin (nonsteroidal anti-inflammatory)-exacerbated respiratory disease]. Choice of treatment is highly individualized including disease burden/severity, comorbid disease, access to treatments, and patient preference.[14]

Clinical use in CRSwNP Key Takeaway: Dupixent is an add-on maintenance treatment to intranasal corticosteroids for inadequately controlled CRSwNP.[15]

[13] The Joint Task Force on Practice Parameters GRADE guidelines for the medical management of chronic rhinosinusitis with nasal polyposis. Rank, Matthew A. et al. Journal of Allergy and Clinical Immunology, Volume 151, Issue 2, 386 - 398

[14] The Joint Task Force on Practice Parameters GRADE guidelines for the medical management of chronic rhinosinusitis with nasal polyposis. Rank, Matthew A. et al. Journal of Allergy and Clinical Immunology, Volume 151, Issue 2, 386 - 398

[15] Dupixent. Tarrytown (NY): Regeneron Pharmaceuticals Inc.; 2025 Jun. Package Insert. NDC 0024-5914-00.

Dupixent® (dupilumab) Place in Therapy for Eosinophilic Esophagitis (EoE)

Eosinophilic Esophagitis (EoE) is a chronic Type-2 inflammatory disease caused by allergens interacting with damaged esophageal tissue with resultant pathogenic eosinophils causing inflammation, remodeling, and fibrosis. It is diagnosed by the presence of symptoms of esophageal dysfunction, such as, but not exhaustive, dysphagia (difficulty swallowing), food impaction, heartburn, chest pain, food refusal, abdominal pain, regurgitation, and vomiting, and at least 15 eosinophils per high powered field on esophageal biopsy. First-line pharmacotherapy treatment for EoE includes high-dose proton pump inhibitors (PPIs) and swallowed topical steroids budesonide or fluticasone. Currently, Dupixent is considered step-up therapy by guidelines, suggested to be used in individuals at least 1 year of age non-responsive to PPI therapy.[16]

Clinical use in EoE Key Takeaway: Dupixent is step-up therapy for eosinophilic esophagitis in individuals at least 1 year of age or older non-responsive to PPI therapy.[17]

Dupixent® (dupilumab) Place in Therapy for Bullous Pemphigoid (BP)

Bullous pemphigoid (BP) is the most common autoimmune subepidermal blistering disease of the skin and mucous membranes. Most affected individuals are older than 70 years of age and symptoms include cutaneous lesions, either localized or nonlocalized, and itching, varying in intensity.[18] First line therapy options are potent or super potent topical corticosteroids and oral corticosteroids. Alternate therapy for cases refractory to high-dose oral prednisone includes immunosuppressive agents (azathioprine, methotrexate, and mycophenolate) and biologics (omalizumab, rituxamab, and Dupixent).[19] The most recent guidelines for bullous pemphigoid predate the FDA-approval of Dupixent for bullous pemphigoid (approved June 2025), limiting current guidance for the use of Dupixent relative to other historical therapies.[20]

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[16] Dellon ES, Muir AB, Katzka DA, Shah SC, Sauer BG, Aceves SS, Furuta GT, Gonsalves N, Hirano I. ACG Clinical Guideline: Diagnosis and Management of Eosinophilic Esophagitis. Am J Gastroenterol. 2025 Jan 1;120(1):31-59. doi: 10.14309/ajg.0000000000003194. Epub 2025 Jan 2. PMID: 39745304.
[17] Dellon ES, Muir AB, Katzka DA, Shah SC, Sauer BG, Aceves SS, Furuta GT, Gonsalves N, Hirano I. ACG Clinical Guideline: Diagnosis and Management of Eosinophilic Esophagitis. Am J Gastroenterol. 2025 Jan 1;120(1):31-59. doi: 10.14309/ajg.0000000000003194. Epub 2025 Jan 2. PMID: 39745304.
[18] Borradori L, et al. Updated S2 K guidelines for the management of bullous pemphigoid initiated by the European Academy of Dermatology and Venereology (EADV). J Eur Acad Dermatol Venereol. 2022 Oct;36(10):1689-1704. doi: 10.1111/jdv.18220. Epub 2022 Jun 29. PMID: 35766904.
[19] Borradori L, et al. Updated S2 K guidelines for the management of bullous pemphigoid initiated by the European Academy of Dermatology and Venereology (EADV). J Eur Acad Dermatol Venereol. 2022 Oct;36(10):1689-1704. doi: 10.1111/jdv.18220. Epub 2022 Jun 29. PMID: 35766904.
[20] Dermatology Times. FDA Approves Dupilumab, First and Only Targeted Medicine for Bullous Pemphigoid. June 20, 2025. https://www.dermatologytimes.com/view/fda-approves-dupilumab-first-and-only-targeted-medicine-for-bullous-pemphigoid.

Clinical use in BP Key Takeaway: Dupixent is indicated to treat bullous pemphigoid in combination with a tapering dose of oral corticosteroids. After oral corticosteroids are tapered off, Dupixent may be continued as monotherapy.[21]

Dupixent® (dupilumab) Place in Therapy for Chronic Spontaneous Urticaria

Chronic spontaneous urticaria (CSU) is a subtype of chronic urticaria and defined as the spontaneous appearance of hives, angioedema, or both for >6 weeks caused by known or unknown causes. First-line treatment for urticaria, regardless of type, is second generation H1-antihistamines, such as loratadine, fexofenadine, cetirizine and levocetirizine, often dosing exceeds standard dosing by 4 times for full effectiveness.[22] Alternative therapies, if second generation H1-antihistamines are ineffective, include omalizumab preferentially followed by systemic (by mouth) corticosteroids. Systemic corticosteroids, particularly of long duration, are avoided due to potential for serious side effects.[23] In April 2025, Dupixent was approved for CSU in adults and children ≥12 years old who remain symptomatic on H1-antihistamine treatment.[24] Given the recent approval, there are no guidelines as of this writing to guide Dupixent place therapy compared to traditional pharmacotherapies, such as omalizumab.

Clinical use in CSU Key Takeaway: Dupixent is a second-line treatment option for CSU in adults and children ≥12 years old who remain symptomatic on H1-antihistamines.

Dupixent® (dupilumab) Place in Therapy for Prurigo Nodularis (PN)

Prurigo Nodularis (PN) is a clinical disease defined by chronic pruritus along with multiple localized or generalized elevated, firm and nodular lesions. Treatment options include topical glucocorticoids, intralesional steroid injections, topical calcineurin inhibitors as well as Dupixent

[21] Dupixent. Tarrytown (NY): Regeneron Pharmaceuticals Inc.; 2025 Jun. Package Insert. NDC 0024-5914-00.
[22] Zuberbier T, Abdul Latiff AH, Abuzakouk M, et al. The international EAACI/GA²LEN/EuroGuiDerm/APAAACI guideline for the definition, classification, diagnosis, and management of urticaria. *Allergy*. 2022; 77: 734–766. doi:**10.1111/all.15090**
[23] Zuberbier T, Abdul Latiff AH, Abuzakouk M, et al. The international EAACI/GA²LEN/EuroGuiDerm/APAAACI guideline for the definition, classification, diagnosis, and management of urticaria. *Allergy*. 2022; 77: 734–766. doi:**10.1111/all.15090**
[24] Sanofi. Press Release: Dupixent approved in the US as the first new targeted therapy in over a decade for chronic spontaneous urticaria. April 18 2025. https://www.sanofi.com/en/media-room/press-releases/2025/2025-04-18-15-15-00-3064131

first-line for cases not controlled by local therapies.[25] Dupixent is the first FDA approved therapy for PN.[26]

Clinical use in PN Key Takeaway: Dupixent is the only FDA approved treatment for PN in adults. Clinically, it is recommended first-line for cases not controlled by local therapies such as topical glucocorticoids and topical calcineurin inhibitors.

[25] Zhang L, et al. Guidelines for the diagnosis and treatment of prurigo nodularis. Chin Med J (Engl). 2025 Nov 20;138(22):2859-2861. doi: 10.1097/CM9.0000000000003732. Epub 2025 Sep 16. PMID: 40958763; PMCID: PMC12634264.
[26] US Food and Drug Administration. FDA approves first treatment for prurigo nodularis https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-first-treatment-prurigo-nodularis

Factor 2.2: The disease burden of the condition that is treated by the prescription drug product

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(ii)
Methodology: Literature review
Data Sources: Medical literature and clinical guidelines

Summary of Clinical Impact

Atopic Dermatitis (AD)

Prevalence & Incidence

- As of 2021, an estimated 187,347 or 3.17% of Marylanders of all ages have atopic dermatitis.[27]
- In 2021, the incidence was 18,077 Marylanders or 0.06%.[28]

Disease Severity

- Atopic dermatitis (AD) is a chronic inflammatory skin condition causing intense pruritus (itching) in most individuals with the disease. Pruritus is difficult to control and is frequently the most burdensome symptom, additional symptoms are skin lesions, scaly appearance, and skin pain. A consensus standard for diagnosis does not exist and there are more than 180 different ways to classify AD; descriptions are mild, moderate, or severe. Burden of the disease varies with moderate to severe cases experiencing daily itch, some with itch more than 18 hours per day and associated sleep disturbance. Frequently individuals with AD report activity limitations, self-consciousness about skin appearance and avoidance of social interactions.[29]

[27] Institute for Health Metrics and Evaluation (IHME), 2021. Global Burden of Disease Collaborative Network. Global Burden of Disease Study 2021 (GBD 2021) Results. Seattle, United States. Available at https://vizhub. healthdata.org/gbd-results
[28] Institute for Health Metrics and Evaluation (IHME), 2021. Global Burden of Disease Collaborative Network. Global Burden of Disease Study 2021 (GBD 2021) Results. Seattle, United States. Available at https://vizhub. healthdata.org/gbd-results
[29] Atopic dermatitis (eczema) guidelines: 2023 American Academy of Allergy, Asthma and Immunology/American College of Allergy, Asthma and Immunology Joint Task Force on Practice Parameters GRADE– and Institute of Medicine–based recommendations. Chu DK. et al. Annals of Allergy, Asthma & Immunology, Volume 132, Issue 3, 274 - 312

Cost of Illness/Financial Impact

- A retrospective study of US adults found adjusted total all-cause healthcare costs in 2018 were $2,687 higher for adults with atopic dermatitis compared to controls. Adjusted all-cause prescription costs were $5,592 higher for adults with atopic dermatitis.[30]
- In 2006, the estimated annual cost of AD in the US across all individuals was $4.228 billion, of which $1.006 billion was direct costs.[31]

Morbidity

- In Maryland in 2021, disability-adjusted life years for AD were 7,966 (range 4,129 to 13,124); percentage 0.36 (range 0.20-0.57).[32]

Mortality

- There is no substantiated, reliable data to associate atopic dermatitis as an underlying cause of death as of this writing.

Chronic Obstructive Pulmonary Disease (COPD)

Prevalence

- As of 2022, an estimated 11.7 million (4.6%) adults in the United States (US) have diagnosed COPD.[33]
- As of 2022, 6% of US adults responded affirmatively that a healthcare professional told them they have COPD, emphysema, or chronic bronchitis.[34]
- In Maryland, the total percentage of adults aged 18 years or older with diagnosed COPD was 5.6% in 2023 (95% confidence interval 5-6.1%).[35]

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[30] Manjelievskaia J, et al. The direct and indirect costs of adult atopic dermatitis. J Manag Care Spec Pharm. 2021 Oct;27(10):1416-1425. doi: 10.18553/jmcp.2021.27.10.1416. PMID: 34595952; PMCID: PMC10391209.

[31] The Burden of Atopic Dermatitis: Summary of a Report for the National Eczema Association. Drucker, Aaron M. et al. Journal of Investigative Dermatology, Volume 137, Issue 1, 26 – 30.

[32] Institute for Health Metrics and Evaluation (IHME), 2021. Global Burden of Disease Collaborative Network. Global Burden of Disease Study 2021 (GBD 2021) Results. Seattle, United States. Available at https://vizhub. healthdata.org/gbd-results

[33] American Lung Association. COPD Trends Brief: Prevalence [Internet]. Chicago, IL: American Lung Association; 2025. Available from: https://www.lung.org/research/trends-in-lung-disease/copd-trends-brief/copd-prevalence

[34] Centers for Disease Control and Prevention. National Trends in COPD [Internet]. Atlanta, GA: National Center for Chronic Disease Prevention and Health Promotion; 2024. Available from: https://www.cdc.gov/copd/php/case-reporting/national-trends-in-copd.html

[35] 2023 Maryland Behavioral Risk Factor Surveillance System, accessed at https://ibis.health.maryland.gov

Incidence

- The age-adjusted incidence rate of COPD in adults age ≥50 years was 700.5 per 100,000 person-years in 2020, a decline from 1031.1 per 100,000 person-years in 2000.[36]
- COPD rates have been stable among adults from 2011-2022.[37]

Disease Severity

- COPD is a collective term encompassing lung conditions which cause obstruction of air flow, interfering with breathing. Emphysema and chronic bronchitis are the most important diseases of COPD.[38] The severity of airflow obstruction, ranging from mild, moderate, severe or very severe, is based on the forced expiratory volume in 1 second (FEV1) as a percentage of the predicted value. As the severity of the disease increases, the associated burdens, including hospitalizations for exacerbations, ambulatory oxygen requirements and costs increase directly and strikingly.[39]

Cost of Illness/Financial Impact

- In 2019 in the US, COPD-attributable medical costs, after adjustment for demographic characteristics and 19 concurrent conditions, were $31.3 billion.[40]
- In the US, direct annual medical cost of COPD among adults aged ≥45 years is $24 billion, comprised of $11.9 billion in prescription drug costs, $6.3 billion inpatient costs, $2.4 billion office-based costs, $1.6 billion home health costs, $900 million emergency care costs, and $800 outpatient costs.[41]

[36] Meng Y, Ji Q, Zhang A, Zhan Y. Trends in the prevalence and incidence of chronic obstructive pulmonary disease among adults aged ≥50 years in the United States, 2000-2020. Chronic Dis Transl Med. 2024 May 31;10(4):302-311. doi: 10.1002/cdt3.135. PMID: 39429487; PMCID: PMC11483547.
[37] Centers for Disease Control and Prevention. National Trends in COPD [Internet]. Atlanta, GA: National Center for Chronic Disease Prevention and Health Promotion; 2024 [cited 2025 Aug 20]. Available from: https://www.cdc.gov/copd/php/case-reporting/national-trends-in-copd.html
[38] American Lung Association. COPD Trends Brief [Internet]. Chicago, IL: American Lung Association; 2025 [cited 2025 August 20]. Available from: https://www.lung.org/research/trends-in-lung-disease/copd-trends-brief
[39] Venkatesan P. GOLD COPD report: 2025 update. Lancet Respir Med. 2025 Jan;13(1):e7-e8. doi: 10.1016/S2213-2600(24)00413-2. Epub 2024 Dec 5. PMID: 39647487.
[40] National and Local Direct Medical Cost Burden of COPD in the United States From 2016 to 2019 and Projections Through 2029. Mannino, David M. et al. CHEST, Volume 165, Issue 5, 1093 – 1106.
[41] American Lung Association. COPD Trends Brief: Burden [Internet]. Chicago, IL: American Lung Association; 2025 [cited 2025 August 21]. Available from: https://www.lung.org/research/trends-in-lung-disease/copd-trends-brief/copd-burden

- In Maryland in 2019, medical treatment cost for COPD in adults aged ≥18 years was estimated at $1.677 billion in total and per capita $6,015 (95% confidence interval, $5990 - $6040), comprising an estimated treatment population of 278,847 adults.[42]

Morbidity

- In Maryland in 2021, hospitalizations for COPD as any diagnosis for Medicare beneficiaries aged ≥ 65 years was 47.74 cases per 1,000 (95% CI 47.26 to 48.23).[43]
- In Maryland in 2021, hospitalizations for COPD as the principal diagnosis for Medicare beneficiaries aged ≥ 65 years was 4.06 cases per 1,000 (95% CI 3.92 to 4.2).[44]

Mortality

- In Maryland in 2021 for adults aged ≥ 45 years, mortality from COPD as the underlying cause was 66.6 cases per 100,000 (95% CI 63.4 to 69.8)[45]
- In Maryland in 2021for adults aged ≥ 45 years, mortality from COPD as the underlying or contributing cause was 203.9 cases per 100,000 (95% CI 198.3 to 209.4)[46]

Asthma

Prevalence & Incidence

- The national rate of asthma in 2024 among adults was 8.6% and the rate among children <18 years of age was 6.5%.[47]
- In Maryland in 2023, the rate of physician-diagnosed asthma in adults at least 18 years of age was 16.4% (95% CI 15.5 - 17.4%).[48]
- In Maryland in 2023, the rate of current doctor diagnosed asthma in adults at least 18 years of age was 10.8% (95% CI 10.0 to 11.6%).[49]

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[42] National and Local Direct Medical Cost Burden of COPD in the United States From 2016 to 2019 and Projections Through 2029. Mannino, David M. et al. CHEST, Volume 165, Issue 5, 1093 – 1106. Supplementary data.
[43] 2021 Centers for Disease Control and Prevention Division of Population Health Chronic Disease Indicators, accessed at https://www.cdc.gov/cdi
[44] 2021 Centers for Disease Control and Prevention Division of Population Health Chronic Disease Indicators, accessed at https://www.cdc.gov/cdi
[45] 2021 Centers for Disease Control and Prevention Division of Population Health Chronic Disease Indicators, accessed at https://www.cdc.gov/cdi
[46] 2021 Centers for Disease Control and Prevention Division of Population Health Chronic Disease Indicators, accessed at https://www.cdc.gov/cdi/
[47] Centers for Disease Control and Prevention. National Center for Health Statistics. Asthma. https://www.cdc.gov/nchs/fastats/asthma.htm
[48] 2023 Maryland Behavioral Risk Factor Surveillance System, accessed at https://ibis.health.maryland.gov
[49] 2023 Maryland Behavioral Risk Factor Surveillance System, accessed at https://ibis.health.maryland.gov

- In Maryland in 2021, the rate of child current asthma was 6.8% (95% CI 5.6 to 8.2%)[50]

Disease Severity

- Asthma severity definitions vary by international guideline. According to the Global Initiative for Asthma (a widely utilized guideline in the US), asthma disease severity is based on a retrospective review of how difficult it is to treat an individual's asthma. Mild asthma is well controlled on low-intensity treatment (low-dose ICS + as needed SABA or as needed low-dose ICS+formoterol). Moderate asthma is well controlled on low or medium-dose ICS+LABA and severe asthma is uncontrolled despite high-dose ICS+LABA or requiring high-dose ICS+LABA to remain controlled.[51]

Cost of Illness/Financial Impact

- In Maryland, the estimated 20-year costs associated with uncontrolled vs controlled asthma are excess direct costs of $3.474 billion, excess indirect costs $12.858 billion and excess QALYs lost 176,601; per capita excess direct costs $950.71, excess indirect costs $3114.06 and excess QALYs lost 0.0483.[52]

Morbidity

- In 2020, the national rate of emergency department visits with asthma as the primary cause was 271 per 100,000 people.[53]
- In 2020, the national rate of inpatient hospitalizations with asthma as the first-listed diagnosis was 2.9 per 10,000 population.[54]

Mortality

- The national rate of death in 2023 from asthma was 1.1 per 100,000 persons.[55]

[50] Centers for Disease Control and Prevention. 2021 Child Asthma Data: Prevalence Tables. https://www.cdc.gov/asthma/brfss/2021/child/tableC1.html
[51] Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2024. Updated May 2024. Available from: www.ginasthma.org
[52] Yaghoubi M, Adibi A, Safari A, FitzGerald JM, Sadatsafavi M. The Projected Economic and Health Burden of Uncontrolled Asthma in the United States. Am J Respir Crit Care Med. 2019 Nov 1;200(9):1102-1112. doi: 10.1164/rccm.201901-0016OC. PMID: 31166782; PMCID: PMC6888652.
[53] American Lung Association. Asthma Trends and Burden [Internet]. Chicago, IL: American Lung Association; 2025. https://www.lung.org/research/trends-in-lung-disease/asthma-trends-brief/trends-and-burden
[54] Centers for Disease Control and Prevention. Asthma. 2020 Healthcare Use Data. https://www.cdc.gov/asthma/healthcare-use/2020/table_b.html
[55] Centers for Disease Control and Prevention. National Center for Health Statistics. Asthma. https://www.cdc.gov/nchs/fastats/asthma.htm

- In Maryland in 2021, rate of death from asthma as the underlying cause was 1.1 per 100,000 persons (95% CI 0.9 to 1.4).[56]

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Prevalence & Incidence

- Chronic rhinosinusitis affects approximately 2.1% of people in the US and 20-30% of cases are with nasal polyps.[57]

Disease Severity

- Chronic rhinosinusitis with nasal polyps is an inflammatory disease of the nasal mucosa and sinuses that lasts at least 12 weeks. Nasal polyps are present, distinguishing it from chronic rhinosinusitis without nasal polyps. Symptoms include loss of smell, nasal obstruction, thick nasal drainage and facial pressure. These symptoms negatively affect quality of life though reduced sleep, productivity and exercise. Many individuals with CRSwNP have asthma due to shared underlying inflammatory pathways.[58]

Cost of Illness/Financial Impact

- In the US in 2019, total annual healthcare costs for a patient with CRSwNP was $11,507 higher than controls, with a total cost of $5.7 billion.[59]

Morbidity

- The prevalence of comorbid asthma is up to 65% in patients with CRSwNP.[60]
- Aspirin (nonsteroidal anti-inflammatory)-exacerbated respiratory disease (AERD) is a serious, recurrent, often treatment-resistant comorbidity of CRSwNP. People with

[56] 2021 Centers for Disease Control and Prevention Division of Population Health Chronic Disease Indicators, accessed at https://www.cdc.gov/cdi/ on [27 Aug 2025]
[57] Bachert C, Bhattacharyya N, Desrosiers M, Khan AH. Burden of Disease in Chronic Rhinosinusitis with Nasal Polyps. J Asthma Allergy. 2021 Feb 11;14:127-134. doi: 10.2147/JAA.S290424. PMID: 33603409; PMCID: PMC7886239.
[58] The Joint Task Force on Practice Parameters GRADE guidelines for the medical management of chronic rhinosinusitis with nasal polyposis. Rank, Matthew A. et al. Journal of Allergy and Clinical Immunology, Volume 151, Issue 2, 386 - 398
[59] Bachert C, Bhattacharyya N, Desrosiers M, Khan AH. Burden of Disease in Chronic Rhinosinusitis with Nasal Polyps. J Asthma Allergy. 2021 Feb 11;14:127-134. doi: 10.2147/JAA.S290424. PMID: 33603409; PMCID: PMC7886239.
[60] Bachert C, Bhattacharyya N, Desrosiers M, Khan AH. Burden of Disease in Chronic Rhinosinusitis with Nasal Polyps. J Asthma Allergy. 2021 Feb 11;14:127-134. doi: 10.2147/JAA.S290424. PMID: 33603409; PMCID: PMC7886239.

CRSwNP with AERD undergo an estimated average of 3 sinus operations in their lifetimes.[61]

- CRSwNP impact on health-related quality of life is comparable to other chronic diseases including COPD, diabetes and asthma.[62]

Mortality

- There is no substantiated, reliable data to associate CRSwNP as an underlying cause of death as of this writing.

Chronic Spontaneous Urticaria (CSU)

Prevalence & Incidence

- The prevalence percentage rate of urticaria among persons of all ages in Maryland in 2021 was 0.84 (range 0.80 to 0.89), affecting a total of 49,788 Marylanders (range 47,256 to 52,344).[63]
- The incidence percentage rate of urticaria among persons of all ages in Maryland in 2021 was 0.30 (range 0.27 to 0.32).[64]

Disease Severity

- Chronic spontaneous urticaria negatively impacts affected individuals' quality of life, mental health and ability to perform daily tasks.[65] Severity of symptoms (hives, pruritus, angioedema) may fluctuate, generally ranging from mild to moderate to severe.[66]

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[61] Bachert C, Bhattacharyya N, Desrosiers M, Khan AH. Burden of Disease in Chronic Rhinosinusitis with Nasal Polyps. J Asthma Allergy. 2021 Feb 11;14:127-134. doi: 10.2147/JAA.S290424. PMID: 33603409; PMCID: PMC7886239.

[62] Bachert C, Bhattacharyya N, Desrosiers M, Khan AH. Burden of Disease in Chronic Rhinosinusitis with Nasal Polyps. J Asthma Allergy. 2021 Feb 11;14:127-134. doi: 10.2147/JAA.S290424. PMID: 33603409; PMCID: PMC7886239.

[63] Institute for Health Metrics and Evaluation (IHME), 2021. Global Burden of Disease Collaborative Network. Global Burden of Disease Study 2021 (GBD 2021) Results. Seattle, United States. Available at https://vizhub. healthdata.org/gbd-results

[64] Institute for Health Metrics and Evaluation (IHME), 2021. Global Burden of Disease Collaborative Network. Global Burden of Disease Study 2021 (GBD 2021) Results. Seattle, United States. Available at https://vizhub. healthdata.org/gbd-results

[65] Maurer M, Abuzakouk M, Bérard F, et al. The burden of chronicspontaneous urticaria is substantial: real- world evidence fromASSURE-CSU. Allergy. 2017;72(12):2005-2016. https://doi.org/10.1111/all.13209

[66] Zuberbier T, Abdul Latiff AH, Abuzakouk M, et al. The international EAACI/GA²LEN/EuroGuiDerm/APAAACI guideline for the definition, classification, diagnosis, and management of urticaria. *Allergy*. 2022; 77: 734–766. doi:10.1111/all.15090

Cost of Illness/Financial Impact

- In 2015 study of US healthcare costs associated with CSU, annual expenditure per affected individual was estimated at $9000.[67]
- Another study in 2024 found that average annual US healthcare costs in 2023 dollars ranged from $5621 to $6933 per affected individual.[68]

Morbidity

- Healthcare utilization is higher amongst respondents with CSU compared to overall population in a national health and wellness survey.[69]

Table 2b. All-cause HCRU in the past 6 months among the overall NHWS population and the physician-diagnosed CSU cohort.

Any healthcare provider visits	Overall NHWS population (N = 74,994)	CSU cohort (n = 635)
Visited, %	77.3	96.5
Number of visits, mean (SD)	4.7 (6.1)	8.6 (11.9)
General practitioner		
Visited, %	49.2	48.7
Number of visits, mean (SD)	1.7 (1.5)	2.2 (2.3)
Allergist		
Visited, %	4.0	29.6

[67] Broder MS, et al. Resource use and costs in an insured population of patients with chronic idiopathic/spontaneous urticaria. Am J Clin Dermatol. 2015;16(4):313-321.doi:10.1007/s4025 7- 015-0134-8

[68] Nochaiwong S, et al. Cost and Cost-Effectiveness of the Management Strategies of Chronic Urticaria: A Systematic Review. *JAMA Dermatol.* 2024;160(11):1225–1236. doi:10.1001/jamadermatol.2024.2863

[69] Soong W, et al. Clinical profile, prevalence, and burden of chronic spontaneous urticaria in the United States, World Allergy Organization Journal, Volume 18, Issue 8, 2025, 101081, ISSN 1939-4551,https://doi.org/10.1016/j.waojou.2025.101081.

Number of visits, mean (SD)	2.4 (3.7)	2.8 (4.3)
Dermatologist		
Visited, %	10.7	19.2
Number of visits, mean (SD)	1.5 (1.4)	1.9 (1.5)
Emergency department visits		
Visited, %	14.5	60.2
Number of visits, mean (SD)	2.1 (3.1)	3.7 (5.0)
Hospitalizations		
Hospitalized, %	9.7	55.9
Number of hospitalizations, mean (SD)	2.4 (4.9)	4.4 (9.8)

Note: mean number of visits is among those who saw the corresponding healthcare provider in the past 6 months. CSU, chronic spontaneous urticaria; HCRU, healthcare resource utilization; NHWS, National Health and Wellness Survey; SD, standard deviation. [70]

Mortality

- There is no substantiated, reliable data to associate CSU as an underlying cause of death as of this writing.

[70] *Id.* at 69

Eosinophilic Esophagitis (EoE)

Prevalence & Incidence

- In 2022, eosinophilic esophagitis affected approximately 142.5 per 100,000 people in the United States.[71]

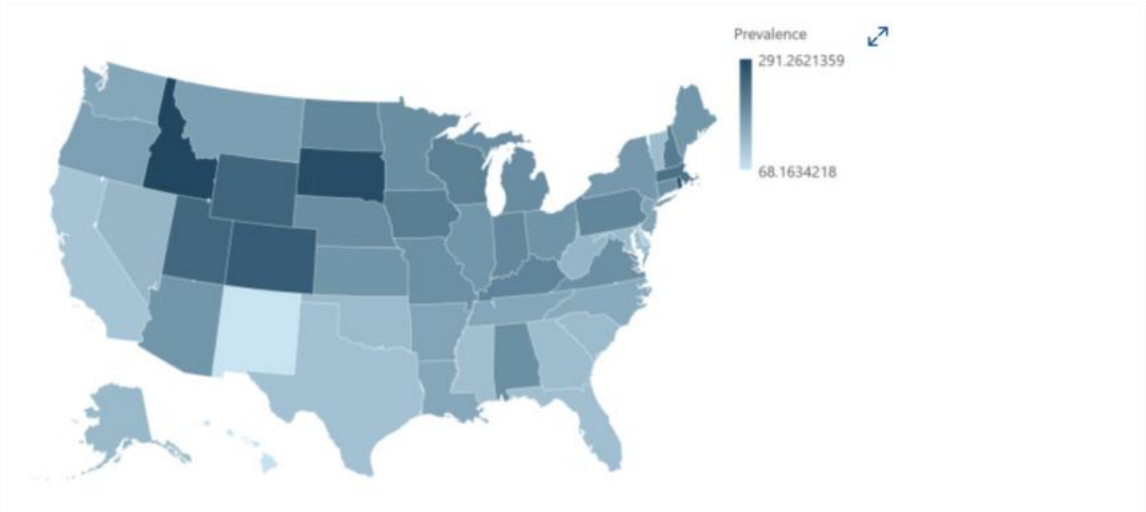


Figure 1. EoE prevalence across the U.S., using the primary case definition (one code) in MarketScan for 2022, with the exception of Vermont and Delaware, where 2021 prevalence estimates were used.[72]

- Based on claims data from 2021 to 2023, the estimated incidence of EoE in the US was 0.06% and the prevalence was 0.15%.[73]

Disease Severity

- The severity of EoE varies from mild to moderate to severe based on a combination of symptoms, complications, and inflammatory and fibrogenotic features as evaluated by the Index of Severity of Eosinophilic Esophagitis.[74]

[71] Thel HL. et al. Prevalence and Costs of Eosinophilic Esophagitis in the United States. Clinical Gastroenterology and Hepatology, Volume 23, Issue 2, 272 - 280.e8
[72] Thel HL, et al. Prevalence and Costs of Eosinophilic Esophagitis in the United States. Clinical Gastroenterology and Hepatology, Volume 23, Issue 2, 272 - 280.e8
[73] Joshua Fitch. Incidence, prevalence of eosinophilic esophagitis increasing in US. Contemporary Pediatrics. https://www.contemporarypediatrics.com/view/incidence-prevalence-of-eosinophilic-esophagitis-increasing-in-us.
[74] Dellon ES, et al. A Clinical Severity Index for Eosinophilic Esophagitis: Development, Consensus, and Future Directions. Gastroenterology. 2022 Jul;163(1):59-76. doi: 10.1053/j.gastro.2022.03.025. Epub 2022 May 20. PMID: 35606197; PMCID: PMC9233087.

Cost of Illness/Financial Impact

- In 2024 in the US, the estimated annual cost of EoE was $1.32 billion.[75]
- As of this writing, the financial impact of EoE specific to Maryland was not available.

Morbidity

- EoE symptoms, dysphagia-related anxiety and social activities involving food negatively impacts individuals' quality of life.[76]
- In a 2023 study, annual EoE-associated ED visits increased from 2934 (95% CI, 2437–3431) in 2009 to 8765 (95% CI, 7514–10,015) in 2019, and are projected to reach 15,445 (95% prediction interval, 14,672–16,218) by 2030.[77]
- In the same study, hospitalizations from ED visits decreased from 25.6% in 2009 to 2011 to 14.0% in 2017 to 2019. Half of EoE patients presenting to the ED required an endoscopy and nearly 40% required an esophageal foreign body removal.[78]

Mortality

- There is no substantiated, reliable data to associate EoE as an underlying cause of death as of this writing.

Bullous Pemphigoid (BP)

Prevalence & Incidence

- The annual incidence is estimated at 6 to 13 new cases per million population in the United States.[79]

[75] Thel HL, et al. Prevalence and Costs of Eosinophilic Esophagitis in the United States. Clinical Gastroenterology and Hepatology, Volume 23, Issue 2, 272 - 280.e8.
[76] Schoepfer AM, et al. Burden of eosinophilic esophagitis in adult and adolescent patients: results from a real-world analysis, Diseases of the Esophagus, Volume 38, Issue 2, April 2025, doaf024, https://doi.org/10.1093/dote/doaf024
[77] Lam AY, et al. Epidemiologic Burden and Projections for Eosinophilic Esophagitis–Associated Emergency Department Visits in the United States: 2009-2030, Clinical Gastroenterology and Hepatology, Volume 21, Issue 12, 2023, Pages 3041-3050.e3, ISSN 1542-3565, https://doi.org/10.1016/j.cgh.2023.04.028.
[78] Lam AY, et al. Epidemiologic Burden and Projections for Eosinophilic Esophagitis–Associated Emergency Department Visits in the United States: 2009-2030, Clinical Gastroenterology and Hepatology, Volume 21, Issue 12, 2023, Pages 3041-3050.e3, ISSN 1542-3565, https://doi.org/10.1016/j.cgh.2023.04.028..
[79] Baigrie D, Nookala V. Bullous Pemphigoid. [Updated 2023 Mar 2]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan. https://www.ncbi.nlm.nih.gov/books/NBK535374/

Disease Severity

- Disease severity ranges from localized to one body type, mild to moderate BP with ≤ 10 new blisters per day and Bullous Pemphigoid Disease Activity Index (BPDAI) score <20 to ≥20 - <57, respectively or severe BP with >10 new blisters per day or BPDAI ≥57.[80]

Cost of Illness/Financial Impact

- As of this writing, financial impact of BP specific to Maryland was not available.
- A study of US claims data from 2016 to 2019 showed the following increased costs for individuals with BP compared to a non-BP cohort

Per-patient-per-month (PPPM) all-cause total healthcare costs

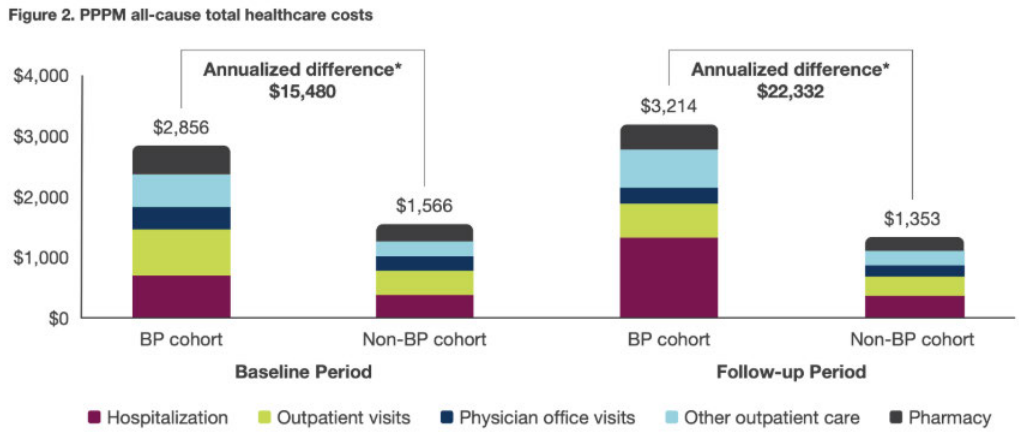
- In the baseline period, regardless of cohort, outpatient visits were the main HCRU cost component, followed by hospitalization (**Figure 2**).
    - PPPM all-cause total healthcare costs in the BP cohort were almost double those in the non-BP cohort ($2,856 vs $1,566); annualized difference was $15,480.
- In the follow-up period, hospitalization was the main cost component for both BP and non-BP patients, followed by outpatient visits (**Figure 2**).
    - PPPM all-cause total healthcare costs increased 13% between baseline and follow-up for the BP cohort, mainly driven by increased hospitalization costs, but decreased 14% for the Non-BP cohort.
- PPPM all-cause total healthcare costs in the follow-up period were almost 2.5 times greater for the BP cohort versus the non-BP cohort (**Figure 2**).

The difference, when annualized, amounted to a $22,332 per year higher cost for BP patients compared with matched non-BP patients.[81]

Figure 2. PPPM All-Cause Total Healthcare Costs

[80] Borradori L, Van Beek N, Feliciani C, Tedbirt B, Antiga E, Bergman R, Böckle BC, Caproni M, Caux F, Chandran NS, Cianchini G, Daneshpazhooh M, De D, Didona D, Di Zenzo GM, Dmochowski M, Drenovska K, Ehrchen J, Goebeler M, Groves R, Günther C, Horvath B, Hertl M, Hofmann S, Ioannides D, Itzlinger-Monshi B, Jedličková J, Kowalewski C, Kridin K, Lim YL, Marinovic B, Marzano AV, Mascaro JM, Meijer JM, Murrell D, Patsatsi K, Pincelli C, Prost C, Rappersberger K, Sárdy M, Setterfield J, Shahid M, Sprecher E, Tasanen K, Uzun S, Vassileva S, Vestergaard K, Vorobyev A, Vujic I, Wang G, Wozniak K, Yayli S, Zambruno G, Zillikens D, Schmidt E, Joly P. Updated S2 K guidelines for the management of bullous pemphigoid initiated by the European Academy of Dermatology and Venereology (EADV). J Eur Acad Dermatol Venereol. 2022 Oct;36(10):1689-1704. doi: 10.1111/jdv.18220. Epub 2022 Jun 29. PMID: 35766904.

[81] *Id.* At 81



Note: PPPM all-cause total healthcare costs were annualized by multiplying by 12. Other outpatient care includes ambulatory surgical center visits, emergency department visits, urgent care visits, home visits, telemedicine consultations, and other outpatient and ancillary care.[82]

Morbidity

- BP primarily affects individuals over the age of 70 years, and disease complications include skin infections, sepsis, viral infections, and adverse effects of immunosuppression from treatments.[83]
- Dementia and debilitating neurological disorders are significantly associated with BP.[84]
- A study of US claims data from 2016 to 2019 showed the following[85]

PPPM all-cause HCRU

[82] *Id.* at 81
[83] Baigrie D, Nookala V. Bullous Pemphigoid. [Updated 2023 Mar 2]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK535374/
[84] Borradori L, Van Beek N, Feliciani C, Tedbirt B, Antiga E, Bergman R, Böckle BC, Caproni M, Caux F, Chandran NS, Cianchini G, Daneshpazhooh M, De D, Didona D, Di Zenzo GM, Dmochowski M, Drenovska K, Ehrchen J, Goebeler M, Groves R, Günther C, Horvath B, Hertl M, Hofmann S, Ioannides D, Itzlinger-Monshi B, Jedličková J, Kowalewski C, Kridin K, Lim YL, Marinovic B, Marzano AV, Mascaro JM, Meijer JM, Murrell D, Patsatsi K, Pincelli C, Prost C, Rappersberger K, Sárdy M, Setterfield J, Shahid M, Sprecher E, Tasanen K, Uzun S, Vassileva S, Vestergaard K, Vorobyev A, Vujic I, Wang G, Wozniak K, Yayli S, Zambruno G, Zillikens D, Schmidt E, Joly P. Updated S2 K guidelines for the management of bullous pemphigoid initiated by the European Academy of Dermatology and Venereology (EADV). J Eur Acad Dermatol Venereol. 2022 Oct;36(10):1689-1704. doi: 10.1111/jdv.18220. Epub 2022 Jun 29. PMID: 35766904.
[85] Xiao Xu, Catherine Datto, Justin Kwiatek, Juliana Meyers, Sean Candrilli, Daniel Mines, Heide Stirnadel-Farrant. Comparison of Healthcare Resource Utilization and Costs in Patients With and Without Bullous Pemphigoid: A Retrospective Analysis of US Health Insurance Claims Data. Presented at ISPOR, May 15-18, 2022, Washington, DC, USA. https://www.ispor.org/docs/default-source/intl2022/ispor-2022-bp-hcru-posterv3-0-pdf.pdf?sfvrsn=fc15ccf8_0

- The prevalence of hospitalization for BP patients was substantially greater in the follow-up period compared to the baseline period (44% vs 15%). The lengths of stay per hospitalization were similar (6.0 vs 6.4 days).
- The non-BP cohort had similar HCRU in the baseline and follow-up periods.[86]

Table 2c. PPPM all-cause HCRU

Mean HCRU PPPM	Baseline BP cohort	Baseline Non-BP cohort	Follow-up BP cohort	Follow-up Non-BP cohort
Hospitalization	0.18	0.10	0.77	0.25
Ambulatory surgical center claims	0.06	0.07	0.05	0.05
ED claims	0.24	0.11	0.23	0.12
Urgent care claims	0.02	0.01	0.02	0.02
Outpatient claims	2.58	1.56	3.03	1.57
Physician office claims	3.31	2.50	3.68	2.32
Home claims	0.47	0.24	0.84	0.24
Other outpatient care claims	2.02	1.01	3.15	1.02

Note: BP, bullous pemphigoid; ED, emergency department; HCRU, healthcare resource utilization; PPPM, per-patient-per-month.[87]

[86] *Id.* at 81
[87] *Id.* at 81

Mortality

- There is considerable variation in reported mortality associated with BP, studies have found no increased mortality[88] vs 2.93-fold increased 1 year mortality worldwide compared with the general population.[89] Another study of individuals with BP in Minnesota found a 19% 1 year morality rate.[90] Mortality is associated with BP itself, effects of treatment and/or comorbidities, with infections and cardiovascular disease as the main causes of death.[91]
- Mortality rates specific to Maryland were not available at the time of this writing.

Prurigo Nodularis

Prevalence & Incidence

- The prevalence of prurigo nodularis (PN) among adults age 18 to 64 years is estimated at 72 per 100,000 in the United States in 2016.[92]

Disease Severity

- PN disease severity is a combination of nodule number, pruritus severity, skin lesion condition and impact on quality of life.[93]

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[88] Parker, Sareeta R.S. et al. Mortality of bullous pemphigoid: An evaluation of 223 patients and comparison with the mortality in the general population in the United States Journal of the American Academy of Dermatology, Volume 59, Issue 4, 582 - 588

[89] Tedbirt B, Gillibert A, Andrieu E, Hébert V, Bastos S, Korman NJ, Tang MBY, Li J, Borradori L, Cortés B, Kim SC, Gual A, Xiao T, Wieland CN, Fairley JA, Ezzedine K, Joly P. Mixed Individual-Aggregate Data on All-Cause Mortality in Bullous Pemphigoid: A Meta-analysis. JAMA Dermatol. 2021 Apr 1;157(4):421-430. doi: 10.1001/jamadermatol.2020.5598. PMID: 33729430; PMCID: PMC7970384.

[90] Brick KE, Weaver CH, Lohse CM, Pittelkow MR, Lehman JS, Camilleri MJ, Al-Hashimi M, Wieland CN. Incidence of bullous pemphigoid and mortality of patients with bullous pemphigoid in Olmsted County, Minnesota, 1960 through 2009. J Am Acad Dermatol. 2014 Jul;71(1):92-9. doi: 10.1016/j.jaad.2014.02.030. Epub 2014 Apr 3. PMID: 24704091; PMCID: PMC4324601.

[91] Tedbirt B, Gillibert A, Andrieu E, Hébert V, Bastos S, Korman NJ, Tang MBY, Li J, Borradori L, Cortés B, Kim SC, Gual A, Xiao T, Wieland CN, Fairley JA, Ezzedine K, Joly P. Mixed Individual-Aggregate Data on All-Cause Mortality in Bullous Pemphigoid: A Meta-analysis. JAMA Dermatol. 2021 Apr 1;157(4):421-430. doi: 10.1001/jamadermatol.2020.5598. PMID: 33729430; PMCID: PMC7970384.

[92] Sarah Chisolm. A Review of the Current Management and Burden of Prurigo Nodularis in the United States. *Am J Manag Care*. 2023;29(suppl 5):S63-S72. https://doi.org/10.37765/ajmc.2023.89366

[93] Zhang, Li1; Diao, Qingchun2; Dou, Xia3; Fang, Hong4; Geng, Songmei5; Guo, Hao1; Chen, Yaolong6; Ji, Chao7; Li, Chengxin8; Li, Linfeng9; Li, Jie10; Li, Jingyi10; Li, Wei11; Li, Zhiming12; Liang, Yunsheng13; Qiao, Jianjun4; Song, Zhiqiang14; Sun, Qing15; Tao, Juan16; Wang, Fang13; Xie, Zhiqiang17; Xu, Jinhua11; Xu, Suling18; Yan, Hongwei19; Yao, Xu20; Zhang, Jianzhong21; Zhang, Litao22; Zhu, Gang23; Hao, Fei24; Gao, Xinghua1. Guidelines for the diagnosis and treatment of prurigo nodularis. Chinese Medical Journal ():10.1097/CM9.0000000000003732, September 16, 2025. | DOI: 10.1097/CM9.0000000000003732

Cost of Illness/Financial Impact

- A study of US healthcare claims data from 2016 to 2019 found mean adjusted all-cause healthcare costs for patients with PN were $17,403 (95% CI $16,623–18,183) vs matched controls $9363 (95% CI $8582–10,143)[94]
- Another study of US healthcare claims data from January 1, 2016 to June 30, 2023, the following costs were determined (in 2022 dollars)[95]

Healthcare Costs and Drivers

- Compared with controls, patients with PN had significantly higher healthcare costs (mean $20,968 [SD $55,294] vs. $15,232 [SD $43,914]). Primary drivers of the cost difference were outpatient services and pharmacy costs.
- Patients in the high-cost cohort had total healthcare costs of $116,239 (SD $140,128) comprised of outpatient services costs (45%), inpatient services (27%), and pharmacy prescriptions (28%).
- Results from the multivariate logistic regression model (results not shown) found that patients with PN with high healthcare costs had increased odds ($p<0.05$) of having many chronic conditions (i.e., renal disease, malignancy, cardiovascular disease, type 2 diabetes) as well as many PN-related comorbid conditions (i.e., other autoimmune disease, infections, anxiety, depression, sleep disorders).[96]

Table 2d. All-Cause Healthcare Costs among PN Cohort and Matched Controls in the 12-Months Following First Diagnosis of PN During the Study Period (January 1, 2017 through June 30, 2022)

Cost Component	Matched PN Cohort	Matched Controls
Total Mean Cost	**$20,968**	**$15,232**

[94] Kwatra SG, Das AK, Chang E, Paydar C, Bahloul D, Chen C, Thomas RB. Healthcare Resource Utilization and Economic Burden of Prurigo Nodularis in the United States. Dermatol Ther (Heidelb). 2025 Feb;15(2):413-425. doi: 10.1007/s13555-025-01349-7. Epub 2025 Feb 8. PMID: 39922987; PMCID: PMC11832852.

[95] Sarina Elmariah; Nicole Princic; Megan Richards; Aamir Qureshi; Lorenzo Sabatelli,; Shawn G. Kwatra. Economic and Comorbidity Burden of Prurigo Nodularis and Drivers of Higher Healthcare Costs in the US: A Retrospective Analysis of Claims Data of Patients Diagnosed between 2017 and 2022. Presented at ISPOR Annual Meeting, May 5-8 2024. Atlanta GA. https://www.ispor.org/docs/default-source/intl2024/galdermaisporpn-poster-final04-29-2024136814-pdf.pdf?sfvrsn=4cae30f_0 [Accessed 28 Sept 2025].

[96] *Id.* At 96

OP pharmacy*	$6,511	$4,154
Other OP service*	$8,585	$6,575
OP Office visit*	$1,648	$927
ER visit*	$538	$413
Inpatient	$3,686	$3,163

Note: *p-value is <0.001 between PN cohort and matched controls. ER, emergency room; OP, outpatient. [97]

Morbidity

- Individuals with PN have a higher comorbid disease burden compared to the general population or individuals with atopic dermatitis or psoriasis. PN is associated with other type 2 inflammatory conditions as well as chronic kidney disease, cerebrovascular disease, depression and anxiety.[98]

Mortality

- PN is associated with a higher risk of mortality due to increased risk of developing cardiac and vascular diseases; all-cause mortality hazard ratio 1.1243 (CI 1.18–1.309; p < 0.0001).[99]

[97] *Id.* At 96
[98] Sarah Chisolm. A Review of the Current Management and Burden of Prurigo Nodularis in the United States. *Am J Manag Care*. 2023;29(suppl 5):S63-S72. https://doi.org/10.37765/ajmc.2023.89366
[99] Olbrich H, Kridin K, Hernández G, Zirpel H, Sadik CD, Terheyden P, Thaçi D, Ludwig RJ, Boch K. Increased cardiovascular risks and mortality in prurigo nodularis: a global cohort study. EBioMedicine. 2024 May;103:105123. doi: 10.1016/j.ebiom.2024.105123. Epub 2024 Apr 16. PMID: 38631094; PMCID: PMC11035034.

Section 3: Regulatory Approval and Market Context

Factor 3.1: Analysis of the prescription drug product's approval process

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(ix)
Methodology: Review of databases and sites
Data Sources: FDA databases and manufacturer website

Dupixent received its first U.S. Food and Drug Administration (FDA) approval on March 28, 2017, for the treatment of adults with moderate-to-severe atopic dermatitis (eczema) that is not adequately controlled with topical prescription therapies.[100] In 2014 the FDA granted the application Breakthrough Therapy designation and Priority Review because Dupixent addressed a significant unmet medical need.[101] As a first-in-class medication, Dupixent introduced a novel mechanism of action by targeting previously unaddressed pathways, marking a major therapeutic advancement in biologic treatment.

Since its original approval, the FDA has approved multiple supplemental applications, significantly expanding the drug's use to a variety of type 2 inflammatory diseases and different age populations.

- **Asthma:**
  - **October 19, 2018:** Approved as an add-on maintenance treatment for moderate-to-severe asthma with an eosinophilic phenotype or with oral corticosteroid dependence in patients aged 12 years and older.[102]
  - **October 20, 2021:** Approval expanded to include children aged 6 to 11 years with moderate-to-severe asthma.[103]
- **Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP):**
  - **June 26, 2019:** Approved as an add-on maintenance treatment for adults with inadequately controlled CRSwNP.[104]
- **Eosinophilic Esophagitis (EoE):**
  - **May 20, 2022:** Approved as the first and only biologic for the treatment of EoE in patients aged 12 years and older weighing at least 40 kg.[105]

[100] https://investor.regeneron.com/news-releases/news-release-details/regeneron-and-sanofi-announce-fda-approval-dupixentr-dupilumab
[101] id. 94
[102] https://www.news.sanofi.us/2018-10-19-FDA-approves-asthsma-indication-for-Dupixent-R-dupilumab
[103] https://www.sanofi.com/en/media-room/press-releases/2021/2021-10-20-21-30-00-2317854
[104] https://investor.regeneron.com/news-releases/news-release-details/fda-approves-dupixentr-dupilumab-chronic-rhinosinusitis-nasal
[105] https://www.sanofi.com/en/media-room/press-releases/2022/2022-05-20-19-15-00-2447906

  - **January 25, 2024:** Approval expanded to include children aged 1 year and older, weighing at least 15 kg.[106]
- **Prurigo Nodularis (PN):**
  - **September 28, 2022:** Approved as the first and only treatment specifically indicated for adult patients with prurigo nodularis.[107]
- **Chronic Spontaneous Urticaria (CSU):**
  - **April 18, 2025:** Approved for adults and adolescents aged 12 years and older with CSU who remain symptomatic despite H1 antihistamine treatment.[108] This approval followed a prior Complete Response letter from the FDA in 2023 requesting additional efficacy data.[109]
  - April 22, 2026: Approval for children aged two to 11 years with CSU who remain symptomatic despite H1 antihistamine treatment.[110]
- **Chronic Obstructive Pulmonary Disease (COPD):**
  - **September 27, 2024:** Approved as an add-on maintenance treatment for adults with inadequately controlled COPD and an eosinophilic phenotype. This marked the first biologic approval for this specific patient population.[111] This approval followed an FDA extension on the Prescription Drug User Fee Act (PDUFA) target action date by three months, from June 27 to September 27, 2024 due to a request for additional efficacy analyses.[112]
- **Bullous Pemphigoid (BP):**
  - **June 20, 2025:** Approved for the treatment of adult patients with bullous pemphigoid.[113]
- **Allergic Fungal Rhinosinusitis:**
  - **February 24, 2026:** Approved, by priority review, for adults and children aged 6 years and older with allergic fungal rhinosinusitis supported by phase 3 study demonstrating Dupixent significantly reduced nasal signs and symptoms and systemic corticosteroid use or surgery compared to placebo. This is the first and only medicine in the U.S. for allergic fungal rhinosinusitis.[114]

[106] https://www.sanofi.com/en/media-room/press-releases/2024/2024-01-25-19-30-00-2817342
[107] https://www.sanofi.com/en/media-room/press-releases/2022/2022-09-28-22-05-26-2524764
[108] https://www.sanofi.com/en/media-room/press-releases/2025/2025-04-18-15-15-00-3064131
[109] https://www.sanofi.com/en/media-room/press-releases/2023/2023-10-20-21-00-00-2764252
[110] https://www.sanofi.com/en/media-room/press-releases/2026/2026-04-22-21-30-00-3279472
[111] https://www.sanofi.com/en/media-room/press-releases/2024/2024-09-27-13-35-00-2954551
[112] https://www.appliedclinicaltrialsonline.com/view/fda-extends-pdufa-date-for-dupixent-in-copd-requesting-additional-data-from-boreas-and-notus-trials
[113] https://www.sanofi.com/en/media-room/press-releases/2025/2025-06-20-05-00-00-3102518
[114] https://www.sanofi.com/en/media-room/press-releases/2026/2026-02-24-14-30-00-3243732

Dupixent remains under investigation in Phase 3 clinical trials for Chronic Pruritus of Unknown Origin and Lichen Simplex Chronicus, while also undergoing broader exploration for various food and environmental allergies.[115,116]

[115] https://clinicaltrials.gov/study/NCT05263206
[116] https://clinicaltrials.gov/study/NCT06687967

Factor 3.2: Analysis of the prescription drug product's shortage status

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(x)
Methodology: Review of databases
Data Sources: FDA Databases

Dupixent (dupilumab) is not currently in shortage.[117]

[117] FDA Drug Shortage Databases. https://dps.fda.gov/drugshortages

Factor 3.3: Analysis of the market context of the prescription drug product including the prescription drug product's lifecycle management, patent management, regulatory exclusivities, and product hopping

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(xi)
Methodology: Review of databases and sites, aggregation of claims data to understand spending and utilization of other products with the same active ingredient by the same manufacturer
Data Sources: FDA Databases, MCDB, Manufacturer Website

Patent and Exclusivity Data

One potential source of patent information for biological products is FDA's "Purple Book." A brand-name manufacturer is required to give the FDA a list of patents and their expiration dates within 30 days after that same list is disclosed to a biosimilar applicant as part of a patent dispute resolution process. The FDA then publishes that information in the Purple Book.[118] Because of the complexities of this process, patent information for biologics is not always available from official FDA sources. In the case of Dupixent, the Purple Book did not contain patent information. Therefore, staff reviewed the I-MAK database to identify patents for Dupixent, however no patents were listed.

Sanofi and Regneron reported seven patents for Dupixent, however this list is not exhaustive. The primary patent, filed prior to FDA approval, expires on March 28, 2031. Four utility patents were also filed prior to FDA approval, two expire in 2031, one in 2027 and one, the last patent expiring in 2032. Two utility patents filed after Dupixent received FDA approval expire in 2031 and 2032. [119] See Patent Listing Table below.

[118] https://purplebooksearch.fda.gov/faqs
[119] https://www.sanofi.us/en/legal-notice/us-patents

Table 3. Dupixent Patent Listing Table

Patent Number	Patent Type	Submission Date	Patent Expiration
7608693B2	Biotechnology/pharmaceutical patent	10/29/2008	03/28/2031
8735095B2	Utility Patent	11/16/2012	02/10/2027
8945559B2	Utility Patent	10/05/2011	10/17/2032
9238692B2	Utility Patent	12/19/2014	10/05/2031
10435473B2	Utility Patent	02/03/2017	10/05/2031
11059896B2	Utility Patent	08/19/2019	10/05/2031
11926670B2	Utility Patent	06/09/2021	04/11/2032

Dupixent, having received initial FDA approval in 2017, Dupixent's data exclusivity is set to expire in 2029, was extended by six months due to new pediatric indications approved by the FDA in 2020 and 2024.[120,121] Additionally, Dupixent received Orphan Drug Designation[122] for the treatment of eosinophilic esophagitis, this designation grants 7 years of indication-specific market exclusivity. These extensions mean that Dupixent's exclusivity is now set to expire in 2029 and 2031 for the Orphan Drug indication.[123]

Lifecycle Management

[120] "Data exclusivity precludes applicants from relying on the reference product's clinical data to demonstrate the safety and effectiveness of the follow-on product." https://www.congress.gov/crsproduct/IF11217#:~:text=There%20are%20two%20general%20categories.necessary%20safety%20and% 20effectiveness%20data.
[121] https://www.accessdata.fda.gov/scripts/opdlisting/oopd/detailedIndex.cfm?cfgridkey=599317
[122] https://www.fda.gov/patients/rare-diseases-fda-This designation is granted by the FDA to medicines intended for the treatment of rare diseases, defined as those affecting fewer than 200,000 people in the U.S."
[123] https://www.accessdata.fda.gov/scripts/opdlisting/oopd/detailedIndex.cfm?cfgridkey=599317

Dupixent has received nine approvals for new indications, including approvals for orphan and pediatric exclusivities. Additionally, Dupixent has received approval for a different delivery mechanism (pre-filled pen).[124]

Dupixent is among the top prescription and over-the-counter pharmaceutical brand spenders in national television drug advertising.[125] In the first three months of 2025 Dupixent spent an estimated $75.7 million on national TV advertising, the most of any pharmaceutical company.[126]

[124] https://www.news.sanofi.us/2020-06-19-FDA-approves-new-Dupixent-R-dupilumab-pre-filled-pen-designed-to-support-more-convenient-self-administration
[125] https://www.fiercepharma.com/marketing/abbvie-revs-skyrizi-spending-top-tv-ad-totals-november-edging-out-jjs-tremfya?utm_medium=email&utm_source=nl&utm_campaign=LS-NL-FiercePharmaMarketing&oly_enc_id=5733J7659390A7J
[126] https://www.mmm-online.com/news/dupixent-tops-pharma-ad-impressions-rankings-for-q1-2025/

Section 4: Utilization of Drug Product Under Review

Factor 4.1: The total gross spending in the State for the prescription drug product under review, the total number of patients in the State using the prescription drug product, and the percentage of overall total prescription drug product spending that the product's spending represents

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi); COMAR 14.01.04.05.C(1)(g)(iv)
Methodology: Calculations
Data Sources: MCDB

For each NDC, the following tables provide the gross spending and number of patients by payor type.

Table 4a. Dupixent Units Dispensed

Drug Information			Units Dispensed			
National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	Commercial (2024)	State Local Gov (2024)	Medicaid (2024)	Medicare (2023)
00024-5914-01	Dupixent	300 MG/2ML	58,506	7,956	12,387	10,094
00024-5915-02	Dupixent	300 MG/2ML	136,096	15,508	27,018	16,366
00024-5918-01	Dupixent	200 MG/1.14ML	3,695	403	2,393	404
00024-5919-02	Dupixent	200 MG/1.14ML	4,323	674	2,390	317

Table 4b. Dupixent Commercial Spending and Utilization

National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	Commercial (2024) Gross Spending	Commercial (2024) Patient Count	Commercial (2024) Pct Total Gross Spend
00024-5914-01	Dupixent	300 MG/2 ML	$52,287,572.00	1,761	0.5720%
00024-5915-02	Dupixent	300 MG/2 ML	$120,074,689.00	4,142	1.3135%
00024-5918-01	Dupixent	200 MG/1.14 ML	$6,222,838.00	264	0.0681%
00024-5919-02	Dupixent	200 MG/1.14 ML	$7,367,404.00	288	0.0806%

Table 4c. Dupixent State and Local Government Spending and Utilization

National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	State Local Gov. Emp. (2024) Gross Spending	State Local Gov. Emp. (2024) Patient Count	State Local Gov. Emp. (2024) Pct Total Gross Spend
00024-5914-01	Dupixent	300 MG/2 ML	$7,462,648.00	230	1.0157%
00024-5915-02	Dupixent	300 MG/2 ML	$13,950,144.00	464	1.8987%
00024-5918-01	Dupixent	200 MG/1.14 ML	$720,703.00	35	0.0981%
00024-5919-02	Dupixent	200 MG/1.14 ML	$1,124,277.00	43	0.1530%

Table 4d. Dupixent 2024 Medicare and Medicaid Spending and Utilization

National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	Medicaid (2024) Gross Spending	Medicaid (2024) Patient Count	Medicaid (2024) Pct Total Gross Spend
00024-5914-01	Dupixent	300 MG/2 ML	$11,300,573.27	497	0.5901%
00024-5915-02	Dupixent	300 MG/2 ML	$24,699,788.24	1,103	1.2897%
00024-5918-01	Dupixent	200 MG/1.14 ML	$4,364,379.83	225	0.2279%
00024-5919-02	Dupixent	200 MG/1.14 ML	$4,381,574.74	202	0.2288%

Table 4e. Dupixent 2023 Medicare and Medicaid Spending and Utilization

National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	Medicare (2023) Gross Spending	Medicare (2023) Patient Count	Medicare (2023) Pct Total Gross Spend
00024-5914-01	Dupixent	300 MG/2 ML	$9,357,085.16	313	0.2302%
00024-5915-02	Dupixent	300 MG/2 ML	$15,271,856.82	591	0.3758%
00024-5918-01	Dupixent	200 MG/1.14 ML	$655,617.06	22	0.0161%
00024-5919-02	Dupixent	200 MG/1.14 ML	$510,592.09	20	0.0126%

Factor 4.2: The change in total gross spending and utilization for a prescription drug product in the State between the two most recent available calendar years and the percent change in total gross spending for a prescription drug product in the State between the two most recent available calendar years

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(v)
Methodology: Aggregation of claims to calculate the total gross spending and utilization
Data Sources: MCDB

For each NDC and payor type, the tables below show the change in total gross spending and utilization.

Table 4f. Dupixent Change in Commercial Spending and Utilization

Drug Information			Change in Commercial Data (2024-2023)				
National Drug Code (11-Digit)	Drug Proprietary Name	Dosage Strength	Gross Spending (Dollar)	Gross Spending (Percent)	Patient Counts	Prescription Counts	Units Sold
00024-5914-01	Dupixent	300 MG/2 ML	$-4,994,100.00	(8.72%)	-110	-2,085	-3,096
00024-5915-00	Dupixent	300 MG/2ML	$999.00	99900.00%	999	999	999
00024-5915-02	Dupixent	300 MG/2 ML	$27,473,924.00	29.67%	910	4,655	38,448
00024-5918-01	Dupixent	200 MG/1.14 ML	$-456,594.00	(6.84%)	13	-204	-13
00024-5919-02	Dupixent	200 MG/1.14 ML	$2,531,519.00	52.35%	93	479	1,725
NOTE: Values of “999” represent suppressed data due to low beneficiary counts (i.e., patient counts < 10).							

Table 4g. Dupixent Change in State and Local Government Spending and Utilization

Drug Information			Change in State Local Gov. Emp. Data (2024-2023)				
National Drug Code (11-Digit)	Drug Proprietary Name	Dosage Strength	Gross Spending (Dollar)	Gross Spending (Percent)	Patient Counts	Prescription Counts	Units Sold
00024-5914-01	Dupixent	300 MG/2 ML	$1,263,197.00	20.38%	25	40	1,046
00024-5915-02	Dupixent	300 MG/2 ML	$4,645,350.00	49.92%	146	666	5,082
00024-5918-01	Dupixent	200 MG/1.14 ML	$-4,476.00	(0.62%)	8	-19	-12
00024-5919-02	Dupixent	200 MG/1.14 ML	$485,115.00	75.90%	16	92	321
00024-5915-00	Dupixent	300 MG/2ML	.	.	.	.	.

Blank spaces indicate that no data was provided.

Table 4h. Dupixent Change in Medicaid Spending and Utilization

Drug Information			Change in Medicaid Data (2024-2023)				
National Drug Code (11-Digit)	Drug Proprietary Name	Dosage Strength	Gross Spending (Dollar)	Gross Spending (Percent)	Patient Counts	Prescription Counts	Units Sold
00024-5914-01	Dupixent	300 MG/2 ML	$-686,238.93	(5.72%)	-11	-29	-1,465
00024-5915-00	Dupixent	300 MG/2ML	$999.00	99900.00%	999	999	999
00024-5915-02	Dupixent	300 MG/2 ML	$7,776,107.91	45.95%	323	625	7,463
00024-5918-01	Dupixent	200 MG/1.14 ML	$608,274.63	16.19%	36	57	219
00024-5919-02	Dupixent	200 MG/1.14 ML	$2,233,346.68	103.96%	84	154	1,149

NOTE: Values of "999" represent suppressed data due to low beneficiary counts (i.e., patient counts < 10).

Table 4i. Dupixent Change in Medicare Spending and Utilization

Drug Information			Change in Medicare Data (2023-2022)				
National Drug Code (11-Digit)	Drug Proprietary Name	Dosage Strength	Gross Spending (Dollar)	Gross Spending (Percent)	Patient Counts	Prescription Counts	Units Sold
00024-5914-01	Dupixent	300 MG/2ML	$1,233,818.19	15.19%	22	238	833
00024-5915-00	Dupixent	300 MG/2ML	$999.00	99900.00%	999	999	999
00024-5915-02	Dupixent	300 MG/2ML	$8,027,569.05	110.81%	264	1,981	8,126
00024-5918-01	Dupixent	200 MG/1.14ML	$62,109.34	10.46%	0	-3	21
00024-5919-02	Dupixent	200 MG/1.14ML	$318,800.68	166.22%	9	56	194

NOTE: Values of "999" represent suppressed data due to low beneficiary counts (i.e., patient counts < 10).

Factor 4.3: Impact of the utilization and spending for the prescription drug product on public budgets and comparison of the spending on the prescription drug product to relevant benchmarks

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(xv)
Methodology: Research, review, and aggregation of claims data to calculate utilization and spending
Data Sources: MCDB and public budget data

Staff conducted research to understand the impact of the utilization and spending on the prescription drug product on public budgets and to compare spending on the prescription drug product to relevant benchmarks. The utilization and spending data is captured for Commercial, State and Local Government Employee, and Medicaid populations in Factor 4.1 "Pct Total Gross Spend."

Staff gathered budget data from local governmental entities (counties). Because the data was not uniform—some local government budgets reflect spending for employee health, some reflect employee prescriptions, and some do not contain information at that level of specificity—staff was unable to assess the impact on public budgets for specific local governments.

In future Cost Review Studies, staff will continue to work with state and local governments, and other public budgets, to identify standardized data to support this analysis or develop other methods of conducting this analysis.

Table 4j. Dupixent Commercial Spending and Utilization

National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	Commercial (2024) Gross Spending	Commercial (2024) Patient Count	Commercial (2024) Pct Total Gross Spend
00024-5918-01	Dupixent	200 MG/1.14ML	$6,222,838.00	264	0.0681%
00024-5919-02	Dupixent	200 MG/1.14ML	$7,367,404.00	288	0.0806%
00024-5914-01	Dupixent	300 MG/2ML	$52,287,572.00	1,761	0.5720%
00024-5915-02	Dupixent	300 MG/2ML	$120,074,689.00	4,142	1.3135%

Table 4k. Dupixent Commercial – State and Local Government Spending and Utilization

National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	State Local Gov. Emp. (2024) Gross Spending	State Local Gov. Emp. (2024) Patient Count	State Local Gov. Emp. (2024) Pct Total Gross Spend
00024-5918-01	Dupixent	200 MG/1.14ML	$720,703.00	35	0.0981%
00024-5919-02	Dupixent	200 MG/1.14ML	$1,124,277.00	43	0.1530%
00024-5914-01	Dupixent	300 MG/2ML	$7,462,648.00	230	1.0157%
00024-5915-02	Dupixent	300 MG/2ML	$13,950,144.00	464	1.8987%

Table 4l. Dupixent Medicaid Spending and Utilization

National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	Medicaid (2024) Gross Spending	Medicaid (2024) Patient Count	Medicaid (2024) Pct Total Gross Spend
00024-5918-01	Dupixent	200 MG/1.14ML	$4,364,379.83	225	0.2279%
00024-5919-02	Dupixent	200 MG/1.14ML	$4,381,574.74	202	0.2288%
00024-5914-01	Dupixent	300 MG/2ML	$11,300,573.27	497	0.5901%
00024-5915-02	Dupixent	300 MG/2ML	$24,699,788.24	1,103	1.2897%

Table 4m. Dupixent Medicare Spending and Utilization

National Drug Code (11-Digit)	Proprietary Name	Dosage Strength	Medicare (2023) Gross Spending	Medicare (2023) Patient Count	Medicare (2023) Pct Total Gross Spend
00024-5918-01	Dupixent	200 MG/1.14ML	$655,617.06	22	0.0161%
00024-5919-02	Dupixent	200 MG/1.14ML	$510,592.09	20	0.0126%
00024-5914-01	Dupixent	300 MG/2ML	$9,357,085.16	313	0.2302%
00024-5915-02	Dupixent	300 MG/2ML	$15,271,856.82	591	0.3758%

Section 5: Pricing Information and Rebates

Factor 5.1: The WAC, AWP, NADAC, SAAC, ASP, and FSS

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(i);
COMAR 14.01.04.05.C(1)(a)(i)
Methodology: Research and calculations to convert unit prices to annual prices
Data Sources: UpToDate (MediSpan), Centers for Medicare and Medicaid Services, Myers and Stauffer, Department of Veterans Affairs, FDA Databases

This section covers various drug pricing metrics, including the Wholesale Acquisition Cost (WAC), Average Wholesale Price (AWP), National Average Drug Acquisition Cost (NADAC), State Average Acquisition Cost (SAAC), Average Sales Price (ASP), and Federal Supply Schedule (FSS) price. The WAC and AWP are proprietary and commercially licensed from UpToDate (MediSpan). The NADAC is publicly available from the Centers for Medicare and Medicaid Services.[127] The SAAC is provided by Myers and Stauffer, a contractor of the State of Maryland.[128] The ASP is publicly available from the Centers for Medicare and Medicaid Services.[129] The FSS is publicly available from the U.S. Department of Veterans Affairs.[130] Staff converted unit prices (in this case the price per pill) to annual prices based on the FDA labels (number of pills per day times 365). Because none of the identified drugs have a reported ASP, that pricing metric is not included in the attached tables.

The following tables reflect (a) the effective date, (b) the current* unit price, and (c) the estimated annual price (based on the FDA's recommended dosing regimens and current* unit prices) for each NDC-11 associated with the prescription drug product under review.

*Current prices will not reflect price changes that occurred after August 1, 2024.

NOTE: WAC, AWP, and NADAC price history plots by NDC-11 are presented in Exhibit 1 of this file.

[127] https://www.medicaid.gov/medicaid/nadac
[128] https://myersandstauffer.com/client-portal/maryland/maryland-pharmacy/
[129] https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files
[130] https://www.va.gov/opal/nac/fss/pharmprices.asp

Table 5a. Dupixent WAC and AWP Pricing

National Drug Code	WAC Unit Price	Est. WAC per Year	AWP Unit Price	Est. AWP per Year
00024-5911-00	[redacted]	[redacted]	[redacted]	[redacted]
00024-5911-02	[redacted]	[redacted]	[redacted]	[redacted]
00024-5914-00	[redacted]	[redacted]	[redacted]	[redacted]
00024-5914-01	[redacted]	[redacted]	[redacted]	[redacted]
00024-5915-00	[redacted]	[redacted]	[redacted]	[redacted]
00024-5915-02	[redacted]	[redacted]	[redacted]	[redacted]
00024-5918-01	[redacted]	[redacted]	[redacted]	[redacted]
00024-5919-00	[redacted]	[redacted]	[redacted]	[redacted]
00024-5919-02	[redacted]	[redacted]	[redacted]	[redacted]
00024-5911-01	.	.	.	.
00024-5911-20	.	.	.	.
00024-5914-02	.	.	.	.
00024-5914-20	.	.	.	.
00024-5915-01	.	.	.	.
00024-5915-20	.	.	.	.
00024-5916-01	.	.	.	.
00024-5918-00	.	.	.	.
00024-5918-02	.	.	.	.
00024-5918-20	.	.	.	.
00024-5919-01	.	.	.	.
00024-5919-20	.	.	.	.

Blank spaces indicate that no data was provided.

Table 5b. Dupixent NADAC, SAAC, and FSS Pricing

National Drug Code	NADAC Unit Price	Est. NADAC per Year	SAAC Rate	Est. SAAC per Year	FSS Unit Price	Est. FSS per Year
00024-5914-01	$1,009.96	$27,268.86	$963.82	$26,023.19	$920.37	$24,849.86
00024-5915-02	$1,008.41	$27,226.99	$963.80	$26,022.65	$920.37	$24,849.86
00024-5918-01	$1,774.75	$47,918.37	$1,694.92	$45,762.76	$1,614.68	$43,596.24
00024-5919-02	$1,772.99	$47,870.77	$1,692.74	$45,703.88	$1,614.68	$43,596.24
00024-5911-00	.	.	.	.	.	.
00024-5911-01	.	.	.	.	.	.
00024-5911-02	.	.	.	.	.	.
00024-5911-20	.	.	.	.	.	.
00024-5914-00	.	.	.	.	.	.
00024-5914-02	.	.	.	.	.	.
00024-5914-20	.	.	.	.	.	.
00024-5915-00	.	.	.	.	.	.
00024-5915-01	.	.	.	.	.	.
00024-5915-20	.	.	.	.	.	.
00024-5916-01	.	.	.	.	.	.
00024-5918-00	.	.	.	.	.	.
00024-5918-02	.	.	.	.	.	.
00024-5918-20	.	.	.	.	.	.
00024-5919-00	.	.	.	.	.	.
00024-5919-01	.	.	.	.	.	.
00024-5919-20	.	.	.	.	.	.

Blank spaces indicate that no data was provided.

Exhibit 1 (attached) reflects pricing history for Dupixent.

Factor 5.2: Information estimating manufacturer net price and net sales amounts of the prescription drug product under review

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(a)(ii)
Methodology: Develop and apply equations to data
Data Sources: Proprietary databases including SSR Health and UpToDate (MediSpan), MCDB

The table below presents (a) the drug product under review, (b) all NDC-11s associated with the drug product, (c) the most recently available SSR rebate estimate (2024 Q2) for the drug product, (d) estimated manufacturer net prices using *equation 1*, below, (e) estimated sales amount for each APCD segment using *equation 2,* below. The previously mentioned data elements are presented at the NDC-11 level.

The proprietary data and the equations used in calculating the estimated net price are redacted to protect confidential and proprietary information in accordance with Health-General Article §§ 21-2C-10 and 21-2C-03 and applicable data and licensing agreements. The equation and estimated net sales calculation are likewise redacted to protect confidential and proprietary information.



Table 5c. Dupixent Annual Price or Sales After SSR

Drug Information		Annual Price or Sales After SSR Application (Price*SSR)					
National Drug Code	Strength	SSR Rebate	Est. WAC per Yr	Commercial (2024) Estimated Net Spend	State Local Govt Emp (2024) Estimated Net Spend	Medicaid (2024) Estimated Net Spend	Medicare (2023) Estimated Net Spend
00024-5914-01	300 MG/2ML	[redacted]					
00024-5915-00	300 MG/2ML	[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
00024-5915-02	300 MG/2ML	[redacted]					
00024-5918-01	200 MG/1.14ML	[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
00024-5919-02	200 MG/1.14ML	[redacted]		[redacted]	[redacted]	[redacted]	[redacted]
00024-5911-00	100 MG/0.67ML	[redacted]		.	.	.	.
00024-5911-01		[redacted]	.	.	.	.	.
00024-5911-02	100 MG/0.67ML	[redacted]		.	.	.	.
00024-5911-20		[redacted]	.	.	.	.	.
00024-5914-00		[redacted]		.	.	.	.
00024-5914-02		[redacted]	.	.	.	.	.
00024-5914-20		[redacted]	.	.	.	.	.
00024-5915-01	300 MG/2ML	[redacted]	.	.	.	.	.
00024-5915-20	300 MG/2ML	[redacted]	.	.	.	.	.
00024-5916-01		[redacted]	.	.	.	.	.
00024-5918-00		[redacted]	.	.	.	.	.

00024-5918-02		[redacted]	.	.	.	.	.
00024-5918-20		[redacted]	.	.	.	.	.
00024-5919-00	200MG/1.14ML	[redacted]	[redacted]	.	.	.	.
00024-5919-01	200MG/1.14ML	[redacted]	.	.	.	.	.
00024-5919-20	200MG/1.14ML	[redacted]	.	.	.	.	.
Blank spaces indicate that no data was provided.							

Table 5d. Dupixent Net Price and Net Spending Estimates

Drug Information			Annual Price or Sales After SSR Application [redacted]				
National Drug Code	Strength	SSR Rebate	Est. WAC per Yr	Commercial (2024) Estimated Net Spend	State Local Govt Emp (2024) Estimated Net Spend	Medicaid (2024) Estimated Net Spend	Medicare (2023) Estimated Net Spend
00024-5914-01	300 MG/2ML	[redacted]	[redacted]	[redacted]		[redacted]	[redacted]
00024-5915-00	300 MG/2ML	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
00024-5915-02	300 MG/2ML	[redacted]	[redacted]	[redacted]			[redacted]
00024-5911-00	100 MG/0.67ML	[redacted]	[redacted]	.	.	.	.
00024-5911-01		[redacted]	.	.	.	.	.
00024-5911-02	100 MG/0.67ML	[redacted]	[redacted]	.	.	.	.
00024-5911-20		[redacted]	.	.	.	.	.
00024-5914-00		[redacted]	[redacted]	.	.	.	.
00024-5914-02		[redacted]	.	.	.	.	.
00024-5914-20		[redacted]	.	.	.	.	.
00024-5915-01	300 MG/2ML	[redacted]	[redacted]	.	.	.	.

Blank spaces indicate that no data was provided.

Factor 5.3: The average price concession, discount, and rebate provided by the manufacturer or expected to be provided to each payor class in the State for the drug under review, expressed as a number and as a percent of the WAC

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(ii); COMAR 14.01.04.05C(1)(b)(i)
Methodology: Calculation of discount as percentage of WAC
Data Sources: Centers for Medicare and Medicaid Services

Pursuant to COMAR 14.01.04.04A, and to facilitate the cost review study, the Board requested information from manufacturers, health plans, PBMs, and wholesalers; in response, entities submitted documents to the Board. In accordance with Health-General Article §§ 21-2C-10 and 21-2C-03, and COMAR 14.01.01.04, information and data obtained by the Board—that is not otherwise publicly available—is trade secret, confidential, and proprietary information, and is not subject to disclosure. Accordingly, documents received in response to the request for information are available to the Board, but not the public, as exhibits to the dossier.

Exhibit 1 contains information responsive to this element.

Factor 5.4: The average price concession, discount, and rebate the manufacturer provided or is expected to provide for the prescription drug product under review to each PBM operating in the State, expressed as a number and as a percent of the WAC

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(iii); COMAR 14.01.04.05C(1)(b)(ii); COMAR 14.01.04.05C(1)(g)(xviii); COMAR 14.01.04.04B(3)(b)
Methodology: Reported by entities
Data Sources: Reported by entities

Pursuant to COMAR 14.01.04.04A, and to facilitate the cost review study, the Board requested information from manufacturers, health plans, PBMs, and wholesalers; in response, entities submitted documents to the Board. In accordance with Health-General Article §§ 21-2C-10 and 21-2C-03, and COMAR 14.01.01.04, information and data obtained by the Board—that is not otherwise publicly available—is trade secret, confidential, and proprietary information, and is not subject to disclosure. Accordingly, documents received in response to the request for information are available to the Board, but not the public, as exhibits to the dossier.

Exhibit 1 contains information responsive to this element.

Factor 5.5: Information supplied by the manufacturer, if any, explaining the relationship between the pricing of the prescription drug product and (a) the cost of development and (b) the therapeutic benefit of the prescription drug product, or information that is otherwise pertinent to the manufacturer's pricing decision

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(iii); COMAR 14.01.04.05C(1)(g)(viii); COMAR 14.01.04.05C(1)(g)(xviii); COMAR 14.01.04.04B(1)(a)
Methodology: Reported by entities
Data Sources: Reported by entities

Pursuant to COMAR 14.01.04.04A, and to facilitate the cost review study, the Board requested information from manufacturers, health plans, PBMs, and wholesalers; in response, entities submitted documents to the Board. In accordance with Health-General Article §§ 21-2C-10 and 21-2C-03, and COMAR 14.01.01.04, information and data obtained by the Board—that is not otherwise publicly available—is trade secret, confidential, and proprietary information, and is not subject to disclosure. Accordingly, documents received in response to the request for information are available to the Board, but not the public, as exhibits to the dossier.

Exhibit 1 contains information responsive to this element.

Section 6: Therapeutic Alternatives, Cost Comparisons, and Health Economics Outcomes and Research (HEOR)

Factor 6.1: The WAC, AWP, NADAC, SAAC, ASP, and FSS at which each therapeutic alternative has been sold in the State

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(iv);
COMAR 14.01.04.05C(1)(c)(ii)
Methodology: Calculation of number of units per year and calculation pricing per year
Data Sources: Proprietary databases including UpToDate (MediSpan); and Centers for Medicare and Medicaid Services, Myers and Stauffer, Department of Veterans Affairs

Factor 6.2: The average price concession, discount, or rebate the manufacturer provides or is expected to provide to health plans in the State for therapeutic alternatives

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(v);
COMAR 14.01.04.05.C(1)(c)(i)
Methodology: Calculation using equation
Data Sources: Proprietary databases including SSR Health and UpToDate (MediSpan)

This section provides pricing and concession information for each therapeutic alternative.

Factor 6.1 (COMAR 14.01.04.05C(1)(c)(ii) and Health-General § 21-2C-09(b)(2)(iv)) address pricing metrics (WAC, AWP, NADAC, SAAC, ASP, and FSS) for therapeutic alternatives. For each therapeutic alternative, staff identified the number of units per year for each alternative based on the FDA label. For pills, the number of units per year is the number of pills per year. For injections, the units are either milliliters, vials, or autoinjectors. For most therapeutic alternatives, staff identified the unit for each drug and the number of units per year. For drugs that have initial loading doses, staff assumed a full year of use for a patient who has previously taken the loading dose.

Factor 6.2 (COMAR 14.01.04.05.C(1)(c)(i) and Health-Gen. § 21-2C-09(b)(2)(v)) address the average price concession, discount, or rebate the manufacturer provides for each therapeutic alternative. Staff calculated the estimated dollar rebate using proprietary data from SSR health.

[redacted]

Staff developed the attached supplemental excel document (Exhibit 3_REDACTED "Dupixent Therapeutic Alternative Pricing_REDACTED") to organize these two factors and the following data for each therapeutic alternative: (a) the effective date of the price; (b) the current* unit price for WAC, AWP, NADAC, FSS and SAC; (c) the estimated annual price (based on the FDA's recommended dosing regimens and current* unit prices); and (d) calculated average dollar rebate.

Exhibit 3_REDACTED "Dupixent Therapeutic Alternative Pricing_REDACTED" contains the information specified above for therapeutic alternatives at the NDC-11.

*Current prices do not reflect price changes that occurred after January 1, 2026.

Factor 6.3: The utilization, costs, and out-of-pocket costs for therapeutic alternatives

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(c)(iii)
Methodology: Aggregation of claims to calculate utilization, spending, and out-pocket cost measures
Data Sources: MCDB

Staff developed the attached supplemental excel document Exhibit 4 (Dupixent Therapeutic Alternative Medical Claims Data Base (MCDB) Statistics (Excel Document)) to organize the following data for each NDC-11 associated with each approved therapeutic alternative by MCDB segment: (a) patient counts; (b) total units dispensed; (c) total gross spending; (d) average, median, and 90th percentile of annual patient OOP costs; and (e) the average deductible, coinsurance, copayment, and other patient liability for applicable MCDB segments.

Factor 6.4: The incremental costs associated with a prescription drug product, including financial impacts to health, medical, or social services as can be quantified and compared to baseline effects of existing therapeutic alternatives

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(ix); COMAR 14.01.04.05C(1)(e)(i)
Methodology: Literature review
Data Sources: Published cost-effectiveness studies and literature

This subsection concerns the incremental costs associated with a prescription drug product. This includes the cost of using the drug and the cost of using other health, medical, and social services to manage other aspects of health addressed by the therapy. Staff compared these costs—cost of using the drug and the cost of using other health, medical and social services—to the same costs when using a therapeutic alternative. Staff considered the costs associated with the use of the therapeutic alternative as the baseline effect. The incremental cost of the therapy is the change in all of these costs compared to the costs associated with the therapeutic alternative.

Staff reviewed published cost-effectiveness literature in the United States to identify the potential incremental costs associated with the use of Dupixent (dupilumab). Staff used Embase (Elsevier interface) to identify potential analyses. Staff combined the following string in Embase with the relevant drug terms: ('economics'/mj OR 'cost'/exp/mj OR ((economic NEAR/2 model*):ti,ab,kw,lnk) OR 'cost minimi*':ti,ab,kw OR 'cost utilit*':ti,ab,kw OR 'health utilit*':ti,ab,kw OR 'economic evaluation*':ti,ab,kw OR 'economic review*':ti,ab,kw OR 'cost outcome*':ti,ab,kw OR 'cost analys?s':ti,ab,kw OR 'economic analys?s':ti,ab,kw OR 'budget* impact analys?s':ti,ab,kw OR 'cost effective*':ti,kw OR pharmacoeconomic*:ti,kw OR 'pharmaco economic*':ti,kw OR 'cost benefit':ti,kw OR costs:ti,kw OR 'life year':ab,kw OR 'life years':ab,kw OR qaly*:ab,kw OR 'cost benefit analys?s':ab,kw OR 'cost effectiveness analys?s':ab,kw OR ((cost:ti,kw OR economic*:ti,kw) AND (costs:ab OR 'cost effectiveness':ab OR markov:ab OR 'monte carlo':ab OR model:ab OR modeling:ab OR modelling:ab))) AND ('dupilumab'/exp OR 'bat 2406':ti,ab,kw OR 'bat2406':ti,ab,kw OR 'dupilumab':ti,ab,kw OR 'dupixent':ti,ab,kw OR 'regn 668':ti,ab,kw OR 'regn668':ti,ab,kw OR 'sar 231893':ti,ab,kw OR 'sar231893':ti,ab,kw) AND ('asthma'/exp OR asthma*:ti,ab,kw OR 'lung allergy':ti,ab,kw OR 'atopic dermatitis'/exp OR ((atopic NEXT/1 (dermatitis OR neurodermatitis)):ti,ab,kw) OR 'coca sulzberger':ti,ab,kw OR ((eczema NEAR/1 (atopic* OR endogenous OR infant*)):ti,ab,kw) OR ((neurodermatitis NEAR/1 (constitutional* OR disseminata)):ti,ab,kw) OR 'bullous pemphigoid'/exp OR 'bullous pemphigoid':ti,ab,kw OR 'chronic obstructive lung disease'/exp OR 'chronic airflow obstruction':ti,ab,kw OR 'chronic airway obstruction':ti,ab,kw OR ((('chronic obstructive' OR 'obstructive chronic') NEAR/1 (bronchopulmonary OR lung OR pulmonary OR respiratory)):ti,ab,kw) OR 'chronic pulmonary obstructive':ti,ab,kw OR 'copd':ti,ab,kw OR

'chronic rhinosinusitis with nasal polyp'/exp OR 'chronic rhinosinusitis with nasal polyps'/exp OR 'chronic rhinosinusitis with nasal polyposis'/exp OR 'chronic rhinosinusitis with polyp'/exp OR 'chronic rhinosinusitis with nasal polyp*':ti,ab,kw OR 'chronic rhinosinusitis with polyp*':ti,ab,kw OR 'eosinophilic esophagitis'/exp OR 'eosinophilic oesophagitis':ti,ab,kw OR 'eosinophilic esophagitis':ti,ab,kw OR 'chronic spontaneous urticaria'/exp OR 'chronic idiopathic urticaria':ti,ab,kw OR 'chronic idiopathic/spontaneous urticaria':ti,ab,kw OR 'chronic spontaneous/idiopathic urticaria':ti,ab,kw OR 'ciu/csu':ti,ab,kw OR 'csu/ciu':ti,ab,kw OR 'idiopathic chronic urticaria':ti,ab,kw OR 'spontaneous chronic urticaria':ti,ab,kw OR 'chronic spontaneous urticaria':ti,ab,kw OR 'prurigo nodularis'/exp OR ((nodular* NEAR/1 prurigo):ti,ab,kw)) AND ('comparative effectiveness'/de OR 'comparative study'/de OR comparative:ti,ab,kw OR comparison:ti,ab,kw) AND ('article'/it OR 'article in press'/it OR 'preprint'/it OR 'review'/it). In total, this search had 23 results.[131]

The results of these studies are summarized in Exhibit 5A.

[131] Search conducted on 11 August, 2025

Factor 6.5: Information derived from health economics and outcomes research that may address the effectiveness of the prescription drug product in treating the conditions for which it is prescribed or in improving a patient's health, quality of life, or overall health outcomes, and the effectiveness of the prescription drug product compared with therapeutic alternatives or no treatment.

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(e)(ii)
Methodology: Literature review
Data Sources: Published cost-effectiveness studies and literature and published comparative effectiveness research and literature

Health Economics and Outcomes Research (HEOR) is a field of study that provides patients, providers, and decision makers with information concerning the effectiveness, costs, and quality of life resulting from health care interventions. This includes both cost effectiveness and comparative effectiveness research: cost effectiveness research compares the relative costs and outcomes (or effects) of different healthcare treatments or interventions; comparative effectiveness research compares different healthcare interventions or therapies to determine clinical effectiveness, benefits, and safety.

This research may be published in academic journals or by non-profit institutions and governmental entities.

Staff reviewed literature from two sources. First, staff used Embase (Elsevier interface) to combine the following string with the relevant drug and approved indications terms: ('treatment outcome'/exp OR (((therap* OR treatment OR clinical OR patient*) NEAR/2 outcome*):ti,ab,kw) OR ((outcome* NEXT/1 (research OR measure* OR assessment*)):ti,ab,kw) OR (((therap* OR treatment OR drug) NEXT/1 (effect* OR efficacy OR response)):ti,ab,kw) OR ((clinical* NEXT/1 significan*):ti,ab,kw) OR 'quality of life'/exp OR 'hrql':ti,ab,kw OR hrqol:ti,ab,kw OR 'health related quality of life':ti,ab,kw OR 'life quality':ti,ab,kw OR 'quality of life':ti,ab,kw) AND ('dupilumab'/exp OR 'bat 2406':ti,ab,kw OR 'bat2406':ti,ab,kw OR 'dupilumab':ti,ab,kw OR 'dupixent':ti,ab,kw OR 'regn 668':ti,ab,kw OR 'regn668':ti,ab,kw OR 'sar 231893':ti,ab,kw OR 'sar231893':ti,ab,kw) AND ('asthma'/exp OR asthma*:ti,ab,kw OR 'lung allergy':ti,ab,kw OR 'atopic dermatitis'/exp OR ((atopic NEXT/1 (dermatitis OR neurodermatitis)):ti,ab,kw) OR 'coca sulzberger':ti,ab,kw OR ((eczema NEAR/1 (atopic* OR endogenous OR infant*)):ti,ab,kw) OR ((neurodermatitis NEAR/1 (constitutional* OR disseminata)):ti,ab,kw) OR 'bullous pemphigoid'/exp OR 'bullous pemphigoid':ti,ab,kw OR 'chronic obstructive lung disease'/exp OR 'chronic airflow obstruction':ti,ab,kw OR 'chronic

airway obstruction':ti,ab,kw OR ((('chronic obstructive' OR 'obstructive chronic') NEAR/1 (bronchopulmonary OR lung OR pulmonary OR respiratory)):ti,ab,kw) OR 'chronic pulmonary obstructive':ti,ab,kw OR 'copd':ti,ab,kw OR 'chronic rhinosinusitis with nasal polyp'/exp OR 'chronic rhinosinusitis with nasal polyps'/exp OR 'chronic rhinosinusitis with nasal polyposis'/exp OR 'chronic rhinosinusitis with polyp'/exp OR 'chronic rhinosinusitis with nasal polyp*':ti,ab,kw OR 'chronic rhinosinusitis with polyp*':ti,ab,kw OR 'eosinophilic esophagitis'/exp OR 'eosinophilic oesophagitis':ti,ab,kw OR 'eosinophilic esophagitis':ti,ab,kw OR 'chronic spontaneous urticaria'/exp OR 'chronic idiopathic urticaria':ti,ab,kw OR 'chronic idiopathic/spontaneous urticaria':ti,ab,kw OR 'chronic spontaneous/idiopathic urticaria':ti,ab,kw OR 'ciu/csu':ti,ab,kw OR 'csu/ciu':ti,ab,kw OR 'idiopathic chronic urticaria':ti,ab,kw OR 'spontaneous chronic urticaria':ti,ab,kw OR 'chronic spontaneous urticaria':ti,ab,kw OR 'prurigo nodularis'/exp OR ((nodular* NEAR/1 prurigo):ti,ab,kw)) AND ('comparative effectiveness'/de OR 'comparative study'/de OR comparative:ti,ab,kw OR comparison:ti,ab,kw) AND ('article'/it OR 'article in press'/it OR 'preprint'/it OR 'review'/it). In total, this search had 267 results.[132] In addition, staff retrieved the cited references from the Comparative Effectiveness section of the drug's monograph in DRUGDEX (via Micromedex).[133] In total, staff retrieved 1 unique results.[134]

See Exhibits 5A and 5B for a summary of the literature.

[132] Search conducted on 11 August, 2025
[133] The monograph was last modified 29 July, 2025
[134] Retrieved 11 August 2025

Factor 6.6: In the case of generic prescription drug products, the number of pharmaceutical manufacturers that produce the prescription drug product

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(iii)
Methodology: Research and review of databases
Data Sources: Drugs@FDA database, FDA Orange Book

Dupixent is not a generic drug product.

Factor 6.7: The utilization and pricing of therapeutically equivalent drug products

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(xii)
Methodology: Research and review
Data Sources: FDA Orange book

This section is not applicable to biologic products because therapeutic equivalence is a concept reserved for small-molecule drugs and associated with the FDA's Orange Book.[135]

[135] For biologic drugs with more complex structures and manufacturing processes, there are other classifications in the FDA's Purple Book (Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations) that more adequately capture the differences in products.

Section 7: Cost-Sharing and Insurance Benefit Design

Factor 7.1: The estimated impact on patient access resulting from the cost of the prescription drug product relative to insurance benefit design

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(vii);
COMAR 14.01.04.05C(1)(d)(ii)
Methodology: Analyses using claims data (see below) and literature review
Data Sources: MCDB

MCDB Analysis

The following analysis aims to estimate the impact on patient access resulting from the cost of prescription drug products under study relative to insurance benefit design. In particular, we are interested in seeing (a) the distribution of coinsurance/copayment utilization among claims for the drug under study, and (b) whether increases or decreases in a patient's average copay/coinsurance per claim impact their utilization of the drug under study.

Methods

1. Extract claims for the prescription drug product of interest from commercial eligibility file
    a. Initial Inclusion Criteria:
        i. Patients filling claims for the prescription drug product of interest must have pharmacy coverage for at least 11 months of the calendar year
        ii. Patients must reside in Maryland as indicated on their pharmacy claims
        iii. Claims must not be denied or contain indicators that the claim was a duplicate submission from either a third-part administrator (i.e.,PBM), health plans providing Medicare Part D, Fee-For-Service, coverage, or commercial health plan providing Medicaid/Medicare managed care coverage.
        iv. Claims must have positive non-zero values for the total paid amount field (i.e., total gross spending) and values greater than 0 for cost-sharing payment fields (i.e., deductible amounts, copay amounts, coinsurance amounts, and other member liability amounts).
        v. Claims for patients whose 30-day normalized ratio (i.e., [total 30-day equivalents received]/[expected 30-day equivalents]) >1 are excluded
        vi. Claims for patients whose first instance of using the prescription drug product was in December were excluded.
2. Assign copay and coinsurance flags to each eligible claim and determine rate at which these cost sharing measures are utilized.
3. Prepare for regression analysis by summarizing patient information among eligible claims

   a. Sum all 30-day equivalents (*total 30-day equivalents)*
   b. Calculate expected 30 day equivalents as
      i. (Total Covered Months +1) – (Month of first prescription fill date)
   c. Calculate Normalized 30 Day Equivalent as
      i. (Total 30-Day Equivalents)/(Expected 30-Day Equivalents)
   d. Assign Continuous user flag for patients who received the drug in January or February of the calendar year
   e. Calculate the average coinsurance and copayment for each patient
   f. Create interaction term between average coinsurance/copayment as
      i. Interaction 1: (cont_user)*(average coinsurance)
      ii. Interaction 2 : (cont_user)*(average copay)
4. Run following regression on data
   a. Yi= **β 0+** β 1x1 **+** β 2x2 + β 3x3 + β 4x4 + β 5x5 where
      i. Yi = Normalized 30 Day Equivalent
      ii. β 0= Intercept
      iii. β 1 = Patient's Average Copay per Claim
      iv. β 2= Patient's Average Coinsurance per Claim
      v. β 3= Continuous User Indicator
      vi. β 4= Interaction Term – Continuous User*Avg Copay
      vii. β 5= Interaction Term – Continuous User*Avg Coinsurance

Results

Table 7a. 2023 Commercial Pharmacy Claims Characteristics for Dupixent Analysis		
	Patient Count	**Claim Count**
Total Population		
Counts	5,281	34,011
Eligible Patients (≥ 11 months of pharmacy coverage)		
Counts	3,397	9,663
Final Summary File for Eligible Claims		
Counts	1,884	24,348

Dupixent

Table 7b. Dupixent Out of Pocket Cost Frequency Analysis

COIN_FLAG	COPAY_FLAG	Frequency	Percent	Cumulative Frequency	Cumulative Percent
0	0	4117	20.94	4117	20.94
0	1	10792	54.88	14909	75.82
1	0	4725	24.03	19634	99.85
1	1	29	0.15	19663	100.00

Among eligible commercial claims for Dupixent, we see copay is used most often (54%) as part of the insurance benefit design. The use of coinsurance as part of the benefit design, either by itself or in conjunction with coinsurance payments, are only observed in about 24% of claims.

Regression Analysis

Table 7c. Summary statistics for regression variables

	N	NMiss	Min	Max	Mean	Std
Normalized 30 Day Equivalent	3397	0	0.08	1.00	0.69	0.29
Continuous User Indicator	3397	0	0.00	1.00	0.59	0.49
Average Coinsurance	3397	0	0.00	14904.00	405.72	1174.95
Average Copay	3397	0	0.00	3572.67	40.62	110.32
Continuous User*Avg. Coinsurance	3397	0	0.00	13391.00	202.16	713.89
Continuous User*Avg. Copay	3397	0	0.00	1283.40	22.75	61.45

Table 7d. Analysis of Variance

Source	DF	Sum of Squares	Mean Square	F Value	Pr > F
Model	5	6.42826	1.28565	16.01	<.0001
Error	3391	272.37867	0.08032		
Corrected Total	3396	278.80693			

Table 7e. Model Statistics.			
Root MSE	0.28341	**R-Square**	0.0231
Dependent Mean	0.69077	**Adj R-Sq**	0.0216
Coeff Var	41.02884		

Table 7f. Parameter Estimates						
Variable	**Label**	**DF**	**Parameter Estimate**	**Standard Error**	**t Value**	**Pr > |t|**
Intercept	Intercept	1	0.72656	0.00841	86.35	<.0001
AVG_COPAY	Average Copay	1	-0.00013802	0.00005225	-2.64	0.0083
AVG_COIN	Average Coinsurance	1	-0.00003128	0.00000517	-6.05	<.0001
CONT_USER	Continuous User Indicator	1	-0.03133	0.01139	-2.75	0.0060
INTX_COIN	Continuous User*Avg. Coinsurance	1	-0.00000928	0.00000878	-1.06	0.2909
INTX_COPAY	Continuous User*Avg. Copay	1	0.00012740	0.00009914	1.29	0.1989

The analysis above suggests that while there are statistically significant relationships between average copays and coinsurance and the number of prescriptions people use in a year, any impact is small.

Literature Review

Staff conducted a literature review of the published literature to determine whether similar results exist nationally. Staff conducted a literature review using Google Scholar and PubMed for articles using the search term “Co-payment Adherence dupilumab.” Staff found no responsive articles with these search terms.

Factor 7.2: The current or expected dollar value of drug-specific patient access programs that are supported by the manufacturer for the drug product under review and the policies surrounding and implementing such programs

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(viii);
COMAR 14.01.04.05C(1)(d)(iii)
Methodology: Research and review
Data Sources: Manufacturer's website

Staff identified one patient access program for Dupixent. The program is DUPIXENT MyWay® Copay Card.[136] The terms of use and eligibility for the program are expressed as follows:

> Eligible patients with commercial health insurance may pay as little as $0* in copay per fill of DUPIXENT® (dupilumab). Terms and conditions apply.
> Patients may be eligible for the *DUPIXENT MyWay*® copay card if they:
>
> - Have commercial insurance
> - Have a DUPIXENT prescription for an FDA-approved condition
> - Are a resident of the 50 United States, the District of Columbia, Puerto Rico, Guam, or the USVI and are a patient or caregiver aged 18 years or older
>
> **Subject to the program maximum per patient per calendar year. Approval is not guaranteed.* ***THIS IS NOT INSURANCE.*** *Not valid for prescriptions paid, in whole or in part, by Medicaid, Medicare, VA, DOD, TRICARE, or other federal or state programs, including any state pharmaceutical assistance programs. This program is not valid where prohibited by law, taxed, or restricted. DUPIXENT MyWay reserves the right to rescind, revoke, terminate, or amend this offer, eligibility, and terms of use at any time without notice. Any savings provided by the program may vary depending on patients' out-of-pocket costs. The program is intended to help patients afford DUPIXENT. Patients may have insurance plans that attempt to dilute the impact of the assistance available under the program. In those situations, the program may change its terms. Additional terms and conditions apply.*

[136] DUPIXENT MyWay. https://www.dupixenthcp.com/patient-support/dupixent-myway

Nationally in 2024, more than 2.3 million patients redeemed a Sanofi copay assistance card, resulting in approximately $1.5 billion in patient savings.[137]

A reasonable search failed to disclose publicly available information concerning the dollar value of Dupixent-specific patient access programs or Maryland-specific utilization.

[137] Sanofi. Our Pricing Principles & Perspectives. https://www.sanofi.us/assets/dot-us/pages/images/our-company/Social-impact/responsible-business-values/pricing-principles/Sanofi-2025-Pricing-Principles-Report_Prioritizing-Patient-Affordability_Our-Patient-Support-Programs.pdf

Factor 7.3: The average patient copay and other cost-sharing data for the prescription drug in the State

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(x);
COMAR 14.01.04.05C(1)(f)(i)
Methodology: Aggregation of claims data to calculate average by out-of-pocket cost category
Data Sources: MCDB

For each NDC-11, the following tables provide the average out-of-pocket costs by payor type. Note that the MCDB includes these fields only for the commercial sector and not Medicare or Medicaid.

Table 7g. Dupixent Average Copays and Other Cost-Sharing

National Drug Code (11-Digit)	Drug Proprietary Name	Dosage Strength	Commercial (2024) Avg Deductible	Commercial (2024) Avg Copay	Commercial (2024) Avg Coinsurance	Commercial (2024) Avg Other Member Liability
00024-5914-01	Dupixent	300 MG/2 ML	$529.30	$248.25	$1,550.55	$38.84
00024-5915-00	Dupixent	300 MG/2ML	$999.00	$999.00	$999.00	$999.00
00024-5915-02	Dupixent	300 MG/2ML	$472.22	$234.69	$1,465.16	$38.66
00024-5918-01	Dupixent	200 MG/1.14 ML	$336.49	$190.31	$2,024.66	$3.80
00024-5919-02	Dupixent	200 MG/1.14 ML	$504.78	$179.90	$1,328.79	$7.88
NOTE: Values of "999" represent suppressed data due to low beneficiary counts (i.e., patient counts < 10).						

Table 7h. Dupixent Average Copays and Other Cost-Sharing

National Drug Code (11-Digit)	Drug Proprietary Name	Dosage Strength	State Local Gov (2024) Avg Deductible	State Local Gov (2024) Avg Copay	State Local Gov (2024) Avg Coinsurance	State Local Gov (2024) Avg Other Member Liability
00024-5914-01	Dupixent	300 MG/2 ML	$22.22	$137.02	$2,135.23	$0.53
00024-5915-02	Dupixent	300 MG/2 ML	$20.52	$146.04	$2,263.30	$0.39
00024-5918-01	Dupixent	200 MG/1.14 ML	$0.00	$80.63	$3,538.00	$0.00
00024-5919-02	Dupixent	200 MG/1.14 ML	$137.63	$99.05	$1,318.19	$0.00
00024-5915-00	Dupixent	300 MG/2 ML	.	.	.	.

Blank spaces indicate that no data was provided.

Factor 7.4: The average cost share

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(f)(ii)
Methodology: Aggregation of claims data to calculate average cost share (the average percentage of gross spending paid by patients)
Data Sources: MCDB

The table below shows the cost share for different types of payors. The table does not include Medicaid because the MCDB does not include out-of-pocket cost data for Medicaid. The cost share is the patient total out-of-pocket costs divided by gross spending, which yields the percentage of gross spending paid by the patient. The average cost share is, on average, the percentage of gross spending paid by patients.

Table 7i. Dupixent Average Cost Share

National Drug Code (11-Digit)	Drug Proprietary Name	Dosage Strength	Commercial (2023) Avg. Cost Share	State Local Gov (2023) Avg. Cost Share	Medicare (2022) Avg. Cost Share
00024-5919-02	Dupixent	200 MG/1.14 ML	0.0274%	0.1383%	0.0886%
00024-5918-01	Dupixent	200 MG/1.14 ML	0.0411%	0.5021%	0.0186%
00024-5915-02	Dupixent	300 MG/2ML	0.0018%	0.0174%	0.0032%
00024-5915-00	Dupixent	300 MG/2ML	99900.0000%	.	99900.0000%
00024-5914-01	Dupixent	300 MG/2 ML	0.0045%	0.0308%	0.0055%

Blank spaces indicate that no data was provided.
NOTE: Values of "999" represent suppressed data due to low beneficiary counts (i.e., patient counts < 10).

Factor 7.5: The mean, median, and 90th percentile out-of-pocket costs per patient compared to State incomes

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(vi)
Methodology: Aggregation of claims data to determine distribution of out-of-pocket costs, research
Data Sources: MCDB, Maryland Manual On-line (derived from U.S. Census Bureau)

The table below shows out-of-pocket costs (average, median, and 90th percentile) by payor type.

Table 7j. Dupixent Average Out-of-Pocket Costs

Drug Information		Commercial (2024) Statistics			State Local Gov (2024) Statistics			Medicare (2023) OOP Statistics		
National Drug Code (11-Digit)	Dosage Strength	Avg.	Median	90th Percentile	Avg.	Median	90th Percentile	Avg.	Median	90th Percentile
00024-5919-02	200 MG/1.14 ML	$2,021.35	$250.00	$7,594.00	$1,554.86	$100.00	$7,092.00	$348.56	$31.05	$939.25
00024-5918-01	200 MG/1.14 ML	$2,555.27	$455.50	$8,904.00	$3,618.63	$1,000.00	$11,086.00	$147.74	$31.05	$520.00
00024-5915-02	300 MG/2ML	$2,210.73	$400.00	$7,195.00	$2,430.26	$225.00	$10,417.00	$611.37	$31.05	$2,661.23
00024-5915-00	300 MG/2ML	$999.00	$999.00	$999.00				$999.00	$999.00	$999.00
00024-5914-01	300 MG/2 ML	$2,366.93	$450.00	$7,698.00	$2,295.01	$200.00	$10,356.50	$634.55	$32.50	$2,873.51

Blank spaces indicate that no data was provided.
NOTE: Values of "999" represent suppressed data due to low beneficiary counts (i.e., patient counts < 10).

The Maryland Manual On-line provides estimates of the Maryland median household income and per capita personal income based on data from the U.S. Census Bureau.[138] The Maryland Manual reports a 2024 median household income of $102,905 and a per capita personal income of $78,538. The Maryland Manual also provides per capita personal income for each county. In 2023, personal income per capita ranged from $37,345 in Somerset County to $100,044 in Montgomery County.

[138] https://msa.maryland.gov/msa/mdmanual/01glance/economy/html/income.html

Factor 7.6: An assessment of the impact of the prescription drug product's cost to access by priority populations and the impact on equity

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(vii)
Methodology: Analysis of claims data
Data Sources: MCDB

Given that the claims data did not include demographic information for the vast majority of patients, staff were unable to make a conclusive assessment. Due to the lack of data and information for this element, staff are unable to provide the Board with this data, information, and analyses for study.

If demographic information were available, staff anticipated using linear regression techniques to assess whether there is a statistically significant difference in spending and utilization between identified priority populations for each selected drug. The priority populations to be assessed are informed by the Agency for Healthcare Research and Quality (AHRQ) reporting of priority populations.[139]

[139] The selection of priority populations informed by AHRQ's definitions. https://www.ahrq.gov/priority-populations/index.html (last checked April 30, 2025).

Factor 7.7: The costs to health plans based on patient access consistent with FDA-labeled indications or standard medical practice

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(vi);
COMAR 14.01.04.05C(1)(d)(i)
Methodology: Aggregation of number of unique patients in claims data and calculation potential gross spending if all patients used a full year of treatment
Data Sources: FDA Databases and MCDB

The tables below summarize the projected spending if all patients used 365 days' worth of the prescription drug product. This data was calculated based on the number of patients using an NDC multiplied by the annual WAC (as estimated in other tables). This number may be an overestimate for total spending across all NDCs because a single patient may use multiple NDCs over the course of a year. In addition, these numbers assume that patients have completed their initial doses, and all prescriptions are based on steady state doses consistent with the maximum or only dose each NDC is designed to administer.

Table 7k. costs to health plans based on patient access consistent with FDA-labeled indications or standard medical practice

National Drug Code	Dosage Strength	Projected Yearly Spending Commercial	Projected Yearly Spending State and Local Government	Projected Yearly Spending Medicare	Projected Yearly Spending Medicaid
00024-5914-01	300 MG/2ML	$49,841,499.35	$6,509,679.08	$8,858,824.13	$14,066,567.39
00024-5915-00	300 MG/2ML	$28,274,716.98	.	$28,274,716.98	$28,274,716.98
00024-5915-02	300 MG/2ML	$117,230,829.26	$13,132,569.96	$16,727,044.93	$31,218,156.61
00024-5918-01	200 MG/1.14ML	$13,108,735.93	$1,737,900.60	$1,092,394.66	$11,172,218.12
00024-5919-02	200 MG/1.14ML	$14,300,439.19	$2,135,135.02	$993,086.06	$10,030,169.16
00024-5911-00		.	.	.	.
00024-5911-01		.	.	.	.
00024-5911-02		.	.	.	.
00024-5911-20		.	.	.	.
00024-5914-00		.	.	.	.
00024-5914-02		.	.	.	.
00024-5914-20		.	.	.	.
00024-5915-01		.	.	.	.

00024-5915-20		.	.	.	.
00024-5916-01		.	.	.	.
00024-5918-00		.	.	.	.
00024-5918-02		.	.	.	.
00024-5918-20		.	.	.	.
00024-5919-00		.	.	.	.
00024-5919-01		.	.	.	.
00024-5919-20		.	.	.	.
Blank spaces indicate that no data was provided.					

Section 8: Other Information

Factor 8.1: Input from the Public

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi); COMAR 14.01.04.05C(1)(g)(xvii)
Methodology: Input received
Data Sources: Public

INITIAL 60-DAY COMMENT PERIOD

60-Day Written Comment: Notice Posted on 5/23/2024

In accordance with COMAR 14.01.04.05C(2)(a), the public may provide written comments concerning the prescription drug product within 60 days of the date the drug selected for a cost review study is posted on the Board's website. The 60-day Public Comment period for Dupixent began on May 23, 2024, and ended July 22, 2024. *See* Exhibit 6A.

WRITTEN COMMENT REQUEST

Written Comment Request: Posted 8/31/2026

In accordance with COMAR 14.01.01.05B(4), the Board requested public written comments for the cost review study process Dupixent and Skyrizi. Patient experience and clinician input regarding these drugs were of particular interest, but all comments were encouraged. Written comments were due by the close of business, Friday, September 15, 2026.

Written comments for Dupixent received in response to this request are attached as Exhibit 6B and are also available on the Board's website.[140]

[140] Ozempic Public Comment Pages 5-6
https://pdab.maryland.gov/Documents/comments/11.8.2024%20Cost%20Review%20Comment%20Packet_updated.pdf

Factor 8.2: Analysis of the impact of state and federal regulatory and compliance issues related to the prescription drug product

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(xiii)
Methodology: Research
Data Sources: Review of FDA. DEA, and State regulations

Staff did not identify any other regulatory or compliance issue that would provide additional context for the market related to this prescription drug product.

Factor 8.3: Input from state and local governmental entities and the entities' contractors such as health plans and plan administrators

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05C(1)(g)(xiv)
Methodology: Outreach to state and local governmental entities
Data Sources: State and Governmental Entities

Although Board staff reached out to state and local government entities, staff did not receive input for the cost review study of Dupixent.

For future Cost Review Studies, staff will continue to work with state and local governments to develop data and mechanisms to support this factor.

Factor 8.4: Information and analyses submitted by an entity under Regulation .04 of this chapter.

Authority: Md. Code Ann., Health-Gen. § 21-2C-09(b)(2)(xi);
COMAR 14.01.04.05.C(1)(g)(xviii)
Methodology: Request for Information
Data Sources: Manufacturer, health plans, PBMS, wholesalers as applicable

Pursuant to COMAR 14.01.04.04A, and to facilitate the cost review study, the Board requested information from manufacturers, health plans, PBMs, and wholesalers; in response, entities submitted documents to the Board. In accordance with Health-General Article §§ 21-2C-10 and 21-2C-03, and COMAR 14.01.01.04, information and data obtained by the Board—that is not otherwise publicly available—is trade secret, confidential, and proprietary information, and is not subject to disclosure. Accordingly, documents received in response to the request for information are available to the Board, but not the public, as Exhibit 2 to the dossier. Under COMAR 14.01.04.05C(1)(g)(xviii), the Board may consider the "[i]nformation and analyses submitted by an entity under Regulation .04 of this chapter."

In accordance with Health-General Article § 21-2C-09 and COMAR 14.01.04.05E, the Board only considers certain categories of information and data if the Board is first unable to make an affordability challenge determination based on the other data and information provided. If the Board is unable to make an affordability determination, the Board may then consider that information. In compliance with these requirements, Board staff redacted the information that may be considered at the second step from the submitted documents provided to the Board as exhibits to the dossier. If the Board is unable to make an affordability challenge determination, staff will provide the Board with unredacted copies of the exhibits that contain the information that may be considered at the second step.

Table of Exhibits

Exhibit 1_REDACTED		Pricing History_REDACTED (PDF)
Exhibit 2		RFI Submissions **(NON-PUBLIC--TRADE SECRET, CONFIDENTIAL, AND PROPRIETARY)**
Exhibit 3_REDACTED		Dupixent Therapeutic Alternative Pricing_REDACTED (Excel Document)
Exhibit 4		Dupixent Therapeutic Alternative Medical Claims Data Base (MCDB) Statistics (Excel Document)
Exhibit 5		
	Exhibit 5A	Dupixent Summary of Cost Effectiveness Analyses
	Exhibit 5B	Dupixent Summary of Comparative Effectiveness Research
Exhibit 6		
	Exhibit 6A	Written Comments (60-day COMAR 14.01.04.05C(2)) (PDF)
	Exhibit 6B	Written Comments (Request September 15, 2026) (PDF)

In accordance with Health-General Article §§ 21-2c-10 and 21-2c-03, information and data obtained by the Board—that is not otherwise publicly available—is trade secret, confidential, and proprietary information, and is not subject to disclosure. The documents contained in Exhibit 2, ~~t~~herefore, not available to the public.