To whom it may concern:

I am contacting you as a dermatologist caring for@NAME@ with regard to the patient's diagnosis of bullous pemphigoid.. My patient has been doing well on dupilumab but her refractory condition is not yet under control. We would like to increase the dosing of dupilumab to weekly dosing in order to obtain sufficient disease control. Unfortunately, the prior authorization was denied and the patient is now unable to fill their prescription. I have reviewed the patient's diagnosis, care plan and clinical guidelines for treatment and **request a formal appeal of your denial for weekly Dupixent dosing.**

Of note, as of 2025, the United States Food and Drug Administration has approved Dupixent (dupilumab) for the treatment of bullous pemphigoid, as well as for multiple other type 2 inflammatory conditions.

Bullous pemphigoid, a debilitating autoimmune skin disorder, can inflict significant distress on patients' lives. This condition manifests through the formation of large, fluid-filled blisters on the skin, often leading to intense itching, pain, and discomfort. Patients endure not only physical agony but also psychological distress due to the disfiguring nature of the disease, which can hinder their ability to engage in daily activities and maintain a sense of normalcy. The relentless cycle of blistering and healing can exacerbate the emotional toll, impacting mental health and overall well-being. Access to comprehensive medical care, including specialized treatments and therapies, is paramount for managing symptoms and preserving patients' quality of life. Therefore, it is imperative for insurance to provide adequate coverage for the treatments necessary to alleviate the burdens of bullous pemphigoid and support patients in their journey towards healing and recovery.

When treating a patient with bullous pemphigoid it is necessary to have access to the full spectrum of accepted treatments as patients may not be able to use one particular treatment due to lack of response, the potential for side effects or even an allergic reaction. It can become a serious safety issue for the patient if I am not able to prescribe a wide variety of treatments for this condition. Dupilumab has been explored as a treatment option to improve outcomes. In the LIBERTY-BP trial[6], Dupixent (dupilumab) demonstrated significant benefits in treating bullous pemphigoid (BP) by achieving improvements in disease remission and symptom control. Among key findings, 59% of Dupixent patients did not experience disease relapse after completing an oral corticosteroid taper, compared to just 16% of those on placebo, indicating a strong steroid-sparing effect. Additionally, Dupixent reduced the need for rescue treatment, with 42% of patients avoiding further intervention compared to only 12% in the placebo group. Secondary endpoints showed additional benefits, including a 90% or greater reduction in disease severity in 41% of Dupixent patients versus 10% in the placebo group, along with a meaningful reduction in itching (40% vs. 11%) and significant reductions in overall disease and itch severity over time. Dupilumab has also been listed as a treatment option for resistant bullous pemphigoid to consider per the European Academy of Dermatology and Venereology (EADV).

The standard dosing regimen for dupilumab in BP has generally mirrored that of atopic dermatitis (600 mg loading dose, then 300 mg every two weeks). However, published case series and systematic reviews document that some patients with severe or refractory BP may require dose escalation to every week to achieve adequate disease control. In these reports, dose intensification was associated with improved clinical outcomes and was well tolerated, with no new safety signals identified. The rationale for increased dosing frequency is supported by the pharmacokinetics of dupilumab and the need for sustained IL-4/IL-13 blockade in patients with high disease activity or rapid relapse upon dose reduction. Given my patient's persistent disease activity despite standard dupilumab dosing, and in accordance with the published literature supporting individualized dose escalation in refractory cases, I respectfully request approval for weekly dupilumab administration. This approach is medically necessary to achieve disease control, minimize corticosteroid exposure, and improve quality of life.

I strongly believe @NAME@ requires access to Dupixent at the weekly dosing. @FNAME@ is currently having numerous erythematous crusted erosions in various stages of healing, despite current medications:

Previous tx: ***

Current tx: Dupixent every other week dosing, prednisone, ***

Additionally, I request that you review the following evidence showing how this medication can be effectively utilized to treat bullous pemphigoid, and to show that weekly dosing is a reasonable and evidence supported tactic in refractory disease:

1. Dupixent. FDA Drug Label. Food and Drug Administration. Updated date: 2025-06-18.
2. Abdat R, Waldman RA, de Bedout V, et al. Dupilumab as a Novel Therapy for Bullous Pemphigoid: A Multicenter Case Series. Journal of the American Academy of Dermatology. 2020;83(1):46-52. doi:10.1016/j.jaad.2020.01.089.
3. Borradori L, Van Beek N, Feliciani C, 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;36(10):1689-1704. doi:10.1111/jdv.18220
4. Chen F, Wang Y, Chen X, Yang N, Li L. Targeting Interleukin 4 and Interleukin 13: A Novel Therapeutic Approach in Bullous Pemphigoid. Annals of Medicine. 2023;55(1):1156-1170. doi:10.1080/07853890.2023.2188487.
5. Russo R, Capurro N, Cozzani E, Parodi A. Use of Dupilumab in Bullous Pemphigoid: Where Are We Now?. Journal of Clinical Medicine. 2022;11(12):3367. doi:10.3390/jcm11123367.
6. Zhang X, Man X, Tang Z, Dai R, Shen Y. Dupilumab as a novel therapy for bullous pemphigoid. Int J Dermatol. 2023;62(4):e263-e266. doi:10.1111/ijd.16525
7. Sanofi. Dupixent is the first and only biologic to achieve significant improvements in disease remission and symptoms in bullous pemphigoid positive pivotal study [press release]. Published September 11, 2024. Accessed October 30, 2024. https://www.sanofi.com/en/media-room/press-releases/2024/2024-09-11-05-00-00-2944237

8. Cao P, Xu W, Zhang L. Rituximab, Omalizumab, and Dupilumab Treatment Outcomes in Bullous Pemphigoid: A Systematic Review. Frontiers in Immunology. 2022;13:928621. doi:10.3389/fimmu.2022.928621.
9. Liang J, Abulikemu K, Maolidan, et al. Nine Cases of Refractory Bullous Pemphigoid Treated With Dupilumab and Literature Review. International Immunopharmacology. 2023;116:109788. doi:10.1016/j.intimp.2023.109788.
10. Zhao L, Wang Q, Liang G, et al. Evaluation of Dupilumab in Patients With Bullous Pemphigoid. JAMA logoJAMA Dermatology. 2023;159(9):953-960. doi:10.1001/jamadermatol.2023.2428.
11. Mainville L, Xu L, Piguet V, Drucker AM, Croitoru DO. Time to Disease Control With Dupilumab for Bullous Pemphigoid: A Systematic Review and Meta-Analysis. Acta Dermato-Venereologica. 2025;105:adv43667. doi:10.2340/actadv.v105.43667.
12. Powers CM, Thakker S, Gulati N, et al. Bullous Pemphigoid: A Practical Approach to Diagnosis and Management in the Modern Era. Journal of the American Academy of Dermatology. 2025;92(6):1337-1350. doi:10.1016/j.jaad.2025.01.086.
13. Zhang Y, Xu Q, Chen L, et al. Efficacy and Safety of Dupilumab in Moderate-to-Severe Bullous Pemphigoid. Frontiers in Immunology. 2021;12:738907. doi:10.3389/fimmu.2021.738907.
14. Huang D, Zhang Y, Yu Y, et al. Long-Term Efficacy and Safety of Dupilumab for Severe Bullous Pemphigoid: A Prospective Cohort Study. International Immunopharmacology. 2023;125(Pt A):111157. doi:10.1016/j.intimp.2023.111157.
15. Wang SH, Shan Y, Li SZ, Zuo YG. Anti-Interleukin 4 Receptor A Antibody for the Treatment of Chinese Bullous Pemphigoid Patients With Diverse Comorbidities and a 1-Year Follow-Up: A Monocentric Real-World Study. Frontiers in Immunology. 2023;14:1165106. doi:10.3389/fimmu.2023.1165106.

On behalf of @FNAME@, I would appreciate your prompt reconsideration of this denial. Please feel free to contact me below for any additional information you may require. I look forward to receiving your response and approval of coverage for this medication.