



May 10, 2024

Maryland Prescription Drug Advisory Board (MD-PDAB)
Subject Line: Drugs Referred to the Stakeholder Council Comment
Sent Via Email comments.pdab@maryland.gov

Dear MD-PDAB Board Members and Staff:

The National Eczema Association submits these comments in response to MD-PDAB's request for comments on drugs referred to the stakeholder council at the March 25, 2024 meeting. We present our concerns with the inclusion of Dupixent (dupilumab) on the referred list.

The National Eczema Association (NEA) is a non-profit, 501(c)(3) organization that is the voice for the more than 31 million Americans and their families who are living with eczema. NEA is the driving force for an eczema community fueled by knowledge, strengthened through collective action and propelled by the promise for a better future.

Eczema is the name for a group of conditions that cause the skin to become itchy, inflamed, and have rash-like lesions. Atopic dermatitis (AD) is the most common, and chronic form of eczema, affecting more than 9.6 million children¹ and about 16.5 million adults² of all races and ethnicities in the United States³.

AD is a multidimensional, heterogeneous disease with significant burden that includes itch, pain, and sleep loss; social, academic, economic and lifestyle consequences; and negative effects on personal mental health as well as the health and wellness of the caregiver and family support system. More than 55% of people who are dealing with moderate to severe eczema have inadequate disease control^{4 5 6}.

The AD community has long-awaited treatments that can more effectively address the myriad negative disease symptoms and impacts to their quality of life. We are in the midst of a new era of care for eczema patients with several new FDA-approved groundbreaking therapies for AD, and dozens more in the drug discovery pipeline, which have the potential to be transformative in their ability to ease numerous physical, psychological, and quality of life burdens^{7 8 9}. Dupilumab is one of these novel treatments and is unique in its FDA approval down to 6 months

¹ Shaw TE, Currie GP, Koudelka CW, Simpson EL. Eczema prevalence in the United States: data from the 2003 National Survey of Children's Health. *J Invest Dermatol.* 2011;131(1):67-73.
² Chiesa Fuxench ZC, Block JK, Boguniewicz M, et al. Atopic Dermatitis in America Study: A Cross-Sectional Study Examining the Prevalence and Disease Burden of Atopic Dermatitis in the US Adult Population. *J Invest Dermatol.* 2019;139(3):583-590.
³ Hanifin JM, Reed ML, Eczema Prevalence and Impact Working Group. A population-based survey of eczema prevalence in the United States. *Dermatitis.* 2007;18(2):82-91.
⁴ McCleary, K.K. *More Than Skin Deep 'Voice of the Patient' Report.* (2020).
⁵ Simpson, E. L. *et al.* Association of Inadequately Controlled Disease and Disease Severity With Patient-Reported Disease Burden in Adults with Atopic Dermatitis. *JAMA Dermatol.* 154, 903-912 (2018)
⁶ Wei, W. *et al.* Extent and consequences of inadequate disease control among adults with a history of moderate to severe atopic dermatitis. *J. Dermatol.* 45, 150-157 (2018).
⁷ Drucker AM, Wang AR, Li WQ *et al.* The burden of Atopic Dermatitis: Summary of a report for the National Eczema Association. *J Invest Dermatol.* 2017;137(1):26-30.
⁸ Chiesa Fuxench ZC, Block, JK, Boguniewicz M, *et al.* Atopic dermatitis in America study: A cross-sectional study examining the prevalence and disease burden of atopic dermatitis in the US adult population. *J Invest Dermatol.* 2019;139(3):583-590.
⁹ Silverberg J, Gelfand J, Margolis D *et al.* Patient burden and quality of life in atopic dermatitis in US adults. *Ann Allergy Asthma Immunol.* 2018;121(3):340-347.

of age. The availability of dupilumab and other newly FDA-approved treatments for AD enables patients and their healthcare providers much needed options to align on therapeutic goals and preferences and identify a treatment approach most appropriate for the unique clinical history, disease burdens, values and needs of those living with this disease.

We recognize that these groundbreaking therapies are presenting emerging coverage, access, and out-of-pocket (OOP) cost considerations for the eczema community. NEA is actively engaged in research that strives to assess and understand the real-world lived experience of AD, and how it is, or is not improving across the diverse patient and caregiver population with advances in care and treatment. Since 2019 we have conducted 10 surveys within the eczema community on the intersecting topics of OOP costs, access to care and prescription treatments, shared decision making, and mental health, among others¹⁰. Collectively, our research efforts have addressed numerous gaps in the understanding of the AD patient and caregiver perspective, identified notable drivers and contributors to patient burden, and illustrated concepts that require additional research to more fully elucidate their interconnectivity.

For example, our research found that 42% percent of individuals affected by AD spend at least \$1,000 OOP annually for disease management¹¹. This research also highlighted the significant breadth of OOP costs for AD, which included over 20 categories of medical, non-medical, and supportive care expenses. While specific data regarding the impact of prescription drug costs as a whole, or by class of drug on household finances remains a gap, our current analyses indicate that Black race, worse AD severity, having Medicaid insurance, and the use of three or more AD therapies were each found to be associated with higher OOP costs^{12 13}.

Importantly however, our OOP survey also assessed costs related to prescriptions covered, and not covered by insurance, finding that 48.6% of individuals had incurred OOP expenses for a prescription which was not covered by their insurance¹¹. Additional NEA research conducted in 2021 found that 50% of AD patients experienced an insurance delay/denial in the past year across all currently available AD topical and systemic therapies, with 31% of prescriptions for biologics encountering a patient-reported insurance delay/denial¹⁴. Our research further highlighted the other 'cost' implications to patients related to these access issues, including additional medical expenses for care (e.g., other medications, emergency/urgent care needs), disease flares, and pursuing other treatment approaches¹⁵.

¹⁰ Research We Do. <https://nationaleczema.org/research-we-do/>

¹¹ Smith Begolka, W., Chovatiya, R., Thibau, I.J. & Silverberg, J.I. Financial Burden of Atopic Dermatitis Out-of-Pocket Health Care Expenses in the United States. *Dermatitis* 32, S62-S70. 2021

¹² Chovatiya, R., Begolka, W.S., Thibau, I.J. & Silverberg, J.I. Financial burden and impact of atopic dermatitis out-of-pocket healthcare expenses among black individuals in the United States. *Arch. Dermatol. Res.* 2021: 10.1007/s00403-021-02282-3.

¹³ Chovatiya, R., Begolka, W.S., Thibau, I.J. & Silverberg, J.I. Impact and Associations of Atopic Dermatitis Out-of-Pocket Health Care Expenses in the United States. *Dermatitis*. 2021. Doc: 10.1097/DER.0000000000000795.

¹⁴ Loisel, A.R., Thibau, I.J. & Guadalupe, M. A patient survey to identify atopic dermatitis prescription treatment access barriers. *J Am Acad Dermatol.* 2022: 10.1016/j.jaad.2022.06.073

¹⁵ Chovatiya, R., Begolka, W.S., Thibau, I.J. & Silverberg, J.I. The burden of atopic dermatitis polypharmacy and out-of-pocket healthcare expenses in the United States. 2022. Revolutionizing Atopic Dermatitis 2022 Conference.



We highlight the interconnectedness of cost and accessibility related to AD prescription treatments as we are concerned that additional cost and/or access issues could be an unintended consequence of MD-PDAB deliberations, should the availability of Dupixent for Maryland residents' change for those using state-based insurance plans.

In addition to the access issues already highlighted, we are additionally concerned about the potential for non-medical switching, which the NIH defines as, "a change in a stable patient's prescribed medication to a clinically distinct, non-generic, alternative for reasons other than poor clinical response, side-effects or non-adherence." Published medical literature has demonstrated multiple negative influences of non-medical switching on medical outcomes and healthcare utilization, including reduced medical adherence and poorer disease control^{16 17}¹⁸. Further, we are unclear how potential cost-savings to the state (i.e., establishing an upper price limit) will trickle down to alleviate patient OOP expenses and access challenges for Dupixent.

The eczema community has long-awaited these new treatments to address their significant unmet needs and improve their quality of life. We commend the MD-PDAB for their goal to reduce patient OOP costs and suggest that additional information is needed to best understand the affordability of newer medications from the perspective of the eczema community. Further, we hope that any discussion of managing costs for payers also results in transparent cost-savings for patients that does not compromise access to potentially life-changing therapies.

As you continue discussions, please consider us a resource to discuss our available data on efforts to improve patient care and address cost, coverage, and access challenges. You can reach out to Michele Guadalupe, Director of Advocacy and Access, at michele@nationaleczema.org with any questions.

Sincerely,

Julie Block, President & CEO

¹⁶ J Mark Access Health Policy. 2020; 8(1): 1829883. Published online 2020 Oct 5. doi: 10.1080/20016689.2020.1829883

¹⁷ Nguyen, Elaine et al. "Impact of non-medical switching on clinical and economic outcomes, resource utilization and medication-taking behavior: a systematic literature review." Current medical research and opinion vol. 32,7 (2016): 1281-90. doi:10.1185/03007995.2016.1170673

¹⁸ Gilbert, Ileen et al. "The Impact of a Forced Non-Medical Switch of Inhaled Respiratory Medication Among Patients with Asthma or Chronic Obstructive Pulmonary Disease: A Patient Survey on Experience with Switch, Therapy Satisfaction, and Disease Control." Patient preference and adherence vol. 14 1463-1475. 20 Aug. 2020. doi:10.2147/PPA.S242215