Asthma and Allergy Foundation of America

Indiana Pharmacy and Therapeutics Committee
October 20, 2025

Dear Committee Members,

On behalf of the Asthma and Allergy Foundation of America, we write to you to encourage the Indiana Pharmacy and Therapeutics Committee to provide meaningful access to currently approved and future needle-free forms that become FDA approved for Medicaid enrollees. Needle-free delivery forms of epinephrine provide another lifesaving option for people with anaphylaxis, especially for those who are reluctant to use needles. Epinephrine is the only option for treating severe allergic reactions and anaphylaxis.[1] Because most anaphylaxis occurs away from a medical setting, having access to choose among all forms of this life-saving drug—including auto-injectors and new needle-free forms—is essential.

Nearly 5.1% of Americans have had anaphylaxis, from a range of causes including food allergy, drug allergy, venom allergy, inhalant allergy and immunotherapy, and from mast cell disorders.[2] Food anaphylaxis is very common and rising rapidly. Between 40-50% of food allergic children and adults have had a severe reaction, and emergency room visits for food reactions have increased by 124%.[3][4][5] All such patients are prescribed self-administrable epinephrine.

There has been a longstanding unmet need for needle-free epinephrine treatments as an option for patients. Some patients will hesitate to use an auto-injector (even for their own child), delaying injection on average 9 minutes. Administering epinephrine immediately without delay is critical.[6] Delay places the patient at risk for needing additional epinephrine doses, having biphasic (rebound) reactions, and hospital admissions.[7]

Needle-free epinephrine forms address gaps in current anaphylaxis treatment while delivering enhanced clinical performance and potential good economic value:

- **Improved portability.** Needle-free forms are significantly smaller and more compact, making them easier to keep in pockets, purses, or small bags. This addresses the 60% of patients who don't always carry auto-injectors due to size and discreet carrying difficulties.[8]
- **Enhanced usability.** Needle-free forms are more intuitive to use, and require less training to do so, making them easier for laypersons in the community and patients to administer. This eliminates barriers with current devices and small failure rate seen even after auto-injector training.[9]

[1] Golden DBK, Wang J, Waserman S, Akin C, Campbell RL, Ellis AK, et al. Anaphylaxis: A 2023 practice parameter update. Ann Allergy Asthma Immunol. 2024;132(2):124-76.
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[5] Motosue et al., "Increasing Emergency Department Visits for Anaphylaxis, 2005-2014." J Allergy Clin Immunol Pract. 2017 Jan - Feb;5(1):171-175.
[6] Rooney E, Tanimoto S, Kaplan H, Lowenthal R. Injectable Devices and Triggers Driving Use: A Patient/Caregiver Survey. Ann Allergy Asthma Immunol 2022; 29(5):S16-S17
[7] Shaker MS, Wallace DV, Golden DBK, Oppenheimer J, Bernstein JA, Campbell RL, Dinakar C, Ellis A, Greenhawt M, Khan DA, Lang DM, Lang ES, Lieberman JA, Portnoy J, Rank MA, Stukus DR, Wang J; Collaborators; Riblet N, Bobrownicki AMP, Bontrager T, Dusin J, Foley J, Frederick B, Fregene E, Hellerstedt S, Hassan F, Hess K, Horner C, Huntington K, Kasireddy P, Keeler D, Kim B, Lieberman P, Lindhorst E, McEnany F, Milbank J, Murphy H, Pando O, Patel AK, Ratliff N, Rhodes R, Robertson K, Scott H, Snell A, Sullivan R, Trivedi V, Wickham A; Chief Editors; Shaker MS, Wallace DV; Workgroup Contributors; Shaker MS, Wallace DV, Bernstein JA, Campbell RL, Dinakar C, Ellis A, Golden DBK, Greenhawt M, Lieberman JA, Rank MA, Stukus DR, Wang J; Joint Task Force on Practice Parameters Reviewers; Shaker MS, Wallace DV, Golden DBK, Bernstein JA, Dinakar C, Ellis A, Greenhawt M, Horner C, Khan DA, Lieberman JA, Oppenheimer J, Rank MA, Shaker MS, Stukus DR, Wang J. Anaphylaxis-a 2020 practice parameter update, systematic review, and Grading of Recommendations, Assessment, Development and Evaluation (GRADE) analysis. J Allergy Clin Immunol. 2020 Apr;145(4):1082-1123.
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[9] El Turki A, Smith H, Llewellyn C, Jones CJ. A systematic review of patients', parents' and healthcare professionals' adrenaline auto-injector administration techniques. Emerg Med J. 2017 Jun;34(6):403-416.

- **Safety profile.** A needle-free design removes variables related to injection depth and eliminates the risk of injury from sudden patient movement during administration. This avoids accidental bone injection in smaller patients and eliminates laceration risks from the 3-10 second thigh pressure requirement for some devices.[10][11]
- **Increased patient compliance.** Allergy specialists and patient advocates are hopeful that having the choice of smaller, easier to carry, needle-free options will encourage patients to carry devices consistently and use them earlier during reactions before they become critically severe. When patients have a device that better fits their lifestyle preferences, they are more likely to have it available when needed and feel confident using it promptly.
- **Pharmacological performance.** Data from the pivotal studies from needle-free options show that these forms have more optimal pharmacokinetic and pharmacodynamic properties. These reach higher blood epinephrine levels, which then stay in the body longer, raising heart rate and blood pressure more rapidly and to higher levels than injectable epinephrine delivery methods.[12] These enhanced pharmacological properties are highly desirable when treating anaphylaxis, as faster onset and sustained elevation of vital hemodynamic parameters can improve patient outcomes during severe reactions.
- **Economic advantages.** Research shows these devices can be cost-effective based on current market prices and improved patient acceptance when compared with existing therapies.[13] [14] The extended shelf life of the needle-free products compared to auto-injectors further enhances economic value by reducing the frequency of prescription refills. The reduced waste from expired devices and improved patient compliance creates cost savings throughout the healthcare system while maintaining therapeutic effectiveness.
- **Updated clinical management approach.** The needle-free epinephrine products have updated package insert instructions which do not state that all patients should immediately seek emergency care after use, reflective of 2023 Joint Taskforce on Allergy Practice Parameters updated anaphylaxis guidelines. This management pathway has been shown to be more cost-effective than all patients universally presenting for emergency care per a 2018 study.[15][16]

The undersigned support Medicaid Preferred Drug Lists including needle-free epinephrine forms an option for patients at risk for anaphylaxis. Our mission includes advocating for expanded treatment choice, and while many patients may prefer auto-injectors, this should be a matter of patient choice rather than one forced by lack of alternatives. When patients are too hesitant to use needle-based devices during severe reactions, this inaction could lead to costly healthcare utilization including emergency department visits, ambulance transport, and potential hospitalization-- defeating the purpose of containing medication costs. Thank you very much for your time and attention. If you would like additional information, please contact Matthew Greenhawt, MD, MBA, MSc or Alexa Jordan, MSt.

Sincerely,

Kenneth Mendez

Kenneth Mendez
President and Chief Executive Officer
Asthma and Allergy Foundation of America

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