Colorado Pharmacy and Therapeutics Committee

Dear Committee Members,

On behalf of the undersigned organizations and medical professionals, we write to you to encourage the Colorado 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. 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.[1]

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.[2] Delay places the patient at risk for needing additional epinephrine doses, having biphasic (rebound) reactions, and hospital admissions.[3] Needle-free epinephrine forms address gaps in current anaphylaxis treatment:

- **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.[4]
- **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.[5][6]
- **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.[7] 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.
- **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.[8][9]

The undersigned collective missions include 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. 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,
Alpha-gal Alliance Action Fund, American Academy of Allergy Asthma & Immunology (AAAAI), American College of Allergy, Asthma & Immunology (ACAAI), Asthma and Allergy Foundation of America (AAFA), Food Allergy and Anaphylaxis Connection Team (FAACT), and FOODiversity.

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