



August 24, 2018

The Honorable Alex M. Azar II
Secretary of the United States Department of Health and Human Services
200 Independence Avenue S.W.
Washington, DC 20201

Dear Mr. Secretary:

On behalf of the Asthma and Allergy Foundation of America (AAFA) and the more than 15 million Americans living with life-threatening food allergies, I am writing with concerns about the recent shortages of epinephrine auto-injectors (EAI). Access to this medication is a matter of life and death for these Americans. The announcement by the Food and Drug Administration of a new generic epinephrine auto-injector is good news. However, the FDA's decision won't solve the current shortage. Patients are getting shortchanged because they do not have access to readily available options.

AAFA (www.aafa.org), a not-for-profit organization founded in 1953 and its division Kids With Food Allergies (www.kidswithfoodallergies.org), is the leading patient organization for people with asthma and allergies, and the oldest asthma and allergy patient group in the world. We are hearing distressing reports from patients and families that they are unable to get prescriptions for epinephrine auto-injectors. As leader of HHS, there are some facts that could help you solve this "shortage" of EAI's and better protect patients.

First, there should be no shortage of EAI's. Kaléo, one of the three companies that manufactures EAI's released a statement that it has ample supplies of its EAI, Auvi-Q®. However, many insurance plans do not cover this device, including some Medicare Part D plans. Kaléo offers a patient assistance program for those who have commercial insurance, but Medicare Part D participants cannot take advantage of this patient assistance program because of federal restrictions. Isn't there a way HHS could work with Kaléo to provide short-term access to these EAI's until supplies from the other two manufacturers catch up?

Even more concerning, we are hearing from patients in our community that Kaiser Permanente is rationing or splitting up dosages of the generic Adrenaclick® EAI. This is a dangerous practice as patients should always have two doses available since one dose is sometimes not enough.

Now is the time for private insurance, pharmacy benefit companies, the federal government and pharmaceutical companies to work together and fast-track coverage for a readily available product. Such cooperation would save lives, solve a drug shortage issue and provide affordable treatment access to patients.

Until supply is restored from the two other manufacturers, here are some solutions to help and protect patients in the short-term:



- Insurers (including Medicare) should offer coverage for any EAI. If the EAI that is covered by their formulary is not available due to shortages, insurers should make an exception and cover other products for their patients.
- Insurers and pharmacy benefit management companies must fill prescriptions for pairs of EAIs and not split the prescription in half. The National Institutes of Health guidelines state that people with food allergies should be provided with a prescription of two doses of epinephrine (twin packs).
- Insurers must allow refills to cover more than one pair of EAIs in a 30-day period to allow patients to catch up with the prescriptions that could not be filled in earlier months because of “shortages”. This allows families to properly stock emergency medications at the beginning of the school year. (School policies require a supply of twin packs. Patients should have another twin pack that is carried outside of school hours.)

These are common sense solutions that can address the current “shortage” and make a difference for people with life-threatening allergies. Patient access to this life-saving drug must be restored, especially when there are options available.

There is no real shortage of EAIs. AAFA respectfully requests to meet with you, Mr. Secretary, to discuss how we can help resolve this urgent issue. We implore HHS to lead coordination among the various stakeholders who can provide swift solutions and save lives.

Sincerely,

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