Bryn PHARMA

A Better Way™

Unmet Need and Disease Burden

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Patients Are Not Adequately Protected for a Serious, Life-Threatening Condition: Anaphylaxis

49M 

Studies have shown that the **at-risk population** may be as large as 49 million[1]

16M 

Estimated prevalence is 16 million[2]

1/2 

Only half of patients who experienced an anaphylactic event have been **prescribed epinephrine**,[2,3] and the majority of patients have **poor carry rates** and **refill rates**[2]

1500 

Anaphylaxis causes 1500 **deaths annually in the United States**[4]

Underdiagnosis of anaphylaxis is common, perhaps due to its varied etiology and presentation[5]

11%–57% of patients leave postanaphylactic care without an identified trigger[3,6]

Food allergies cause 65% of anaphylactic events in children[5,7]

Medications and insect stings/venom become more prevalent triggers in adult populations[3]

1. Fromer L. *Am J Med.* 2016;129(12):1244-1250. **2.** Bryn Pharma Data on File. **3.** Wood RA et al. *J Allergy Clin Immunol.* 2014;133(2):461-467. **4.** Lindor RA et al. *West J Emerg Med.* 2018;19(4):693-700. **5.** Simons FE et al. *World Allergy Organ J.* 2015;8(1):32. **6.** Motosue MS et al. *J Allergy Clin Immunol Pract.* 2017;5(1):171-175e3. **7.** Wright CD et al. *Ann Allergy Asthma Immunol.* 2017;118(4):461-464.

Guidelines Unequivocally Recommend First-Line Epinephrine As the Only Effective Treatment for Patients With Anaphylaxis[1-4]

Epinephrine (adrenaline) is the standard of care in the treatment of patients with anaphylaxis.[1]

- FDA approved with no absolute contraindications
- Exhibits alpha- and beta-adrenergic properties to tighten blood vessels and open airways during anaphylaxis
- Epinephrine is the only effective treatment to reduce hospitalizations and death

After treatment of an acute anaphylactic event, guidelines recommend, in part:[2]

- Dispensing an epinephrine auto-injector to the patient
- Providing an anaphylaxis action plan to the patient

"Two auto-injectors should be provided because up to 30% of patients who develop anaphylaxis will require more than 1 dose of epinephrine."[2]

2015 Anaphylaxis Practice Parameter developed by the AAAAI, ACAAI, and JCAAI

AAAAI: American Academy of Allergy, Asthma and Immunology; ACAAI: American College of Allergy, Asthma and Immunology; FDA: Food and Drug Administration; JCAAI: Joint Council of Allergy, Asthma and Immunology.

1. Simons FE et al. *World Allergy Organ J*. 2015;8(1):32. **2.** Lieberman P et al. *Ann Allergy Asthma Immunol*. 2015;115:341-384. **3.** Sampson HA et al. *J Allergy Clin Immunol*. 2006;117(2):391-397. **4.** Prince BT et al. *J Asthma Allergy*. 2018;11:143-151.

Epinephrine Auto-injectors Elicit Concern, Anxiety, and Discomfort Among Children, Caregivers, and Adults[1-5]

Affordability[5]

Fear of Administration/ Needles[5,6]

Social Stigma and Embarrassment[7]

Portability Concerns[7]

Patients, caregivers, and physicians uniformly cite cost and size/portability of EAIs as their first and second unmet needs in anaphylaxis treatment[8]

EAIs: epinephrine auto-injectors.

1. Shemesh E et al. *J Allergy Clin Immunol Pract.* 2017;5(2):391-397.e4. **2.** Fleischer DM et al. *Pediatrics.* 2012;130:e25-e32. **3.** Chad L et al. *Allergy.* 2013;68:1605-1609. **4.** Ward CE. *Ann Allergy Asthma Immunol.* 2015;114(4):312-318. **5.** Prince BT et al. *J Asthma Allergy.* 2018;11:143-151. **6.** Motosue MS et al. *J Allergy Clin Immunol Pract.* 2017;5(1):171-175e3. **7.** Akeson N et al. *Clin Exp Allergy.* 2007;37(8):1213-1220. **8.** Bryn Pharma Data on File.

There Are Many Factors That Can Cause Patients to Delay the Use of an EAI

Misinformation, infrequent linkages to care, and humanistic and economic burdens underscore barriers to proper anaphylaxis management/protection

Acute Setting Barriers

- Patients are often not referred to specialists (eg, allergy, immunology)[1]
- 50% of patients are discharged without outpatient epinephrine prescriptions[2,3]
- Anaphylaxis action plans are provided to <50% of patients[2]
- >80% of patients cannot demonstrate accurate injection technique[4]

- Fear of using auto-injector/needles[4]
- Cost[5]
- Expired auto-injector[6]
- Not carrying 1 or 2 auto-injectors[3,7]

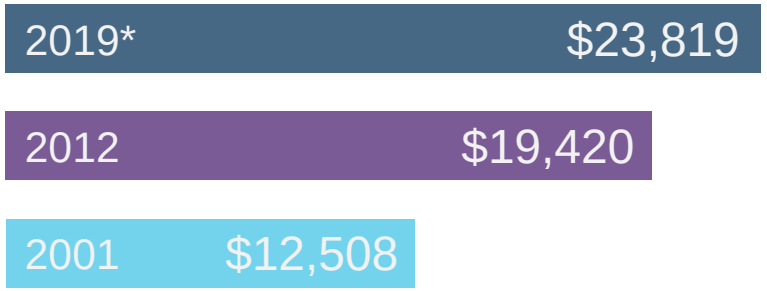
Secondary Prevention Barriers

1. Chooniedass R et al. *Ann Allergy Asthma Immunol*. 2017;119(2):108-110. **2.** Wood RA et al. *J Allergy Clin Immunol*. 2014;133(2):461-467. **3.** Bryn Pharma Data on File. **4.** Prince BT et al. *J Asthma Allergy*. 2018;11:143-151. **5.** Warren CM et al. *Ann Allergy Asthma Immunol*. 2018;121(4):479-491. **6.** Dunn JD et al. *Am J Med*. 2014;127:S45-S50. **7.** Brooks C et al. *Ann Allergy Asthma Immunol*. 2017;119(5):467-468.

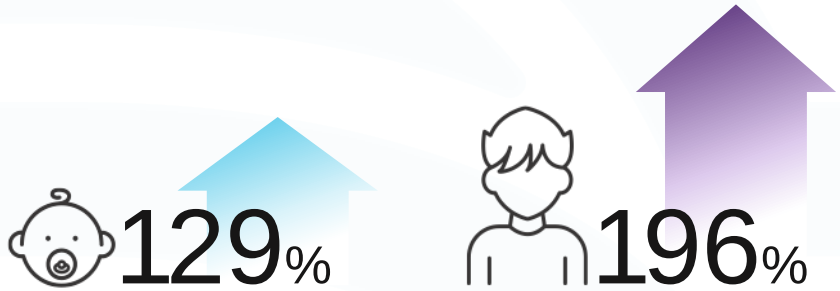
Delaying Timely Epinephrine Administration Has Been Associated With Poor Outcomes and Increased Cost[1-4]

- There are **~100,000** yearly ED visits due to anaphylaxis[5]
- When epinephrine is administered prior to ED arrival, the likelihood of hospital admission is reduced significantly[1]
- Most cases of death from anaphylaxis are due to delayed administration of epinephrine[6]

Mean Total Cost of an Anaphylaxis-Related Hospitalization Is Projected to Approach $24,000 in 2019[7]



Children Account for the Greatest Increase in Anaphylaxis ED Visits Between 2005 and 2014[8]



ED: emergency department.
*2019 forecasted value obtained from extrapolating yearly increase observed between 2001 and 2012.

1. Fleming JT et al. *J Allergy Clin Immunol Pract.* 2015;3(1):57-62. **2.** Lindor RA et al. *West J Emerg Med*. 2018;19(4):693-700. **3.** Tsai G et al. *Allergy Asthma Clin Immunol*. 2014;10(1):39. **4.** Nowak R et al. *J Emerg Med.* 2013;45(2):299-306. **5.** Bryn Pharma Data on File. **6.** Prince BT et al. *J Asthma Allergy.* 2018;11:143-151. **7.** Candrilli S et al. *Value Health.* 2015;18(7):A503. **8.** Greenberger PA et al. *Ann Allergy Asthma Immunol.* 2017;119(4):333-338.