Mylan's Commitment to EpiPen® (epinephrine injection, USP) Auto-Injector Access

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“Mylan has worked tirelessly over the past several years advocating for increased anaphylaxis awareness, preparedness and access to treatment for those living with potentially life-threatening (severe) allergies. Ensuring access to epinephrine – the only first-line treatment for anaphylaxis – is a core part of our mission.

We are proud of the programs which we have implemented over the past several years to help support access to treatment, including our My EpiPen Savings Card®, a patient assistance program, and the *EpiPen4Schools*® program which provides free EpiPen® (epinephrine injection, USP) Auto-Injectors to U.S. schools.

- In 2015, nearly 80% of commercially insured patients using the My EpiPen Savings Card® received EpiPen® Auto-Injector for $0.
- Since the start of the *EpiPen4Schools*® initiative in 2012, more than 700,000 free EpiPen® Auto-Injectors have been distributed, and more than 65,000 schools, approximately half of all U.S. schools, have participated in the program.

With the current changes in the healthcare insurance landscape, an increasing number of people and families have enrolled in high deductible health plans, and deductible amounts continue to rise. This current and ongoing shift has presented new challenges for consumers, and now they are bearing more of the cost. This new change to the industry is not an easy challenge to address, but we recognize the need and are committed to working with customers and payors to find solutions to meet the needs of the patients and families we serve.”

Additional Information:

The Evolving Healthcare Insurance Landscape

- According to the Kaiser Family Foundation, deductibles (the amount a patient must pay before their insurance coverage is applied) have increased significantly over the past five years.
- Previously a patient may have paid a $25 co-pay for a prescription regardless of the product cost. Today, with a high deductible health plan, they must pay the full product cost, which they may have previously been unaware of, until their deductible is reached.
- We encourage all patients and families to thoroughly review and understand their healthcare insurance coverage. Premiums, prescription coverage, out-of-pocket limits and deductibles can vary widely. Often, plans offering lower premiums have higher deductibles, and many options now have separate pharmacy and medical expense deductibles.

Mylan’s Commitment to Access

With up to 43 million Americans at risk for anaphylaxis, a potentially life-threatening reaction, Mylan is committed to serving the community at risk for life-threatening allergic reactions and continues to invest in EpiPen® Auto-Injector in traditional and unconventional ways to address patient needs. Given the unpredictable and life-threatening nature of anaphylaxis, avoidance of known allergens is critical to the prevention of anaphylaxis, and nothing is more costly than failed or no treatment.

Our Initiatives

- With an estimated one in 13 children affected by food allergies, we started our efforts in 2012 advocating for increased access and legislation to permit stock, or undesignated, epinephrine in the school setting. Forty-seven states now have laws related to stocking epinephrine auto-injectors so they may be available to someone experiencing anaphylaxis in the school setting. In the same year, we launched our *EpiPen4Schools*® program. Today, we’re continuing this mission to expand access to epinephrine in public entities beyond schools; 28 states now have entity epinephrine stocking legislation.
    - The findings from a recent survey of more than 6,000 schools participating in the *EpiPen4Schools*® program during the 2013-2014 academic year underscore the importance of access to epinephrine in this setting and the positive impact of the program. Survey results include:
        - More than 1,000 episodes of anaphylaxis were reported.
        - More than 75% of the anaphylactic episodes were treated with epinephrine auto-injectors.
            - Of those anaphylactic events treated with epinephrine auto-injectors, nearly 40% were treated with

an EpiPen® Auto-Injector provided through the *EpiPen4Schools®* program.

- 25 percent of reported anaphylaxis events occurred in individuals with no known allergies.

- Mylan's My EpiPen Savings Card® provides up to $100 savings for each EpiPen 2-Pak® carton per prescription, up to three EpiPen 2-Pak® or EpiPen Jr 2-Pak® cartons. Mylan has significantly invested in this program since its inception in 2013 to help millions of patients access this important treatment. The majority of patients using the savings card have received, and continue to receive, EpiPen® Auto-Injector for $0.

- Today nearly 250 million insured Americans have access to EpiPen® Auto-Injector. This is a result of our work with a variety of parties such as wholesalers, pharmacy retailers, and payors including pharmacy benefit managers and managed care organizations, to help provide the best access to treatment for patients.

- Mylan has supported numerous educational initiatives and resources to help improve anaphylaxis awareness and preparedness.

EpiPen® Auto-Injector

- EpiPen® Auto-Injector product features have been updated over time to help provide ease of use in emergency situations. Some of the features include a flip-top carry case designed for single-handed opening during an emergency situation, a never-see-needle design that offers needle protection for patients and caregivers, and a unique design that helps facilitate fast retrieval and a steady grip to assist in the administration process.

- To align with the National Institute of Allergy and Infectious Diseases (NIAID) food allergy guidelines, each EpiPen 2-Pak® and EpiPen Jr 2-Pak® carton contains two single auto-injectors, instructions for use, and a training device and instructions on how to use the training device to help patients become familiar with the administration technique. The training device contains no drug product or needle.

- Since the launch of EpiPen® Auto-Injector, training and support have been a primary focus. Mylan continues to provide a robust training program with a broad range of materials for patients, caregivers and healthcare practitioners. Resources include:

    - A "How To" video that is available on EpiPen.com, our YouTube Channel and through the MyEpiPlan® app.

    - Additional EpiPen® Trainers offered on EpiPen.com.

    - My EpiPlan® app helps patients track allergens, the location of EpiPen® Auto-Injectors, expiration dates, emergency contact information and more.

Indications

EpiPen® (epinephrine injection, USP) 0.3 mg and EpiPen Jr® (epinephrine injection, USP) 0.15 mg Auto-Injectors are for the emergency treatment of life-threatening allergic reactions (anaphylaxis) caused by allergens, exercise, or unknown triggers; and for people who are at increased risk for these reactions. EpiPen® and EpiPen Jr® are intended for immediate administration as emergency supportive therapy only. Seek immediate emergency medical help right away.

Important Safety Information

Use EpiPen® or EpiPen Jr® Auto-Injectors right away when you have an allergic emergency (anaphylaxis). **Get emergency medical help right away.** You may need further medical attention. Only a healthcare professional should give additional doses of epinephrine if you need more than two injections for a single anaphylactic episode. EpiPen® or EpiPen Jr® should **only** be injected into the middle of your outer thigh (upper leg), through clothing if necessary. Do not inject into your veins, buttocks, fingers, toes, hands or feet. Hold the leg of young children firmly in place before and during injection to prevent injuries. In case of accidental injection, please seek immediate medical treatment.

Rarely, patients who have used EpiPen® or EpiPen Jr® may develop an infection at the injection site within a few days. Some of these infections can be serious. Call your healthcare professional right away if you have any of the following at an injection site: redness that does not go away, swelling, tenderness, or the area feels warm to the touch.

Tell your healthcare professional about all of your medical conditions, especially if you have asthma, a history of depression, thyroid problems, Parkinson's disease, diabetes, high blood pressure or heart problems, have any other medical conditions, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed. Be sure to also tell your healthcare professional all the medicines you take, especially medicines for asthma**. If you have certain medical conditions, or take certain medicines, your condition may get worse or you may have longer lasting side effects when you use EpiPen® or EpiPen Jr®.**

Common side effects include fast, irregular or "pounding" heartbeat, sweating, nausea or vomiting, breathing problems, paleness, dizziness, weakness, shakiness, headache, feelings of over excitement, nervousness or anxiety. These side effects usually go away quickly if you lie down and rest. **Tell your healthcare professional if you have any side effect that bothers you or that does not go away.**

Please see the full Prescribing Information and Patient Information.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For additional information, please contact us at 800-395-3376.