

Med-Sense Guaranteed Association JOURNAL

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What is an Emergency Use Authorization

(BPT) - Sponsored by Pfizer. According to the FDA, an Emergency Use Authorization (EUA) is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic.¹ An EUA allows the use of medical products, not yet approved, when there are no adequate, approved and available alternatives.²

Since the start of the COVID-19 pandemic, the FDA has issued EUAs for select medical products and drugs it believes may help address the impact of the virus on the American public.³

What are the criteria for a COVID-19 vaccine candidate to receive an EUA?

When the Health and Human Services (HHS) Secretary has issued a public health emergency the FDA may issue an EUA after it has determined that the following requirements are met²:

- Based on available scientific evidence, including data from clinical trials, it is reasonable to believe that the product may be effective to prevent, diagnose or treat serious or life-threatening diseases or conditions that can be caused by SARS-CoV-2 (the virus that causes COVID-19).
- The identified and potential benefits of the product, when used to diagnose, prevent or treat the identified serious or life-threatening disease or condition, outweigh the identified and potential risks of the product.
- There is no adequate, approved and available alternative to the product for diagnosing, preventing or treating the disease or condition.

Who will have access to a vaccine that receives an EUA?

In the U.S., the Centers for Disease Control and Prevention

(CDC) will recommend the allocation of vaccine doses and who should receive a vaccine first, if there are not enough doses of the vaccine for everyone. On December 1, the CDC's Advisory Committee on Immunization Practices (ACIP) made initial recommendations on who should be offered COVID-19 vaccination in the initial phase of the U.S. COVID-19 vaccination program, while there is limited vaccine supply, and recommended that healthcare personnel and residents of long-term care facilities should be prioritized first.⁴

Will an EUA mean that the vaccine has been tested for safety?

Issuance of an EUA for a COVID-19 vaccine requires a determination by the FDA that the vaccine's known and potential benefits outweigh its known and potential risks based on data from at least one well-designed Phase 3 clinical trial that demonstrates the vaccine's safety and efficacy in a clear and compelling manner.² An EUA for COVID-19 vaccines will be assessed by the FDA on a case-by-case basis considering all available scientific evidence.²

"The FDA's Emergency Use Authorization process serves an absolutely critical role during public health emergencies. Throughout the COVID-19 global pandemic, we have

welcomed the opportunity to work collaboratively with the FDA, CDC and regulatory agencies around the world to help fight the COVID-19 global pandemic," noted Donna Boyce, vice president of Global Regulatory Affairs for Vaccines at Pfizer.

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1 Emergency Use Authorization for Vaccines Explained. U.S. Food and Drug Administration. Accessed December 10, 2020. <https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained>. Published 2020.

2 US Food and Drug Administration. Emergency use authorization for vaccines to prevent COVID-19 - Guidance for industry. Accessed October 2020. <https://www.fda.gov/media/142749/download>.

3 Emergency Use Authorization. U.S. Food and Drug Administration. Accessed December 4, 2020. <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>. Published 2020.

4 Centers for Disease Control and Prevention. How CDC is making COVID-19 vaccine recommendations. Accessed November 6, 2020. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations-process.html>. Published 2020.

MSGA members now have access to Drive.Fitness

Drive.Fitness is a free benefit exclusively for members of Med-Sense Guaranteed Association. Drive.Fitness has partnered with a team of experienced trainers to provide workout routines designed to help you lose weight, gain strength or stay fit.

Download the Drive.Fitness app on your iOS or Android device and use it at work, home or in the gym. The app offers over 200 different exercises for cardio and strength training and over 60 workout plans. You can even connect the Drive.Fitness app to other applications such as Fitbit, MapMyRun, and MyFitnessPal.

Use the app to view on-demand instructional videos that can guide you through your workout. After your workout you're able to track what you did - how long you worked out, how many reps you did, how much weight you lifted, etc. You can even track results such as weight, waist size and BMI!

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YOUR COVID-19 VACCINATION QUESTIONS, ANSWERED



(BPT) - With COVID-19 vaccination underway in the United States, many Americans are preparing to get the vaccine to protect themselves and help slow the spread of COVID-19. If you're able to get the vaccine, you probably have a lot of questions. Knowing what to expect and how to properly prepare for your appointment can help put your mind at ease.

COVID-19 vaccine basics

COVID-19 vaccines are now available in the U.S., and according to the Centers for Disease Control and Prevention (CDC), the vaccines approved in the U.S. do not contain the live virus that causes COVID-19 and therefore you cannot contract COVID-19 from them. The CDC states these vaccines have been carefully evaluated in clinical trials and are deemed safe and effective by the U.S. Food & Drug Administration (FDA) with a full advisory committee meeting review for all vaccines.

Preparing for the COVID-19 vaccine

Getting a vaccine not only protects you, but also the people around you, especially those who are unable to get vaccinated. The CDC offers guidance summarized below to help you prepare for your vaccination, whether it's your first or second dose:

1. If you're approved to get a vaccine, talk to your healthcare provider ahead of time. You may be going to a vaccination clinic where your healthcare provider is not directly administering the injection, so if you have questions, speak with them before your appointment.

2. Do not schedule any other vaccinations within two weeks before your COVID-19 vaccination. If you feel ill before your appointment, call the vaccination clinic and ask if you should still come in or reschedule.
3. Get good rest the days prior to the appointment, especially the night before. Eat a light meal or snack before your appointment and stay hydrated. Rest and good nutrition help prepare your immune system for the vaccination.
4. Ask about side effects. While some people have no symptoms, others may experience headache, muscle/joint pain, chills, fever and fatigue that generally subside after 48 hours. Plan for several low-key days following your vaccination.
5. Plan ahead for post-vaccination care by having the essentials on hand in your medicine cabinet. According to the CDC, over-the-counter medications (like Advil) can reduce pain, fever or discomfort associated with post-COVID-19 vaccine, including mild aches or arm soreness. According to Dr. Jeffrey Fudin, B.S., Pharm.D., FCCP, FASHP, FFSMB, "Aches and fever are common side effects of coronavirus vaccination, and can easily be treated with a pain reliever like Advil."
6. If your vaccine requires two doses, consult with your vaccination clinic or pharmacy to schedule your second dose.

While millions in the U.S. have received the COVID-19 vaccine, availability is currently limited and you may not be able to get it right away. Continue to take smart safety measures such as washing your hands frequently with soap and water, wearing a mask when out in public, avoiding large crowds, and appropriate social distancing. When it is time to get your COVID-19 vaccination, these preparatory steps will help you feel empowered as you take an important step to end the pandemic. For more information about how to prepare for the COVID-19 vaccine visit www.cdc.gov, and visit www.Advil.com for more information on Advil.



Enjoy member-only discounts and corporate rates on everything from pizza and the zoo, to movie tickets, car rentals, and hotels. With over 302,000 offers across 10,000 cities and easy mobile access, you'll always have a reason to *Celebrate Your Savings!*



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Abernity



WHAT TO LOOK FOR IN AN INFANT DAYCARE

(Family Features) It can be challenging to raise a baby even in the best of times, but many parents need additional support for the education and care of their young children amid the COVID-19 pandemic. According to the U.S. Bureau of Labor, both parents work in nearly two-thirds of families with children. The number of working single parents is even higher.

However, as long as teachers and staff follow rigorous health and safety practices, day care centers are among the safest places for children right now.

“More than ever before, families are struggling with balancing the need to return to consistent routines with concerns about the possible health risks to their children,” said Dr. Elanna Yalow, chief academic officer of KinderCare Learning Centers. “Our rigorous safety protocols give families confidence they can count on our programs when traditional support systems may not be available.”

Although the decision to place your baby in someone else’s care can be difficult, the benefits of day care can be significant, especially for children who start a program as babies. Consider these important factors when choosing an infant day care.

Exceeding Recommended Guidelines

Parents will want to make sure their day care center follows Centers for Disease Control and Prevention, American Academy of Pediatrics and local health department guidelines. These include masks and social distancing, restricted access to classrooms, consistent grouping of children, health screenings upon entry, handwashing throughout the day and frequent cleaning and sanitizing. In addition to knowing the steps teachers and staff are taking to keep children safe, ask about staff training and the checks and balances the center has in place to make sure written policies translate into best practices in classrooms.

Teachers Who See Each Baby as an Individual

Responsive, caring teachers tend to each baby's specific needs. From the moment you meet them, they'll ask what your baby enjoys, what comforts him or her, what milestones your baby is working on and so forth. The best teachers see each baby as a unique person and work to meet your child wherever he or she is, whether that's watching for signs of tiredness and holding him or her or responding to your baby's babbling and coos as signs of early language development.

Strong Communication

Trusting someone else to look after your bundle of joy is a tremendous leap of faith for many parents, particularly as safety-conscious providers are limiting access to their classrooms and parents may not be able to go any further than the front door. That leap is easier if you

know you'll receive updates about your child throughout the day. Whether you want videos and photos, phone calls or texts, or short notes about the things your child is doing while you're at work, talk with your potential provider about how often you want updates and what kind of information is most meaningful to you. While it's natural to feel a twinge of nervousness when you get a phone call from your child's day care, you should also be contacted with good news and friendly reminders.

For many parents, the most important thing is that their baby is safe, happy and flourishing in a loving, caring and engaging environment. Once they find this, they can rest assured they made the best decision for their family. Find more information and tips to find the right center at kindercare.com.

In 2020, MSGA proudly awarded 28 college scholarships in the amount of \$5,000 each to MSGA members and their dependents.

For the 2021-2022 school year, MSGA plans to continue this scholarship program. These scholarships will be awarded prior to August 1, 2021.

To be eligible, applicants must be able to demonstrate how their scholarship funds will be used to help with their academic success. The Scholarship Committee will also review letters of recommendation, overall GPA, and the student's goals when awarding scholarships.

More information regarding the 2021-2022 scholarship program will soon be available on the member website at www.medsensemembersonline.com. Members will also be receiving emails announcing the beginning of the program.



For information regarding your membership
and association services, call or write:

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