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What's Inside…

FDA NEWS

FDA Grants Emergency Use Authorization to Pfizer-BioNTech COVID-19 Vaccine

On the evening of Friday, December 11, 2020, the FDA granted Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine. The vaccine, officially known as BNT162b2, is the first approved in the United States to prevent disease caused by the SARS-CoV-2 coronavirus. Approval was based on clinical trials which demonstrated safety and efficacy; the Phase 3 trial involved 42,000 subjects and showed the vaccine to be 95% effective against the coronavirus. The EUA allows for use in patients 16 years of age and older, and administration of the vaccine to priority populations (healthcare workers and long-term care facility residents) is expected to begin within a matter of days. The vaccine requires two doses, given 21 days apart. For more product information, including storage, dosage, and administration, see our coronavirus vaccine chart on page 3 of this issue.

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VEKLURY (Remdesivir).
Category: COVID-19 antiviral.
Initial Dose: 200 mg on day 1, followed by 100 mg daily.
MDD: 200 mg.

Gilead Sciences, Inc. has received FDA approval for Veklury, the first and only fully approved treatment for COVID-19 in the United States. Veklury, a SARS-CoV-2 nucleotide analog RNA polymerase inhibitor, is indicated in adults and pediatric patients (12 years and older) for the treatment of COVID-19 requiring hospitalization. The recommended dosage in adults and children 12 years of age and older and weighing at least 40 kg is: 200 mg once daily on day 1, followed by once daily maintenance doses of 100 mg from day 2, infused over 30 to 120 minutes. For patients not requiring mechanical ventilation and/or ECMO, the recommended total treatment duration is 5 days. For patients requiring mechanical ventilation and/or ECMO, the recommended total treatment duration is 10 days. The FDA has also issued an EUA for the use of Eli Lilly's rheumatoid arthritis drug Olumiant to be given in combination with Veklury.

CASIRIVIMAB/IMDEVIMAB.
Category: Monoclonal antibodies for the treatment of COVID-19.
Initial Dose: 1200 mg of each component.
MDD: 1200 mg of each component.

The FDA has granted Emergency Use Authorization (EUA) for two investigational drug products manufactured by Regeneron Pharmaceuticals, Inc. Casirivimab and Imdevimab are monoclonal antibodies designed to mimic the human immune response to the SARS-CoV-2 virus, which causes COVID-19. The EUA authorizes use of the antibody "cocktail" for the treatment of mild to moderate coronavirus disease (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) who are at high risk for progressing to severe COVID-19 and/or hospitalization. Casirivimab and Imdevimab are NOT authorized for use in patients already hospitalized for COVID-19, OR who require oxygen therapy due to COVID-19. The recommended dosage is 1200 mg of Casirivimab and 1200 mg of Imdevimab administered together as a single intravenous infusion over at least 60 minutes. The solutions must be diluted prior to administration.

Pharmacists to Play a Major Role in Vaccination Against COVID-19

The nation's pharmacists are set to play a key role in the administration of vaccines against COVID-19. The two leading pharmacy chains in the U.S., **CVS** and **Walgreens**, have entered into an agreement with the Federal government to administer COVID-19 vaccinations to residents of the approximately 50,000 long-term care (LTC) facilities in the country. The *Pharmacy Partnership for Long-Term Care Program*, created in October, 2020, will facilitate vaccination of this vulnerable population at no cost to the LTC facilities. Vaccinations will be available for residents in all long-term care facilities, including skilled nursing facilities, nursing homes, assisted living facilities, residential care homes, and adult family homes. LTC staff members will also be offered vaccination as part of the program. In anticipation of the initial vaccine approval, both CVS and Walgreens have begun aggressive recruiting programs to hire pharmacists, pharmacy technicians, and nurses. According to a report on Bloomberg.com[1], Walgreens has 8,000 to 9,000 positions open to support COVID testing and vaccine administration. On the CVS website, CVS.com, a banner announces "Join our COVID-19 Support Team." Recruiters are reportedly reaching out to pharmacy schools, independent pharmacies, and retired practitioners.

CVS pharmacy®

Walgreens

Now that the first COVID-19 vaccine has been approved, pharmacists willing to join in the fight against the pandemic should begin to familiarize themselves with the proper storage, handling, reconstitution, and administration of the vaccine. The FDA has issued a FACT SHEET which contains all of the pertinent information for administration of the Pfizer-BioNTech vaccine. Click here to download a pdf of the FACT SHEET.

Federal Agency Expands Pharmacist's Immunization Authority

The U.S. Department of Health and Human Services (HHS) has taken action to expand the immunization authority of all licensed pharmacists practicing in the United States. The authorization provided by this federal agency preempts any state or local laws that prohibit pharmacists in their jurisdiction from administering the vaccines in question.

Expanded Access to Childhood Vaccines

The first action taken by HHS, announced on August 19, 2020, authorized all State-licensed pharmacists and pharmacy interns to administer any necessary childhood vaccines (MMR, Varicella, etc.) to children ages 3 through 18 years. This authorization overrides current New York State regulations, which permit pharmacists to administer only influenza vaccines to persons under the age of 18. The authorization stipulates that pharmacists must be up-to-date on all required immunization training, including basic cardiopulmonary resuscitation, and comply with the CDC's current childhood vaccination schedules (available here). On its website, the New York State Board of Pharmacy states that it has been notified of the HHS policy and is working with the Department of Health to determine the implications of this policy for New York State licensed pharmacists.

Expanded Access to COVID-19 Vaccines

On September 9, 2020, HHS issued guidance under the Public Readiness and Emergency Preparedness Act (PREP Act) to expand access to COVID-19 vaccines when they are made available. The guidance authorizes licensed pharmacists in all states to order and administer, and pharmacy interns to administer, COVID-19 vaccinations to persons age 3 and older. The vaccination must be ordered and administered according to the Advisory Committee on Immunization Practices (ACIP) COVID-19 vaccine recommendation, and the pharmacist must have completed all relevant vaccine administration training and have a current certificate in basic CPR. The authorization preempts any state or local laws that prohibit or effectively prohibits those who satisfy these requirements from ordering or administering COVID-19 vaccines.

Current New York State Pharmacist Vaccine Authorization

As a reminder, the chart below lists all the vaccines which New York State has authorized registered and immunization-certified pharmacists and pharmacy interns to administer.

Vaccine	Products Available	Pharmacist's Restrictions	Notes
INFLUENZA	**Afluria, Flublok, Flucelvax, Fluzone**, etc.	Patients 2 years of age and older.	Select appropriate product for patient (e.g., High Dose for patients 65 years of age and older).
PNEUMONIA	**Prevnar 13** **Pneumovax 23**	Patients 18 years of age and older. For patients under 65, a qualifying medical condition must exist.	Give Prevnar first, followed by Pneumovax at least 12 months later.
TDAP	**Boostrix** **Adacel**	Patients 18 years of age and older. Pregnant women, with *every* pregnancy, between 27 and 36 weeks gestation.	When possible, administer Boostrix to patients ≥65 y.o. (Adacel is approved for *up to* 64 y.o.)
MENINGITIS	**Menactra** **Menveo** **Bexsero** **Trumenba**	Patients 18 years of age and older, including first year college students and other high risk groups.	Menactra and Menveo cover meningococcal groups A, C, Y, and W-135. Bexsero and Trumenba cover group B.
SHINGLES	**Shingrix** **Zostavax**	Patients 50 years of age and older for Shingrix, 60 and older for Zostavax; otherwise a prescription is required.	Shingrix is now preferred over Zostavax. Shingrix requires 2 doses, given 2 to 6 months apart.

FEATURE ARTICLE...

Preview of COVID-19 Coronavirus Vaccines

December, 2020 marks a grim anniversary; it has now been a full year since the discovery of SARS-CoV-2, the virus which brought about the worldwide coronavirus pandemic. But this month also offers hope, as the first vaccines protecting against COVID-19 will likely be released. Of the 58 vaccines currently undergoing clinical trials in humans, 2 have already applied to the FDA for Emergency Use Authorization, and a third may soon join them. At least 2 of these 3 vaccine candidates are likely to receive approval and begin distribution before the end of the year. For this article we will focus on these three vaccine candidates and the plans, both Federal and State, on how to prioritize their use.

Comparison of 3 Leading COVID-19 Coronavirus Vaccine Candidates

Maker	Pfizer-BioNTech	Moderna	AstraZeneca/Oxford
Name	BNT162b2	mRNA-1273	AZD1222
Type	Nucleoside-modified mRNA vaccine formulated with lipid nanoparticles	Nucleoside-modified mRNA vaccine formulated with lipid nanoparticles	Modified chimpanzee adenovirus vector DNA vaccine
Efficacy	Primary efficacy data: 95% effective against COVID-19 beginning 28 days after first dose. 162 confirmed infections in placebo group vs. 8 in vaccine group.	Primary efficacy data: 94.1% effective against COVID-19 beginning 14 days after second dose. 185 confirmed infections in placebo group vs. 11 in vaccine group.	Interim efficacy data: 70% effective against COVID-19. This overall figure combines results of two different dosing regimens: two standard doses = 62% effective; low dose followed by standard dose = 90% effective.
Dosage and Administration	2 doses of **0.3 mL** given 21 days apart. Thaw prior to use and dilute multidose vial with 1.8 mL of supplied saline diluent. Invert gently 10 times. Vial supplies 5 doses of vaccine, which must be used within 6 hours of reconstitution.	2 doses of **0.5 mL** given 28 days apart Thaw prior to use and swirl gently before withdrawing dose. No dilution required. Vial supplies 10 doses of vaccine.	2 doses of **0.5 mL** given 28 days apart. No dilution required. Vial supplies 10 doses of vaccine, which must be used within 4 hours of first needle puncture.
Storage	Frozen Can be stored for up to 6 months at –70ºC (–94ºF) Can be stored for up to 5 days at 2º to 8ºC (36º to 46ºF)	Frozen Can be stored for up to 6 months at –20ºC (–4ºF) Can be stored for up to 30 days at 2º to 8ºC (36º to 46ºF)	Refrigerated Can be stored at 2º to 8ºC (36º to 46ºF) until expiration date printed on packaging

Prioritization: The Federal Plan

On December 3, 2020, the CDC accepted the recommendations of an expert panel on which groups should be first to receive vaccination against COVID-19. Group 1A includes the following:

Health care Personnel[1,2] (HCP) (~21million)	Long-Term Care Facility (LTCF) Residents[3] (~3M)
Examples	
• Hospitals • Long-term care facilities • Outpatient clinics • Home health care • Pharmacies • Emergency medical services • Public health	• Skilled nursing facilities (~1.3 M beds) • Assisted living facilities (~0.8 M beds) • Other residential care (~0.9 M beds)

Prioritization: The New York State Plan

The New York State Department of Health published the following Vaccine Prioritization Matrix on its website on October 16, 2020:

	High COVID-19 Prevalence in Geographic Area	Low COVID-19 Prevalence in Geographic Area
High Risk Population/ Essential Healthcare Workers	PRIORITY 1	PRIORITY 2
Lower Risk Population/ Other Essential Workers	PRIORITY 3	PRIORITY 4
General Population	PRIORITY 5	PRIORITY 6

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ASK PRN...

Due to the recent shortage of generic prescription colonoscopy preparation products, we often need to call physicians to switch patients to the more expensive brand-name preps. In cases where the available products are not covered by the patient's insurance, some prescribers have asked the pharmacist to instruct the patient on an over-the-counter alternative, such as MiraLAX mixed in Gatorade. Is there a standard protocol for this preparation?

There are a few different version of this prep, but they are all quite similar. The following protocol is the one used by the teams at Memorial Sloan Kettering:

- **No solid foods on the day before the procedure.**
- **Have the patient purchase the following:**
  - **4 tablets of Bisacodyl 5 mg.**
  - **A 238 gm bottle of MiraLAX.**
  - **A 64 ounce bottle of Gatorade or Powerade (no red, purple, or orange color, and use sugar-free if diabetic).**
- **Mix all 238 grams of MiraLAX into the 64 ounces of Gatorade/Powerade and refrigerate.**
- **Take 2 Bisacodyl tablets at 4 PM and drink four 8 ounces glasses of the prepared liquid (one every 15 minutes) starting at 4:15 PM. Continue to drink clear liquids thereafter.**
- **Repeat the same regimen at 11 PM for early morning procedures. If the colonoscopy is scheduled for the afternoon, the second dose may be taken at 6 AM on the day of the procedure.**

GOT QUESTIONS? WE HAVE ANSWERS!
Send your questions to us at:
questions@prnnewsletter.com

PRN welcomes your questions on any topics relating to the practice of pharmacy. All answers are researched by our staff and, when necessary, discussed with the appropriate regulatory agencies. The information provided is not intended as legal advice, nor is it a substitute for professional judgment in clinical practice.

DID YOU KNOW?

DID YOU KNOW that the Christmas Factor, also known as coagulation factor IX, was named not for this month's holiday, but for a 5 year-old Canadian boy named Stephen Christmas? Suffering from hemophilia, he was being studied by doctors at Oxford, England because he was *not* deficient in factor VIII, the traditional cause of the disease. Instead, it was discovered that another coagulation factor deficiency was the cause and that factor was named after the patient. His physicians published their discovery in the British Medical Journal on December 27, 1952— the Christmas issue.

PHARMACY FUN

It's the holiday edition of Pharmacy Fun! Each of the following clues refer to prescription medications, some common, some not. After solving for all eight clues (using generic names), rearrange the first letters of each answer to make a word which is an old English term for the Christmas season. The first reader to submit the correct answers to *puzzle@prnnewsletter.com* will receive a $25 Amazon gift card.

1. **Reverse Transcriptase Inhibitor; may cause abnormal dreams**
2. **Methylxanthine for asthma**
3. **Antitubercular hydrazide**
4. **Liquid osmotic laxative; also for encephalopathy**
5. **The original macrolide**
6. **Alpha-2 blocker; found in tree bark**
7. **Treatment for acute malignant hyperthermia**
8. **Dissolves gallstones**

Answers to last month's ***PHARMACY FUN***:
1. Acetyl-Para-AminoPhenol 2. 5-Amino Salicylic Acid 3. Azidothymidine 4. Bacillus Calmette-Guérin
5. Isonicotinic Acid Hydrazide 6. Kindly Oblige With 7. Neutral Protamine Hagedorn 8. Ana-Ana
9. Pro Re Nata 10. Saturated Solution of Potassium Iodide 11. Quantity Suficient 12. Semis

References:
1. LaVito, Angelica. CVS, Walgreens Seek Pharmacists on the Eve of Vaccination Rush. *Bloomberg.com*. December 8, 2020.