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**.....RX NEWS.....RX NEWS.....RX NEWS.....RX NEWS.....**

**PIVYA** (Pivmecillinam tablets).  
**Category:** Penicillin class antibiotic for the treatment of uncomplicated urinary tract infections.  
**Initial Dose:** 185 mg three times a day.  
**MDD:** 555 mg.

**OHTUVAYRE** (Ensifentrine suspension for oral inhalation).  
**Category:** PDE3/PDE4 inhibitor for treatment of COPD.  
**Initial Dose:** 3 mg (one ampule) twice daily.  
**MDD:** 6 mg.

The FDA has approved Pivya (Pivmecillinam tablets), a new penicillin class antibiotic. Pivya is indicated for the treatment of female patients 18 years of age and older with uncomplicated urinary tract infections (uUTI) caused by susceptible isolates of *Escherichia coli*, *Proteus mirabilis*, and *Staphylococcus saprophyticus*. The recommended dose of Pivya is one 185 mg tablet orally three times a day for 3 to 7 days as clinically indicated. Pivya may be administered with or without food. Pivya is a prodrug, which is metabolized by non-specific esterases to the active beta lactam antibiotic, mecillinam. As such, Pivya is contraindicated in patients with serious hypersensitivity reactions to penicillins and cephalosporins. Other contraindications include primary or secondary carnitine deficiency and porphyria.

Verona Pharma has announced approval of Ohtuvayre (Ensifentrine), a product with a novel mechanism of action, for the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adult patients. Ohtuvayre is a first-in-class phosphodiesterase 3 (PDE3) and phosphodiesterase 4 (PDE4) inhibitor. As a dual inhibitor, this agent is able to act as both a bronchodilator (PDE3) and as a non-steroidal anti-inflammatory (PDE4). The recommended dosage is 3 mg (one ampule) twice daily administered by oral inhalation using a standard jet nebulizer with a mouthpiece. Patients should be advised that Ohtuvayre should not be used to treat acute symptoms of bronchospasm, and that if paradoxical bronchospasm occurs, to discontinue use of Ohtuvayre and institute alternative therapy.

**CDC NEWS**

**CDC Updates RSV Vaccination Advice**

On June 26, 2024, The CDC announced that it has updated its recommendations for the use of the Respiratory Syncytial Virus (RSV) vaccine in people ages 60 and older. For the upcoming RSV season, the CDC now recommends:

- Everyone age 75 years and older should receive the RSV vaccine.
- People between the ages of 60 and 74 who are at increased risk of severe RSV, meaning they have certain chronic medical conditions, such as lung or heart disease, or they live in a nursing home, should receive the RSV vaccine.

NOTE: This recommendation is for adults who did not get an RSV vaccine last year. The RSV is not currently an annual vaccine, meaning people do not need to get a dose every season. The best time to get vaccinated is in late summer and early fall.

**Pharmacists Granted New Authority to Prescribe and Administer Drugs**

Pharmacists practicing in New York State have recently been granted new powers to prescribe and administer certain drugs to their patients. As of March 19, 2024, pharmacists are authorized to dispense hormonal contraceptive drugs, in pill, patch, and ring form, to patients pursuant to a non-patient specific standing order. Some additional training is required, and patients will need to fill out a self-screening risk assessment questionnaire. For more details on these protocols, see *Law Review* on page 2 of this issue.



The other new authority granted pharmacists, effective April 1, 2024, is the ability to administer certain long-acting injectable (LAI) medications to patients. Specifically, pharmacists can administer doses of LAIs for the treatment of mental health and substance abuse. No additional training is required of pharmacists, but they must have a certificate of administration (designated by an "I" on their license, which authorizes the administration of vaccines). The patient must have a valid prescription for the medication, and they must have received the initial dose of the medication from their prescriber. More details can be found on page 2 of this issue.



Photos by James Murphy



## New York Pharmacists Granted Authority to Prescribe Hormonal Contraceptives

Effective March 19, 2024, pharmacists in New York State may dispense hormonal contraceptive prescription drugs (pill, patch, or ring) pursuant to a non-patient specific standing order. The original effective date of the new law was November, 2024, but that date was amended to January 1st by legislative action, and the necessary standing order was signed by Health Commissioner James V. McDonald on March 19. Pharmacists wishing to dispense under this standing order must have completed training related to hormonal contraception, and must obtain a completed self-screening intake form from the patient. Pharmacists would then consult a clinical workflow before dispensing any medication. The pertinent regulations can be found in the *Commissioner's Regulations, Part 63.16*, which states that a licensed pharmacist may execute a non-patient specific order to dispense hormonal contraceptives, provided that:

- The **non-patient specific order** is prescribed or ordered by the commissioner of health, a physician licensed in this state, or a nurse practitioner certified in this state.
- The pharmacist has successfully completed training in the dispensing of self-administered hormonal contraceptives. (Editor's note: as of this writing, we know of one such applicable course, available at [birthcontrolpharmacist.com](http://birthcontrolpharmacist.com))
- Prior to dispensing hormonal contraceptives to a patient, and at a minimum of every 12 months for each returning patient, the pharmacist shall provide the patient with a **self-screening risk assessment questionnaire**. The pharmacist should compare the patient's responses to a **clinical workflow** to ensure there are no safety issues with the birth control options.
- The pharmacist shall notify the patient's primary health care practitioner within 72 hours of dispensing the hormonal contraceptive, unless the patient opts out of such notification.

Nothing in this regulation shall prevent a pharmacist from refusing to dispense a non-patient specific order for hormonal contraceptives if, in their professional judgement, potential adverse effects, interactions, or other therapeutic complications could endanger the life of the patient.

## New York Pharmacists Authorized to Administer Certain Long-Acting Injectable Medications

As of April 1, 2024, pharmacists registered in New York State may administer Long-Acting Injectable (LAI) medications for the treatment of mental health and substance abuse disorder pursuant to a patient-specific prescription. Here are some of the specifics, found in *Part 63.17* of the *Commissioner's Regulations*:

- There are no specific additional training requirements for pharmacists seeking to administer LAIs, but only those pharmacists with a certificate of administration, designated by an "I" on their registration, may participate.
- Administration of LAIs by pharmacists can only be conducted pursuant to a valid patient specific prescription issued by a prescriber within their scope of practice. Patient consent is also required.
- Patients receiving their LAI from a certified pharmacist must have already received their initial dose of medication from their prescriber and be deemed eligible for maintenance treatment by them.
- After administering an LAI to a patient, the certified pharmacist or their designee must notify the patient's prescriber of the administration within 5 days of said administration.
- If a patient misses their scheduled dose of an LAI, the certified pharmacist is required to notify the patient's prescriber as soon as possible, but no later than 72 hours after the medication was scheduled to be administered.
- Certified pharmacists may notify a patient's prescriber via electronic medical records, electronic transmission, or facsimile, or by telephone if none of these methods are available.
- A certified pharmacist can refuse to administer an LAI to a patient, if in their professional judgement such administration could endanger the health of the patient.

## RECENT ADDITIONS TO THE VACCINE ARSENAL

**In Recent Years**, the neighborhood pharmacy has become the primary vaccination destination for many Americans. A recent report by APhA<sup>1</sup> indicated that pharmacists now administer more vaccines than do physicians. Nowhere is this more apparent than at chain pharmacies, such as CVS, where pharmacists are now routinely rewarded, or punished, based upon their ability to reach immunization quotas set by the company. Unfortunately, it does not seem that much, if any, of the profits gained through vaccinations have been invested in the training necessary to administer vaccines safely. With RSV alone, there have been more than 150 reports of patients being administered the wrong vaccine. As such, it is up to each individual pharmacist to keep informed of the many changes taking place every year in the area of immunization. In support of that goal, we here present information on the latest additions to the vaccinations available for the prevention of Respiratory Syncytial Virus (RSV) and Hepatitis B.

### mRESVIA

Moderna has received FDA approval to market mRESVIA, a new vaccine to prevent Respiratory Syncytial Virus in adults age 60 and older. This represents the second time Moderna has used their mRNA platform to produce a vaccine, the first being their COVID-19 vaccine, Spikevax. mRESVIA is the only RSV vaccine available in a pre-filled syringe, which does not require reconstitution.

**Dosage and Administration:** Administer a single dose (0.5 mL) of mRESVIA as an intramuscular injection. DO NOT SHAKE.

**Preparation for Administration:** mRESVIA contains a frozen suspension that must be thawed prior to administration. If thawed in a refrigerator, let each prefilled syringe stand at room temperature for 10 to 20 minutes before administration. If thawed at room temperature, the vaccine is ready for administration.

**Storage and Handling:** Store mRESVIA frozen between -40 to +5 degrees Fahrenheit (F). After thawing, the vaccine may be stored in a refrigerator (36 to 46 degrees F) for up to 30 days. The vaccine may be kept at room temperature (46 to 77 degrees F) for up to 24 hours. Do not refreeze once thawed. Do not shake.

Vaccine	Indications
<b>mRESVIA</b>	Individuals 60 years of age and older.
<b>Arexvy</b>	Individuals 60 years of age and older. Individuals age 50 to 59 with increased risk of severe disease from RSV.
<b>Abrysvo</b>	Individuals 60 years of age and older. Pregnant women at 32 weeks 0 days to 36 weeks 6 days of gestation, from September through January in most of the continental United States.

### PreHevbrio

The fourth, and most recent, addition to the list of available Hepatitis B vaccines is called PreHevbrio. PreHevbrio is indicated for the prevention of Hepatitis B infection in adults 18 years of age and older. Updated ACIP guidelines indicate that all adults ages 19 through 59 should receive Hepatitis B vaccination. While similar in indication and usage to the other 3 available Hepatitis B vaccines, there are some features unique to the new vaccine. Unlike the other vaccines in this category, PreHevbrio is not produced in yeast cells, making it a safe alternative for patients with serious yeast allergies. Additionally, PreHevbrio is the only 3-antigen Hepatitis B vaccine (the others are single-antigen). Due to a lack of sufficient safety data, neither PreHevbrio nor Heplisav-B is indicated for use in pregnant women. If Hepatitis B vaccination is ordered during pregnancy, administer Recombivax HB or Engerix-B **only**.

**Dosage and Administration:** Administer a series of 3 doses on a 0-, 1-, and 6-month schedule. Shake the vial well to obtain a slightly opaque, white suspension. Administer the vaccine by intramuscular injection.

**Storage and Handling:** Store in a refrigerator between 36 to 46 degrees Fahrenheit. Do not freeze.

Vaccine	# of Adult Doses	Timing of Doses
<b>Recombivax HB</b>	3	0, 1, and 6 Months
<b>Engerix-B</b>	3	0, 1, and 6 Months
<b>Heplisav-B</b>	2	0, and 1 Month
<b>PreHevbrio</b>	3	0, 1, and 6 Months



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**Are the various Hepatitis B vaccines on the market interchangeable? If a patient starts their series with one product, can it be completed with a different one?**

Not all Hepatitis B vaccines are considered "interchangeable." However, if for any reason the initial vaccine used to start the series cannot be obtained or used to complete the series, another product can be substituted, according to the following protocols:

- Recombivax HB and Engerix-B are interchangeable. Either one can be used for any or all of the 3-dose series.
- If possible, the Hepatitis B series should consist of one product, but the CDC has stated that the series may be

completed with another product.

- The 2-dose series is only valid if both doses consist of Heplisav-B. Series consisting of one dose of Heplisav-B and a different Hepatitis B vaccine must adhere to the 3-dose schedule, with minimum intervals of four weeks between dose 1 and 2, eight weeks between dose 2 and 3, and sixteen weeks between dose 1 and 3. However, if Heplisav-B is substituted for dose 2 of any other product, the provider has the option to administer the next dose of Heplisav-B four weeks later to complete the three dose series.

### GOT QUESTIONS? WE HAVE ANSWERS!

Send your questions to us at: [askprn@prnnewsletter.com](mailto:askprn@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 a number of famous individuals, in fields ranging from poetry to politics, were once pharmacists, or pharmacists in training? The great English poet John Keats, author of "Ode to a Nightingale," received his apothecary's license in 1816. Two other noted authors, Agatha Christie ("Murder on the Orient Express") and O. Henry ("The Gift of the Magi") practiced as pharmacists before finding greater fame with the written word. And the 38th Vice President of the United States, Hubert H. Humphrey, worked as a licensed pharmacist in his father's store from 1931 to 1937. Humphrey served as VP to President Lyndon Johnson from 1965 to 1969.

### PHARMACY FUN

This issue's Pharmacy Fun is from the Fun With Words! Department. Complete the following sentence, using the *same six letters* in the *same exact order* to fill in each of the 3 blanks. The first blank is a single word, while the last two blanks represent two words each, yet all the letters filling in those blanks are the same, and in the same order! The first reader to submit the correct answers to [puzzle@prnnewsletter.com](mailto:puzzle@prnnewsletter.com) will receive a \$25 gift card from Amazon.

The \_\_\_\_\_ compounding pharmacist was \_\_\_\_\_ to prepare the product because she had \_\_\_\_\_.

Answers to last issue's **PHARMACY FUN**:

ACROSS: 1. Anoro 5. AU 6. NP 7. RRR 9. PSE 10. EMTs  
DOWN: 1. AARP 2. Nurse 3. RN 4. OPD 8. REM

### References:

1. Lam, Vivian H. *New Report Finds Pharmacists Administer More Vaccinations Than Physicians.* APhA News online, March 3, 2023.