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No. 58 | **The Newsletter for Community Pharmacists** | **September, 2017**

What's Inside…

FDA NEWS

Advice on Dosing of Kayexalate with Other Medications

The FDA has announced recommendations on the use of the potassium-lowering agent Kayexalate (sodium polystyrene sulfonate, or SPS) in conjunction with other oral medications. Based on a study that found that SPS binds to many commonly prescribed oral mediations, thereby decreasing their absorption and effectiveness, the agency recommends the following:

- **Patients should take orally administered prescription and over-the-counter (OTC) medications at least 3 hours before or 3 hours after taking SPS**
- **The spacing should be increased to 6 hours for patients with gastroparesis or other conditions resulting in delayed emptying of food from the stomach into the small intestine**

The study tested the interaction of SPS with six commonly administered oral drugs: amoxicillin, amlodipine, phenytoin, furosemide, and warfarin. The study found significant binding with SPS occurred with all of these medications.

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DUZALLO (Lesinurad and Allopurinol).
Category: Antigout agent.
Initial Dose: 200 mg lesinurad/300 mg allopurinol taken in the morning with food and water (200 mg/200 mg dose available for patients with renal impairment).
MDD: 200 mg lesinurad/300 mg allopurinol.

Ironwood Pharmaceuticals has been granted approval to market Duzallo, a combination agent for the treatment of hyperuricemia associated with gout in patients not achieving target serum uric acid levels with allopurinol alone. Duzallo contains the uric acid transporter 1 (URAT1) inhibitor lesinurad, and the xanthine oxidase inhibitor allopurinol.

BENZNIDAZOLE
Category: Chagas disease treatment.
Initial Dose: 5 mg/kg to 8 mg/kg daily in two divided doses separated by approximately 12 hours for a duration of 60 days.
MDD: 200 mg twice a day.

The FDA has approved Benznidazole for the treatment of Chagas disease (American trypanosomiasis). The approval was granted through the accelerated approval pathway for drugs treating serious conditions where there is an unmet medical need. Chagas disease is often transmitted by the so-called "kissing bug," and affects between 6 and 7 million people, mostly in Latin American countries.

CAROSPIR (Spironolactone oral suspension).
Category: Aldosterone antagonist.
Initial Dose: 20 mg to 75 mg daily.
MDD: 100 mg daily (for patients requiring doses greater than 100 mg, use a different formulation. Doses of the suspension greater than 100 mg may result in concentrations higher than expected).

CMP Pharma has received approval for the first commercially available oral liquid formulation of the potassium-sparing diuretic spironolactone. Carospir will be available as a banana-flavored 25 mg/5 mL oral suspension, and is indicated for use as an add-on therapy for the treatment of hypertension, for the management of edema in adult cirrhotic patients, and for the treatment of NYHA Class III-IV heart failure and reduce ejection fraction.

EUCRISA (Crisaborole).
Category: Phosphodiesterase 4 inhibitor for the treatment of atopic dermatitis..
Initial Dose: Apply a thin layer topically twice daily to affected areas.
MDD: One application twice daily.

Anacor Pharmaceuticals, Inc. is marketing a novel treatment for mild to moderate atopic dermatitis in patients 2 years of age and older. Eucrisa is a phosphodiesterase 4 (PDE-4) inhibitor. PDE-4 inhibition results in increased intracellular cyclic adenosine monophosphate (cAMP) levels. The specific mechanism by which Eucrisa exerts its therapeutic action, however, is not known.

Maker of EpiPen Faces Massive Fine and Increased FDA Scrutiny

The U.S. Department of Justice has announced that Mylan, the marketer of **EpiPen**, has agreed to pay a settlement of $465 million to resolve claims that the company committed Medicaid fraud by knowingly misclassifying EpiPen as a generic drug. The intentional misclassification led to the company avoiding up to $1.27 billion in Medicaid rebates, according to Iowa senator Chuck Grassley, who believes that the settlement amount is not large enough[1]. During the period EpiPen was misclassified as a generic, the company raised the price of a 2-pack of EpiPen from $100 to $600, all the while claiming that no other epinephrine injector could be classified as a "generic" EpiPen. Interestingly, the whistleblower in this case was the drug maker Sanofi-Aventis, manufacturer of **Auvi-Q**, an EpiPen competitor. As the whistleblower, Sanofi-Aventis will receive a $38.7 million share of the recovery. Shortly after the announcement of the settlement, the Food and Drug Administration (FDA) issued a warning letter to Pfizer, the company that manufactures EpiPen for Mylan, accusing the company of failing to investigate numerous reports of malfunctions, some of which led to severe illness or death. Pfizer and Mylan eventually recalled 13 lots of EpiPen due to the malfunctions, but did so only after the FDA inspected the manufacturing facility and after "multiple discussions" with the agency.

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Clarification of Copayment Collection Rule for Medicaid Managed Care Recipients

In response to reports of some pharmacies refusing to dispense medications to patients who are unable to pay their copayment, the Department of Health has issued the following reminder:

Federal law requires that no Medicaid enrolled provider deny care or services to an individual eligible for such care or services on account of such individual's inability to pay a deduction, cost-sharing, or similar charge. This applies to *all* Medicaid providers, both fee-for-service *and managed care*. Providers may attempt to collect any outstanding copayments through methods such as requesting the copayment each time the member is provided services or goods, sending bills, or any other legal means.

This rule applies to all Medicaid managed care plans in New York, including Affinity Health Plan, AmidaCare, Emblem Health, Excellus, Fidelis Care, Healthfirst, Empire Blue Cross Blue Shield, Independent Health, MetroPlus, Molina Healthcare, MVP Healthcare, UnitedHealthcare Community Plan, VNS Choice Health Plans, WellCare, and YourCare Health Plan.

Initial 7-Day Opioid Supply Enforcement

Effective August 24, 2017, the New York State Medicaid fee-for-service program has implemented a 7-day supply limit on initial opioid prescribing for acute pain (previously a 15 day supply limit was in place). This conforms with changes to section 3331 of the Public Health Law which placed a 7-day supply limit on initial prescriptions for schedule II, III, or V opioid medications. Those changes took effect on July 22, 2016. Prior authorization (PA) will be required for any claim that does not meet the above criteria.

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

Governor Cuomo Announces Naloxone Co-Pay Assistance

New York Governor Andrew Cuomo announced in August that the state has implemented a program to provide no-cost or lower-cost naloxone at pharmacies across New York. Effective August 9, 2017, patients with prescription insurance coverage, including Medicaid and Medicare, can receive up to $40 in co-pay assistance. Complete information on the program, known as **N-CAP**, is available on the Department of Health website at: www.health.ny.gov/overdose. In addition, uninsured individuals and individuals without prescription coverage will still be able to receive naloxone at no cost through New York's network of registered opioid overdose prevention programs (the current list of such programs is available on the above listed website or by clicking here in our digital edition). The key elements of the program are:

- **Co-payments for naloxone in an amount of up to $40 for each prescription dispensed will be billed to N-CAP, not to the individual getting naloxone**
- **Individuals who are themselves at risk for an overdose or their family members may acquire naloxone using a patient specific prescription, or through a standing order at over 2000 pharmacies in New York State**
- **No individual enrollment is necessary**
- **Pharmacies participating in the New York State AIDS Drug Assistance Program are eligible to participate in N-CAP (see billing information below)**
- **Only the following naloxone formulations are covered:**
  - **Narcan nasal spray:** NDC 69547-0353-02
  - **Naloxone used for intranasal administration:** NDC 76329-3369-01
  - **Naloxone for intramuscular administration:**

    NDCs 00409-1215-01, 67457-0292-02, and 00641-6132-25

FEATURE ARTICLE...

Update on Vaccines for the 2017-18 Flu Season

Flu Season is nearly here, which means it's time for our annual review of the latest vaccines and recommendations. We are focusing on the quadrivalent versions (*inactivated influenza vaccine, quadrivalent*, or IIV4) this year, since they have become the predominant vaccine for influenza in the community pharmacy setting.

Quadrivalent Inactivated Influenza Vaccine (IIV4)

The 2017-18 quadrivalent influenza vaccine contains the following 4 antigens:

- **A/Michigan/45/2015 (H1N1)pdm09-like virus**
- **A/Hong Kong/4801/2014 (H3N2)-like virus**
- **B/Brisbane/60/2008-like virus (Victoria lineage)**
- **B/Phuket/3073/2013-like virus (Yamagata lineage)**

The composition of this year's vaccine represents a change in the influenza A(H1N1)pdm09 virus component from the previous season. To permit time for production of protective antibody levels, vaccination should optimally occur before the onset of influenza activity in the community. Vaccination should continue to be offered as long as influenza viruses are circulating and unexpired vaccine is available. Of the five IIV4s available this season, all but one are prepared in fertilized eggs. The exception, **Flucelvax**, is prepared in mammalian cells, but may still contain some egg proteins due to the fact that some of the initial viruses provided to the manufacturer are egg-derived. Only **Flublok** (RIV) is considered an egg-free vaccine.

Who Should Get Vaccinated?

The CDC recommends that all persons aged 6 months and older should be vaccinated. For certain people, however, vaccination is especially important because they are at high risk of developing complications. These include:

- **Pregnant women**
- **Children aged 6 through 59 months**
- **People 50 years of age and older**
- **People who live in nursing homes**
- **American Indians/Alaska Natives**
- **Morbidly obese persons (BMI 40 or greater)**
- **Healthcare personnel**
- **Immunosuppressed patients**
- **Adults and children who have chronic pulmonary, cardiovascular, renal, hepatic, neurological, hematological or metabolic disorders**
- **Children (≤18 years) on long-term aspirin therapy**
- **People who live with or care for those at high risk, and household contacts and caregivers of adults aged ≥50 years and children aged <5 years (particularly contacts of children less than 6 months of age)**

Other Options for the 2017-18 Season

There are several alternatives to IIV4 which are available this season, including:

Flublok Quadrivalent and Trivalent: a recombinant hemagglutinin (HA) vaccine (RIV4 and RIV3) recommended for persons aged 18 years and older. Flublok is manufactured by replicating a key protein from the wild-type influenza virus and growing it in cultured cells. No actual influenza virus is used in production, and since Flublok also contains no egg proteins, it can be safely administered to people with severe egg allergies.

Fluad: an adjuvanted inactivated influenza vaccine, trivalent (aIIV3) indicated for patients aged 65 years and older. An adjuvant (in this case, MF59, an oil-in-water emulsion of squalene oil) is added to vaccines to create a stronger immune response to vaccination. Fluad is the second influenza vaccine specifically indicated for people aged 65 years and older, who often have a lower immune response to influenza vaccination. The Centers for Disease Control and Prevention (CDC) estimates that 80 to 90 percent of seasonal flu-related deaths occur among people 65 years of age and older

Fluzone High-Dose: a trivalent inactivated influenza vaccine (IIV3) which was the first vaccine specifically targeted to people 65 years of age and older. Fluzone High-Dose contains 4 times the amount of antigen as standard influenza vaccine.

FluMist Quadrivalent: a live-attenuated influenza vaccine (LIAV4) for nasal administration, indicated for healthy, nonpregnant persons aged 2 to 49 years of age. However, due to its low effectiveness in the past, the CDC **no longer recommends the use of this vaccine.**

Mercury Content (mcg per 0.5 mL dose) of IIV4 Vaccines

Vaccine Trade Name	Prefilled Syringe	Multidose Vial
AFLURIA	0.0	24.5
FLUARIX	0.0	
FLUCELVAX	0.0	25.0
FLULAVAL	0.0	< 25.0
FLUZONE	0.0	25.0
FLUZONE INTRADERMAL	0.0	

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ASK PRN...

For a pharmacy dispensing naloxone for opioid overdose under the New York City standing order, which formulations are currently authorized, and what is required to appear on the prescription label?

Currently, the NYC standing order for naloxone includes the following formulations:

- **Single-step Intranasal:**
  Narcan (NDC # 69547-0353-02)
- **Multi-step Intranasal:**
  Naloxone Luer-lock
  (NDC #76329-3369-01)
- **Intramuscular:**
  Naloxone Injection
  (NDC # 00409-1215-01 or
  # 67457-0292-02)

The label for dispensing naloxone under the NYC standing order must contain the following elements:

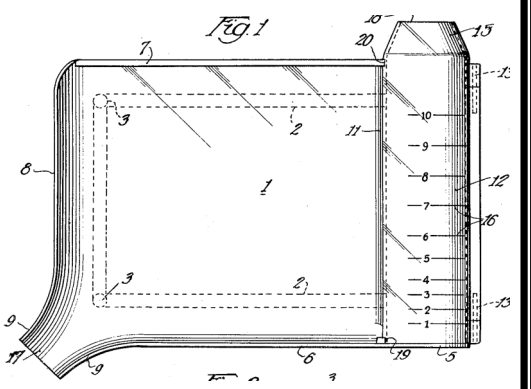
- **Name of recipient/patient**
- **Prescriber name: Mary T. Bassett, MD**
- **Naloxone formulation/concentration**
- **Date dispensed**
- **Refills: 12 (recommended)**
- **Below terms:**
  "Dispensed per standing order"
  "Use as directed"
  "Trained opioid overdose responder"

GOT QUESTIONS? WE HAVE ANSWERS!
Send your questions to us at:
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 the sanitary counting tray, used by most pharmacists even today, was invented by Mack R. Fields and patented by Abbott in 1950? U.S. patent # 2,530,009 (see original patent drawing at right) reveals the secret of the strange numerical scale on the cover— it is to be used to create a chart matching the level of pills in the chamber (1 to 10) to the most appropriate vial size stocked by the pharmacy. Do you know anyone who has ever made such a chart?!



PHARMACY FUN

It's September, and around these parts that means only one thing...time for our annual back-to-school quiz, seventh edition. Cast your mind back to those halcyon days, when you roamed the halls of your dear alma mater, your head filled with facts, figures, and formulae. How many of them do YOU remember? Send the correct answers *puzzle@prnnewsletter.com* for a chance to win a custom-printed *PRN* binder.

1. How many grains in a scruple?
2. How many scruples in a dram?
3. How many minims in a fluidram?
4. "C" indicates what liquid quantity?
5. Abbreviation "aa" stands for?
6. Abbreviation "ss" stands for?
7. Abbreviation "d.t.d" stands for?
8. 100 proof EtOH is what % alcohol?
9. The negative log of H+ concentration?
10. Density of water at 4 degrees C?

Answers to last month's ***PHARMACY FUN***:
1. 68 to 77° F (20 to 25° C) **2.** 36 to 46° F (2 to 8° C) **3.** -13 to 14° F (-25 to -10° C) **4.** any temp not exceeding 46° F (8° C) **5.** 46 to 59° F (8 to 15° C) **6.** 86 to 104° F (30 to 40° C) **7.** -40° **8.** 451° F

References:
1. Mangan, Dan. "Sen. Grassley Says Mylan's $465 Million EpiPen Settlement "Shortchanges" Taxpayers." *www.cnbc.com.* August 17, 2017