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No. 61 | **The Newsletter for Community Pharmacists** | **January/February, 2018**

What's Inside…

FDA NEWS

FDA Heightens Heart Warning for Biaxin

In a Drug Safety Communication, the FDA has announced it will add a new warning to the label of the antibiotic **Biaxin** (clarithromycin) regarding use in patients with heart disease. The updated information will recommend that prescribers weigh the benefits and risks before prescribing clarithromycin to patients with heart disease, even for short periods, and consider using other available antibiotics. This action is based on the review of a 10-year follow up study of the CLARICOR trial, which was conducted in Denmark to determine if a 2-week course of clarithromycin could prevent cardiac events in patients with stable coronary artery disease (CAD). In fact, the results revealed an unexpected increase in deaths among CAD patients treated with the macrolide antibiotic. The FDA initially discussed the CLARICOR trial in 2005, but at that time made no recommendations on use of the drug.

.....RX NEWS.....RX NEWS.....RX NEWS.....RX NEWS.....

OZEMPIC (Semaglutide injection).
Category: Antidiabetic (GLP-1 agonist).
Initial Dose: 0.25 mg once weekly.
MDD: 1 mg once weekly.

Novo Nordisk has announced FDA approval of Ozempic, an injectable glucagon-like peptide 1 (GLP-1) receptor agonist, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Ozempic will be available in single-patient-use pens for injection into the abdomen, thigh, or upper arm. The starting dose is 0.25 mg once weekly. After 4 weeks, the dose is increased to 0.5 mg weekly. If, after at least 4 more weeks, additional glycemic control is needed, the dose may be increased to 1 mg weekly. The dose is administered once weekly at any time of day, with or without meals, and if a dose is missed, it may be administered within 5 days of the missed dose. As with other GLP-1 receptor agonists (**Victoza, Byetta, Trulicity,** etc.), Ozempic will carry a **black-box warning** about the risk of thyroid C-cell tumors and the contraindication in patients with a personal or family history of medullary thyroid carcinoma (MTC) and in patients with multiple endocrine neoplasia syndrome type 2 (MEN 2).

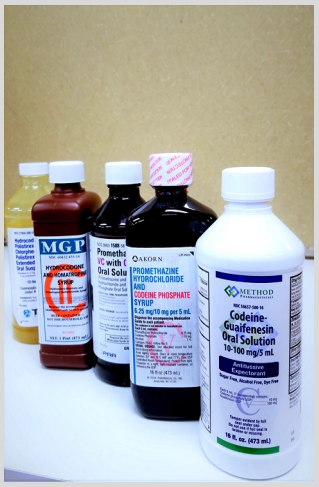
BYDUREON BCicse (Exenatide injection, extended release).
Category: Antidiabetic (GLP-1agonist).
Initial Dose: 2 mg once weekly.
MDD: 2 mg once weekly.

AstraZeneca will introduce a new version of their once-weekly injectable GLP-1 agonist **Bydureon**, which will be called Bydureon BCise (pronounced like "precise"). The active ingredient, strength, and dosing is the same as for Bydureon, but it is packaged in an improved delivery system. Instead of tapping the pen against the palm 80 times or more, the BCise pen just needs to be shaken for 15 seconds. And BCise has a built-in, hidden needle, which activates when pressed against the skin. The recommended dose to increase glycemic control in adults with type 2 diabetes mellitus is 2 mg by subcutaneous injection once every 7 days, at any time of day, with or without meals. The dose should be administered immediately after it is prepared. The standard GLP-1 agonist **black-box warning** applies, concerning the risk of thyroid C-cell tumors and the contraindication in patients with a personal or family history of medullary thyroid carcinoma (MTC) and in patients with multiple endocrine neoplasia syndrome type 2 (MEN 2).

FDA to Limit Opioid Cough Medications to Patients 18 years and Older

On January 11, 2018, the Food and Drug administration (FDA) announced that it will require label changes for all opioid-containing prescription cough preparations to reflect that these products are no longer indicated for use in children under the age of 18. The agency took this action after conducting an extensive review and convening a panel of outside experts; they concluded that the risks of slowed or difficult breathing, misuse, abuse, addiction, overdose, and death with these medicines outweigh their benefits in patients younger than 18. Additional information regarding these risks will also be added to the **black-box warning** for these drugs. The following is a list of affected products:

Active Ingredients	Brand Names
Codeine, promethazine	Only generics available
Codeine, promethazine, phenylephrine	Only generics available
Codeine, chlorpheniramine	Tuzistra XR, etc.
Codeine, pseudoephedrine, tripolidine	Triacin C, etc.
Hydrocodone, chlorpheniramine	Tussionex, etc.
Hydrocodone, homatropine	Only generics available
Hydrocodone, guaifenesin	Flowtuss, Obredon
Hydrocodone, guaifenesin, pseudoephedrine	Hycofenix, etc.
Hydrocodone, chlorpheniramine, pseudoephedrine	Zutripro, etc.



MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Updates to the Dispense Brand Name Drug when Less Expensive than Generic Program

There have recently been several updates to the Dispense Brand Name Drug when Less Expensive than Generic Program, including 1 addition and 7 deletions:

Addition (effective 2/22/2018)
Reyataz

Deletions (effective 2/22/2018)
Benzaclin gel pump
Efudex cream
Myfortic
Pulmicort respules 0.25 and 0.5 mg
Retin-A gel
Tegretol XR
Valcyte tablets

Prescriptions for drugs in the program **do not require** *"DAW"* or *"Brand Medically Necessary"* on the prescription, and have a generic copayment. If a drug is removed from the program, a new prescription is not required. The current list of drugs in the program is as follows:

Adderall XR
Aggrenox
Alphagan P 0.15%
Butrans
Catapres-TTS
Cellcept Susp
Copaxone 20 mL SQ
Diastat
Edecrin
Emend Tripack
Exelon patch
Focalin
Focalin XR
Fosrenol chewable tablets
Gleevec
Hepsera
Kapvay
Lexiva tablets
Pataday
Protopic
Pulmicort respules 1 mg
Retin-A cream
Reyataz capsules
Tegretol Suspension
Tobradex suspension
Transderm-Scop
Trizivir
Valcyte solution
Vigamox
Voltaren gel
Xeloda
Xenazine
Zyflo CR

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

Governor Cuomo Extends Emergency Order on Influenza and Proposes Legislation to Make Changes Permanent

On January 25, 2018, New York Governor Andrew Cuomo issued an executive order, number 176, authorizing pharmacists in the state to administer influenza vaccinations to children 2 years of age and older. The order temporarily suspended the regulations which specify that pharmacists may only vaccinate individuals 18 years of age and older. The order officially declared a State disaster emergency for the entire State of New York, based upon seasonal influenza having reached epidemic proportions in the first months of flu season, with more than 25,000 confirmed cases. Originally set to expire on February 23, the order has been extended by the Governor to continue through March 22, 2018, and Cuomo has also announced a 30-day amendment to the fiscal year 2019 executive budget which would make the change permanent.

30-Day Budget Amendment Affecting Pharmacy Practice

As part of the budget process in New York State, each year the Governor must submit an executive budget to the legislature, usually before the first of February. At any time within 30 days of submitting said budget, the Governor may unilaterally amend or supplement the budget plan; these changes are known as 30-day amendments. For fiscal year 2019, Governor Cuomo is advancing a 30-day amendment which would permanently suspend the regulation prohibiting pharmacists from administering influenza vaccinations to patients under the age of 18. The amendment would also allow pharmacies to enroll in the New York State Vaccines for Children Program, a federally-funded program that provides vaccines at no cost to eligible children. Should the amendment make it through the budgetary process in the State Senate and Assembly, New York State pharmacists will be authorized to provide influenza vaccinations to patients 2 years of age and older on a permanent basis.

The New York State Vaccines for Children Program

A child is eligible for the Vaccines for Children Program if he or she is younger than 19 years of age and meets any of the following criteria:

- **Uninsured (does not have health insurance)**
- **Underinsured (has health insurance but the insurance does not cover the flu vaccine, or the insurance caps coverage at a certain amount or number of visits)**
- **Native American or Alaska Native**
- **Medicaid-enrolled or Medicaid-eligible, or**
- **Enrolled in Child Health Plus**

Standing Order for Influenza Vaccine for Ages 2 to 18

In response to Executive Order 176, the New York State Department of Health has issued a non-patient specific order for the administration of influenza vaccine. Under this protocol, a licensed pharmacist who is authorized to administer vaccinations in New York State may vaccinate patients between 2 years and 18 years of age against seasonal influenza. Pharmacist opting to immunize those in the pediatric population must have completed appropriate immunization training pertinent to this population (e.g., pediatric CPR). The standing order is signed by Commissioner of Health Howard A. Zucker, MD, and was issued on January 27, 2018. It will expire concomitantly Executive Order 176. Pharmacists whose training is limited to vaccination in the deltoid muscle may vaccinate children 3 years of age and older (2 year-olds are vaccinated in the anterolateral thigh muscle). The recommended needle size for IM deltoid muscle vaccination in children is 5/8th inch to 1 inch (a 5/8th inch needle may be used in patients weighing less than 130 lbs., if the skin is stretched tight and the subcutaneous tissue is not bunched).

FEATURE ARTICLE...

REVIEW OF GLP-1 RECEPTOR AGONISTS

Recently, the FDA approved *Ozempic*, the sixth Glucagon-like peptide 1 (GLP-1) receptor agonist currently on the market (see this month's Rx News, on page 1). In addition to these six individual products, there are 2 insulin/GLP-1 combinations available (*Xultophy* and *Soliqua*), as well a version of *Victoza* used exclusively for weight loss (*Saxenda*). Below is a review of the currently available GLP-1 agonists used in the treatment of type 2 diabetes mellitus.

GLP-1 Agonists: The Mechanism

Glucagon-like peptide 1 is a hormone released in the small intestine in response to glucose; it reduces blood sugar in several ways. GLP-1 produces a glucose-dependent increase in insulin secretion, inhibits glucagon secretion, delays stomach emptying, and may increase the number of pancreatic beta cells, which store and release insulin. GLP-1 agonists are synthetic mimetics of GLP-1, and have been shown to reduce blood sugar, cause weight loss, and reduce HbA1c by between 1 and 1.5%. The first approved GLP-1 agonist, Byetta (exenatide), is a synthetic version of a substance discovered in the saliva of the Gila monster.

GLP-1 Agonists: The Warnings

GLP-1 agonists carry two **black-box warnings** on their label.

- **GLP-1 agonists cause thyroid C-cell tumors in rats. It is unknown if these agents cause thyroid tumors in humans.**
- **GLP-1 agonists are contraindicated in patients with a personal or family history of medullary thyroid carcinoma (MTC) and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).**

Other serious adverse effects associated with use of GLP-1 agonists include pancreatitis and bile duct and gall bladder disease.

Comparison of Glucagon-Like Peptide 1 (GLP-1) Receptor Agonists

Product	Dosage Forms	Dosing	Storage
Adlyxin (lixisenatide)	• 50mcg/mL in 3 mL prefilled pen (14 doses of 10 mcg) • 100 mcg/mL in 3 mL prefilled pen (14 doses of 20 mcg)	Start at 10 mcg once daily for 14 days. On day 15, increase dosage to 20 mcg once daily. Administer within 1 hour of first meal of the day.	• Keep refrigerated until activation. • Once activated, keep pen at room temperature. Discard after 14 days.
Bydureon (exenatide extended release)	• Single-dose vial containing 2 mg of exenatide • Single-dose pen containing 2 mg of exenatide	Administer 2 mg subcutaneously once every 7 days (weekly), at any time of day, with or without meals. Administer immediately after the dose is prepared.	• Keep refrigerated until first use • If needed, may be kept at room temperature for up to 4 weeks.
Bydureon BCise (exenatide extended release)	• 2 mg of exenatide in a 0.85 mL single-dose auto-injector	Administer 2 mg subcutaneously once every 7 days (weekly), at any time of day, with or without meals. Administer immediately after the dose is prepared.	• Keep refrigerated, stored flat, until first use. • If needed, auto-injector may be kept at room temperature, unmixed, for up to 4 weeks.
Byetta (exenatide)	• 5 mcg per dose, 60 doses, 1.2 mL prefilled pen • 10 mcg per dose, 60 doses, 2.4 mL prefilled pen	Start at 5 mcg twice daily; increase to 10 mcg twice daily after 1 month if needed. Inject within 60 minutes prior to morning and evening meals (or between the two main meals of he day, approximately 6 hours or more apart).	• Keep refrigerated until first use • Once in use, pen may be kept at room temperature for up to 30 days.
Ozempic (semaglutide)	• Multi-dose pen that delivers 0.25 or 0.5 mg per injection • Multi-dose pen that delivers 1 mg per injection	Start at 0.25 mg once weekly, at any time of day, with or without meals. After 4 weeks, increase to 0.5 mg weekly. Increase to 1 mg weekly, if needed, after at least 4 more weeks.	• Keep refrigerated until first use • Once in use, pen may be kept at room temperature for up to 56 days.
Trulicity (dulaglutide)	• 0.75 mg in a single-dose pen or prefilled syringe • 1.5 mg in a single-dose pen or prefilled syringe	Start at 0.75 mg once weekly, at any time of day. Dose can be increased to 1.5 mg once weekly for additional glycemic control.	• Keep refrigerated before use • If needed, may be kept at room temperature for up to 14 days.
Victoza (liraglutide)	• 3 ml multi-dose pens, each containing 6 mg/mL which can deliver doses of 0.6 mg, 1.2 mg, or 1.8 mg	Start at 0.6 mg daily, at any time of day, with or without meals, for 1 week, then increase to 1.2 mg daily. May increase to 1.8 mg daily if needed for glycemic control.	• Keep refrigerated until first use • Once in use, pen may be kept at room temperature for up to 30 days.

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ASK PRN...

What are the regulations in New York regarding availability of translations of prescription labels for non-English speaking patients?

The issue of translating labels and other pharmacy materials is addressed in section 6829 of the Education Law and in Part 63.11 of the Regulations of the Commissioner. The key points are as follows:

- **Any pharmacy that is part of a group of 8 or more pharmacies located within New York State and owned by the same corporate entity is required to provide translations.**
- **Such pharmacies shall provide free, competent oral interpretation services and translation services of prescription labels, warning labels, and other written material to individuals who identify as being, or are evidently, unable to speak, read, or write English at a level required to understand health-related material.**
- **Such pharmacies shall post at each counter a notification of the right to free, competent oral interpretation services and translation services for limited English proficient (LEP) individuals.**
- **Such pharmacies must provide services in up to 7 languages spoken by 1% or more of the community or region.**

Is it permitted to dispense a prescription with a label written exclusively in the foreign language of an LEP individual?

Since the wording of the regulation is not specific in this area, we reached out to the Board of Pharmacy to answer this question. The Board replied that such labels must *also* include English wording, since caregivers and health care providers caring for the patient may not be bilingual.

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 there is tick whose bite can render its human victims permanently allergic to meat? *Amblyomma americanum*, variously known as the lone star, turkey, or northeast water tick, is found in the Eastern, Southeastern, and Midwestern United States. The bite of this particular critter can cause a person to develop an allergy, sometimes severe and life-threatening, to a carbohydrate called alpha gal (galactose-α-1,3-galactose) found in mammalian meat products[1]. The allergy causes a delayed reaction, ranging from urticaria to anaphylaxis, several hours after consuming beef, pork, lamb, venison, goat, or bison.

Lone star tick

PHARMACY FUN

Its anagram time here at Pharmacy Fun, with a twist! First you must find the correct word indicated by each clue below, then rearrange the letters of that word to form the name of a brand-name prescription drug. The first reader to forward the correct answers for all 10 clues to *puzzle@prnnewsletter.com* will receive a set of *PRN* combination pens and touchscreen styli.

1. **The capital city of Libya**
2. **Below average, as in golf**
3. **Not sane**
4. **A salted cracker**
5. **A lightweight rifle with a short barrel**
6. **Land next to the sea; the seashore**
7. **Title for a ruler of the Ottoman Empire**
8. **Audaciously rude or disrespectful**
9. **A poem or stanza containing 8 lines (plural)**
10. **Based on casual observations, rather than rigorous or scientific analysis**

Answers to last month's **PHARMACY FUN**:
1. Diflucan 2. Gardasil 3. Suboxone 4. Axid

References:
1. Sanders, Lisa. "A Strange Itch, Trouble Breathing, Then Anaphylactic Shock." *New York Times* 7 January, 2018: MM20.