

What's Inside...

Rx News.....1

Medicaid Update.....2

Law Review.....2

Feature Article:
Update: Prescription Nasal Sprays for AR.....3

Ask PRN.....4

Did You Know?.....4

Pharmacy Fun.....4

.....NEW DRUGS.....NEW DRUGS.....NEW DRUGS.....

SPRIX (Ketorolac Tromethamine Nasal Spray).
Category: NSAID.
Initial Dose: *Adults <65 years old:* 1 spray in each nostril every 6 to 8 hours. *Adults ≥65 years old, renally impaired patients, and patients weighing less than 50 kg:* 1 spray in one nostril every 6 to 8 hours Maximum duration of therapy is 5 days.
MDD: *Adults <65 years old:* 8 sprays. *Adults ≥65 years old, renally impaired patients, and patients weighing less than 50 kg:* 4 sprays. Maximum duration of therapy is 5 days.

Regency Therapeutics is marketing Sprix, a new nasal spray formulation of the NSAID ketorolac. As with other systemic dosage forms of ketorolac (tablet, injection), duration of therapy must not exceed 5 days, due to the risk of gastrointestinal bleeding. Sprix is supplied in packages of 5 single-day nasal spray bottles, each containing enough solution to deliver 8 sprays. Before first use, the pump must be primed by releasing 5 sprays into the air; the pump does not need to be primed again for subsequent uses of the same bottle. The bottle should be discarded 24 hours after priming, even if there is still medication remaining. Using a bottle of Sprix after 24 hours can lead to an incorrect dose being dispensed, and could also result in a patient taking the drug for more than 5 days. Bottles of Sprix should be refrigerated until ready for use; the in-use bottle should be kept at room temperature and always discarded after 24 hours. Patient should be counseled to administer Sprix while standing or sitting up straight with their head tilted slightly forward.

PICATO (Ingenol Mebutate Gel)
Category: Topical treatment for actinic keratoses.
Initial Dose: *Face and scalp:* use **0.015%** gel applied to the affected area once daily for 3 days. *Trunk and extremities:* use **0.05%** gel applied to the affected area once daily for 2 consecutive days.
MDD: Once daily for 2 or 3 days, depending on treatment site.

Leo Pharma has announced the FDA approval of Picato, a novel therapy for actinic keratoses. The active ingredient in Picato, ingenol, is derived from the *Euphorbia peplus* plant and is believed to induce cell death by unknown mechanisms. Dosing is based on the area being treated (see above). Patients should be counseled to avoid contact with the eyes, and to allow the treated area to dry for 15 minutes after application.

QNASL (Beclomethasone Dipropionate Nasal Spray).
Category: Nasal steroid.
Initial Dose: 2 sprays in each nostril once daily.
MDD: 4 sprays.

Teva has been granted FDA approval for QNASL, the latest in the growing field of nasal steroids (see our updated chart of prescription nasal sprays on page 3). QNASL contains the same active ingredient as **Beconase AQ**, but in a nonaqueous, “dry” aerosol form. QNASL is indicated for the treatment of nasal symptoms associated with seasonal and perennial allergic rhinitis in adults and adolescents 12 years of age and older.

FDA NEWS

FDA Weighs in on Question of Aliskiren Use

In our last issue (*PRN #42*), we reported on the discontinuation of the ALTITUDE trial, a study of aliskiren (**Tekturna**) in conjunction with an ACE or ARB, due to an increased incidence of cardiovascular and renal events in diabetic patients. At that time we noted that the FDA had not yet taken a position on the continued use of aliskiren-containing products (**Amturnde**, **Tekturna**, **Tekturna HCT**, **Tekamlo**, **Valturna**) in diabetics. On April 20, 2012, the agency published its recommendations, which include:

- Concomitant use of aliskiren and an ACE or ARB is contraindicated in diabetic patients.
- Avoid use of aliskiren with an ACE or ARB in patients with renal impairment where GFR is less than 60 mL/min.
- Valturna (a combination product containing both aliskiren and the ARB valsartan) should not be used in diabetic patients. Valturna will no longer be marketed after July 2012.

FDA Issues Updated Warning on DRSP-containing Oral Contraceptives

In a follow-up to previous Drug Safety Communications regarding the safety of oral contraceptives containing drospirenone (DRSP), the Food and Drug Administration (FDA) has concluded that DRSP-containing birth control pills may be associated with a higher risk for blood clots than other progestin-containing pills. Drospirenone is a synthetic version of progesterone, referred to as a progestin, which is combined with ethinyl estradiol in several combination oral contraceptives developed and marketed by Bayer. In some epidemiologic studies, the risk of blood clots was three times greater for DRSP-containing products when compared to products containing levonorgestrel or some other progestins, although it is not yet clear that this effect is due to DRSP alone. The list of DRSP-containing oral contraceptives is printed below:

Beyaz	Ocella	Yasmin
Gianvi	Safyral	Yaz
Loryna	Syeda	Zarah



Information Regarding the New York State Medicaid Program

Drug Utilization Review Program

The New York Medicaid fee-for-service program recently implemented a new drug utilization review program, which includes both step therapy restrictions and frequency/quantity/duration limits. Drug Utilization Review Board recommendations are based on best practice, as established by FDA approved labeling, official compendia, and major treatment guidelines. Prescription claims which do not comply with the parameters of the program will be rejected with code 85- "Claim Not Processed" as well as code 75 with additional detailed messages. It should be noted that even Preferred Drugs may be subject to the DUR program, and claims for these agents will be rejected if they do not conform to program limits. A complete and up-to-date listing of all program restrictions and limitations is available online at: www.health.ny.gov/health_care/medicaid/program/dur/index.htm. The most recent updates to the program, which take effect April 12, 2012, are listed below:

ACE/ARB/Direct Renin Inhibitors:

⇒ Require trial with ACE prior to initiating preferred ARB

⇒ Require trial with ACE or ARB prior to initiating preferred Direct Renin Inhibitor

Amitiza:

⇒ Require trials of both a bulking-agent and an osmotic laxative prior (defined as within 89 days) to initiating lubiprostone

⇒ Duration limit of 30 days with 2 refills per prescription

SSRI/SNRI:

⇒ Require trial with a Selective Serotonin Reuptake Inhibitor (SSRI) prior to a Serotonin-Norepinephrine Reuptake Inhibitor (SNRI) (exception for specific indications: Chronic musculoskeletal pain [CMP], Diabetic peripheral neuropathy [DPN], and Fibromyalgia [FM])

Human Growth Hormone (HGH):

⇒ Require diagnosis for all HGH products regardless of patient age

Regulatory Issues Affecting Pharmacy in New York State

Department of Health Addresses Pharmacists' Questions Regarding Medicaid Managed Care Prescriptions

Starting in October, 2011, New York State Medicaid beneficiaries enrolled in Medicaid and Family Health Plus managed care plans began receiving pharmacy benefits through their managed care plans, rather than through traditional fee-for-service Medicaid (sometimes referred to as "straight Medicaid"). This change, affecting a majority of Medicaid recipients, has led to a good deal of confusion among patients and pharmacists alike. Many of the questions pharmacists are asking center around the fact that fee-for-service Medicaid has unique rules and regulations regarding prescriptions that do not apply to any other pharmacy plans (e.g., prescriptions must be filled within 60 days of being issued, maximum of 5 refills, etc.). The New York State Department of Health has recently released an update clarifying a number of these issues. Some of the key questions the department has answered include the following:

Do pharmacies contracting with the Medicaid managed care plans have to adhere to the terms and conditions of the individual managed care contracts or do we still have to adhere to the NY Medicaid guidelines or both? All pharmacies must continue to adhere to all State Education Department and Bureau of Narcotic Enforcement rules, requirements and regulations, regardless of the insurer. Managed care plans do have the authority to operationalize the pharmacy benefit differently than the Medicaid fee-for-service program. As examples, managed care plans and/or their Pharmacy Benefit Managers are permitted to:

- Establish formularies and reimbursement rates.
- Create specific prior authorization processes.
- Administer the enrollment and credentialing of their network providers.
- Establish their own utilization management controls such as quantity limits, step therapy and limitations on days supply.
- Determine policies for their members, such as establishing the period of time from the date written in which a prescription can be filled, the number of refills allowed, or the requirements for medical supplies.
- Determine "proof of delivery" signature requirements. Note- All managed care plans require that a signature be obtained as "proof of delivery" of a prescription.
- Establish the time period for which prescription records related to claims paid by the plan must be retrievable.
- Determine whether to provide extended supplies (>30 days) of medications.

If a Medicaid client (FFS, Managed Care or Family Health Plus) states that he/she is unable to pay a co-payment can a pharmacy provider refuse to dispense the medication? No. 42 U.S.C. § 1396o(e) 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 outstanding copayments through methods such as requesting the co-payment each time the member is provided services or goods, sending bills or any other legal means.

Is the NYS prescription serial number required on managed care plan prescription claims? Currently, managed care plans are not required to report the NYS prescription serial number to the Medicaid program. *In September 2012*, the pharmacy claim data submitted by the managed care plans to the state must include the NYS prescription serial number. Managed care plans and/or their Pharmacy Benefit Managers will be working with their network pharmacy providers to alert them regarding these changes and the timeline for managed care plan implementation.

Is the OMIG aware that the card swipe requirement does not apply to managed care beneficiaries? Yes. The Office of the Medicaid Inspector General (OMIG) is aware that the card swipe requirement will not apply to managed care beneficiaries. OMIG is also aware of DOH's strategy to move all recipients into managed care and/or care management over the next three years. The pharmacy card swipe program for fee-for-service beneficiaries will continue during the course of the transition to managed care, as there will continue to be fee-for-service pharmacy expenditures until the transition is complete. During that time, the initiative will be evaluated and its continuation determined accordingly.

UPDATE: PRESCRIPTION NASAL SPRAYS FOR ALLERGIC RHINITIS

The Headlines seem to repeat every year at this time: climate change = early spring = early and intense allergy season. This year is no different, except that some experts are going so far as to predict that 2012 will be the worst allergy season on record. Prescription nasal sprays for allergic rhinitis, a 2.5 billion dollar sector, are the mainstay of therapy, and it seems a new product in this category is introduced every season. In recognition of this fact, we present a newly updated version of our prescription nasal spray chart.

Steroid Nasal Sprays				
Product (active)	Generic?	Pediatric Dose	Adult Dose	Counseling Points
Beconase AQ (beclomethasone 42 mcg/spray)	No	6-12 yo: 1 to 2 sprays in each nostril BID	1 to 2 sprays in each nostril BID	Shake well before use
Flonase (fluticasone propionate 50 mcg/spray)	Yes	4-12 yo: 1 to 2 sprays in each nostril QD	2 sprays in each nostril QD	Shake gently before use
Flunisolide (29 mcg/spray)	Yes	6-14 yo: 2 sprays in each nostril BID or 1 spray TID	2 sprays in each nostril 2 to 3 times a day	Does not need shaking
Nasacort AQ (triamcinolone 55 mcg/spray)	Yes	2-5 yo: 1 spray in each nostril QD 6-12 yo: 1 to 2 sprays in each nostril QD	1 to 2 sprays in each nostril QD	Shake well before use
Nasonex (mometasone 50 mcg/spray)	No	2-12 yo: 1 spray in each nostril QD	2 sprays in each nostril QD	Shake well before use
Omnaris (ciclesonide 50 mcg/spray)	No	≥6 yo: 2 sprays in each nostril QD	2 sprays in each nostril QD	Shake gently before use
QNASL (Beclomethasone 80 mcg/spray)	No	None	2 sprays in each nostril QD	Shake well before use
Rhinocort Aqua (budesonide 32 mcg/spray)	No	6-12 yo: 1 to 2 sprays in each nostril QD	1 to 4 sprays in each nostril QD	Shake gently before use
Veramyst (fluticasone furoate 27.5 mcg/spray)	No	2-11 yo: 1 to 2 sprays in each nostril QD	2 sprays in each nostril QD	Shake well before use
Antihistamine Nasal Sprays				
Product (active)	Generic?	Pediatric Dose	Adult Dose	Counseling Points
Astelin (azelastine 137 mcg/spray)	Yes	5-11 yo: 1 spray in each nostril BID	1 to 2 sprays in each nostril BID	May cause drowsiness
Astepro (azelastine 205.5 mcg/spray)	No	≥12 yo: 1 to 2 sprays in each nostril BID (alt. 2 sprays in each nostril QD)	1 to 2 sprays in each nostril BID (alt. 2 sprays in each nostril QD)	May cause drowsiness
Patanase (olopatadine 665 mcg/spray)	No	6-11 yo: 1 spray in each nostril BID	2 sprays in each nostril BID	May cause drowsiness
Anticholinergic Nasal Sprays				
Product (active)	Generic?	Pediatric Dose	Adult Dose	Counseling Points
Atrovent Nasal (ipratropium 0.03%)	Yes	Perennial allergic or non-allergic rhinitis: ≥6 yo: 2 sprays in each nostril 2 to 3 times a day	Perennial allergic or non-allergic rhinitis: 2 sprays in each nostril 2 to 3 times a day	May cause nasal dryness
Atrovent Nasal (ipratropium 0.06%)	Yes	Seasonal allergic rhinitis: ≥5 yo: 2 sprays in each nostril 4 times a day Common cold: 5-11 yo: 2 sprays in each nostril 3 times a day	Seasonal allergic rhinitis: 2 sprays in each nostril 4 times a day Common cold: 2 sprays in each nostril 3 to 4 times a day	May cause nasal dryness May cause nasal dryness

SUBSCRIPTION INFORMATION

Subscriptions are available:

One year (6 issues).....\$45.00
(Student Discount Available Online)

To pay by credit card via secure server go to the **SERVICES** page of our website: www.prnnewsletter.com

or

Send a check or money order payable to PRN Publishing to:

PRN Publishing
68-37 Yellowstone Boulevard
Suite C-22
Forest Hills, New York 11375



ASK PRN...

Is a prescription required to purchase a nebulizer at a pharmacy? The labeling on these devices specifies only "on the order of a physician."

Yes, a prescription is required. Nebulizers are regulated federally by the Food and Drug Administration (FDA). Nebulizers are considered "prescription devices," and, as such, are covered under **21 CFR 801.109**, which states that they must be labeled as follows: "*Caution: Federal law restricts this device to sale by or on the order of a physician.*" A call to the FDA's division of medical devices confirmed that, in the setting of a community pharmacy, this regulation requires that a prescription be presented in order to obtain a nebulizer. This restriction would also apply to metered dose inhaler spacers, such as Aero-chamber and Optichamber, which are also labeled for sale only on the order of a physician. Peak flow meters for personal use, on the other hand, do not require a prescription for purchase.

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.

As the percentage of prescriptions coming into our pharmacy electronically has increased, we are seeing more and more e-scripts for syringes, needles, and pre-filled insulin pens. Are electronic prescriptions for these devices acceptable?

No. In New York, syringes and/or needles, insulin cartridges and pens, and pre-filled syringes, such as EpiPen, are regulated under section **80.131** of the Rules and Regulations on Controlled Substances, and, as such, are not eligible for e-prescribing. Currently, the Bureau of Narcotic Enforcement (BNE) is working on promulgating new regulations for syringes, based on recent legislation, which may authorize electronic prescribing. But until those new regulations take effect, electronic prescribing of syringes and/or needles is not yet permissible.

GOT QUESTIONS? WE HAVE ANSWERS!

Send your questions to us at:

askprn@prnnewsletter.com

DID YOU KNOW?

DID YOU KNOW that Vicks VapoRub got its name through a lucky accident of marriage? In 1905, a North Carolina pharmacist, Lunsford Richardson, combined menthol and petroleum jelly into an ointment to treat cold symptoms and called it *Richardson's Croup and Pneumonia Cure Salve*. Realizing the name was less than catchy, the inventor determined to come up with something shorter, and, remembering that he first concocted the product in his brother-in-law's laboratory, he decided to name it in his honor. Richardson's brother-in-law was a local physician by the name of Dr. Joshua Vick!

PHARMACY FUN

Bud Abbott is famous for saying "they give baseball players very peculiar names nowadays," at the start of Abbott and Costello's "Who's on first?" routine. Well, the same could be said of oral contraceptives-- they all seem to sound vaguely like someone or something else. Using the clues below, name the OC we have in mind (note that the spellings may vary slightly). The first reader to submit the correct answers to puzzle@prnnewsletter.com will receive a custom-printed PRN binder.

1. The nickname of the Boston Red Sox's greatest hitter
2. Television actress best known for roles in *Dynasty*, *Melrose Place*, and *Spin City*
3. Legal clerk and activist whose story is told in a Julia Roberts movie
4. Long-time female lead on *Baywatch*
5. A violet or purple variety of quartz used in jewelry
6. Heroine of Shakespeare's *Merchant of Venice* ("The quality of mercy is not strain'd...")

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

1. Kadian
2. Cialis
3. Benicar

References:

1. Photography by James Murphy