

Express Scripts Drug Information & Wellness Center Drug Information Updates

In the News:

New Recommendations for PSA testing

- The US Preventative Services Task Force issued a draft recommendation against the routine use of PSA testing for prostate cancer screening.
- There is substantial evidence that PSA screening results in overdiagnosis of prostate tumors, but almost no reduction in prostate cancer deaths.
- Additionally, the PSA test does not provide evidence of the rate at which a prostate tumor may grow.
- Roughly 90% of men who are diagnosed with prostate cancer will choose early treatment surgery, radiation, or hormone therapy. Each of these treatments includes a variety of side effects, such as bowel dysfunction, erectile dysfunction, urinary incontinence, etc.

ACIP Recommends HPV Vaccine for boys

- The Advisory Committee on Immunization Practices (ACIP), an advisory panel to the CDC, has recommended routine vaccination of boys 11 and 12 years old with the Gardasil® vaccine to protect against human papillomavirus (HPV).
- Approximately 7,000 HPV-related cancers affect males annually.
- Of the two approved HPV vaccines, only Gardasil® is approved for use in boys.
- Gardasil® is indicated for use in boys and girls age 9 to 26 years old and is administered as a three-dose series at approximately \$100 a dose.

FDA Warns Not to Give Influenza Vaccine by Jet Injection

- October 24, 2011, the FDA advised not to use the jet injection influenza vaccine because the device has not been approved for use with the influenza vaccine.
- At this time, the jet injection device is only approved for use with the MMR vaccine.
- For individuals who received the influenza vaccine with the jet injection device, the CDC advises that it is not necessary to re-vaccinate at this time.

Obama Signs Executive Order to Help Reduce Drug Shortages

- The executive order expands the FDA's current powers to help alleviate and mitigate future drug shortages through the following tools:
 - Broader requirements for drug manufacturers regarding mandatory and voluntary reporting of drug supply problems.
 - Shorter review times of manufacturer's applications regarding changes in or beginning production of drugs in short supply.
 - Reporting of suspected price gouging or collusion among drug distributors taking advantage of drug shortages.
- At this time, there are over 200 drugs in short supply in the United States.

Special points of interest:

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- > New Formulations and Indications
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October is American Pharmacist Month!



American Pharmacists Month

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New Formulations and Indications

Erbitux (cetuximab) by Bristol-Myers Squibb

Class: Monoclonal Antibody

Indication: Metastatic colorectal cancer and non-metastatic head and neck cancer

MOA: As an epidermal growth factor receptor antagonist, cetuximab inhibits tumor cell growth and survival by binding EGRF to block phosphorylation.

New Indication: FDA approved for the treatment of late-stage (metastatic) head and neck cancer

Byetta (exenatide) by Amylin Pharmaceuticals & Eli Lilly and Co

Class: Glucagon-Like Peptide 1 Receptor agonist

Indication: Diabetes mellitus type 2

MOA: Incretin mimetic; enhances glucose-dependent insulin secretion

New Dosage Regimen: Add-on therapy to insulin glargine

Cialis (tadalafil) by Eli Lilly and Co

Class: PDE-5 Inhibitor

Indication: Erectile dysfunction, pulmonary hypertension

MOA: Inhibits PDE-5 to increase cGMP to enhance smooth muscle relaxation in the prostate, bladder, and urethra

New Indication: Benign prostatic hyperplasia (BPH)

Combivent (albuterol and ipratropium) by Boehringer Ingelheim

Class: Bronchodilator

Indication: COPD, for patients requiring a second bronchodilator

MOA: Reduces bronchospasm through anticholinergic and sympathomimetic mechanisms

New Generic Approvals

Levetiracetam Extended-Release Tablets	Keppra XR
Felbamate Tablets	Felbatol
Doxercalciferol Capsules	Hectorol

Recent Guideline Updates

Management of Community Acquired Pneumonia in Infants and Children Older than 3 months of Age

Pediatric Infectious Disease Society and IDSA

- Bacterial Pneumonia (*S. pneumoniae*): Preferred oral therapy - Amoxicillin (90mg/kg/day in 2 doses or 45mg/kg/day in 3 doses; max: 4g/day)
- *H. flu* coverage/missing Hib vaccination: Amoxicillin/clavulanate
- Atypical bacteria (*Mycoplasma*): Azithromycin 10mg/kg day 1 (max: 500mg), then 5mg/kg days 2-5 (max 250mg)
- CAP due to influenza: Oseltamivir or zanamivir



Pediatric Infectious
Diseases Society



Newly Approved Drugs

Exparel (bupivacaine) Injectable Suspension by Pacira Pharmaceuticals, Inc.

Class: Local anesthetic

Indication: Management of postsurgical pain

MOA: Combines bupivacaine with DepoFoam® to provide long term analgesia

Dosing: Based on surgical site and the volume required to cover the area; see prescribing information

Onfi (clobazam) Tablets by Lundbeck Inc.

Class: Anticonvulsant, short/intermediate acting benzodiazepine

Indication: Lennox-Gastaut Syndrome, adjunct

MOA: Mechanism not fully elucidated, potentiates neurotransmission by binding to benzodiazepine site of GABA(A) receptor

Dosing: > 30 kg initial, 10 mg ORALLY daily (in 2 divided doses), titrating to 20 mg daily (2 divided doses) on day 7 and to 40 mg daily (2 divided doses) on day 14; ≤ 30 kg initial, 5 mg ORALLY daily (in 2 divided doses), titrating to 10 mg daily (2 divided doses) on day 7 and to 20 mg daily (2 divided doses) on day 14

Ferriprox (deferiprone) Tablets by ApoPharm Inc.

Class: Chelating Agent

Indication: Iron overload, transfusional-Thalassemia syndrome

MOA: Binds ferric ions to form stable complexes over a wide pH range

Dosing: Initial 25 mg/kg, orally, three times daily; MAX: 33 mg/kg, orally, three times daily [round to nearest 250 mg]

Juvisync (simvastatin and sitagliptin) Tablets

Class: HMG-CA reductase inhibitor and dipeptidyl peptidase-4 inhibitor

Indication: Hyperlipidemia and type 2 diabetes

MOA: inhibits biosynthesis of cholesterol (simvastatin) and inhibits the breakdown of incretion hormones (sitagliptin)

Dosing: Sitagliptin 100 mg/simvastatin 40 mg, orally, every evening [simvastatin dose available in combination: 10, 20, 40 mg]

Drug Information Question

Is there data to support use of metformin in Type 1 Diabetes patients?

There has been speculation that the American Diabetes Association may be adding metformin to the type 1 diabetes treatment guidelines, which has brought about the question concerning data to support its use in this population. Several studies and two meta-analyses^{1,2} were found related to using metformin for adults with type 1 diabetes. The meta-analysis by Vella et al. well summarized the most pertinent literature for adult use, and results will be summarized here. Both meta-analysis citations are provided for further detail, if needed and additional literature is available for use in children that is not detailed here. Vella et al. performed a systematic review using Cochrane guidelines and found 10 studies involving use of metformin in type 1 diabetic patients that met their specific criteria. These studies were evaluated for effects on cardiovascular disease, HbA1c, insulin dosing regimen, BMI, lipid profile, and adverse events.

As metabolic complications are associated with both types of diabetes, adding metformin may theoretically produce benefits in patients with type 1 diabetes similar to those observed in patients with type 2 diabetes on metformin therapy by improving insulin sensitivity. In this systematic review, Vella et al. concluded there is not a significant benefit for achieving glycemic control. Within the studies reviewed that evaluated HbA1c specifically, the authors estimated from combined study data an absolute HbA1c reduction of 0.11%, which was not statistically significant. Even though individual studies may suggest greater benefit of adjunctive metformin therapy to insulin in type 1 diabetes to achieve glycemic control, data is conflicting and meta-analyses suggest stronger evidence is required from larger studies with longer durations.¹



It appears metformin may only be useful as adjunct to insulin for those needing to lower the daily dose of insulin. When analyzing combined study effects for insulin dose, the authors noted significant reduction in insulin daily dose requirements by an average of 6.6 units per day. Due to limited study duration, it is unclear if this effect was sustained beyond one year of therapy.¹

The authors were unable to make conclusions regarding key clinical or cardiovascular outcomes associated with metformin in type 1 diabetes, and, although not statistically significant, there may be small reductions in body weight (1.7-6.0 kg) and total cholesterol (11.6-15.9 mg/dL). Two of the ten studies showed a statistically significant increase in hypoglycemic adverse events. Otherwise, metformin was well-tolerated in all studies with gastrointestinal adverse effects rarely mentioned.¹

Based on the Cochrane GRADE system, the grade of evidence for the main outcomes reviewed (glycemic control and insulin dose) is moderate, and authors note this is an important area for future evaluation.¹ There is currently a phase III trial pending completion in December 2013 regarding safety and efficacy of using metformin adjunctive to insulin in adolescent "double diabetes," which is a new phenomenon being observed when a patient transitions from type 1 to exhibiting a hybrid of type 1 and type 2 diabetes. The use of adjunctive metformin in type 1 patients should be evaluated on a case by case basis.

References:

1. Vella S, Buetow L, Royle P, Livingstone S, Colhoun HM, Petrie JR. The use of metformin in type 1 diabetes: a systematic review of efficacy. *Diabetologia*. 2010 May;53(5):809-20.
2. Abdelghaffar S, Attia AM. Metformin added to insulin therapy for type 1 diabetes mellitus in adolescents. *Cochrane Database Syst Rev*. 2009 Jan 21;(1):CD006691.





Express Scripts
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SOUTHERN ILLINOIS UNIVERSITY
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Apps of the Month

The following applications for smartphones have been reviewed and critiqued by students and pharmacists:

Critical Care ACLS Guide

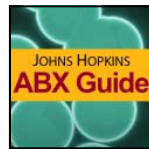


Cost: \$5.99

Content: Contains current ACLS guideline algorithms and has indexes with common lab values, emergency medications, EKG rhythms, and toxicology. It also includes information on pediatric management and has charts for calculating things such as Glasgow Coma Scale. Simple phrases are also translated to Spanish for communicating in emergent situations. This app is designed by Informed Publishing with data coming from scientific literature and guidelines.

Rating (1-5): 

John Hopkins ABX Guide



Cost: Free

Content: This app contains monographs for 21 vaccines. Monographs include: vaccine type, ACIP recommendations and indications, available vaccine forms, pathogen directed protection, dosing and administration information, adverse reactions, vaccine-drug interactions, contraindications, and immune response. ABX Guide provides additional information within the monographs such as onset of protection, preferred vaccine type for different patient populations, and vaccine cost when available.

Rating (1-5): 

Black Bag *Medical Resources*



Cost: Free

Content: This app is a news resource for new and practice-changing medical updates. The news feed subscription feature provides the option to choose the specific topic areas of interest to avoid unwanted news stories. Example subscriptions include cardiology, pain management, geriatrics, infectious disease, and endocrinology. Each news article provides a short summary and offers links for more information. Medical podcasts and videos are also available through the app.

Rating (1-5): 