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Key Inforbits

- 3 new drugs
- New indications
- Pharmacists good for heart failure patients
- Guidelines for osteoporosis in men
- How secure Internet medical records?
- TPR requirements effective last month

NEW DRUGS, and other related stuff …

New Drug … (4/22/2008) The FDA has approved **certolizumab pegol (Cimzia®** by UCB, Inc) for adults with moderate to severe Crohn's disease who have not responded to conventional therapies. This product was approved with a Medication Guide. Patients will receive an injection every two weeks for the first three injections. Once benefit has been established, Cimzia® should be given once every four weeks. The most common side effects of Cimzia® are headache, upper respiratory infections, abdominal pain, injection site reactions and nausea. Patients are at increased risk for serious adverse effects, including serious infections that can lead to hospitalization or death. Because Cimzia® affects the immune system, it can lower the body's ability to fight infections, such as tuberculosis and other opportunistic infections. Cimzia® blocks TNF (tumor necrosis factor) and may cause lymphomas (a form of cancer) and other malignancies. In cases of serious infections, the drug should be discontinued immediately.
For more information on Crohn's disease, visit:
Crohn's Disease–National Institute of Diabetes and Digestive and Kidney Diseases
www.digestive.niddk.nih.gov/ddiseases/pubs/crohns/index.htm
http://www.fda.gov/bbs/topics/NEWS/2008/NEW01821.html
http://www.cimzia.com/Default1.asp [Manufacturer site]

New Drug … (4/24/2008) The FDA has approved **methylnaltrexone bromide (Relistor™** by Wyeth Pharmaceuticals and Progenics Pharmaceuticals) to help restore bowel function in patients with late-stage, advanced illness who are receiving continuous opioids for pain. Opioids can interfere with normal bowel elimination function by relaxing the intestinal smooth muscles and preventing them from contracting and pushing out waste products. Relistor™ acts by blocking opioid entrance into the cells thus allowing the bowels to continue to function normally. Relistor™ is delivered via subcutaneous injection; the starting schedule is one dose every other day as needed. Relistor™ is not recommended for patients with known or suspected intestinal obstructions. Common side effects include abdominal pain, gas, nausea, dizziness and diarrhea.
http://www.fda.gov/bbs/topics/NEWS/2008/NEW01826.html

New Drug … (5/20/2008) The FDA has approved **alvimopan (Entereg®**, by Adolor and GlaxoSmithKline, collaborators on development and marketing) to accelerate the restoration of normal bowel function in patients ≥18 years old who have undergone partial large or small bowel resection surgery. FDA is approving Entereg® with a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of the drug outweigh the risks and it will include

limits on dispensing. Following major abdominal surgery, some patients develop postoperative ileus (POI) that causes temporary impairment of the gastrointestinal (GI) tract's motility. POI can be a by-product of opioid pain relievers, prescribed after surgery which can slow or inhibit normal motility. Entereg® blocks opioid effects in the bowel. The recommended dose for Entereg® is one 12 mg capsule given just prior to surgery and then another 12 mg dose twice daily for up to 7 days or not to exceed 15 doses. The product will only be available to hospitals. The most common side effects reported were low blood calcium levels, anemia and gastrointestinal problems, including constipation, dyspepsia (heartburn) and flatulence.
http://www.fda.gov/bbs/topics/NEWS/2008/NEW01838.html

New Combination … (4/15/2008) The FDA has approved **Treximet® (sumatriptan 85 mg and naproxen sodium 500 mg) tablets**, manufactured by GlaxoSmithKline and Pozen.
http://www.gsk.com/media/pressreleases/2008/2008_us_pressrelease_10034.htm

New Indication … (4/23/2008) The FDA has **approved the use of Amitiza®** (lubiprostone, jointly marketed by Sucampo and Takeda Pharmaceuticals America) for the treatment of **Irritable Bowel Syndrome with Constipation (IBS-C)** in adult women aged 18 and over. Irritable bowel syndrome is a disorder characterized by cramping, abdominal pain, bloating, constipation, and diarrhea. IBS causes a great deal of discomfort and distress to its sufferers. It affects at least twice as many women as men. Common side effects of Amitiza® include nausea, diarrhea, and abdominal pain. Other rare side effects include urinary tract infections, dry mouth, syncope (fainting), peripheral edema (swelling of the extremities), dyspnea (difficulty breathing), and heart palpitations. Amitiza® should be taken twice-a-day in 8 microgram doses with food and water. Amitiza® is also approved for the treatment of chronic idiopathic constipation (CIC), but the dose for that indication is higher, 24 micrograms twice a day.
http://www.fda.gov/bbs/topics/NEWS/2008/NEW01828.html

New Indication … (4/23/2008) The FDA has approved use of **Vyvanse® (lisdexamfetamine dimesylate, by Shire, CII) to treat adult attention deficit hyperactivity disorder (ADHD)**. The drug was approved in July 2007 for ADHD in children 6 to 12 years old. Lisdexamfetamine is a prodrug, d-amphetamine covalently bonded to l-lysine. Its currently available strengths are 30, 50 and 70 mg; new strengths of 20, 40 and 60 mg will be available this summer.
http://www.shire.com/shire/NewsAndMedia/PressReleases/showShirePress.jsp?ref=889&tn=3&m1=8&m2=13

Discontinued … (4/8/2008) Pfizer has discontinued **Geocillin (carbenicillin indanyl sodium)** tablets, 382 mg. There are no other FDA approved manufacturers for this product.
http://www.fda.gov/cder/drug/shortages/default.htm#Geocillin

MedWatch … (3/27/2008) The FDA announced an investigation of the possible association between the use of **Singulair® and behavior/mood changes, suicidality (suicidal thinking and behavior) and suicide**. Singulair® is a leukotriene receptor antagonist used to treat asthma and the symptoms of allergic rhinitis, and to prevent exercise-induced asthma. Patients should not stop taking Singulair® before talking to their doctor if they have questions about the new information. Healthcare professionals and caregivers should monitor patients taking Singulair® for suicidality (suicidal thinking and behavior) and changes in behavior and mood.
Read the complete 2008 MedWatch Safety Summary, and other information at:
http://www.fda.gov/medwatch/safety/2008/safety08.htm#Singulair

FROM THE MEDICAL LITERATURE …

Heart failure patients – Pharmacists good … After a thorough search of the literature, 12 randomized controlled trials, with a total of 2060 heart failure patients, were reviewed for the involvement of pharmacists in their care. Pharmacist-directed care was present in 11 of 12 studies and showed significant reductions in all-cause hospitalizations (2026 patients) (OR, 0.71; 95% CI, 0.54-0.94) and heart failure hospitalizations (1977 patients) (OR, 0.69; 95% CI, 0.51-0.94) and a nonsignificant reduction in mortality. Collaborative pharmacist care showed reductions in the rate of heart failure hospitalizations. Overall, pharmacist involvement is a good thing for heart failure patients, and cost of health care.

Koshman SL, Charrois TL, Simpson SH, McAlister FA, Tsuyuki RT. Pharmacist care of patients with heart failure: A systematic review of randomized trials. Arch Intern Med. 2008 Apr 14;168(7):687-694.

Guidelines … **Screening for osteoporosis in men** … A new guideline has been published concerning the screening of men for osteoporosis, by the American College of Physicians. Three

recommendations are made: 1) Older men should be periodically assessed individually for risk factors of osteoporosis, 2) Dual-energy x-ray absorptiometry should be used for men at increased risk for osteoporosis and are candidates for drug therapy, 3) Further research is needed on evaluation of screening tests in men. These guidelines are based on a systematic review of the literature. Key risk factors for low bone mineral density-mediated fracture include increased age, low body weight, weight loss, physical inactivity, prolonged corticosteroid use, previous osteoporotic fracture and androgen deprivation therapy.

Qaseem A, Snow V, Shekelle P, Hopkins R Jr, Forciea MA, Owens DK, for the clinical Efficacy Assessment Subcommittee of the American College of Physicians. Screening for osteoporosis in men: A clinical practice guideline from the American College of Physicians. Ann Intern Med. 2008;148:680-684.

Liu H, Paige NM, Goldzweig CL, Wong E, Zhou A, Suttorp MJ, et al. Screening for osteoporosis in men: A systematic review for an American College of Physicians Guideline. Ann Intern Med. 2008;148:685-701.

Reviews of Note …

- LaFleur J, McAdam-Marx C, Kirkness C, Brixner DI. Clinical risk factors for fracture in postmenopausal osteoporotic women: A review of the recent literature. Ann Pharmacother. 2008 Mar;42(3):375-386.
- Levin B, Lieberman DA, McFarland B, Smith RA, Brooks D, Andrews KS, et al, for the American Cancer Society Colorectal Cancer Advisory Group, the US Multi-Society Task Force, and the American College of Radiology Colon Cancer Committee. Screening and surveillance for the early detection of colorectal cancer and adenomatous polyps, 2008: A **joint guideline** from the American Cancer Society, the US Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology. CA Cancer J Clin 2008. doi: 10.3322/CA.2007.0018.
  http://caonline.amcancersoc.org/cgi/content/full/CA.2007.0018v1
- Ciardiello F, Tortora G. EGFR antagonists in cancer treatment. N Engl J Med. 2008 Mar 13;358(11):1160-1174.
- Munoz-Price LS, Weinstein RA. Acinetobacter infection. N Engl J Med. 2008 Mar 20;358(12):1271-1281.
- Uhlmann WR, Guttmacher AE. Key internet genetics resources for the clinician. JAMA. 2008 Mar 19;299(11):1356-1358.

FROM THE LAY LITERATURE about medicine …

Warning – Storage of Health Records … As online storage of health records for individuals begins to proliferate (eg, Microsoft, Google), warnings are also beginning to sound. An article in the New York Times (and citing the New England Journal of Medicine) lays out some of the concerns we need to recognize. In addition to the basic security concerns for the data (hackers, theft of computers), these new players are also not regulated by privacy restrictions of the government, eg, HIPAA. While the intent may be pure(?) the lure of big dollars for thousands/hundreds of thousands/millions of health records by companies, advertisers, etc, will be significant and your name and information may be buffeted on this new sea of greed. However, there are many advantages for these online storage systems, so there will be a significant shake-out period.

Lohr S. Warning on storage of health records. New York Times. 2008 Apr 17. http://www.nytimes.com/2008/04/17/business/17record.html?ref=health&pagewanted=print

Mandl KD, Kohane IS. Tectonic shifts in the health information economy. N Engl J Med. 2008 Apr 17;358(16):1732-1737.

Update …

TRP Requirements – April 1, 2008 … The Medicaid Tamper Resistant Prescription requirements are effective beginning April 1, 2008. The law applies only to written prescriptions for covered outpatient drugs; prescriptions that are transmitted from the prescriber to the pharmacy verbally, by fax, or through an e-prescription are not impacted by the statute, and so those methods may be used as alternatives to a written prescription. The law applies whenever Medicaid pays any portion of the cost of a prescription. To be considered tamper resistant on April 1, 2008, a prescription pad must contain at least one of the following three characteristics:

- one or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form;
- one or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription pad by the prescriber;
- one or more industry recognized features designed to prevent the use of counterfeit prescription forms.

By October 1, 2008, a prescription pad must contain all three of the above characteristics to be considered tamper-resistant. For more information go to:
http://www.medicaid.state.al.us/programs/pharmacy_svcs/tamper-resistant_Rx_pads.aspx?tab=4

The last "dose" …

Summer afternoon - summer afternoon; to me those have always been the two most beautiful words in the English language.
~Henry James [Author, 1843-1916]

An electronic bulletin of drug and health-related news highlights, a service of …
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