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RX BENEFIT MANAGEMENT

PharmNOTES

Summary about new FDA products,
generic medication, medical products,
and WHAT IS IN THE PIPELINE.

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Pharmacy Benefit Management
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NEWS……

Drug Issue	Date	News/Event
Opana™ ER (oxymorphone extended release) removal	07/06/2017	OPANA™ ER is an opioid agonist indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Endo Pharmaceuticals announced that it will remove Opana™ ER (oxymorphone extended release) tablets from sale in the U.S. While maintaining confidence in the safety and effectiveness of Opana™ ER when it is taken appropriately, Endo plans a gradual market withdrawal. The company will work with the FDA and prescribers to assure that Opana™ ER patients have adequate alternatives to treat their constant, long-term, moderate-to-severe pain. Although it was reformulated in 2012, Opana™ ER was not FDA designated as abuse-deterrent. It still can be abused by injecting or snorting it. More information available at: http://www.prnewswire.com/news-releases/endo-provides-update-on-opana-er-300484191.html.
FDA Considers Label Changes for Some Immunotherapies Due to Potential Vision Loss	07/17/2017	The FDA is considering adding the risk of ocular inflammatory conditions to labels for 3 immune checkpoint inhibitors due to sight-threatening complications. The labels that may face changes include (1) Bristol-Myers Squibb's **Yervoy (ipilimumab)**, (2) **Opdivo (nivolumab)** and (3) Merck's **Keytruda (pembrolizumab)**. The 3 labels currently list uveitis, a type of eye inflation, as a potential immune-mediated adverse reaction, but the FDA's post-marketing reviews have found further complications including retinal detachment and vision loss. Ocular inflammation resulting in vision loss is also observed in a study that treated metastatic melanoma with ipilimumab. • The study involves a patient that was diagnosed with melanoma that continued to progress during treatment. Eventually, he participated in a clinical trial for ipilimumab and received 3mg/kg every 3 weeks for 3 doses. Following treatment, he experienced adverse side effects including a rash and diarrhea which were treated with supportive therapy, and then headaches that were resolved with steroids. However, 4 months after the initial treatment, the participant experienced acute vision loss in his left eye, followed by visual loss in his right eye after 5 months. Furthermore, the steroids taken by the patient to treat the adverse effects from the ipilimumab treatment caused further complications. The FDA is considering labeling changes to emphasize the risks of these complications. More information available at: http://www.ajmc.com/newsroom/fda-considers-label-changes-for-some-immunotherapies-due-to-potential-vision-loss

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Endari™ (L-glutamine) powder, for oral use / Emmaus Life Sciences Inc.	Amino acid supplement; Gastrointestinal agent	To reduce severe complications such as pain, swelling and other complications of sickle cell anemia in adult and pediatric patients 5 years of age and older.	07/07/2017	**DOSAGE AND ADMINISTRATION** The recommended dose for adults and pediatric patients 5 years of age and older varies with weight: • Less than 30 kg: 5 g orally twice daily • 30 to 65 kg: 10 g orally twice daily • Greater than 65 kg: 15 g orally twice daily Each dose of Endari should be mixed in 8 oz. (240 mL) of cold or room temperature beverage or 4 oz. to 6 oz. of food before ingestion. **DOSAGE FORMS AND STRENGTHS** Oral powder: 5 grams of L-glutamine powder per paper-foil-plastic laminate packet **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • Glutamate and ammonia levels may increase in patients receiving intravenous parenteral nutrition; monitoring recommended. **ADVERSE REACTIONS** Most common adverse reactions: constipation, nausea, headache, abdominal pain, cough, pain in extremity, back pain, and chest pain. **DRUG INTERACTIONS** No major drug-drug interactions.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Endari™ (L-glutamine) powder, for oral use / Emmaus Life Sciences Inc. (continuation…)	Amino acid supplement; Gastrointestinal agent	To reduce severe complications such as pain, swelling and other complications of sickle cell anemia in adult and pediatric patients 5 years of age and older.	07/07/2017	**USE IN SPECIFIC POPULATIONS** • **Pregnancy:** There are no available data on Endari use in pregnant women to inform a drug-associated risk of major birth defects and miscarriage • **Lactation:** There are no data on the presence of Endari in human milk, the effect on the breastfed infant or the effect on milk production. However, infant risk cannot be ruled out. • **Pediatric use:** The safety and effectiveness of Endari have been established in pediatric patients 5 years and older. • **Geriatric use:** Clinical studies of Endari did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Tremfya™ (guselkumab) Injection, for subcutaneous use / Janssen Biotech, Inc.	Antipsoriatic; Interleukin-23 blocker	Treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.	07/13/2017	**DOSAGE AND ADMINISTRATION** The recommended dose is 100 mg subQ at week 0, week 4, and every 8 weeks thereafter. **DOSAGE FORMS AND STRENGTHS** Injection: 100 mg/mL in a single-dose prefilled syringe. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Concomitant use:** Avoid use of live vaccines. • **Immunologic:** Active TB or reactivation of latent TB may occur. Avoid use in patients with active TB; monitoring recommended. • **Infection:** Increased risk of infection, particularly upper respiratory tract infection, gastroenteritis, tinea infections, and herpes simplex infections. Avoid use in patients with active infection; monitoring recommended and discontinuation required. **ADVERSE REACTIONS** Most common adverse reactions: upper respiratory infections, headache, injection site reactions, arthralgia, diarrhea, gastroenteritis, tinea infections, and herpes simplex infections. **DRUG INTERACTIONS** No major drug-drug interactions. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** There are no available data on TREMFYA use in pregnant women to inform a drug associated risk of adverse developmental outcomes. Human IgG antibodies are known to cross the placental barrier; therefore, TREMFYA may be transmitted from the mother to the developing fetus.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Tremfya™ (guselkumab) Injection, for subcutaneous use / Janssen Biotech, Inc. (continuation…)	Antipsoriatic; Interleukin-23 blocker	Treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.	07/13/2017	**USE IN SPECIFIC POPULATIONS (continuation…)** • **Lactation:** There are no data on the presence of guselkumab in human milk, the effects on the breastfed infant, or the effects on milk production. • **Pediatric use:** The safety and efficacy of TREMFYA in pediatric patients (less than 18 years of age) have not been established. • **Geriatric use:** No overall differences in safety or effectiveness were observed between older and younger subjects who received TREMFYA. However, the number of subjects aged 65 years and older was not sufficient to determine whether they respond differently from younger subjects.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Nerlynx™ (neratinib) Tablets / Puma Biotechnology, Inc.	Tyrosine kinase inhibitor	Extended adjuvant treatment of early-stage HER2-positive breast cancer in adult patients who have been previously treated with a regimen that includes the drug trastuzumab.	07/17/2017	**DOSAGE AND ADMINISTRATION** The recommended dose is 240 mg orally once daily with food, continuously for 1 year. • Antidiarrheal prophylaxis with the first dose and during the first 2 neratinib cycles (56 days): Loperamide 4 mg orally 3 times daily during weeks 1 and 2 and 4 mg twice daily during weeks 3 through 8. Beyond the second cycle (week 9 or greater), use loperamide 4 mg as needed (maximun 16 mg/day). Titrated to 1 to 2 bowel movements/day. **DOSAGE FORMS AND STRENGTHS** Tablets: 40 mg. **CONTRAINDICATIONS** None. **WARNINGS AND PRECAUTIONS** • **Gastrointestinal:** Severe diarrhea and sequelae (eg, dehydration, hypotension, and renal failure) have been reported; monitoring and antidiarrheal prophylaxis recommended. Treatment interruption, dosage adjustment, and additional supportive measures may be necessary for severe diarrhea with dehydration. • **Hepatic:** Hepatotoxicity, characterized by increased liver enzymes, has been reported; monitoring recommended. • **Reproduction:** May cause fetal harm; advise women of reproductive potential to use effective contraception during treatment and for at least 1 month after the last dose. **ADVERSE REACTIONS** Most common adverse reactions: diarrhea, nausea, abdominal pain, fatigue, vomiting, rash, swollen and sore mouth (stomatitis), decreased appetite, muscle spasms, indigestion (dyspepsia), liver damage (AST or ALT enzyme increase), nail disorder, dry skin, abdominal swelling (distention), weight loss and urinary tract infection.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Nerlynx™ (neratinib) Tablets / Puma Biotechnology, Inc. (continuation…)	Tyrosine kinase inhibitor	Extended adjuvant treatment of early-stage HER2-positive breast cancer in adult patients who have been previously treated with a regimen that includes the drug trastuzumab.	07/17/2017	**DRUG INTERACTIONS** • **Gastric acid reducing agents:** Avoid concomitant use with proton pump inhibitors (PPI) and H2-receptor antagonists. Separate NERLYNX by 3 hours after antacid dosing. • **Strong or moderate CYP3A4 inhibitors:** Avoid concomitant use. • **Strong or moderate CYP3A4 inducers:** Avoid concomitant use. • **P-glycoprotein (P-gp) substrates:** Monitor for adverse reactions of narrow therapeutic agents that are P-gp substrates when used concomitantly with NERLYNX. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** Based on animal studies, NERLYNX can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should have a pregnancy test prior to starting treatment with NERLYNX. • **Contraception:** (1) Female – Advise females of reproductive potential to use effective contraception during treatment with NERLYNX and for at least 1 month after the last dose. (2) Male – Advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 3 months after the last dose of NERLYNX. • **Lactation:** Advise lactating women not to breastfeed while taking NERLYNX and for at least 1 month after the last dose. • **Pediatric use:** The safety and efficacy of NERLYNX in pediatric patients has not been established. • **Geriatric use:** In the ExteNET trial, there was a higher frequency of treatment discontinuations due to adverse reactions in the ≥ 65 years age group than in the < 65 years age group. • **Hepatic impairment (Severe, Child Pugh C):** Initially 80 mg orally once daily.

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Vosevi™ (sofosbuvir, velpatasvir and voxilaprevir) / Gilead Sciences, Inc.	Nucleotide analog NS5B polymerase inhibitor (SOF), a pangenotypic NS5A inhibitor (VEL), and a pangenotypic NS3/4A protease inhibitor (VOX)	Re-treatment of genotype 1, 2, 3, 4, 5, and 6 chronic hepatitis C virus (HCV) infection in patients previously treated with an NS5A inhibitor-containing regimen, or with genotype 1a or 3 previously treated with a sofosbuvir-containing regimen without an NS5A inhibitor. **Black Box Warning** Test all patients for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment with sofosbuvir/velpatasvir/voxilaprevir. HBV reactivation has been reported in HCV/HBV coinfected patients who were undergoing or had completed treatment with HCV direct-acting antivirals and were not receiving HBV antiviral therapy. Some cases have resulted in fulminant hepatitis, hepatic failure, and death. Monitor HCV/HBV coinfected patients for hepatitis flare or HBV reactivation during HCV treatment and post-treatment follow-up. Initiate appropriate patient management for HBV infection as clinically indicated.	07/18/2017	**DOSAGE AND ADMINISTRATION** The recommended dose is one tablet (sofosbuvir 400 mg/velpatasvir 100 mg/voxilaprevir 100 mg) orally once daily with food for 12 weeks. **DOSAGE FORMS AND STRENGTHS** Tablets: 400 mg sofosbuvir, 100 mg velpatasvir, and 100 mg voxilaprevir. **CONTRAINDICATIONS** • Concomitant use with rifampin. **WARNINGS AND PRECAUTIONS** • **Black box warning:** Hepatitis B virus (HBV) reactivation has occurred in patients coinfected with hepatitis C virus (HCV) during treatment for HCV with direct-acting antiviral agents, including cases of fulminant hepatitis and hepatic failure with fatalities. Screen all patients for evidence of current or prior HBV infection before initiation. Monitor HCV/HBV coinfected patients for HBV flare-ups or reactivation during treatment and post-treatment followup, and treat as clinically indicated. • **Cardiovascular:** (1) Bradycardia and fatal cardiac arrest have been reported during concurrent use of amiodarone, with some cases requiring pacemaker intervention; monitoring recommended and discontinuation may be necessary. (2) Increased risk of bradycardia during concurrent amiodarone among patients with concomitant beta blocker use, underlying cardiac comorbidities, and advanced liver disease; monitoring recommended. • **Concomitant use:** (1) Use with amiodarone not recommended. (2) Not recommended with P-glycoprotein inducers, and moderate to strong inducers of CYP2B6, CYP2C8, and CYP3A4. • **Hepatic:** Use in patients with moderate or severe hepatic impairment (Child-Pugh B or C) is not recommended

New FDA Approved Products

Drug/ Manufacturer	Therapeutic Class	Indications	Date	Comments
Vosevi™ (sofosbuvir, velpatasvir and voxilaprevir) / Gilead Sciences, Inc. (continuation…)	Nucleotide analog NS5B polymerase inhibitor (SOF), a pangenotypic NS5A inhibitor (VEL), and a pangenotypic NS3/4A protease inhibitor (VOX)	Re-treatment of genotype 1, 2, 3, 4, 5, and 6 chronic hepatitis C virus (HCV) infection in patients previously treated with an NS5A inhibitor-containing regimen, or with genotype 1a or 3 previously treated with a sofosbuvir-containing regimen without an NS5A inhibitor. **Black Box Warning** Test all patients for evidence of current or prior hepatitis B virus (HBV) infection before initiating treatment with sofosbuvir/velpatasvir/voxilaprevir. HBV reactivation has been reported in HCV/HBV coinfected patients who were undergoing or had completed treatment with HCV direct-acting antivirals and were not receiving HBV antiviral therapy. Some cases have resulted in fulminant hepatitis, hepatic failure, and death. Monitor HCV/HBV coinfected patients for hepatitis flare or HBV reactivation during HCV treatment and post-treatment follow-up. Initiate appropriate patient management for HBV infection as clinically indicated.	07/18/2017	**ADVERSE REACTIONS** Most common adverse reactions: headache, fatigue, diarrhea and nausea. **DRUG INTERACTIONS*** • **P-gp inducers and/or moderate to potent CYP inducers (e.g., St. John's wort, carbamazepine):** May decrease concentrations of sofosbuvir, velpatasvir, and/or voxilaprevir. Use of VOSEVI with Pgp inducers and/or moderate to potent CYP inducers is not recommended. *Consult the full prescribing information prior to use for potential drug interactions. **USE IN SPECIFIC POPULATIONS** • **Pregnancy:** The risk of major birth defects and miscarriage is unknown. • **Lactation:** The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VOSEVI and any potential adverse effects on the breastfed child from VOSEVI or from the underlying maternal condition. • **Pediatric use:** Safety and effectiveness of VOSEVI have not been established in pediatric patients. • **Geriatric use:** No dosage adjustment required. • **Hepatic impairment (moderate to severe, Child-Pugh B or C):** Use is not recommended.

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Orencia™ (abatacept) Injection / Bristol-Myers Squibb's	Anti-rheumatic Immune modulator Selective T cell costimulation modulator	Treatment of rheumatoid arthritis, juvenile idiopathic arthritis and psoriatic arthritis. **New indication:** Treatment of Active Psoriatic Arthritis in Adults	06/30/2017	The approval was based on results from two randomized, double-blind, placebo-controlled trials in which Orencia™ improved (or reduced) disease activity in both TNF-naive and exposed patients with high disease activity, high tender and swollen joints, and a disease duration of more than seven years.
Blincyto™ (blinatumomab) Injection /	Bispecific CD19-directed CD3 T-cell engager	Treatment of Philadelphia chromosome-negative relapsed or refractory B-cell precursor Acute Lymphoblastic Leukemia (ALL). **New indication:** Treatment of relapsed or Refractory B-cell Precursor Acute Lymphoblastic Leukemia in Adults and Children.	07/11/2017	Blincyto™ is the first single-agent immunotherapy to treat patients with Philadelphia chromosome-negative (Ph-) relapsed or refractory B-cell precursor ALL. Also is the first-and-only FDA-approved CD19-directed CD3 bispecific T cell engager (BiTE®) immunotherapy. The approval is based on results from the TOWER study, which found that Blincyto™ demonstrated a superior improvement in median overall survival (OS) over standard of care (SOC) chemotherapy, nearly doubling median OS. The study showed that median OS was 7.7 months (95 percent CI: 5.6, 9.6) for Blincyto™ versus four months (95 percent CI: 2.9, 5.3) for SOC (hazard ratio for death=0.71; p=0.012). The approval is also based on data from the Phase 2 ALCANTARA study, which evaluated the efficacy of Blincyto™ in adult patients with Ph+ relapsed or refractory B-cell precursor ALL.

Soruce: https://www.drugs.com/new-indications.html

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Yervoy™ (ipilimumab) Injection / Bristol-Myers Squibb Company	Human cytotoxic T-lymphocyte antigen 4 (CTLA-4)-blocking antibody	Treatment of unresectable or metastatic melanoma. **New indication** Treatment of unresectable or metastatic melanoma in pediatric patients 12 years of age and older.	07/21/2017	U.S. Food and Drug Administration (FDA) has expanded the indication for Yervoy™ (ipilimumab) injection for intravenous use to now include the treatment of unresectable or metastatic melanoma in pediatric patients 12 years of age and older. Yervoy™ was evaluated in two trials of pediatric patients: a dose-finding study in 33 patients aged 2 to 21 years with relapsed or refractory solid tumors and an open-label, single-arm trial in 12 adolescents (ages ranging from 12 to 16 years) with previously treated or untreated, unresectable Stage 3 or 4 malignant melanoma. The overall safety profile of Yervoy™ in children and adolescents was consistent with the safety profile in adults, and similarities in disease between adult and pediatric patients 12 years and older allow for extrapolation of data. Based on a population pharmacokinetic analysis, exposure in adolescents 12 years and older is comparable to that in adults for the approved dose of 3 mg/kg, administered intravenously over 90 minutes every three weeks for a total of four doses. It is important to keep in mind that Yervoy™ is associated with a Black Box Warning and can result in severe to fatal immune-mediated adverse reactions.
Abilify Maintena™ (aripiprazole) for Extended-Release Injectable Suspension / H. Lundbeck A/S (Lundbeck) and Otsuka Pharmaceutical Co., Ltd. (Otsuka)	Atypical antipsychotic	Treatment of schizophrenia, and maintenance monotherapy treatment of bipolar I disorder. **New indication:** Maintenance monotherapy treatment of bipolar I disorder in adults.	07/27/2017	Based on phase III study data, Abilify Maintena™ delayed the time to recurrence of any mood episode in adult patients experiencing a manic episode at screening compared to placebo.

Soruce: https://www.drugs.com/new-indications.html

New FDA Approved Indications

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Opdivo™ (nivolumab) Injection / Bristol-Myers Squibb Company	Programmed death receptor-1 (PD-1) blocking antibody	Treatment of advanced melanoma, advanced non-small cell lung cancer, advanced renal cell carcinoma, classical Hodgkin lymphoma, advanced squamous cell carcinoma of the head and neck, urothelial carcinoma, and MSI-H or dMMR metastatic colorectal cancer. **New indication:** Treatment of adult and pediatric (12 years and older) patients with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (mCRC) that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.	07/31/2017	Approval for this indication has been granted under accelerated approval based on overall response rate (ORR) and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. In the CheckMate-142 trial, among patients who received prior treatment with a fluoropyrimidine, oxaliplatin, and irinotecan, 28% responded to treatment with Opdivo™. The percentage of patients with a complete response was 1.9% (and the percentage of patients with a partial response was 26%. Among these responders, the median duration of response was not reached. Among all enrolled patients, 32% responded to treatment with Opdivo™; 2.7% experienced a complete response, 30% experienced a partial response.

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New FDA Approved Formulations

Drug/ Manufacturer	Therapeutic class	Indications	Date	Comments
Benlysta (belimumab) Injection / GSK	B-lymphocyte stimulator (BLyS)-specific inhibitor	Treatment of adult patients with active, autoantibody-positive, systemic lupus erythematosus (SLE) who are receiving standard therapy.	07/20/2017	Systemic Lupus Erythematosus (SLE) is the most common form of lupus, a chronic, incurable autoimmune disease producing autoantibodies that can attack almost any system in the body. US Food and Drug Administration (FDA) has approved a new subcutaneous formulation of Benlysta™ (belimumab). The approval is based on data from the BLISS-SC phase III pivotal study of more than 800 patients with active SLE, which measured reduction in disease activity at Week 52 in patients receiving belimumab plus standard of care, versus those receiving placebo plus standard of care (assessed by SRI, a composite measure of efficacy in lupus). The approval marks the first subcutaneous self-injection treatment option for patients with SLE. After training from their health care provider, patients will be able to administer the medicine as a once weekly injection of 200mg, from either a single-dose prefilled syringe or from a single-dose autoinjector. This is the second formulation of Benlysta™ to be granted approval for SLE, adding to the existing intravenous (IV) formulation, approved in 2011, which is administered by healthcare professionals to patients as a weight-based dose of 10mg/kg, via a one-hour infusion in a hospital or clinic setting every four weeks (following an initial loading phase given on days 0, 14 and 28).

Soruce: https://www.drugs.com/new-indications.html

New First Time Generic Drug Approval

Drug/Manufacturer	Therapeutic Class	Date	Comments
Prasugrel Tablets 5 mg and 10 mg / Mylan Pharmaceuticals Inc.	ADP-Induced Aggregation Inhibitor; Blood Modifier Agent; Platelet Aggregation Inhibitor	07/12/2017	Generic for: Effient™
Sevelamer Carbonate Tablets 800mg / Aurobindo Pharma Limited	Phosphate binder; Bile acid sequestrant	07/17/2017	Generic for: Renvela™ Tablets

Source: https://www.drugs.com/generic-approvals.html

PIPELINE…….

Drug/Manufacturer	Date	Indications	Comments	Impact
Migalastat / Amicus Therapeutics	07/11/2017	Treatment of Fabry disease	Migalastat (AT1001) is an investigational pharmacological chaperone in development. FDA Confirms Amicus Therapeutics May Submit New Drug Application for Migalastat for Fabry Disease.	High

Soruce: https://www.drugs.com/new-drug-applications.html

References:

- Drugs.com (www.drugs.com)
- Food and Drug Administration (www.fda.gov)
- Micromedex® Solutions - Truven Health Analytics (www.micromedexsolutions.com)
- Pharmacist Letter (www.pharmacistletter.com)
- P&T Community (www.ptcommunity.com)