



New Drugs September 2014 (Original New Drug Applications: FDA)

Generic Name	Trade Name	Indication(s)	CPG Action/Date
May 2014			
Dapagliflozin Formulary Pg. 9	Farxiga	<i>Endocrine & Metabolic Agents: Antidiabetic Agents: Sodium-Glucose 2 Transporter 2 Inhibitors.</i> Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	9/22/14 CTP holder may prescribe.
Umeclidinium/ Vilanterol Formulary Pg. 13	Anoro Ellipta	<i>Respiratory Agents: Respiratory Inhalant Combinations.</i> Indicated for maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease.	9/22/14 CTP holder may prescribe.
Luliconazole Formulary Pg. 24	Luzu	<i>Dermatologic Agents: Anti-Infectives, Topical.</i> Indicated for topical treatment of tinea pedis, tinea cruris, and tinea corporis.	9/22/14 CTP holder may prescribe.
June 2014			
Tetrastarch Formulary Pg. 8	Voluven	<i>Hematological Agents: Plasma Expanders.</i> Indicated for treatment and prevention of hypovolemia.	9/22/14 In accordance with the SCA.
Metreleptin Formulary Pg. 9	Myalept	<i>Endocrine & Metabolic Agents: Lipodystrophy Agents.</i> Indicated for replacement therapy to treat the complications of leptin deficiency, in addition to diet, in patients with congenital or acquired generalized lipodystrophy.	9/22/14 CTP holder may NOT prescribe.

Diclofenac Formulary Pg. 16	Zorvolex	<i>Central Nervous System Agents: NSAIDs.</i> Indicated for relief of mild to moderate acute pain in adults.	9/22/14 CTP holder may prescribe.
July 2014			
Tasimelteon Formulary Pg. 17	Hetlioz	<i>Central Nervous System Agents: Sedatives and Hypnotics, nonbarbiturate: Melatonin Receptor Agonists.</i> Indicated for treatment of non-24 hour sleep wake disorder.	9/22/14 CTP holder may prescribe.
Ribavirin Formulary Pg. 22	Moderiba	<i>Anti-Infectives, Systemic: Antiviral Agents.</i> Indicated in combination with peginterferon alfa-2b for the treatment of chronic HCV infection.	9/22/14 In accordance with the SCA.
Miltefosine Formulary Pg. 23	Impavido	<i>Anti-Infectives, Systemic: Antiprotozoals.</i> Indicated for treatment of visceral cutaneous and mucosal leishmaniasis in adults and adolescents 12 years and older.	9/22/14 In accordance with the SCA.
Apremilast Formulary Pg. 23	Otezla	<i>Biologic/ Immunologic Agents: Immunologic Agents: Immunomodulators.</i> Indicated for treatment of adult patients with active psoriatic arthritis.	9/22/14 In accordance with the SCA.
August 2014			
Elosulfase Alfa Injection Formulary Pg. 10	Vimizim	<i>Endocrine & Metabolic Agents: Elosulfase Alfa.</i> Indicated for the treatment of mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome)	9/22/14 CTP holder may NOT prescribe.
Droxidopa Formulary Pg. 12	Northera	<i>Cardiovascular Agents: Vasopressors.</i> Indicated for the treatment of orthostatic	9/22/14 CTP holder may prescribe.

		dizziness, light-headedness, or the “feeling that you are about to black out” in adult patients with symptomatic neurogenic orthostatic hypotension.	
Miconazole/Zinc Oxide Formulary Pg. 24	Vusion	<i>Dermatological Agents: Diaper Rash Products.</i> Indicated for the adjunctive treatment of diaper dermatitis only when complicated by documented candidiasis in immunocompetent children 4 weeks of age and older.	9/22/14 CTP holder may prescribe.
Ramucirumab Formulary Pg. 27	Cyramza	<i>Antineoplastic Agents: Monoclonal Antibodies.</i> Indicated for the treatment of gastric cancer.	9/22/14 CTP holder may NOT prescribe.
Ceritinib Formulary Pg. 27	Zykadia	<i>Antineoplastic Agents: Kinase Inhibitors.</i> Indicated for the treatment of patients with anaplastic lymphoma kinase positive metastatic nonsmall cell lung cancer.	9/22/14 CTP holder may NOT prescribe.

New Drugs Indications/ Warnings September 2014

(New Drug Indications/ Black Box Warnings: FDA)

Generic Name	Trade Name	Indication(s)	CPG Action/Date
May 2014			
Anti-Inhibitor Coagulant Complex Formulary Pg. 7	FEIBA	<i>Hematological Agents: Antihemophilic Agents.</i> New Indications for use in patients with hemophilia A and B with inhibitors for perioperative management and for routine prophylaxis to prevent or reduce the frequency of bleeding episodes.	Current: In accordance with the SCA. 9/22/14 No Change

Collagenase Clostridium Histolyticum Formulary Pg. 24	Xiaflex	<i>Dermatologic Agents: Enzyme Preparations.</i> New Black Box Warning for corporal rupture or other serious penile injury.	Current: CTP holder may NOT prescribe. 9/22/14 No Change
June 2014			
none			
July 2014			
Dabigatran Etexilate Formulary Pg. 7	Pradaxa	<i>Hematological Agents: Direct Thrombin Inhibitors.</i> New Indication for the treatment of deep vein thrombosis and pulmonary embolism. New Black Box Warning for the potential of epidural or spinal hematomas to occur in patients treated with dabigatran who are receiving neuraxial anesthesia or undergoing spinal puncture.	Current: In accordance with the SCA. 9/22/14 No Change
Omalizumab Formulary Pg. 13	Xolair	<i>Respiratory Agents: Monoclonal Antibodies.</i> New indication for treatment of chronic idiopathic urticaria in adults and adolescents 12 years and older.	Current: In accordance with the SCA. 9/22/14 No Change
Ibrutinib Oral Formulary Pg. 27	Imbruvica	<i>Antineoplastic Agents: Kinase Inhibitors.</i> New indication for treatment of patients with chronic lymphocytic leukemia who have received at least one prior therapy.	Current: CTP holder may NOT prescribe. 9/22/14 No Change
August 2014			
Androgens	Testosterone gel or solution	<i>Endocrine & Metabolic Agents: Androgens.</i> New black box warning for virilization in children	Current: In accordance with the SCA.

Formulary Pg. 8		who are secondarily exposed to testosterone transdermal gel or solution.	9/22/14 No Change
Ofatumumab	Arzerra	<i>Antineoplastic Agents: Monoclonal Antibodies.</i> New black box warning for Hepatitis B reactivation in patients receiving ofatumumab, and for progressive multifocal leukoencephalopathy and death. New indication for the treatment of previously untreated chronic lymphocytic leukemia.	Current: CTP holder may NOT prescribe. 9/22/14 No Change
Formulary Pg. 27			

Review of Prescribing Designations “In Accordance with the SCA” and CTP Holder May NOT Prescribe

Gastrointestinal Agents
(September 2014)

Drug Category/ Drug Name	Indication(s): If reviewing a specific drug in a drug category	Current Prescribing Designation	CPG Action/Date
GI Stimulants			
Cisapride (Propulsid) Formulary Pg. 20	<i>GI Stimulants.</i> Indicated for the treatment of GERD, gastroparesis, pseudo-obstruction, or severe chronic constipation.	CTP holder may NOT prescribe.	9/22/14 No Change
Gallstone Solubilizing Agents			
Gallstone Solubilizing Agents Formulary Pg. 20	<i>Gallstone Solubilizing Agents.</i>	In accordance with the SCA.	9/22/14 No change except for Ursodiol – CTP holder may prescribe

Review of Prescribing Designations “In Accordance with the SCA” and CTP Holder May NOT Prescribe

Anti-Infectives, Systemic
(September 2014)

Drug Category/ Drug Name	Indication(s): If reviewing a specific drug in a drug category	Current Prescribing Designation	CPG Action/Date
Chloramphenicol			
Chloramphenicol (Chloramphenicol Sodium Succinate) Formulary Pg. 21	<i>Chloramphenicol.</i> Indicated for use with serious infections for which less potentially dangerous drugs are ineffective or contraindicated. Also indicated for treatment of typhoid fever.	CTP holder May NOT prescribe.	9/22/14 No Change
Glycylcyclines			
Tigecycline (Tygacil) Formulary Pg. 21	<i>Glycylcyclines.</i> Indicated for the treatment of community-acquired bacterial pneumonia, complicated intra- abdominal infections, and complicated skin and skin structure infections.	In accordance with the SCA.	9/22/14 No Change
Ketolides			
Telithromycin (Ketek) Formulary Pg. 21	<i>Ketolides.</i> Indicated for the treatment of community-acquired pneumonia.	CTP holder May NOT prescribe.	9/22/14 In accordance with the SCA.
Streptogramins			
Quinupristin/ Dalfopristin (Synercid) Formulary Pg. 21	<i>Streptogramins.</i> Indicated for the treatment of patients with serious or life-threatening infections associated with vancomycin-resistant <i>Enterococcus faecium</i> bacteremia, and for treatment of complicated skin and skin structure infections.	In accordance with the SCA.	9/22/14 No Change

Lipopeptides			
Daptomycin (Cubicin) Formulary Pg. 21	<i>Lipopeptides.</i> Indicated for the treatment of complicated skin and skin structure infections and for the treatment of <i>S. aureus</i> bloodstream infections.	In accordance with the SCA.	9/22/14 No Change
Lipoglycopeptides			
Telavancin Hydrochloride (Vibativ) Formulary Pg. 21	<i>Lipoglycopeptides.</i> Indicated for the treatment of adults with complicated skin and skin structure infections caused by susceptible isolates of certain gram-positive microorganisms.	In accordance with the SCA.	9/22/14 No Change
Oxazolidones			
Linezolid (Zyvox) Formulary Pg. 21	<i>Oxazolidinones.</i> Indicated for the treatment of community-acquired pneumonia, complicated skin and skin structure infections, nosocomial pneumonia, uncomplicated skin and skin structure infections, and vancomycin-resistant enterococcal infections.	In accordance with the SCA.	9/22/14 No Change
Lincosamides			
Lincosamides Lincomycin (Lincocin) Formulary Pg. 21	<i>Lincosamides.</i> Indicated for the treatment of serious infections caused by susceptible strains of streptococci, pneumococci, and staphylococci, and anaerobic bacteria.	CTP holder May NOT prescribe except for Clindamycin.	9/22/14 In accordance with the SCA.
Colistimethate Sodium			
Colistimethate Sodium (Coly-Mycin M) Formulary Pg. 21	<i>Colistimethate Sodium.</i> Indicated for the treatment of acute or chronic infections due to sensitive strains of certain gram-negative bacilli.	Parenteral- CTP holder May NOT prescribe.	9/22/14 In accordance with the SCA.

Polymyxin B Sulfate			
Polymyxin B Sulfate Injection Formulary Pg. 21	<i>Polymyxin B Sulfate.</i> Indicated for the treatment of acute infections caused by susceptible strains of <i>Pseudomonas aeruginosa.</i>	Parenteral- CTP holder May NOT prescribe.	9/22/14 No Change
Bacitracin			
Bacitracin Injection Formulary Pg. 21	<i>Bacitracin.</i> Indicated for the treatment of infants with pneumonia and empyema caused by staphylococci shown to be sensitive to the drug.	Parenteral- CTP holder May NOT prescribe.	9/22/14 No Change
Novobiocin			
Novobiocin (Albamylin) Formulary Pg. 21	<i>Novobiocin.</i> Indicated for the treatment of serious infections due to susceptible <i>S. Aureus</i> when other effective antibiotics are contraindicated.	CTP holder May NOT prescribe.	9/22/14 No Change
Antifungal Agents			
Antifungal Agents IV Formulary Pg. 22	<i>Antifungal Agents.</i>	In accordance with the SCA.	9/22/14 No Change
Micafungin Sodium Injection (Mycamine) Formulary Pg. 22	<i>Antifungal Agents.</i> Indicated for the treatment of patients with candidemia, acute disseminated candidiases, Candida peritonitis, and abscesses, for the treatment of patients with esophageal candidiases, and for prophylaxis of Candida infections.	In accordance with the SCA.	9/22/14 No Change
Triazole Antifungals IV	<i>Antifungal Agents: Triazole Antifungals.</i>	In accordance with the SCA.	9/22/14 No Change

Formulary Pg. 22			
Antituberculosis Agents			
Antituberculosis Agents	<i>Antituberculosis Agents.</i> Indicated for treatment of tuberculosis.	In accordance with the SCA. INH – CTP holder may prescribe.	9/22/14 No Change
Formulary Pg. 22			
Antiviral Agents			
Foscarnet Sodium (Foscavir)	<i>Antiviral Agents.</i> Indicated for the treatment of CMV retinitis in patients with AIDS, in combination therapy with ganciclovir for patients who have relapsed after monotherapy with either drug, and for treatment of acyclovir-resistant mucocutaneous HSV infections in immunocompromised patients.	In accordance with the SCA.	9/22/14 No Change
Formulary Pg. 22			
Ganciclovir (Cytovene)	<i>Antiviral Agents.</i> Indicated for treatment of CMV retinitis in immunocompromised patients, including patients with AIDS, and for prevention of CMV disease in transplant recipients at risk for CMV disease.	IV- In accordance with the SCA.	9/22/14 No Change
Formulary Pg. 22			
Telaprevir (Incivek)	<i>Antiviral Agents.</i> Indicated for the treatment of genotype 1 chronic hepatitis C virus.	In accordance with the SCA.	9/22/14 No Change
Formulary Pg. 22			
Boceprevir	<i>Antiviral Agents.</i> Indicated for the treatment of chronic hepatitis C virus genotype I infection.	In accordance with the SCA.	9/22/14 No Change
Formulary Pg. 22			
Simeprevir	<i>Antiviral Agents.</i> Indicated for treatment of genotype I chronic hepatitis C virus.	In accordance with the SCA.	9/22/14 No Change
Formulary Pg. 22			

<p>Cidofovir (Vistide)</p> <p>Formulary Pg. 22</p>	<p><i>Antiviral Agents.</i> Indicated for the treatment of CMV retinitis in patients with AIDS.</p>	<p>CTP holder May NOT prescribe.</p>	<p>9/22/14 No Change</p>
<p>Ribavirin (Copegus, Ribasphere, Rebetol, Virazole)</p> <p>Formulary Pg. 22</p>	<p><i>Antiviral Agents.</i> Tablets – Indicated in combination with peginterferon alfa-2a for the treatment of adults with chronic HCV infection who have compensated liver disease and have not previously been treated with interferon alpha.</p> <p>Capsules/Solution - Indicated in combination with interferon alfa-2b for the treatment of chronic HCV in patients 18 years of age and older with compensated liver disease previously untreated with alpha interferon and in patients 18 years of age and older who have relapsed following alpha interferon therapy.</p> <p>Inhalation – Indicated for the treatment of hospitalized infants and young children with severe lower respiratory tract infection due to severe respiratory syncytial virus.</p>	<p>In accordance with the SCA.</p>	<p>9/22/14 No Change</p>
<p>Adefovir Dipivoxil (Hepsera)</p>	<p><i>Antiviral Agents.</i> Indicated for the treatment of chronic hepatitis B virus in patients 12 years of age and older with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases (ALT</p>	<p>In accordance with the SCA.</p>	<p>9/22/14 No Change</p>

Formulary Pg. 22	or AST) or histologically active disease.		
Entecavir (Baraclude) Formulary Pg. 22	<i>Antiviral Agents.</i> Indicated for the treatment of chronic HBV infection in adults with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease.	In accordance with the SCA.	9/22/14 No Change
Antiretroviral Agents			
Protease Inhibitors Formulary Pg. 23	<i>Antiretroviral Agents: Protease Inhibitors.</i>	In accordance with the SCA.	9/22/14 No Change
Nucleotide Analog Reverse Transcriptase Inhibitor Formulary Pg. 22	<i>Antiretroviral Agents. Nucleotide Analog Reverse Transcriptase Inhibitor.</i>	In accordance with the SCA.	9/22/14 No Change
Nucleoside Reverse Transcriptase Inhibitors Formulary Pg. 22	<i>Antiretroviral Agents: Nucleoside Reverse Transcriptase Inhibitors.</i>	In accordance with the SCA.	9/22/14 No Change
Non-Nucleoside Reverse Transcriptase Inhibitors. Formulary Pg. 22	<i>Antiretroviral Agents. Non-Nucleoside Reverse Transcriptase Inhibitors.</i>	In accordance with the SCA.	9/22/14 No Change
Nucleoside Analog Reverse Transcriptase Inhibitor Combinations Not currently listed on the Formulary	<i>Antiretroviral Agents: Nucleoside Analog Reverse Transcriptase Inhibitor Combinations.</i>	Not currently listed on the Formulary	9/22/14 In accordance with the SCA.

<p>Cellular Chemokine Receptor Antagonist</p> <p>Maraviroc (Selzentry)</p> <p>Formulary pg. 23</p>	<p><i>Antiretroviral Agents: Cellular Chemokine Receptor Antagonist.</i></p> <p>Indicated in combination with other antiretroviral agents, for treatment of adult patients infected only with chemokine receptor 5 (CCR5)-tropic HIV-1.</p>	<p>In accordance with the SCA.</p>	<p>9/22/14 No Change</p>
<p>Integrase Inhibitors</p> <p>Raltegravir (Isentress)</p> <p>Formulary Pg. 23</p>	<p><i>Antiretroviral Agents: Integrase Inhibitors.</i></p> <p>Indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adult patients.</p>	<p>In accordance with the SCA.</p>	<p>9/22/14 No Change</p>
<p>Fusion Inhibitors</p> <p>Enfuvirtide (Fuzeon)</p> <p>Formulary Pg. 23</p>	<p><i>Antiretroviral Agents: Fusion Inhibitors.</i></p> <p>Indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment- experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy.</p>	<p>In accordance with the SCA.</p>	<p>9/22/14 No Change</p>
Leprostatics			
<p>Leprostatics</p> <p>Formulary Pg. 23</p>	<p><i>Leprostatics.</i></p>	<p>In accordance with the SCA.</p>	<p>9/22/14 No Change</p>
CDC Anti-Infective Agents: Not commercially available			
<p>CDC Anti-Infective Agents</p> <p>Formulary Pg. 23</p>	<p><i>CDC Anti-Infective Agents</i></p>	<p>CTP holder may NOT prescribe.</p>	<p>9/22/14 No Change</p>