



New Drugs May 2015

(Original New Drug Applications: FDA)

Generic Name	Trade Name	Indication(s)	CPG Action/Date
September 2014			
Vorapaxar Formulary Pg. 7	Zontivity	<i>Hematological Agents:</i> <i>Antiplatelet Agents:</i> <i>Aggregation Inhibitors.</i> Indicated for reduction of thrombotic cardiovascular events in patients with a history of MI or with peripheral arterial disease.	CTP holder may prescribe.
Polidocanol Formulary Pg. 12	Variithena	<i>Cardiovascular Agents:</i> <i>Sclerosing Agents.</i> Indicated for treatment of incompetent great saphenous veins, accessory saphenous veins, and visible varicosities of the great saphenous vein system above and below the knee.	CTP holder may prescribe.
Sulfanilamide Vaginal Formulary Pg. 13	AVC	<i>Renal & Genitourinary Agents: Vaginal Preparations.</i> Indicated for the treatment of vulvovaginitis caused by <i>Candida albicans</i> .	CTP holder may prescribe.
October 2014			
Albiglutide Injection Formulary Pg. 9	Tanzeum	<i>Endocrine & Metabolic Agents: Antidiabetic Agents: Glucagon-like Peptide 1 Receptor Agonists.</i> Indicated as an adjunct to diet and exercise to improve glycemic control in the treatment of type 2 diabetes mellitus.	CTP holder may prescribe.
Naloxone Hydrochloride Formulary Pg. 11	Evzio	<i>Endocrine & Metabolic Agents: Detoxification Agents: Antidotes.</i> Indicated for the emergency treatment of	CTP holder may prescribe.

		known or suspected opioid overdose.	
Indomethacin Oral Formulary Pg. 16	Tivorbex	<i>Central Nervous System Agents: NSAIDs.</i> Indicated for the treatment of mild to moderate acute pain in adults.	CTP holder may prescribe.
Dalvavancin Formulary Pg. 21	Dalvance	<i>Anti-Infectives, Systemic: Lipoglycopeptides.</i> Indicated for the treatment of adult patients with acute bacterial skin and skin structure infections.	In accordance with the SCA.
Siltuximab Formulary Pg. 23	Sylvant	<i>Biologic/ Immunologic Agents: Monoclonal Antibodies.</i> Indicated for treatment of patients with multicentric Castleman disease who are HIV negative and human herpesvirus negative.	In accordance with the SCA.
Vedolizumab Formulary Pg. 23	Entyvio	<i>Biologic/ Immunologic Agents: Immunomodulators.</i> Indicated for treatment of moderately to severely active Crohn disease and moderately to severely active ulcerative colitis.	In accordance with the SCA.
Efinaconazole Formulary Pg. 23	Jublia	<i>Dermatologic Agents: Anti-Infectives, Topical: Antifungal Agents.</i> Indicated for the treatment of onychomycosis of the toenails.	CTP holder may prescribe.
November 2014			
Avanafil Formulary Pg. 13	Stendra	<i>Renal & Genitourinary Agents: Impotence Agents.</i> Indicated for treatment of erectile dysfunction.	CTP holder may prescribe.

Umeclidinium Formulary Pg. 13	Incruse Ellipta	<i>Respiratory Agents: Bronchodilators.</i> Indicated for maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease.	CTP holder may prescribe.
Tedizolid Phosphate Formulary Pg. 21	Sivextro	<i>Anti-Infectives, Systemic: Oxazolidinones.</i> Indicated for treatment of adult patients with acute bacterial skin and skin structure infections.	In accordance with the SCA.
Tavaborole Formulary Pg. 23	Kerydin	<i>Dermatologic Agents: Anti-Infectives, Topical.</i> Indicated for topical treatment of onychomycosis of the toenails.	CTP holder may prescribe.
Idelalisib Formulary Pg. 27	Zydelig	<i>Antineoplastic Agents: Kinase Inhibitors.</i> Indicated for the treatment of relapsed chronic lymphocytic leukemia, relapsed follicular B-cell non-Hodgkin lymphoma, and relapsed small lymphocytic lymphoma.	CTP holder may NOT prescribe.
December 2014			
C1 Inhibitor Formulary Pg.7	Ruconest	<i>Hematological Agents: Protein C1 Inhibitors.</i> Indicated for the treatment of acute attacks of hereditary angioedema in adult and adolescent patients.	In accordance with the SCA.
Canagliflozin/ Metformin Hydrochloride Formulary Pg. 9	Invokamet	<i>Endocrine & Metabolic Agents: Antidiabetic Agents: Antidiabetic Combination Products.</i> Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 DM	CTP holder may prescribe.
Olodaterol Formulary Pg. 13	Striverdi Respimat	<i>Respiratory Agents: Bronchodilators.</i> Indicated as long-term	CTP holder may prescribe.

		maintenance treatment of airflow obstruction in chronic obstructive pulmonary disease.	
Fluticasone Inhalation Formulary Pg. 13	Arnuity Ellipta	<i>Respiratory Agents: Respiratory Inhalant Products.</i> Indicated for maintenance treatment of asthma as prophylactic therapy in patients 12 years and older.	CTP holder may prescribe.
Naltrexone Hydrochloride/ Bupropion Hydrochloride Formulary Pg. 15	Contrave	<i>Central Nervous System Agents: Anorexiant.</i> Indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with an initial BMI of at least 30 or at least 27 in the presence of at least 1 weight-related comorbid condition.	In accordance with the SCA.
Belinostat Injection Formulary Pg. 27	Beleodaq	<i>Antineoplastic Agents: Histone Deacetylase Inhibitors.</i> Indicated for the treatment of relapsed or refractory peripheral T-cell lymphoma.	CTP holder may NOT prescribe.
January 2015			
Insulin Regular (Human) Inhalation Formulary Pg. 9	Afrezza	<i>Endocrine & Metabolic Agents: Antidiabetic Agents: Insulins.</i> Indicated as an adjunct to diet and exercise to improve glycemic control in adults and children with type 1 and type 2 diabetes mellitus.	CTP holder may prescribe.
Dulaglutide Formulary Pg. 9	Trulicity	<i>Endocrine & Metabolic Agents: Antidiabetic Agents: Glucagonlike Peptide 1 Receptor Agonists.</i> Indicated as an adjunct to diet and exercise to improve glycemic control	CTP holder may prescribe.

		in adults with type 2 diabetes mellitus.	
Eliglustat Tartrate Oral Formulary Pg. 10	Cerdelga	<i>Endocrine & Metabolic Agents: Glucosylceramide Synthase Inhibitor.</i> Indicated for treatment of adult patients with Gaucher disease type 1 who are cytochrome P450 (CYP-450) 2D6 extensive metabolizers, intermediate metabolizers, or poor metabolizers.	CTP holder may NOT prescribe.
Colchicine Oral Formulary Pg. 10	Mitigare	<i>Endocrine & Metabolic Agents: Agents for Gout.</i> Indicated for prophylaxis of gout flares in adults.	CTP holder may prescribe.
Naloxegol <i>c-ii</i> Formulary Pg. 11	Movantik	<i>Endocrine & Metabolic Agents: Detoxification Agents: Antidotes.</i> Indicated for the treatment of opioid-induced constipation in adult patients with chronic noncancer pain.	CTP holder may prescribe. (Schedule II restrictions apply)
Buprenorphine/ Naloxone Formulary Pg. 16	Bunavail	<i>Central Nervous System Agents: Narcotic Agonist- Antagonist Analgesics (non-schedule II).</i> Indicated for the treatment of opioid dependence.	CTP holder may NOT prescribe.
Abacavir/ Dolutegravir/ Lamivudine Formulary Pg. 22	Trilumeq	<i>Anti-Infectives, Systemic: Antiretroviral Agents: Miscellaneous Antiretroviral Combinations.</i> Indicated for the treatment of HIV-1 infection.	In accordance with the SCA.
Pembrolizumab Formulary Pg. 23	Keytruda	<i>Biologic & Immunologic Agents: Immunologic Agents: Immunomodulators.</i> Indicated for the treatment of unresectable or	CTP holder may NOT prescribe.

		metastatic melanoma.	
February 2015			
Testosterone Intranasal Formulary Pg. 8	Natesto	<i>Endocrine & Metabolic Agents: Sex Hormones: Androgens.</i> Indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.	In accordance with the SCA.
Empagliflozin Formulary Pg. 9	Jardiance	<i>Endocrine & Metabolic Agents: Antidiabetic Agents: Sodium-Glucose Co-Transporter 2 Inhibitors.</i> Indicated for treatment of type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycemic control.	CTP holder may prescribe.
Nintedanib Ethanesulfonate Formulary Pg. 13	Ofev	<i>Respiratory Agents: Tyrosine Kinase Inhibitors (Respiratory).</i> Indicated for treatment of idiopathic pulmonary fibrosis.	In accordance with the SCA.
Netupitant/ Palonosetron Formulary Pg. 16	Akynzeo	<i>Central Nervous System Agents: Antiemetic/ Antivertigo Agents.</i> Indicated for prevention of acute and delayed nausea and vomiting associated with chemotherapy.	CTP holder may prescribe.
Suvorexant Formulary Pg. 17	Belsomra	<i>Central Nervous Systems Agents: Sedatives and Hypnotics, Nonbarbiturates.</i> Indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.	CTP holder may prescribe.

Oritavancin Formulary Pg. 21	Orbactiv	<i>Anti-Infectives, Systemic: Lipoglycopeptides.</i> Indicated for treatment of adult patients with acute bacterial skin and skin structure infections.	In accordance with the SCA.
Ledipasvir/ Sofosbuvir Formulary Pg. 22	Harvoni	<i>Anti-Infectives, Systemic: Antiviral Agents.</i> Indicated for the treatment of chronic hepatitis C genotype I in adults.	CTP holder may prescribe.
Elvitegravir Oral Formulary Pg. 22	Vitekta	<i>Anti-Infectives: Systemic: Antiretroviral Agents: Integrase Inhibitors.</i> Indicated for use in combination with an HIV protease inhibitor co-administered with ritonavir and with other antiretroviral drugs(s) for the treatment of HIV-1 infection.	In accordance with the SCA.
Cobicistat Formulary Pg. 22	Tybost	<i>Anti-Infectives, Systemic: Antiretroviral Agents: Antiretroviral Boosting Agents.</i> Indicated for treatment of HIV-1 Infection to increase systemic exposure or atazanavir or darunavir in combination with other antiretroviral agents.	CTP holder may prescribe.
March 2015			
Ferric Citrate Formulary Pg. 5	Ferric Citrate	<i>Nutrients & Nutritional Agents: Trace Elements.</i> Indicated for the control of serum phosphorus levels in patients with chronic kidney disease receiving dialysis.	CTP holder may prescribe.
Dapagliflozin/ Metformin Formulary Pg. 9	Xigduo XR	<i>Endocrine & Metabolic Agents: Antidiabetic Agents: Antidiabetic Combination Products.</i> Indicated as an adjunct	CTP holder may prescribe.

		to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	
Vasopressin Formulary Pg. 10	Vasostrict	<i>Endocrine & Metabolic Agents: Posterior Pituitary Hormone.</i> Indicated to increase blood pressure in adult patients with vasodilatory shock	In accordance with the SCA.
Pirfenidone Formulary Pg. 13	Esbriet	<i>Respiratory Agents: Antifibrotic Agents.</i> Indicated for the treatment of idiopathic pulmonary fibrosis	CTP holder may prescribe.
Peginterferon Beta-1a Formulary Pg. 23	Plegridy	<i>Biologic/ Immunologic Agents: Immunologic Agents: Immunomodulators.</i> Indicated for treatment of patients with relapsing forms of multiple sclerosis.	In accordance with the SCA.
Thiotepa Injection Formulary Pg. 26	Thiotepa, Thioplex	<i>Antineoplastic Agents: Alkylating Agents: Ethylenimines/ Methylmelamines.</i> Not currently available in the US market, however FDA is allowing temporary importation of a European product for the treatment of a wide variety of neoplastic diseases.	CTP holder may NOT prescribe.
April 2015			
Edoxaban Tosylate Formulary Pg. 7	Savaysa	<i>Hematological Agents: Anticoagulants: Factor Xa Inhibitors.</i> Indicated for the treatment of deep vein thrombosis and pulmonary embolism, and to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation	In accordance with the SCA.

Antihemophilic Factor VIII Formulary Pg. 7	Obizur	<i>Hematological Agents: Antihemophilic Agents.</i> Indicated for treatment of bleeding episodes in adults with acquired hemophilia A.	In accordance with the SCA.
Ceftolozane/ Tazobactam Formulary Pg. 20	Zerbaxa	<i>Anti-Infectives, Systemic: Cephalosporins and Related Antibiotics.</i> Indicated for the treatment of complicated intra-abdominal infections and complicated urinary tract infections.	CTP holder may prescribe.
Ombitasvir/ Paritaprevir/ Ritonavir/ Dasabuvir Formulary Pg. 22	Viekira Pak	<i>Anti-Infectives, Systemic: Antiviral Agents.</i> Indicated for treatment of genotype I chronic hepatitis C virus infection.	In accordance with the SCA.
Peramivir Formulary Pg. 22	Rapivab	<i>Anti-Infectives, Systemic: Antiviral Agents.</i> Indicated for the treatment of acute, uncomplicated influenza in adults who have been symptomatic 2 days or less.	CTP holder may prescribe.
Olaparib Formulary Pg. 26	Lunparza	<i>Antineoplastic Agents: Parp Enzymes Inhibitor.</i> Indicated for treatment of advanced ovarian cancer.	CTP holder may NOT prescribe.
Blinatumomab Formulary Pg. 26	Blincyto	<i>Antineoplastic Agents: Monoclonal Antibodies.</i> Indicated for treatment of Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia.	CTP holder may NOT prescribe.

New Drugs Indications/ Warnings May 2015

(New Drug Indications/ Black Box Warnings: FDA)

Generic Name	Trade Name	Indication(s)	CPG Action/Date
September 2014			
None			Current:
October 2014			
Factor VIIa, Recombinant Formulary Pg. 7	NovoSeven RT	<i>Hematological Agents: Antihemophilic Agents.</i> New black box warning for serious arterial and venous thrombotic events following administration of factor VIIa.	Current: In accordance with the SCA. 5/18/2015 No change.
November 2014			
Protamine Sulfate Formulary Pg. 7	Protamine Sulfate	<i>Hematological Agents: Coagulants: Heparin Antagonist.</i> New black box warning for severe hypotension, cardiovascular collapse. Noncardiogenic pulmonary edema, catastrophic pulmonary vasoconstriction, and pulmonary hypertension.	Current: In accordance with the SCA. 5/18/2015 No change.
December 2014			
Eltrombopag Olamine Oral Formulary Pg. 6	Promacta	<i>Hematological Agents: Hematopoietic Agents: Thrombopoietin Receptor Agonist.</i> New indications for treatment of thrombocytopenia in patients with chronic hepatitis C and for severe aplastic anemia.	Current: In accordance with the SCA. 5/18/2015 No change.
January 2015			
Methylnaltrexone Bromide Formulary Pg. 11	Relistor	<i>Endocrine & Metabolic Agents: Detoxification Agents: Antidotes.</i> New indication for the treatment of opioid-induced constipation in adult patients with chronic noncancer pain	Current: CTP holder may prescribe. 5/18/2015 No change.
Apremilast Oral Formulary Pg. 23	Otezla	<i>Biologic & Immunologic Agents: Immunologic Agents: Immunomodulators.</i>	Current: In accordance with the SCA.

		New indication for the treatment of psoriasis.	5/18/2015 No change.
February 2015			
None			
March 2015			
None			
April 2015			
Aripiprazole Formulary Pg. 17	Abilify	<i>Central Nervous System Agents: Antipsychotic Agents: Benzisoxazole Derivatives.</i> New indication for the treatment of Tourette syndrome.	Current: CTP holder may prescribe. 5/18/2015 No change.
Rifapentine Formulary Pg. 22	Priftin	<i>Anti-Infectives, Systemic: Antituberculosis Agents.</i> New indication for the treatment of latent tuberculosis infection.	Current: In accordance with the SCA. 5/18/2015 No change.
Denosumab Formulary Pg. 23	Xgeva	<i>Biologic/ Immunologic Agents: Monoclonal Antibody.</i> New indication for treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.	Current: CTP holder may prescribe. 5/18/2015 No change.
Ramucirumab Formulary Pg. 26	Cyramza	<i>Antineoplastic Agents: Monoclonal Antibodies.</i> New indication for treatment on non-small cell lung cancer.	Current: CTP holder may NOT prescribe. 5/18/2015 No change.
Ruxolitinib Formulary Pg. 27	Jakafi	<i>Antineoplastic Agents: Kinase Inhibitors.</i> New indication for treatment of polycythemia vera.	Current: In accordance with the SCA. 5/18/2015 No change. (The pre-meeting posting incorrectly listed Ruxolitinib as "CTP holder may NOT prescribe.")

		adult patients with an initial body mass index of 30 or greater or 27 or greater in the presence of at least 1 weight-related comorbidity. Requesting: CTP holder may prescribe.	4731-11-04, OAC).
Formulary Review Revision Request from Deborah Magnotta, CNP			
Androgens Formulary Pg. 8	Testosterone, Fluoxymesterone, Methyltestosterone	<i>Endocrine & Metabolic Agents: Sex Hormones: Androgens.</i> Indicated for replacement therapy in hypogonadism associated with a deficiency or absence of endogenous testosterone and for metastatic mammary cancer. Requesting: CTP holder may prescribe.	Current: In accordance with the SCA. 5/18/2015 No change.

Review of Prescribing Designations CTP Holder May NOT Prescribe and in Accordance with the SCA
Biologic/Immunologic Agents
(May 2015)

Drug Category/ Drug Name	Indication(s): If reviewing a specific drug in a drug category	Current Prescribing Designation	CPG Action/Date
Immune Globulins			
Immune Globulins Formulary Pg. 23	<i>Immune Globulins.</i> Indicated to provide passive immunization to greater than or equal to 1 infectious diseases, for treatment of immune thrombocytopenic purpura, and suppression of Rh isoimmunization in	In Accordance with the SCA	5/18/2015 No change.

	nonsensitized Rho negative women with an Rh-incompatible pregnancy.		
Monoclonal Antibody			
Eculizumab (Soliris) Formulary Pg. 23	<i>Monoclonal Antibody.</i> Indicated for the treatment of patients with atypical hemolytic uremic syndrome and paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.	In Accordance with the SCA	5/18/2015 No change.
Belimumab (Benlysta) Formulary Pg. 23	<i>Monoclonal Antibody.</i> Indicated for the treatment of adult patients with active, autoantibody-positive, systemic lupus erythematosus who are receiving standard therapy.	In Accordance with the SCA	5/18/2015 No change.
Immunologic Agents			
Immunostimulants Pegademase Bovine (Adagen) Formulary Pg. 23	<i>Immunologic Agents: Immunostimulants.</i> Indicated for enzyme replacement therapy for adenosine deaminase (ADA) deficiency in patients with severe combined immunodeficiency disease who are not suitable candidates for or who have failed bone marrow therapy transplantation.	In Accordance with the SCA	5/18/2015 No change.
Immunosuppressives Formulary Pg. 23	<i>Immunologic Agents: Immunosuppressives.</i>	In Accordance with the SCA	5/18/2015 No change.

Immunomodulators Formulary Pg. 23	<i>Immunologic Agents: Immunomodulators.</i>	In Accordance with the SCA	5/18/2015 No change.
Antirheumatic Agents			
Antirheumatic Agents Formulary Pg. 24	<i>Antirheumatic Agents.</i>	In Accordance with the SCA	5/18/2015 No change.
Keratinocyte Growth Factors			
Palifermin (Kepivance) Formulary Pg. 23	<i>Keratinocyte Growth Factors.</i> Indicated to decrease the incidence and duration of severe oral mucositis in patients with hematologic malignancies who are receiving myelotoxic therapy requiring hematopoietic stem cell support.	In Accordance with the SCA	5/18/2015 No change.

**Review of Prescribing Designations PI/PC and CTP Holder May
NOT Prescribe and in Accordance with the SCA**
Dermatologic Agents
(May 2015)

Drug Category/ Drug Name	Indication(s): If reviewing a specific drug in a drug category	Current Prescribing Designation	CPG Action/Date
Anti-Psoriatic Agents			
Methotrexate (Rheumatrex, Trexall) Formulary pg. 23	<i>Anti-Psoriatic Agents.</i> Indicated for the symptomatic control of severe recalcitrant, disabling psoriasis, which is not adequately responsive to other therapy.	In accordance with the SCA.	5/18/2015 No change.
Enzyme Preparations			
Collagenase Clostridium Histolyticum (Xiaflex) Formulary Pg. 23	<i>Enzyme Preparations.</i> Indicated for the treatment of adult patients with Dupuytren contracture with a palpable cord.	CTP holder May NOT prescribe.	5/18/2015 No change.

Photochemotherapy			
Photochemotherapy Formulary Pg. 24	<i>Photochemotherapy.</i>	CTP holder May NOT prescribe.	5/18/2015 In accordance with the SCA.
Methoxsalen Oral & Topical Formulary Pg. 24	<i>Photochemotherapy.</i>	In accordance with the SCA.	5/18/2015 No change.
Aminolevulinic Acide Formulary Pg 24	<i>Photochemotherapy.</i>	In accordance with the SCA.	5/18/2015 No change.
Pigment Agents			
Pigment Agents Formulary Pg. 24	<i>Pigment Agents.</i>	CTP holder May NOT prescribe.	5/18/2015 In accordance with the SCA.
Retinoids			
First Generation Retinoids Isotretinoin Amnesteem, Claravis, Zenatane, Myorisan, Absorica Formulary Pg. 24	<i>First Generation Retinoids.</i> Indicated for the treatment of severe recalcitrant nodular acne.	In accordance with the SCA.	5/18/2015 No change.
Second Generation Retinoids			
Acitretin (Soriatane) Formulary Pg. 24	<i>Second Generation Retinoids.</i> Indicated for the treatment of severe psoriasis in adults.	Not currently listed on the Formulary	5/18/2015 In accordance with the SCA.
Alitretinoin Formulary Pg. 24	<i>Second Generation Retinoids.</i> Indicated to the topical treatment of cutaneous lesions in patients with AIDS related Kaposi sarcoma.	Not currently listed on the Formulary	5/18/2015 In accordance with the SCA.

Rexinoids			
Bexarotene Topical Formulary Pg. 24	<i>Rexinoids.</i> Indicated for the topical treatment of cutaneous lesions in patients with cutaneous T-cell lymphoma.	In accordance with the SCA.	5/18/2015 No change.