



New Drugs October 2013 (Original New Drug Applications: FDA)

Generic Name	Trade Name	Indication(s)	CPG Action/Date
May 2013			
Alogliptin Benzoate Formulary Pg. 9	Nesina	<i>Endocrine & Metabolic Agents: Antidiabetic Agents: Dipeptidyl Peptidase-4 Inhibitor.</i> Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	10/21/13 CTP holder may Prescribe.
Alogliptin Benzoate/ Metformin Hydrochloride Formulary Pg. 9	Kazano	<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 diabetes mellitus when treatment with both alogliptin and metformin is appropriate.	10/21/13 CTP holder may Prescribe.
Alogliptin Benzoate/ Pioglitazone Hydrochloride Formulary Pg. 9	Oseni	<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 diabetes mellitus when treatment with both alogliptin and pioglitazone is appropriate.	10/21/13 CTP holder may Prescribe.
Glycerol Phenylbutyrate Formulary Pg. 9	Ravicti	<i>Endocrine & Metabolic Agents: Glycerol Phenylbutyrate.</i> Indicated for the long-term management of patients 2 years and older with urea cycle disorders who cannot be managed by dietary	10/21/13 CTP holder may Prescribe.

		protein restriction and/or amino acid supplementation alone.	
Mipomersen Sodium Formulary Pg. 11	Kynamro	<i>Cardiovascular Agents: Antihyperlipidemic Agents.</i> Indicated as an adjunct to lipid-lowering medications and diet to reduce low-density lipoprotein cholesterol, apolipoprotein B, total cholesterol, and non-high-density lipoprotein cholesterol in patients with homozygous familial hypercholesterolemia.	10/21/13 CTP holder may Prescribe.
Bedaquiline Formulary Pg. 22	Sirturo	<i>Anti-Infectives, Systemic: Antituberculosis Agents.</i> Indicated as part of combination therapy in adults with pulmonary multidrug-resistant tuberculosis.	10/21/13 Physician Initiated/ Physician Consult
Meningococcal Vaccine Formulary Pg. 23	Menveo	<i>Biologic/ Immunologic Agents: Agents for Active Immunization.</i> Indicated for active immunization of persons 2 to 55 years of age.	10/21/13 CTP holder may Prescribe.
Pomalidomide Formulary Pg. 23	Pomalyst	<i>Biologic/ Immunologic Agents: Immunologic Agents: Immunomodulators.</i> Indicated for patients with multiple myeloma who have received at least 2 prior therapies including lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of the last therapy.	10/21/13 Physician Initiated/ Physician Consult

Formulary Pg. 28		positive, metastatic breast cancer.	
July 2013			
Canagliflozin Formulary Pg. 9	Invokana	<i>Endocrine & Metabolic Agents: Antidiabetic Agents: Sodium-Glucose Co-Transporter 2 Inhibitors.</i> Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	10/21/13 CTP holder may Prescribe.
Brompheniramine Maleate Formulary Pg. 13	J-Tan PD	<i>Respiratory Agents: Antihistamines.</i> Indicated for the temporary relief of sneezing; itchy, watery eyes; itchy nose or throat; and runny nose caused by hay fever or other upper respiratory allergies.	10/21/13 CTP holder may Prescribe.
Dexchlorpheniramine Maleate Formulary Pg. 13	Ala-Hist IR	<i>Respiratory Agents: Antihistamines.</i> Indicated for the temporary relief of runny nose, sneezing, itching of the nose or throat, and itchy, water eyes due to hay fever or other respiratory allergies.	10/21/13 CTP holder may Prescribe.
Chlorcyclizine Hydrochloride Formulary Pg. 13	Ahist	<i>Respiratory Agents: Antihistamines.</i> Indicated for the temporary relief of runny nose, sneezing, itching of the nose or throat, and itchy, water eyes due to hay fever or other respiratory allergies.	10/21/13 CTP holder may Prescribe.
Doxylamine Succinate/ Pyridoxine Hydrochloride	Diclegis	<i>Central Nervous System Agents: Antiemetic/ Antivertigo Agents.</i> Indicated for the treatment of nausea and	10/21/13 CTP holder may Prescribe.

Formulary Pg. 16		vomiting of pregnancy in women who do not respond to conservative management.	
Botulism Antitoxin Heptavalent, (Equine)	Botulism Antitoxin Heptavalent	<i>Biologic/ Immunologic Agents: Antitoxins and Antivenins.</i> Indicated for the treatment of symptomatic botulism following documented or suspected exposure to Botulinum neurotoxin serotypes A,B,C,D,E,F,or G in adults and pediatric patients.	10/21/13 CTP holder may Prescribe.
Formulary Pg. 23			
Dimethyl Fumarate	Tecfidera	<i>Biologic / Immunologic Agents: Immunomodulators.</i> Indicated for the treatment of patients with relapsing forms of multiple sclerosis.	10/21/13 Physician Initiated/ Physician Consult
Formulary Pg. 23			
August 2013			
Prothrombin Complex Concentrate (Human)	Kcentra	<i>Hematological Agents: Hemostatics.</i> Indicated for the urgent reversal of acquired coagulation factor deficiency induced by vitamin K antagonist (e.g. warfarin) therapy in adult patients with acute major bleeding.	10/21/13 Physician Initiated/ Physician Consult
Formulary Pg. 7			
Levonorgestrel	Skyla	<i>Endocrine & Metabolic Agents: Sex Hormones: Contraceptive Hormones.</i> Indicated for the prevention of pregnancy for up to 3 years.	10/21/13 CTP holder may Prescribe.
Formulary Pg. 8			
Budesonide Oral	Uceris	<i>Endocrine & Metabolic Agents: Adrenocortical Steroids: Glucocorticoids.</i> Indicated for the induction of remission in	10/21/13 CTP holder may Prescribe.

		patients with active mild to moderate ulcerative colitis.	
Formulary Pg. 9 Ezetimibe/ Atorvastatin	Liptruzet	<i>Cardiovascular Agents: Antihyperlipidemic Agents: Combination Agents.</i> Indicated as an adjunct to diet for the reduction of elevated total cholesterol, and low-density lipoprotein cholesterol in patients with other lipid-lowering treatments or if such treatments are unavailable.	10/21/13 CTP holder may Prescribe.
Formulary Pg. 11 Ciclesonide	Alvesco	<i>Respiratory Agents: Respiratory Inhalant Products.</i> Indicated for the maintenance treatment of asthma as prophylactic therapy in adult and adolescent patients 12 years of age and older.	10/21/13 CTP holder may Prescribe.
Formulary Pg. 13 Aripiprazole	Abilify Maintena	<i>Central Nervous System Agents: Antipsychotic Agents: Quinolinone Derivatives.</i> Indicated for the treatment of schizophrenia.	10/21/13 CTP holder may prescribe for Psych CTP holder. Physician Initiated/ Physician Consult for CTP holders other than psych.
Formulary Pg. 23 Immune Globulin (Human) Intravenous	Bivigam	<i>Biologic/ Immunologic Agents: Immune Globulins.</i> Indicated for the treatment of patients with primary humoral immunodeficiency.	10/21/13 Physician Initiated/ Physician Consult
Radium RA 223 Dichloride	Xofigo	<i>Antineoplastic Agents: Radiopharmaceuticals.</i> Indicated for the treatment of patients with castration-resistant prostate cancer,	10/21/13 CTP holder may NOT prescribe.

Formulary Pg. 27		symptomatic bone metastases, and no known visceral metastatic disease.	
September 2013			
Fluticasone Furoate/ Vilanterol Formulary Pg. 13	Breo Ellipta	<i>Respiratory Agents: Respiratory Inhalant Combinations.</i> Indicated for the maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. It is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations.	10/21/13 CTP holder may Prescribe.
Lorcaserin Hydrochloride Formulary Pg. 15	Belviq	<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 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 comorbid condition.	10/21/13 CTP holder may NOT prescribe.
Dabrafenib Formulary Pg. 28	Tafinlar	<i>Antineoplastic Agents: Kinase Inhibitors.</i> Indicated for the treatment of unresectable or metastatic melanoma in patients with a BRAF V600E mutation.	10/21/13 CTP holder may NOT prescribe.
Trametinib	Mekinist	<i>Antineoplastic Agents: Kinase Inhibitors.</i> Indicated for the treatment of unresectable metastatic melanoma in patients	10/21/13 CTP holder may NOT prescribe.

Formulary Pg. 28		with a BRAF V600E or BRAF V600K mutation as detected by a Food and Drug Administration (FDA) approved test.	
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New Drugs Indications/ Warnings October 2013

(New Drug Indications/ Black Box Warnings: FDA)

Generic Name	Trade Name	Indication(s)	CPG Action/Date
May 2013			
Telaprevir Formulary Pg. 22	Incivek	<i>Anti-Infectives, Systemic: Antiviral Agents.</i> New black box warning for fatal and nonfatal serious skin reactions, including Stevens-Johnson syndrome, drug reaction with eosinophilia and systemic symptoms, and toxic epidermal necrolysis, have been reported in patients treated with telaprevir combination treatment.	Current: Physician Initiated/ Physician Consult 10/21/13 No change
Anakinra Formulary Pg. 23	Kineret	<i>Biologic/ Immunologic Agents: Immunomodulators.</i> New indication for the treatment of neonatal-onset multisystem inflammatory diseases.	Current: Physician Initiated/ Physician Consult. 10/21/13 No change
June 2013			
none			
July 2013			
none			
August 2013			
Regorafenib Formulary Pg. 28	Stivarga	<i>Antineoplastic Agents: Kinase Inhibitors.</i> New indication for the treatment of patients with locally advanced, unresectable or metastatic GI stromal tumor who have been previously treated with imatinib and sunitinib.	Current: CTP holder may NOT prescribe. 10/21/13 No change
September 2013			
Everolimus	Zotress	<i>Antineoplastic Agents:</i>	Current: Physician

<p>Rocuronium Bromide</p> <p>Formulary Pg. 19</p>	<p>Zemuron</p>	<p><i>Central Nervous System Agents: Muscle Relaxants- Adjuncts to Anesthesia.</i> Indicated as an adjunct to general anesthesia for inpatients and outpatients to facilitate rapid sequence and routine tracheal intubation and to provide skeletal muscle relaxation during surgery or mechanical ventilation.</p> <p>Requesting: Per Institution Protocol.</p>	<p>Current: CTP holder may NOT prescribe.</p> <p>10/21/13 CTP holder may prescribe in institutional setting per institutional standards for urgent and emergent respiratory care.</p>
<p>Succinylcholine Chloride</p> <p>Formulary Pg. 19</p>	<p>Anectine, Quelicin</p>	<p><i>Central Nervous System Agents: Muscle Relaxants- Adjuncts to Anesthesia.</i> Indicated as an adjunct to general anesthesia to facilitate endotracheal intubation, and to induce skeletal muscle relaxation during surgery or mechanical ventilation.</p> <p>Requesting: Per Institution Protocol.</p>	<p>Current: CTP holder may NOT prescribe.</p> <p>10/21/13 CTP holder may prescribe in institutional setting per institutional standards for urgent and emergent respiratory care.</p>
<p>Formulary Review Revision Request from Cindy Edwards-Tuttle, FNP-BC</p>			
<p>Fluorouracil</p>	<p>Carac, Efudex, Fluoroplex</p>	<p><i>Dermatological Agents: Pyrimidine Antagonist, Topical.</i> Indicated for the topical treatment of multiple actinic or solar keratosis and for the treatment of superficial basal cell carcinomas when conventional methods are impractical, such as with multiple lesion sites.</p>	<p>Current: CTP holder may prescribe for CTP holders with SCA with physician specializing in Derm. or Physician Initiated/ Physician Consult.</p> <p>10/21/13 CTP holder may prescribe.</p>

<p>Formulary Pg. 18</p>		<p>maintenance of anesthesia as part of a balanced anesthetic technique for inpatient and outpatient surgery, for maintenance of anesthesia, to initiate and maintain MAC sedation during diagnostic procedures, for MAC sedation in conjunction with local/regional anesthesia in patients undergoing surgical procedures, and for continuous sedation and control of stress responses in intubated or respiratory-controlled adult patients in ICUs. Requesting: Only Acute Care/ Critical Care NP may prescribe in critical care setting for sedation of patients who have a secure artificial airway and receiving mechanical ventilation. CTP holder may not prescribe for the purposes of conscious sedation during procedures or the induction of general anesthesia prior to the establishment of a secure artificial airway.</p>	<p>10/21/13 CTP holder may prescribe in institutional setting per institutional standards for urgent and emergent respiratory care.</p>
<p>Formulary Review Revision Request from Louise A. Smith, RN, CNP</p>			
<p>Atorvastatin</p>	<p>Lipitor</p>	<p><i>Cardiovascular Agents: Antihyperlipidemic Agents: HMG-CoA Inhibitors.</i> Indicated to reduce the risk of myocardial infarction, for treatment of dysbetalipoproteinemia, as an adjunct to diet to</p>	<p>Current: CTP holder may prescribe or Physician Initiated/ Physician Consult for pediatric dosing. 10/21/13 CTP holder may prescribe.</p>

<p>Formulary Pg. 18</p>		<p>and outpatient surgery, for maintenance of anesthesia, to initiate and maintain MAC sedation during diagnostic procedures, for MAC sedation in conjunction with local/regional anesthesia in patients undergoing surgical procedures, and for continuous sedation and control of stress responses in intubated or respiratory-controlled adult patients in ICUs. Requesting: Only Acute Care/ Critical Care NP may prescribe in critical care setting for sedation of patients who have a secure artificial airway and receiving mechanical ventilation. CTP holder may not prescribe for the purposes of conscious sedation during procedures or the induction of general anesthesia prior to the establishment of a secure artificial airway. Requesting: CTP holder may prescribe for ACNP in critical care-like setting.</p>	<p>standards for urgent and emergent respiratory care.</p>
<p>Formulary Review Revision Request from Susan Yeager, CNP</p>			
<p>Nimodipine</p>	<p>Nimodipine</p>	<p><i>Cardiovascular Agents: Calcium Channel Blocking Agents.</i> Indicated for the improvement of neurological outcome by reducing the incidence and severity of ischemic deficits in patients with SAH from ruptured</p>	<p>Current: Physician Initiated/ Physician Consult 10/21/13 CTP holder may prescribe.</p>

Formulary Pg. 11		intracranial berry aneurysms regardless of their postictus neurological condition. Requesting: CTP holder may prescribe.	
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**Review of Prescribing Designations PI/PC and CTP Holder May
NOT Prescribe
Cardiovascular Agents
(October 2013)**

Drug Category/Drug Name	Indications(s)	Current Prescribing Designation	CPG Action/Date
Calcium Channel Blocking Agents			
Nimodipine (Nimodipine, Nimotop) Formulary Pg. 11	<i>Calcium Channel Blocking Agents.</i> Indicated for the improvement of neurological outcome by reducing the incidence and severity of ischemic deficits in patients with subarachnoid hemorrhage.	Physician Initiated/ Physician Consult	10/21/13 CTP holder may prescribe.
Vasodilators			
Endothelin Receptor Antagonist Formulary Pg. 11	<i>Vasodilators: Endothelin Receptor Antagonist.</i>	Physician Initiated/ Physician Consult	10/21/13 No change
Peripheral Vasodilators Epoprostenol Sodium Injection (Flolan)	<i>Vasodilators: Peripheral Vasodilators.</i> Indicated for the long-	Physician Initiated/ Physician Consult for CTP holder within	10/21/13 Physician Initiated/ Physician Consult

Formulary Pg. 11	failure, and to improve patient-reported functional status.		
Agents for Pheochromocytoma			
Formulary Pg. 11	<i>Agents for Pheochromocytoma</i>	CTP holder May NOT prescribe.	10/21/13 No Change
Antihyperlipidemic Agents			
Formulary Pg. 11	HMG-CoA Reductase Inhibitors <i>Antihyperlipidemic Agents: HMG-CoA Reductase Inhibitors.</i> Indicated for primary prevention of cardiovascular disease in patients with multiple risk factors, reducing angina risk, reducing MI risk, reducing stroke risk, reducing risk for revascularization procedures, reduce risk of CV mortality, slow progression of coronary atherosclerosis, reduce risk of total mortality by reducing coronary death, and hypercholesterolemia.	Physician Initiated/ Physician Consult for pediatric dosing.	10/21/13 CTP holder may prescribe.
Cardioplegic Solutions			
Formulary Pg. 12	Cardioplegic Solution (Plegisol) <i>Cardioplegic Solutions.</i> Indicated for inducing cardiac arrest during open-heart surgery.	CTP holder May NOT prescribe.	10/21/13 No change
Agents for Patent Ductus Arteriosus			
	Alprostadil (Prostin VR Pediatric) <i>Agents for Patent Ductus Arteriosus.</i> Indicated for palliative, not definitive, therapy	Physician Initiated/ Physician Consult	10/21/13 No change

Formulary Pg. 12	to temporarily maintain the patency of the ductus arteriosus until corrective or palliative surgery can be performed in neonates who have congenital heart defects and who depend upon the patent ductus for survival.		
Ibuprofen Lysine (NeoProfen) Formulary Pg. 12	<i>Agents for Patent Ductus Arteriosus.</i> Indicated to close a clinically significant PDA in premature infants who are no more than 32 weeks gestational age when usual medical management is ineffective.	Neonatal NP CTP holder only may prescribe. Physician Initiated/ Physician Consult all other CTP holders.	10/21/13 No change
Indomethacin (Indocin I.V.) Formulary Pg. 12	<i>Agents for Patent Ductus Arteriosus.</i> Indicated for closure of hemodynamically significant PDA in premature infants if, after 48 hours, usual medical management is ineffective.	Neonatal NP CTP holder only may prescribe. Physician Initiated/ Physician Consult all other CTP holders.	10/21/13 No change
Sclerosing Agents			
Sclerosing Agents Polidocanol (Asclera) Formulary Pg. 12	<i>Sclerosing Agents.</i> Indicated for treatment of small, uncomplicated varicose veins of the lower extremities. Indicated to treat uncomplicated spider veins and uncomplicated reticular veins in the lower extremity.	CTP holder May NOT prescribe.	10/21/13 CTP holder may prescribe.