



## New Drugs Reviewed by CPG October 17, 2016

(Original New Drug Applications: FDA)

Generic Name	Trade Name	Indication(s)	CPG Action
cabozantinib s-malate	Cabometyx	Antineoplastic Agents: Kinase Inhibitors; Tyrosine Kinase Inhibitors Treatment of advanced renal cell carcinoma.	<b>May not prescribe</b>
pimavanserin	Nuplazid	<i>Central Nervous System Agents: Antipsychotic Agents; Second Generation (Atypical) Treatment of hallucinations and delusions associated with Parkinson disease psychosis.</i>	<b>In accordance with the SCA</b>
atezolizumab	Tecentriq	<i>Antineoplastic Agents: Monoclonal Antibodies (Antineoplastic) Treatment of locally advanced or metastatic urothelial carcinoma in patients who have disease progression during or following platinum-containing chemotherapy....</i>	<b>May not prescribe</b>
obeticholic	Ocaliva	<i>Gastrointestinal Agents: Farnesoid X Receptor Agonists: Oral tablets for the treatment of primary biliary cholangitis with UDCA in adults with inadequate response to UDCA, or as a monotherapy in adults unable to tolerate UDCA.</i>	<b>May not prescribe</b>
linagliptin/metformin HCL	Jentaduetto XR (new formulation of existing drug)	<i>Endocrine and Metabolic Agents: Antidiabetic Agents; Antidiabetic Combination Products. New formulation of</i>	<b>May prescribe</b>

		<i>existing drug in combination. Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes for the treatment of type 2 diabetes in adults.</i>	
daclizumab	Zinbryta	<i>Biologic and Immunological Agents: Immunologic Agents; Immunomodulators Once monthly, subcutaneous injection for the treatment of adults with relapsing forms of multiple sclerosis. Should generally be reserved for patients who have had an inadequate response to 2 or more MS drugs.</i>	<b>In accordance with the SCA</b>
Nebivolol/Valsartan	Byvalson	<i>Cardiovascular Agents: Antihypertensive Combinations</i>	<b>May prescribe</b>
cholera vaccine	Vaxchora	<i>Biologic and Immunological Agents: Agents for Active Immunization: Vaccines, Bacterial: Provides active immunization against disease caused by Vibrio cholera serogroup O1 in adults 18 through 64 years of age traveling to cholera-affected areas.</i>	<b>May prescribe</b>
calcifediol	Rayaldee	<i>Therapeutic Categories: Nutrients and Nutritional agents: Vitamins; Fat-Soluble Vitamins For secondary hyperparathyroidism in adults with stage 3 or 4 chronic kidney disease and serum total 25-hydroxyvitamin D levels less than 30ng/ml</i>	<b>May prescribe</b>

sofosbuvir 400mg and velpatasvir 100mg	Epclusa	<i>Anti-Infective Agents: Antiviral Agents; Hepatitis C Virus Direct-Acting Antivirals Treatment of genotype chronic Hepatitis C (CHC) 1, 2, 3, 4, 5, or 6 infection in adult patients without cirrhosis or with compensated cirrhosis or in combination with ribavirin in patients with decompensated cirrhosis.</i>	<b>In accordance with the SCA</b>
lifitegrast	Xiidra	<i>Ophthalmic and Otic Agents: Ophthalmic Lymphocyte Function-Associated Antigen-1 Antagonists Treatment of the signs and symptoms of dry eye disease.</i>	<b>May prescribe</b>
lixisenatide	Adlyxin	<i>Endocrine and Metabolic Agents: Antidiabetic Agents; Glucagonlike Peptide 1 Receptor Agonists Treatment of type 2 diabetes mellitus to improve glycemic control in adult patients as an adjunct to diet and exercise.</i>	<b>May prescribe</b>
	SMOFlipid (awaiting full monograph)	*****	*****
Granisetron extended release injection	Sustol	<i>Central Nervous System Agents: Antiemetic/Antivertigo Agents; 5-HT3 Receptor Antagonists Prevention of chemotherapy-induced nausea and vomiting.</i>	<b>In accordance with SCA</b>
Oxycodone/naltrexone	Troxyca ER	<i>Central Nervous System Agent: Opioid Agonist-Antagonist Analgesics Management of pain severe enough to</i>	<b>In accordance with SCA</b>

		<i>require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.</i>	
Afluria Quadrivalent	Influenza vaccine, inactivated	<i>Biologic and Immunological Agents; Agents for active immunization; Vaccines Vital; Influenza types A and B Vaccine. Active immunization for adults against influenza disease caused by influenza A subtype viruses and type B viruses contained in the vaccine.</i>	<b>May prescribe</b>



## New Drug Indications/ Warnings Reviewd by CPG October 17, 2016

(New Drug Indications/ Boxed Warnings: FDA)

Generic Name	Trade Name	Indication(s)	CPG Action
Budesonide  (expanded indication)	Entocort EC	<i>Endocrine and Metabolic Agents: Adrenocortical Steroids; Glucocorticoids</i>	<b>Current: CTP holder may prescribe</b>  <b>October 17, 2016 No change</b>
Albuterol (salbutamol)  (expanded indication)	ProAir RespiClick	<i>Respiratory Agents: Bronchodilators; Sympathomimetics</i>	<b>Current: CTP holder may prescribe</b>  <b>October 17, 2016 No change</b>
Ibrutinib  (expanded indication)	Imbruvica	<i>Therapeutic Categories: Antineoplastic Agents; Kinase Inhibitors; Tyrosine Kinase Inhibitors</i>	<b>Current: CTP holder may not prescribe</b>  <b>October 17, 2016 No change</b>
Olanzapine (safety alert)	ZyPrexa	Central Nervous System Agents: Antipsychotic Agents; Second Generation (Atypical).	<b>Current: CTP holder may prescribe</b>  <b>October 17, 2016 CTP holder may prescribe oral formulation and change extended release injectable formulation in accordance with SCA.</b>
Fluoroquinolones:  (safety alert)		<i>Anti-infective Agents:</i>	<b>Current: CTP holder may prescribe</b>  <b>October 17, 2016 No change</b>
Lenvatinib	Lenvima	<i>Antineoplastic Agents: Kinase Inhibitors;</i>	<b>Current: CTP holder may not</b>

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(expanded indication)		<i>Tyrosine Kinase Inhibitors</i>	<b>prescribe</b> <b>October 17, 2016</b> <b>No change</b>
Nivolumab (expanded indication)	Opdivo	<i>Antineoplastic Agents: Monoclonal Antibodies (antineoplastic)</i>	<b>Current: CTP holder may not prescribe</b> <b>October 17, 2016</b> <b>No change</b>
Canagliflozina (safety alert)	Invokana	<i>Endocrine and Metabolic Agents: Antidiabetic Agents; Sodium-Glucose Co-Transporter 2 Inhibitors</i>	<b>Current: CTP holder may prescribe</b> <b>October 17, 2016</b> <b>No change</b>
Dapagliflozin (safety alert)	Farxiga	<i>Endocrine and Metabolic Agents: Antidiabetic Agents; Sodium-Glucose Co-Transporter 2 Inhibitors</i>	<b>Current: CTP holder may prescribe</b> <b>October 17, 2016</b> <b>No change</b>
Rosuvastatin (expanded indication)	Crestor	<i>Cardiovascular Agents: Antihyperlipidemic Agents; HMG-COA Reductase Inhibitors</i>	<b>Current: CTP holder may prescribe</b> <b>October 17, 2016</b> <b>No change</b>
Ceftaroline Fosamil (expanded indication)	Teflaro	<i>Anti-Infective Agents; Cephalosporins</i>	<b>Current: CTP holder may prescribe</b> <b>October 17, 2016</b> <b>No change</b>
Dolutegravir (expanded indication)	Tivicay	<i>Anti-infectives: Antiretroviral Agents; Integrase Inhibitors</i>	<b>October 17, 2016 determined: In accordance with the SCA</b>
Adalimumab (expanded indication)	Humira	<i>Biologic and Immunological Agents: Immunologic Agents; Immunomodulators</i>	<b>Current: In accordance with the SCA</b> <b>October 17, 2016</b> <b>No change</b>

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Omalizumab (expanded indication)	Xolair	<i>Respiratory Agents: Monoclonal Antibodies (Respiratory)</i>	<b>Current: In accordance with the SCA</b>  <b>October 17, 2016 No change</b>
Pneumococcal conjugate vaccine, 13 valent (expanded indication)	Prevnar 13	<i>Biologic and Immunological Agents: Agents for Active Immunization: Vaccines, Bacterial</i>	<b>Current: CTP holder may prescribe</b>  <b>October 17, 2016 No change</b>
Dexlansoprazole (expanded indication)	Dexilant	<i>Gastrointestinal Agents: Proton Pump Inhibitors</i>	<b>Current: CTP holder may prescribe</b>  <b>October 17, 2016 No change</b>
C1 Inhibitor, Human (expanded indication)	Berinert	<i>Hematologic Agents: Protein C1 Inhibitors</i>	<b>Current: In accordance with the SCA</b>  <b>October 17, 2016 No change</b>
Riboflavin 5-Phosphate (expanded indication)	Photrexa	<i>Ophthalmic and Otic Agents: Ophthalmic Surgical Adjuncts</i>	<b>Current: CTP holder may not prescribe</b>  <b>October 17, 2016 No change</b>
Abobotulinumtoxina (expanded indication)	Dysport	Central Nervous System Agents: Botulinum Toxins: Botulinum Toxin Type A	<b>Current: In accordance with the SCA</b>  <b>October 17, 2016 No change</b>
Pembrolizumab (expanded indication)	Keytruda	<i>Biologic and Immunological Agents: Immunologic Agents; Immunomodulators</i>	<b>Current: CTP holder may not prescribe</b>  <b>October 17, 2016 No change</b>
Topiramate (expanded indication)	Trokendi XR	<i>Central Nervous System Agents: Anticonvulsants</i>	<b>Current: CTP holder may prescribe</b>

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			<b>October 17, 2016 No change</b>
Blinatumomab	Blincyto	Antineoplastic Agents; Monoclonal Antibodies(antineoplas tic)	<b>Current: CTP holder may not prescribe</b>  <b>October 17, 2016 No change</b>
ofatumumab	Arzerra	Antineoplastic Agents; Monoclonal Antibodies(antineoplas tic).	<b>Current: CTP holder may not prescribe</b>  <b>October 17, 2016 No change</b>
pegloticase	Krystexxa	<i>Endocrine and Metabolic Agents; Agents for Gout.</i>	<b>CTP holder may prescribe</b>  <b>October 17, 2016 No change</b>
Influenza A (H5N1) Immunization		<i>Biologic and Immunological Agents: Agents for Active Immunization; Vaccines, Viral:</i>	<b>CTP holder may prescribe</b>  <b>October 17, 2016 No change</b>



## Formulary Revision Request October 2016

Generic Name	Trade Name	Indication(s)	CPG Action
<b>Formulary Review Revision Requests from Tammy Joseph, CNP</b>			
methotrexate	Otrexup, Trexall	Symptomatic control of psoriasis and rheumatoid arthritis	<p><b>Current: As anti-psoriatic agent, in accordance with SCA. Otherwise CTP holder may not prescribe</b></p> <p><b>October 17, 2016 Change to In accordance with SCA limited to treatment of rheumatoid arthritis and psoriasis only</b></p>
Topical 5-fluorouracil	Efudex, Tolak	Management of multiple actinic or solar keratoses	<p><b>Current: CTP holder may prescribe</b></p> <p><b>October 17, 2016 No change</b></p>
phentermine	Adipex	Anorexiant	<p><b>Current: CTP holder may not prescribe</b></p> <p><b>October 17, 2016 Change to In accordance with SCA</b></p>
<b>Formulary Review Revision Request from Mandi Cafasso, CNP</b>			
histreline acetate	Suppreline LA, Vantas	Central precocious puberty	<p><b>Current: CTP holder may not prescribe</b></p> <p><b>October 17, 2016 No change</b></p>

<b>Formulary Review, Revision Request from Kathy Foreman, Kirsten Tychonievich, and Meleana Burt</b>			
phentermine	Adipex	anorexiant	<b>Current: CTP holder may not prescribe</b>  <b>October 17, 2016 Change to In accordance with SCA</b>



**Review of Prescribing Designations In Accordance with Standard Care Arrangement and CTP Holder May NOT Prescribe Cardiovascular Agents (October 2016)**

<b>Drug Category/ Drug Name</b>	<b>Current Prescribing Designation</b>	<b>CPG Action</b>
<b>Vasodilators:</b> <ul style="list-style-type: none"> <li>• Endothelin Receptor Antagonist</li> <li>• Epoprostenol Sodium Injection</li> <li>• Treprostinil Sodium Injection</li> <li>• Trepronstinil Inhalations</li> <li>• Iloprost</li> <li>• Soluble Guanylate Cyclase Stimulator (Riociguat)</li> <li>• Prostacyclin IP receptor Agonists</li> </ul>	In accordance with SCA	<b>October 17, 2016 No change</b>
<b>Agents for Pheochromocytoma</b>	CTP Holder may not prescribe	<b>October 17, 2016 No change</b>
<b>Cardioplegic Solutions</b>	CTP Holder may not prescribe	<b>October 17, 2016 No change</b>
<b>Agents for Patent Ductus Arteriosus</b>	In accordance with the SCA	<b>October 17, 2016 No change</b>
<b>Miscellaneous Antianginal Agent: Ivabrdine oral</b>	In accordance with SCA	<b>October 17, 2016 No change</b>