



## New Drugs Reviewed by CPG May 16, 2016

(Original New Drug Applications: FDA)

Generic Name	Trade Name	Indication(s)	CPG Action
Ixazomib oral	Ninlaro	<i>Antineoplastic Agents: Proteasome Inhibitors.</i> Treatment of multiple myeloma (in combination with lenalidomide and dexamethasone) in patients who have received at least 1 prior therapy.	<b>May not prescribe</b>
Necitumumab	Portrazza	<i>Antineoplastic Agents: Monoclonal Antibodies (Antineoplastic):</i> First-line treatment of metastatic squamous non-small cell lung cancer (NSCLC) in combination with gemcitabine and cisplatin.	<b>May not prescribe</b>
Elotuzumab	Empliciti	<i>Antineoplastic Agents: Monoclonal Antibodies (Antineoplastic):</i> Treatment of multiple myeloma (in combination with lenalidomide and dexamethasone) in patients who have received 1 to 3 prior therapies.	<b>May not prescribe</b>
Sebelipase alfa	Kanuma	<i>Endocrine and Metabolic Agents: Sebelipase Alfa:</i> Treatment of patients with lysosomal acid lipase (LAL) deficiency.	<b>In accordance with the SCA</b>
Von Willebrand factor (recombinant)	Vonvendi	<i>Hematological Agents: Antihemophilic Agents.</i> Treatment (on demand) and control of bleeding episodes in adults (age 18 years and older) diagnosed with von Willebrand disease.	<b>In accordance with the SCA</b>
Alectinib	Alecensa	<i>Antineoplastic Agents: Kinase Inhibitors: Tyrosine Kinase</i>	<b>May not prescribe</b>

		<i>Inhibitors:</i> Treatment of anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC) in patients who have progressed on or are intolerant to crizotinib.	
Sugammadex	Bridion	<i>Endocrine and Metabolic Agents:</i> <i>Detoxification Agents:</i> <i>Antidotes:</i> For the reversal of neuromuscular blockade induced by rocuronium or vecuronium in adults undergoing surgery.	<b>May prescribe</b>
Selexipag	Uptravi	<i>Cardiovascular Agents:</i> <i>Vasodilators:</i> <i>Prostacyclin IP</i> <i>Receptor Agonists:</i> treatment of pulmonary arterial hypertension (PAH) (WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH	<b>In accordance with the SCA (new subcategory)</b>
Lesinurad	Zurampic	<i>Endocrine and Metabolic Agents:</i> <i>Agents for Gout: Uric Acid Transporter 1 Inhibitor:</i> Treatment of hyperuricemia associated with gout (in combination with a xanthine oxidase inhibitor) in patients who have not achieved target serum uric acid levels with a xanthine oxidase inhibitor alone.	<b>May prescribe</b>
Eribulin Mesylate	Halaven	<i>Antineoplastic Agents:</i> <i>Antimitotic Agents:</i> <i>Halichondrin B Analog</i>	<b>May not prescribe</b>
Sumatriptan	Onzetra Xsail	<i>Central Nervous System Agents: Agents for Migraine: Serotonin 5-HT<sub>1</sub> Receptor Agonists (Triptans):</i> Nasal powder, a serotonin 5-HT <sub>1B/1D</sub> receptor agonist, indicated	<b>May prescribe</b>

		for the short-term treatment of migraine with or without aura in adults.	
Elvasvir/Grazoprevir	Zepatier	<i>Anti-Infective Agents: Antiviral Agents: Hepatitis C Virus Direct-Acting antivirals. For the treatment of chronic hepatitis C virus genotypes 1 or 4 infection in adults.</i>	<b>In accordance with the SCA</b>
Brivaracetam	Briviact	<i>Central Nervous System Agents: Anticonvulsants: Tablets, solution, and injection for the treatment of partial-onset seizures in patients 16 years of age and older with epilepsy.</i>	<b>May prescribe</b>
Coagulation factor IX [recombinant], albumin fusion protein	Idelvion	<i>Hematological Agents: Antihemophilic Agents: Injection, a recombinant human blood coagulation factor, indicated for treatment in adults and children with hemophilia B (congenital factor IX deficiency) for on-demand control and prevention of bleeding episodes; perioperative management of bleeding; and routine prophylaxis to prevent or reduce the frequency of bleeding episodes.</i>	<b>In accordance with the SCA</b>
Antihemophilic factor (recombinant), lyophilized powder	Kovaltry	<i>Hematological Agents: Antihemophilic Agents: Antihemophilic Factor (Factor VIII; AHF): Lyophilized powder for solution for intravenous injection indicated for the treatment of adults and children with hemophilia A (congenital factor VIII deficiency) for on-demand treatment and control of bleeding episodes, perioperative management of bleeding, and routine</i>	<b>In accordance with the SCA</b>

		prophylaxis to reduce the frequency of bleeding episodes.	
Obiltoximab injection	Anthim	<i>Biologic and Immunological Agents: Monoclonal Antibodies (Biologic/immunologic).</i> Injection in adult and pediatric patients for the treatment of inhalational anthrax due to <i>Bacillus anthracis</i> in combination with appropriate antibacterial drugs, and for prophylaxis of inhalational anthrax when alternative therapies are not available or are not appropriate	<b>In accordance with the SCA</b>
Ixekizumab injection	Taltz	<i>Biologic and Immunological Agents: Immunologic Agents: Immunomodulators:</i> For the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.	<b>In accordance with the SCA</b>
Reslizumab injection	Cinqair	<i>Biologic and Immunological Agents: Immunologic Agents: Immunomodulators:</i> Injection, an interleukin-5 antagonist monoclonal antibody, indicated for add-on maintenance treatment of patients 18 years and older with severe asthma and an eosinophilic phenotype.	<b>In accordance with the SCA</b>
Defibrotide sodium	Defitelio	<i>Hematological Agents: Thrombolytic Agents:</i> injection for the treatment of adult and pediatric patients with hepatic veno-occlusive disease (VOD), also known as sinusoidal obstruction syndrome, with renal or pulmonary dysfunction following	<b>May not prescribe</b>

		hematopoietic stem-cell transplantation.	
Infliximab-dyyb	Inflectra	<i>Biologic and immunological Agents:</i> <i>Immunologic Agents:</i> <i>Immunomodulators:</i> <i>Tumor Necrosis Factor-Alpha Blockers (TNF-Alpha Blockers)</i> injection, a biosimilar product, for the treatment of adult and pediatric patients (ages 6 years and older) with moderately to severely active Crohn disease who have had an inadequate response to conventional therapy; adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy; patients with moderately to severely active rheumatoid arthritis, in combination with methotrexate; patients with active ankylosing spondylitis; patients with psoriatic arthritis; and adult patients with chronic severe (ie, extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate.	<b>In accordance with the SCA</b>
Emtricitabine/tenofovir alafenamide	Descovy	<i>Anti-Infective Agents:</i> <i>Antiretroviral Agents:</i> <i>Reverse Transcriptase Combinations:</i> oral tablets indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older.	<b>In accordance with the SCA</b>

<p>emtricitabine/ rilpivirine/ tenofovir alafenamide</p>	<p>Odefsey</p>	<p><i>Anti-Infective Agents:</i> <i>Antiretroviral Agents:</i> <i>Reverse Transcriptase</i> <i>Combinations:</i> Oral tablets indicated as a complete regimen for the treatment of HIV-1 infection in patients 12 years and older as initial therapy in those with no antiretroviral treatment history with HIV-1 RNA less than or equal to 100,000 copies per mL; or to replace a stable antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA less than 50 copies per mL) for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of <i>Odefsey</i>.</p>	<p><b>In accordance with the SCA</b></p>
<p>Venetoclax</p>	<p>Venclexta</p>	<p><i>Antineoplastic Agents: B-Cell Lymphoma-2 Inhibitor:</i> Oral tablets for the treatment of patients with chronic lymphocytic leukemia (CLL) with 17p deletion, as detected by an FDA-approved test, who have received at least 1 prior therapy.</p>	<p><b>May not prescribe</b></p>



## New Drug Indications/ Warnings Reviewed by CPG May 16, 2016

(New Drug Indications/ Black Box Warnings: FDA)

Generic Name	Trade Name	Indication(s)	CPG Action/Date
BCG Live Intravesical	TheraCys  Tice BCG	<i>Therapeutic Categories: Antineoplastic Agents: Biological Response Modifiers.</i> Expanded warning for reconstituted suspension.	Current: CTP holder may not prescribe  May 16, 2016 No change
Secukinumab	Cosentyx	<i>Therapeutic Categories: Biologic and Immunological Agents: Immunologic Agents: Immunomodulators.</i> Expanded indications for injection to include treatment of adult patients with active psoriatic arthritis or active ankylosing spondylitis and also indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.	Current: In accordance with SCA  May 16, 2016 No change
Haemophilus B Polysacc Tetanus Conj Vacc	Hiberix	<i>Therapeutic Categories: Biologic and immunological Agents: Agents for Active Immunization: Vaccines, Bacterial.</i> Expanded indication for Hiberix solution for intramuscular injection to include use in children 6 weeks through 4 years of age (prior to fifth birthday). <i>Hiberix</i> was previously approved for use in children 15 months to 4 years of age	Current: CTP holder may prescribe  May 16, 2016 No change
Ofatumumab	Arzerra	<i>Therapeutic Categories: Antineoplastic Agents:</i>	Current: CTP holder may not prescribe

		<p><b>Monoclonal Antibodies (Antineoplastic).</b> Expanded indication for injection to include extended treatment of patients who are in complete or partial response after at least 2 lines of therapy for recurrent or progressive chronic lymphocytic leukemia (CLL).</p>	<p>May 16, 2016 No change</p>
<p>Glubulin Immune/Globulin Immune IV</p>	<p>Flebogamma</p>	<p><i>Therapeutic Categories: Biologic and Immunological Agents: Immune Globulins: Immune Globulin (Human) Intravenous.</i> Expanded indication for intravenous administration to include treatment of patients 2 years and older with chronic primary immune thrombocytopenia.</p>	<p>Current: In accordance with SCA  May 16, 2016 No change</p>
<p>Onabotulinumtoxina</p>	<p>Botox</p>	<p><i>Therapeutic Categories: Central Nervous System Agents: Botulinum Toxins: Botulinum Toxin Type A.</i> Expanded indication for injection to include the treatment of lower limb spasticity in adult patients to decrease the severity of increased muscle tone in ankle and toe flexors</p>	<p>Current: In accordance with SCA  May 16, 2016 No change</p>
<p>Carfilzomib</p>	<p>Kyprolis</p>	<p><i>Therapeutic Categories: Antineoplastic Agents: Proteasome Inhibitors.</i> Expanded indication for injection as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who have</p>	<p>Current: CTP holder may not prescribe  May 16, 2016 No change</p>

New Drug Indications May 2016

		received 1 or more lines of therapy.	
Naloxone Hydrochloride Nasal Spray  Formulary Pg. 4	Narcan	<i>Endocrine &amp; Metabolic Agents: Detoxification Agents: Antidotes.</i> Indicated for reversal of opioid overdose.	Current: CTP holder may prescribe  May 16, 2016 No change
Daclatasvir	Daklinza	<i>Therapeutic Categories: Anti-Infective Agents: Antiviral Agents: Hepatitis C Virus Direct-Acting Antivirals.</i> Expand indication to include treatment of chronic hepatitis C virus (HCV) genotype 1 or 3 infection in combination with sofosbuvir, with or without ribavirin.	Current: In accordance with SCA  May 16, 2016 No change
Buprenorphine HCL Oral  Buccal Film	Belbuca	<i>Central Nervous System Agents: Opioid Agonist-Antagonist Analgesics.</i> Indicated for treatment of patients with chronic pain severe enough to require daily, around the clock, long term opioid treatment.	Current: CTP holder may not prescribe except for Neonatal Abstinence Syndrome.  May 16, 2016 No change
Omeprazole	PriLOSEC	<i>Therapeutic Categories: Gastrointestinal Agents: Proton Pump Inhibitors.</i> Expanded indication for delayed-release capsules and oral suspension to include short-term treatment (up to 6 weeks) of erosive esophagitis (EE) due to acid-mediated gastroesophageal reflux disease (GERD) in pediatric patients 1 month to less than 1 year of age	Current: CTP holder may prescribe  May 16, 2016 No change
Palbociclib	Ibrance	<i>Therapeutic Categories: Antineoplastic Agents:</i>	Current: CTP holder may not prescribe

		<p><i>Kinase Inhibitors: Cyclin-Dependent Kinase Inhibitors. (Capsules)</i> Expanded indication for the treatment of hormone receptor-positive, human epidermal growth factor receptor 2 (HER-2)-negative advanced or metastatic breast cancer in combination with letrozole as initial endocrine-based therapy in postmenopausal women, or in combination with fulvestrant in women with disease progression following endocrine therapy.</p>	<p>May 16, 2016 No change</p>
Emtricitabine/rilpivirine/tenofovir disoproxil fumarate	Complera	<p><i>Therapeutic Categories: Anti-Infective Agents: Antiretroviral Agents: Reverse Transcriptase Combinations. (Tablets)</i> Expanded indications for use in patients 12 years of age and older. <i>Complera</i> was previously approved for use in adults only. <i>Complera</i> is indicated for the treatment of HIV-1.</p>	<p>Current: In accordance with SCA  May 16, 2016 No change</p>
Everolimus	Afinitor	<p><i>Therapeutic Categories: Antineoplastic Agents: Kinase Inhibitors: Mtor Inhibitors. (Tablets)</i> Expanded indications for the treatment of adult patients with progressive, well-differentiated, non-functional neuroendocrine tumors</p>	<p>Current: CTP holder may not prescribe  May 16, 2016 No change</p>

		of gastrointestinal or lung origin that are unresectable, locally advanced or metastatic	
Fulvestrant	Faslodex	<i>Therapeutic Categories:</i> <i>Antineoplastic Agents:</i> <i>Hormones:</i> <i>Antiestrogens.</i> ( Injection) Expanded indication, in combination with palbociclib, for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in women with disease progression following endocrine therapy. <i>Faslodex</i> is also indicated as a monotherapy for the treatment of HR-positive metastatic breast cancer in postmenopausal women with disease progression following anitestrogen therapy.	Current: In accordance with SCA  May 16, 2016 No change
Ibrutinib	Imbruvica	<i>Therapeutic Categories:</i> <i>Antineoplastic Agents:</i> <i>Kinase Inhibitors:</i> <i>Tyrosine Kinase Inhibitors. (Capsules)</i> Expanded indication for the treatment of chronic lymphocytic leukemia (CLL) regardless of the patient's treatment history.	Current: CTP holder may not prescribe  May 16, 2016 No change
Crizotinib	Xalkori	<i>Therapeutic Agents:</i> <i>Antineoplastic Agents:</i> <i>Kinase Inhibitors:</i> <i>Tyrosine Kinase Inhibitors. (Capsules)</i>	Current: CTP holder may not prescribe  May 16, 2016 No change

		Expanded indication for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS1-positive.	
Emtricitabine/tenofovir disoproxil fumarate	Truvada	<i>Therapeutic Categories: Anti-Infective Agents: Antiretroviral Agents: Reverse Transcriptase Combinations. (Tablets)</i> Expanded indication in combination with other antiretroviral agents for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 17 kg.	Current: In accordance with SCA  May 16, 2016 No change
Afatinib	Gilotrif	<i>Therapeutic Categories: Antineoplastic Agents: Kinase Inhibitors: Tyrosine Kinase Inhibitors: (Tablets)</i> Expanded indication for the treatment of patients with metastatic squamous non-small cell lung cancer progressing after platinum-based chemotherapy.	Current: CTP holder may not prescribe  May 16, 2016 No change
Incobotulinumtoxin A	Xeomin	<i>Central Nervous System Agents: Botulinum Toxins: Botulinum Toxin Type A.</i> Treatment for upper limb spasticity in adult patients.	Current: In accordance with SCA  May 16, 2016 No change
Obinutuzumab Injection	Gazyva	Antineoplastic agents; monoclonal antibodies: Expanded indication in combination with bendamustine followed by <i>Gazyva</i> monotherapy, treatment of patients with follicular lymphoma who relapsed after, or are refractory to, a rituximab-containing	Current: CTP holder may not prescribe  May 16, 2016 No change

New Drug Indications May 2016

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## Formulary Revision Request May 2016

(Original New Drug Applications: FDA)

Generic Name	Trade Name	Indication(s)	CPG Action/Date
<b>Formulary Review Revision Requests from Dawn Boyle Same request from Stephanie Alter</b>			
Buprenorphine buccal film	Belbuca	Treatment of chronic pain	<b>Current: CTP holder may not prescribe</b>  <b>May 16, 2016</b> <b>No change</b>
<b>Formulary Review Revision Request from Jill Marie Warner</b>			
Deoxycholic Acid	Kybella	Cosmetic injectable medication	<b>Current: CTP holder may not prescribe.</b>  <b>May 16, 2016</b> <b>No change</b>



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

<b>Drug Category/ Drug Name</b>	<b>Indication(s): If reviewing a specific drug in a drug category</b>	<b>Current Prescribing Designation</b>	<b>CPG Action/Date</b>
<b>Sex Hormones:</b> Androgens; Danazol	Males: primary hypogonadism (congenital or acquired); Hypogonadotropic hypogonadism (congenital or acquired); Delayed puberty Females: metastatic breast cancer	In accordance with SCA	May 16, 2016 No change
<b>Sex Hormones:</b> Anabolic Steroids	Anemia; anemia of renal insufficiency; bone pain; weight gain	CTP Holder may not prescribe	May 16, 2016 No change
<b>Uterine-Active Agents:</b> <b>Dinoprostone</b>	Cervical ripening	In accordance with SCA	May 16, 2016 No change
<b>Adrenocortical Steroids:</b> <b>Corticotropins</b>	Treatment of exacerbation of Lupus; Stevens-Johnson Syndrome, Acute exacerbation of MS in adults.	May not prescribe (Exception: May prescribe ONLY Cosyntropin)	May 16, 2016 No change
<b>Bile Acids</b>	Treatment of bile acid synthesis disorders.	In accordance with SCA	May 16, 2016 No change
<b>Cystic Fibrosis Transmembrane Regulator Protein:</b>	Treatment of cystic fibrosis in patients age 12 and older.	In accordance with SCA	May 16, 2016 No change
<b>Growth Hormone</b>	Treat HIV associated	In accordance with	May 16, 2016 No change

<b>Releasing Factor:</b> Tesamoreline Acetate Injection	lipodystrophy	SCA	
<b>Insulin-like Growth Factor</b>	Treatment of growth factor in children with specific hormone deficiency.	In accordance with SCA	May 16, 2016 No change
<b>Lipdystrophy Agents</b>	Treat complications of leptin deficiency, in addition to diet, in patients with congenital or acquired generalized lipodystrophy.	May not prescribe	May 16, 2016 No change
<b>Lipolytic Agents</b>	Improvement in the appearance of moderate to severe convexity or fullness associated with submental fat in adults.	May not prescribe	May 16, 2016 No change
<b>Growth Hormone</b>	Treat growth failure	In accordance with SCA	May 16, 2016 No change
<b>Vasopressin</b>	Treatment of diabetes insipidus, vasodilatory shock	In accordance with SCA	May 16, 2016 No change
<b>Vasopressin Receptor Antagonist</b>	Treatment of hypervolemic and euvolemic hyponatremia	In accordance with SCA	May 16, 2016 No change
<b>Velaglucerase Alfa Injection</b>	Treatment of Gaucher disease	In accordance with SCA	May 16, 2016 No change
<b>Imiglucerase</b>	Treatment of Gaucher disease	Maya not prescribe	May 16, 2016 No change
<b>Somatostatin Analogs</b>	Treatment of Acromegaly	May not prescribe	May 16, 2016 No change
<b>Pegvisomant</b>	Treatment of Acromegaly	May not prescribe	May 16, 2016 No change
<b>Laronidase</b>	Treatment of mucopolysaccharidosis I.	May not prescribe	May 16, 2016 No change
<b>Elosulfase alfa</b>	Treatment of	May not prescribe	May 16, 2016

	mucopolysaccharidosis type IVA		No change
<b>Agalsaidase beta</b>	Treatment of Fabry disease	May not prescribe	May 16, 2016 No change
<b>Glucosylceramide Synthase Inhibitor</b>	Treatment of Gaucher disease	May not prescribe (Eliglustate Tartrate only may be prescribed in accordance with the SCA)	May 16, 2016 No change
<b>4-hydroxyphenylpyruvate Dioxygenase Inhibitor</b>	Treatment of hereditary tyrosinemia type 1	May not prescribe	May 16, 2016 No change
<b>Alglucerase</b>		May not prescribe	May 16, 2016 No change
<b>Alglucosidase Alfa</b>	Treatment of patients with Pompe disease	May not prescribe	May 16, 2016 No change
<b>Sodium Phenylbutyrate:</b>	Adjunctive therapy in cycle disorder involving deficiencies of carbamoyl phosphate synthetase, ornithine transcarbamoylase, or argininocuccinic acid synthetase.	May not prescribe	May 16, 2016 No change
<b>Betaine Anhydrous;</b>	Treatment of homocystinuria	May not prescribe	May 16, 2016 No change
<b>Cysteamine Bitartrate</b>	Treatment of Nephropathic cystinosis	May not prescribe	May 16, 2016 No change
<b>Sodium Benzoate/ Sodium Phenylacetate</b>	Treatment of hyperammonemia	May not prescribe	May 16, 2016 No change
<b>Cabergoline</b>	Treatment of hyperprolactinemic disorders	In accordance with the SCA	May 16, 2016 No change
<b>Phenylketonuria Agents</b>	To reduce blood phenylalanine levels with patients with hyperphenylalanemia.	May not prescribe	May 16, 2016 No change
<b>Chelating agents</b>	Example monograph	May not prescribe	May 16, 2016

Review of Endocrine & Metabolic Section May 2016

	for lead poisoning	(except may prescribe Only trientine)	No change
<b>Succimer</b>	Treatment of poisoning in children	In accordance with SCA	May 16, 2016 No change
<b>Deferasirox</b>	Chronic iron overload	IN accordance with the SCA	May 16, 2016 No change
<b>Antidotes: Idarucizumab Injection</b>	Reversal of the anticoagulant effects of dabigatran for emergency surgery procedures	In accordance with the SCA.	May 16, 2016 No change