



New Drugs Reviewed by CPG January 11, 2016

(Original New Drug Applications: FDA)

Generic Name	Trade Name	Indication(s)	CPG Action
Cangrelor Injection	Kengreal	<i>Hematological Agents:</i> <i>Antiplatelet Agents:</i> <i>Platelet P2Y12 Receptor Antagonists.</i> Indicated as an adjunct to percutaneous coronary intervention to reduce the risk of periprocedural MI.	In accordance with the SCA.
Deoxycholic Acid Injection	Kybella	<i>Endocrine & Metabolic Agents: Lipolytic Agents (new classification).</i> Indicated to improve the appearance of moderate to severe convexity or fullness associated with submental fat in adults.	CTP holder may NOT prescribe.
Tiotropium Bromide/ Olodaterol Hydrochloride Inhalation	Stiolto	<i>Respiratory Agents:</i> <i>Respiratory Inhalant Products.</i> Indicated for maintenance treatment of airflow obstruction in patients with COPD.	CTP holder may prescribe.
Brexpirazole Oral	Rexulti	<i>Central Nervous System Agents: Antipsychotic Agents: Quinolinone Derivatives.</i> Indicated for treatment of major depressive disorder and schizophrenia.	CTP holder may prescribe.
Daclatasvir Dihydrochloride Oral	Daklinza	<i>Anti-Infectives, Systemic: Antiviral Agents: Hepatitis C Virus Direct-Acting Antiviral (new classification).</i> Indicated for treatment of chronic hepatitis C virus infection in combination with sofosbuvir.	In accordance with the SCA.

Ombitasvir/ Paritaprevir/ Ritonavir Oral	Technivie	<i>Anti-Infectives, Systemic: Antiviral Agents: Hepatitis C Virus Direct-Acting Antiviral (new classification).</i> Indicated for treatment of chronic hepatitis C virus without cirrhosis in combination with ribavirin.	In accordance with the SCA.
Fibrin Sealant, Human Topical	Raplixa	<i>Dermatologic Agents: Fibrin Agents.</i> Indicated as an adjunct to hemostasis for mild to moderate bleeding in adults undergoing surgery when control of bleeding by standard surgical techniques is ineffective or impractical.	CTP holder may prescribe.
Sonidegib Oral	Odomzo	<i>Antineoplastic Agents: Miscellaneous Antineoplastic Agents.</i> Indicated for treatment of adult patients with locally advanced basal cell carcinoma.	CTP holder may NOT prescribe.
Ferric Pyrophosphate Citrate Injection	Triferic	<i>Nutrients & Nutritional Agents: Trace Elements.</i> Indicated for replacement of iron to maintain hemoglobin in adult patients with hemodialysis dependent chronic kidney disease.	CTP holder may prescribe.
Flibanserin Oral	Addyi	<i>Central Nervous System Agents: Mixed 5-HT1A Agonist/ 5-HT2A Antagonist (new classification).</i> Indicated for treatment of premenopausal women with hypoactive sexual desire disorder.	In accordance with the SCA.

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Factor IX Recombinant Injection	Alprolix	<i>Hematological Agents: Antihemophilic Agents.</i> Indicated for prevention and control of bleeding in patients with factor IX deficiency.	In accordance with the SCA.
Aripiprazole Lauroxil Injection	Aristada	<i>Central Nervous System Agents: Antipsychotic Agents.</i> Indicated for treatment of schizophrenia.	CTP holder may prescribe.
Ferric Citrate Oral	Auryxia	<i>Nutrients & Nutritional Agents: Trace Elements.</i> Indicated for the control of serum phosphorus levels in patients with chronic kidney disease.	CTP holder may prescribe.
Eliglustat Tartrate Oral	Cerdelga	<i>Endocrine & Metabolic Agents: Glucosylceramide Synthase Inhibitor.</i> Indicated for the treatment of adult patients with Gaucher disease type 1.	In accordance with the SCA.
Cholic Acid Oral	Cholbam	<i>Endocrine & Metabolic Agents: Bile Acids (new classification).</i> Indicated for the treatment of bile acid synthesis disorders due to singly enzyme deficits.	In accordance with the SCA.
Ivabradine Oral	Corlanor	<i>Cardiovascular Agents: Miscellaneous Antianginal Agents.</i> Indicated to reduce the risk of hospitalization for worsening heart failure patients.	In accordance with the SCA.
Cobimetinib Fumarate Oral	Cotellic	<i>Antineoplastic Agents: Kinase Inhibitors.</i> Indicated for treatment of unresectable or metastatic melanoma in patients with a BRAF V600E or V600K mutation.	CTP holder may NOT prescribe.

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Antihemophilic Factor, Recombinant Injection	Eloctate	<i>Hematological Agents: Antihemophilic Agents.</i> Indicated for routine prophylactic treatment to reduce the frequency of bleeding episodes in adults and children with hemophilia A.	In accordance with the SCA.
Sacubitril/Valsartan Oral	Entresto	<i>Cardiovascular Agents: Antihypertensive Combinations.</i> Indicated to reduce the risk of cardiovascular death and hospitalization for heart failure patients with chronic heart failure and reduced ejection fraction.	CTP holder may prescribe.
Elvitegravir/ Cobicistat/ Emtricitabine/ Tenofovir Alafenamide Fumarate Oral	Genvoya	<i>Anti-Infective Agents, Systemic: Antiretroviral Agents: Miscellaneous Antiretroviral Combinations.</i> Indicated for treatment of HIV-1 infection and adults and pediatric patients 12 years and older.	In accordance with the SCA.
Talimogene Laherparepvec Injection	Imlygic	<i>Antineoplastic Agents: Oncolytic Virus (new classification).</i> Indicated for treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patient with melanoma recurrent after initial surgery.	CTP holder may NOT prescribe.
Olaparib Oral	Lynparza	<i>Antineoplastic Agents: Parp Enzymes Inhibitor.</i> Indicated for treatment of deleterious or suspected deleterious germline BRCA mutated advanced ovarian cancer.	CTP holder may NOT prescribe.

Phenylephrine Hydrochloride/ Ketorolac Tromethamine Intraocular.	Omidria	<i>Ophthalmic & Otic Agents: Ophthalmic Surgical Adjuncts.</i> Indicated to prevent intraoperative miosis and to reduce postoperative ocular pain during cataract surgery or intraocular lens replacement.	CTP holder may prescribe.
Lumacaftor/ Ivacaftor Oral	Orkambi	<i>Endocrine & Metabolic Agents: Cystic Fibrosis Transmembrane Regulator Protein (new classification).</i> Indicated for treatment of cystic fibrosis.	In accordance with the SCA.
Alirocumab Injection	Praluent	<i>Cardiovascular Agents: Antihyperlipidemic Agents.</i> Indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with familiar hypercholesterolemia or clinical atherosclerotic cardiovascular disease who require additional lowering of LDL cholesterol.	CTP holder may prescribe.
Idarucizumab Injection	Praxbind	<i>Endocrine & Metabolic Agents: Detoxification Agents: Antidotes.</i> Indicated for reversal of the anticoagulant effects of dabigatran for emergency surgery/ urgent procedures or in life-threatening or uncontrolled bleeding.	In accordance with the SCA.
Perindopril/ Amlodipine Oral	Prestalia	<i>Cardiovascular Agents: Antihypertensive Combinations.</i> Indicated for treatment of hypertension in patients not adequately controlled with monotherapy or as initial therapy in patients who	CTP holder may prescribe.

		require multiple antihypertensives for adequate control .	
Evolocumab Injection	Repatha	<i>Cardiovascular Agents: Antihyperlipidemic Agents.</i> Indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia.	CTP holder may prescribe.
Asfotase Alfa Injection	Strensiq	<i>Endocrine & Metabolic Agents: Asfotase Alfa (new classification).</i> Indicated for treatment of patients with perinatal/infantile – and juvenile-onset hypophosphatasia.	CTP holder may prescribe.
Empagliflozin/ Metformin Hydrochloride Oral	Synjardy	<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.	CTP holder may prescribe.
Oxycodone Hydrochloride/ Naloxone Hydrochloride Oral	Targiniq ER	<i>Central Nervous System Agents: Opioid Analgesic Combinations.</i> Indicated for the management of severe pain requiring daily, around-the-clock, long term opioid treatment and for which alternative treatment options are inadequate.	In accordance with the SCA.
Abacavir Sulfate/ Dolutegravir Sodium/ Lamivudine Oral	Triumeq	<i>Anti-Infectives, Systemic: Antiretroviral Agents: Miscellaneous Antiretroviral Combinations.</i> Indicated for treatment of HIV-1 infection.	In accordance with the SCA.

Eluxadoline Oral	Viberzi	<i>Gastrointestinal Agents: Eluxadoline (new classification).</i> Indicated for treatment of irritable bowel syndrome with diarrhea in adults.	In accordance with the SCA.
Oxycodone/ Acetaminophen Oral (Schedule II)	Xartemis XR	<i>Central Nervous System Agents: Schedule II Analgesics.</i> Indicated for management of acute pain severe enough to require opioid treatment while reducing the risk of serious adverse outcomes resulting from inappropriate prescribing, misuse, and abuse.	In accordance with the SCA.
Uridine Triacetate Oral	Xuriden	<i>Endocrine & Metabolic Agents: Uridine Triacetate (new classification).</i> Indicated for treatment of hereditary orotic aciduria.	CTP holder may prescribe.
Trabectedin Injection	Yondelis	<i>Antineoplastic Agents: Miscellaneous Antineoplastics.</i> Indicated for treatment of unresectable or metastatic soft tissue sarcoma.	CTP holder may NOT prescribe.
Antihemophilic Factor, Human	Nuwiq	<i>Hematologic Agents: Antihemophilic Agents.</i> Indicated for the prevention and control of hemorrhagic episodes in patients with classical hemophilia in which there is a demonstrated deficiency of activity of the plasma clotting factor, factor VIII.	In accordance with the SCA.
Daratumumab	Darzalex	<i>Antineoplastic Agents: Monoclonal Antibodies.</i> Indicated for the treatment of patients with multiple myeloma.	CTP holder may NOT prescribe.

Antihemophilic Factor Recombinant	Adynovate	<i>Hematological Agents: Antihemophilic Agents.</i> Indicated for on-demand treatment and control of bleeding episodes and for routine prophylaxis to reduce the frequency of bleeding episodes.	In accordance with the SCA.
Osimertinib Oral	Tagrisso	<i>Antineoplastic Agents: Kinase Inhibitors.</i> Indicated for the treatment of patients with metastatic epidermal growth factor receptor T790M mutation positive non-small cell lung cancer.	CTP holder may NOT prescribe.
Mepolizumab Injection	Nucala	<i>Respiratory Agents: Monoclonal Antibodies.</i> Indicated for add-on maintenance treatment of patients with severe asthma.	CTP holder may prescribe.
Indacaterol/ Glycopyrrolate Oral Inhalation	Utibron	<i>Respiratory Agents: Bronchodilators.</i> Indicated for the long-term maintenance treatment of airflow obstruction in patients with COPD.	CTP holder may prescribe.
Irinotecan Liposome Injection	Onivyde	<i>Antineoplastic Agents: Topoisomerase Inhibitor.</i> Indicated in combination with fluorouracil and leucovorin for treatment of patients with advanced metastatic pancreatic cancer.	CTP holder may NOT prescribe.
Patiromer Oral	Veltassa	<i>Cardiovascular Agents: Potassium Removing Agents.</i> Indicated for treatment	CTP holder may prescribe.

		of hyperkalemia.	
Coagulation Factor X, Human	Coagadex	<i>Hematological Agents: Antihemophilic Agents.</i> Indicated for on-demand treatment and control of bleeding episodes in patients with hereditary factor X deficiency.	In accordance with the SCA.
Insulin Degludec	Tresiba	<i>Endocrine & Metabolic Agents: Antidiabetic Agents: Insulin.</i> Long acting insulin indicated to improve glycemic control in adults with diabetes mellitus.	CTP holder may prescribe.
Insulin Degludec/ Insulin Aspart	Ryzodeg 70/30	<i>Endocrine & Metabolic Agents: Antidiabetic Agents: Insulin.</i> Indicated to improve glycemic control in adults with diabetes mellitus.	CTP holder may prescribe.
Trifluridine/ Tipiracil	Lonsurf	<i>Antineoplastic Agents: Antimetabolites.</i> Indicated for the treatment of patients with metastatic colorectal cancer.	CTP holder may NOT prescribe.
Cariprazine	Vraylar	<i>Central Nervous System Agents: Antipsychotic Agents.</i> Indicated for the treatment of adults with schizophrenia and short-term treatment of manic or mixed episodes associated with bipolar 1 disorder.	CTP holder may prescribe.
Uridine Triacetate	Xuriden	<i>Endocrine and Metabolic: treatment of hereditary orotic aciduria</i>	CTP holder may prescribe.
Gefitinib Oral	Iressa	<i>Antineoplastic Agents: Kinase Inhibitors: Tyrosine Kinase Inhibitors.</i>	CTP holder may NOT prescribe.

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Rolapitant	Varubi	<i>Central Nervous System Agents:Antiemetic/Anti-vertigo Agents.</i> Indicated in combination with other antiemetic agents, for the prevention of delayed nausea and vomiting associated with initial and repeat courses of chemotherapy.	CTP holder may prescribe.
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New Drugs Indications/ Warnings Reviewed by CPG January 2016 (New Drug Indications/ Black Box Warnings: FDA)

Generic Name	Trade Name	Indication(s)	CPG Action/Date
Perampanel Oral	Fycompa	<i>Central Nervous System Agents: Anticonvulsants.</i> New indication for treatment of primary generalized tonic-clonic seizures.	Current: CTP holder may prescribe. January 11, 2016 No Change
Aflibercept Ophthalmic	Eylea	<i>Ophthalmic & Otic Agents: Selective Vascular Endothelial Growth Factor Antagonists.</i> New indication of treatment of diabetic retinopathy in patients with diabetic macular edema.	Current: In accordance with the SCA. January 11, 2016 No Change
Sirolimus Oral	Sirolimus	<i>Biologic/ Immunologic Agents: Immunologic Agents: Immunosuppressives.</i> New indication for the treatment of lymphangiomyomatosis.	Current: In accordance with the SCA. January 11, 2016 No Change
Eslicarbazepine Acetate Oral	Aptiom	<i>Central Nervous System Agents: Anticonvulsants.</i> Expanded indication for treatment of partial-onset seizures as monotherapy.	Current: CTP holder may prescribe. January 11, 2016 No Change
Moxifloxacin Hydrochloride Oral	Avelox	<i>Anti-Infective Agents, Systemic: Flouroquinolones.</i> New indication for treatment of Plaque.	Current: CTP holder may prescribe. January 11, 2016 No Change
Abobotulinumtoxina Injection	Dysport	<i>Central Nervous System Agents: Botulinum Toxins.</i> New indication for treatment of upper limb spasticity.	Current: CTP holder may prescribe. January 11, 2016 No Change

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Ferumoxytol Injection	Feraheme	<i>Nutrients and Nutritional Agents: Trace Elements.</i> New black box warning for fatal and serious hypersensitivity reactions including anaphylaxis.	Current: CTP holder may prescribe. January 11, 2016 No Change
Adalimumab Injection	Humira	<i>Biologic/ Immunologic Agents: Immunologic Agents: Immunomodulators.</i> Expanded indication for treatment of moderate to severe hidradenitis suppurativa	Current: In accordance with the SCA. January 11, 2016 No Change
Ibrutinib Oral	Imbruvica	<i>Antineoplastic Agents: Kinase Inhibitors.</i> New indication for treatment of patients with Waldenstrom macroglobulinemia	Current: CTP holder may NOT prescribe. January 11, 2016 No Change
Pembrolizumab Injection	Keytruda	<i>Biologic/Immunologic Agents: Immunologic Agents: Immunomodulators.</i> Expanded indication for treatment of patients with metastatic non-small cell lung cancer	Current: In accordance with the SCA. January 11, 2016 No Change
Ranibizumab Intravitreal	Lucentis	<i>Ophthalmic & Otic Agents: Selective Vascular Endothelial Growth Factor Antagonists.</i> New indication for treatment of diabetic retinopathy in patients with diabetic macular edema	Current: In accordance with the SCA. January 11, 2016 No Change
Lisdexamfetamine Dimesylate Oral	Vyvanse	<i>Central Nervous System Agents: Stimulants: Amphetamines.</i> New indication for treatment of binge eating disorder	Current: CTP holder may prescribe with formal established diagnosis. May prescribe in

New Drug Indications January 2016

			<p>accordance with the SCA without a formal establish diagnosis.</p> <p>January 11, 2016 No Change</p>
Nivolumab	Opdivo	<p><i>Antineoplastic Agents: Monoclonal Antibodies.</i> New indication for treatment of patients with BRAF V600 wild-type unresectable or metastatic melanoma.</p>	<p>Current: CTP holder may NOT prescribe.</p> <p>January 11, 2016 No Change</p>
Pegfilgrastim	Neulasta	<p><i>Hematological Agents: Hematopoietic Agents: Colony Stimulating Factors.</i> Expanded indication for use for increased survival in patients acutely exposed to myelosuppressive doses of radiation.</p>	<p>Current: CTP holder may prescribe.</p> <p>January 11, 2016 No Change</p>
Rifaxamin	Xifaxan	<p><i>Anti-Infective Agents, Systemic: Rifaximin.</i> New indication for treatment of irritable bowel syndrome with diarrhea.</p>	<p>Current: CTP holder may prescribe.</p> <p>January 11, 2016 No Change</p>



Formulary Revision Request January 2016

(Original New Drug Applications: FDA)

Generic Name	Trade Name	Indication(s)	CPG Action/Date
Formulary Review Revision Request from Kim Kombrinck			
Ketamine	Ketalar	Procedural sedation in procedures not requiring skeletal muscle relaxation.	Current: For urgent and emergent respiratory care. January 11, 2016 In accordance with the SCA for analgesia, mild and moderate sedation only
Vasopressin	Vasostriect	Treatment of diabetes insipidus	Current: May not prescribe for diabetes insipidus January 11, 2016, In accordance with the SCA
Formulary Review Revision Request from Cheryl Kollman			
Desmopressin	DDAVP	Treatment of diabetes insipidus	Current: May not prescribe for diabetes insipidus January 11, 2016, In accordance with the SCA
Formulary Review Revision Request from Heather Ryle			
Buprenorphine	Subutex	Treatment of Opioid dependence.	Current: May not prescribe January 11, 2016 In accordance with SCA only for treatment of NAS



CPG Review of Prescribing Designations In Accordance with Standard Care Arrangement and CTP Holder May NOT Prescribe

Nutrients and Nutritional Agents
 Hematologic Agents
 (January 2016)

Drug Category/ Drug Name	Indication(s): If reviewing a specific drug in a drug category	Current Prescribing Designation	CPG Action/Date
Nutrients and Nutritional Agents			
Peritoneal Dialysis Solutions	Electrolytes: Peritoneal Dialysis Solutions. Indicated for acute or chronic renal failure, acute poisoning by dialyzable toxins, intractable edema, hyperkalemia, hypercalcemia, azotemia and uremia.	In accordance with SCA	January 11, 2016 No change
Hemodialysis Solutions	Dialysis Solutions: Hemodialysis.	In accordance with SCA	January 11, 2016 No change
Hematologic Agents			
Hematopoietic Agents			
Thrombopoietin Receptor Agonist Eltrombopag	<i>Hematopoietic Agents: Thrombopoietin Receptor Agonist.</i> Indicated for the treatment of thrombocytopenia in patients with chronic ITP who have an insufficient response to corticosteroids, immunoglobulins, or splenectomy.	In accordance with SCA	January 11, 2016 No change

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Thrombopoietin Mimetic Agents: Romiplostim Injection	Hematopoietic Agents: Thrombopoietin Mimetic Agents. Indicated for the treatment of thrombocytopenia in patients with chronic ITP who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.	In accordance with SCA	January 11, 2016 No change
Antiplatelet Agents			
Glycoprotein Inhibitors	Antiplatelet Agents. Glycoprotein Inhibitors. Indicated for the treatment of acute coronary syndrome.	In accordance with SCA	January 11, 2016 No change
Anticoagulants			
Antithrombin Agents	<i>Anticoagulants: Antithrombin Agents.</i> Indicated for the treatment of patients with hereditary AT-III deficiency in connection with surgical or obstetrical procedures of when they suffer from thromboembolism.	In accordance with SCA	January 11, 2016 No change
Thrombin Inhibitors	<i>Anticoagulants: Thrombin Inhibitors.</i> Indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation.	In accordance with SCA	January 11, 2016 No change
Factor Xa Inhibitor	<i>Anticoagulants: Selective Factor Xa Inhibitor.</i> Indicated for the prophylaxis of deep vein thrombosis	In accordance with SCA	January 11, 2016 No change

	(DVT), which may lead to pulmonary embolism (PE) and for the treatment of acute DVT and acute PE when administered in conjunction with warfarin.		
Coumarin Anticoagulants	<i>Anticoagulants: Coumarin Anticoagulants.</i> Indicated to reduce the risk of death, recurrent MI, and thromboembolic events. For prophylaxis and/or treatment of thromboembolic complications associated with atrial fibrillation and/or cardiac valve replacement. For the prophylaxis and/or treatment of venous thrombosis and pulmonary embolism.	In accordance with SCA	January 11, 2016 No change
Coagulants: Heparin antagonists	<i>Coagulants: Heparin Antagonist.</i> Indicated for the treatment of heparin overdose.	In accordance with SCA	January 11, 2016 No change
Thrombolytic Agents	Acute myocardial infarction and restoration of function to central venous access device.	May not prescribe (exception: may prescribe for catheter occlusions only)	January 11, 2016 No change
Antisickling Agents: Hydroxyurea	Antisickling Agents. Indicated to reduce the frequency of painful crises and to reduce the need for blood transfusions in adult patients with sickle cell anemia.	In accordance with SCA	January 11, 2016 No change

Protein C1 Inhibitor	Protein C1 Inhibitor. Indicated for the treatment of acute abdominal, facial, or laryngeal attacks of hereditary angioedema in adult and adolescent patient and for routine prophylaxis against angioedema attacks in adolescent and adult patients with hereditary angioedema.	In accordance with SCA	January 11, 2016 No change
Antihemophilic Agents	<i>Antihemophilic Agents.</i>	In accordance with SCA	January 11, 2016 No change
Antihemophilic Factor Combinations	Antihemophilic Factor Combination. Indicated for the treatment and prevention of bleeding in adult patients with hemophilia A and in adults and children with von Willebrand disease	In accordance with SCA	January 11, 2016 No change
Hemostatics			
Fibrinogen Concentrate (Human)	Treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency.	May not prescribe	January 11, 2016 No change
Aminocaproic Acid	Enhances hemostasis when fibrinolysis contributes to bleeding.	In accordance with SCA	January 11, 2016 No change
Prothrombin complex Concentrate	Urgent treatment of acquired coagulation factor deficiency induced by Vitamin K antagonist therapy in adult patients with acute major bleeding.	In accordance with SCA	January 11, 2016 No change

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Plasma Expanders: Tetrastarch	Plasma Expanders. Used in treatment and prevention of hypovolemia	In accordance with SCA	January 11, 2016 No change
Hemin	Management of recurrent attacks of acute intermittent porphyria	May not prescribe	January 11, 2016 No change
Kallikrein Inhibitors: Ecallanatide	Kallikrein Inhibitor. Indicated for treatment of acute attacks of hereditary angioedema in patients 16 years of age and older.	In accordance with SCA	January 11, 2016 No change
Bradykinin Inhibitors: Icatibant	Bradykinin Inhibitors. Indicated for treatment of acute attacks of hereditary angioedema in adults 18 years and older.	IN accordance with SCA	January 11, 2016 No change