

**Commissioner for the Department for Medicaid Services
Selections for Preferred Products**

This is a summary of the final Preferred Drug List (PDL) selections made by the Commissioner for the Department for Medicaid Services based on the September 19, 2013 Pharmacy and Therapeutics Advisory Committee (PTAC) Meeting.

Description of Recommendation	Final Decision (s)
<p><u>New Products to Market: Kynamro™</u> Place this product preferred in the PDL class titled Familial Hypercholesterolemia Agents. Approval of mipomersen sodium will be granted as described below.</p> <ul style="list-style-type: none"> • For initial treatment, approve for 6 months if ALL of the following are true: <ul style="list-style-type: none"> ○ Diagnosis of homozygous familial hypercholesterolemia (HoFH) with untreated total cholesterol (TC) >500 mg/dL; AND ○ Must be used as an adjunct to a low-fat diet supplying < 20% of energy from fat; AND ○ Baseline alanine and aspartate aminotransferases (ALT, AST), alkaline phosphatase, and total bilirubin lab values must be obtained prior to initiating treatment; AND ○ Baseline low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high density lipoprotein cholesterol (non-HDL-C) labs must be obtained prior to initiating treatment and required for renewal; AND ○ Patient tried and failed at least a 3 month trial of the maximally tolerated dose with two (2) of the following statins: simvastatin 40mg (Zocor), atorvastatin 80mg (Lipitor) OR rosuvastatin 40mg (Crestor), unless contraindicated; AND ○ Patient tried and failed at least a 3 month trial combination with both ezetimibe 10mg (Zetia) AND atorvastatin 80mg (Lipitor) OR simvastatin 40mg (Zocor), unless contraindicated; AND ○ Despite the pharmacological treatment with statins and ezetimibe, patient's LDL cholesterol ≥ 300 mg/dL (or non-HDL cholesterol ≥ 330 mg/dL). • For continuation of treatment, approve for one year 	<p>Kynamro™ will be added as preferred in the PDL class titled Familial Hypercholesterolemia Agents. Approval of mipomersen sodium will be granted as described below.</p> <ul style="list-style-type: none"> • For initial treatment, approve for 6 months if ALL of the following are true: <ul style="list-style-type: none"> ○ Diagnosis of homozygous familial hypercholesterolemia (HoFH) with untreated total cholesterol (TC) >500 mg/dL; AND ○ Must be used as an adjunct to a low-fat diet supplying < 20% of energy from fat; AND ○ Baseline alanine and aspartate aminotransferases (ALT, AST), alkaline phosphatase, and total bilirubin lab values must be obtained prior to initiating treatment; AND ○ Baseline low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high density lipoprotein cholesterol (non-HDL-C) labs must be obtained prior to initiating treatment and required for renewal; AND ○ Patient tried and failed at least a 3 month trial of the maximally tolerated dose with two (2) of the following statins: simvastatin 40mg (Zocor), atorvastatin 80mg (Lipitor) OR rosuvastatin 40mg (Crestor), unless contraindicated; AND ○ Patient tried and failed at least a 3 month trial combination with both ezetimibe 10mg (Zetia) AND atorvastatin 80mg (Lipitor) OR simvastatin 40mg (Zocor), unless contraindicated; AND ○ Despite the pharmacological treatment with statins and ezetimibe, patient's LDL cholesterol ≥ 300 mg/dL (or non-HDL

<p>if ALL of the following are true:</p> <ul style="list-style-type: none"> ○ Documented reduction of low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high density lipoprotein cholesterol (non-HDL-C) from baseline; AND ○ Documentation of dosage adjustment if ALT or AST is ≥ 3 times the upper limit of normal (ULN); AND ○ Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: elevations in transaminases (ALT, AST), hepatic steatosis, serious injection site reactions, and flu-like symptoms. 	<p>cholesterol ≥ 330 mg/dL).</p> <ul style="list-style-type: none"> ● For continuation of treatment, approve for one year if ALL of the following are true: <ul style="list-style-type: none"> ○ Documented reduction of low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high density lipoprotein cholesterol (non-HDL-C) from baseline; AND ○ Documentation of dosage adjustment if ALT or AST is ≥ 3 times the upper limit of normal (ULN); AND ○ Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: elevations in transaminases (ALT, AST), hepatic steatosis, serious injection site reactions, and flu-like symptoms.
<p><u>New Products to Market: Juxtapid™</u> Place this product non preferred with similar approval criteria in the PDL class titled Familial Hypercholesterolemia Agents.</p>	<p>Juxtapid™ will be placed non preferred with similar approval criteria in the PDL class titled Familial Hypercholesterolemia Agents.</p>
<p><u>New Products to Market: Liptruzet™</u> Place this product as non preferred with appropriate quantity limits in the PDL class titled High Potency Statins.</p>	<p>Liptruzet™ will be placed non preferred with appropriate quantity limits in the PDL class titled High Potency Statins.</p>
<p><u>New Products to Market: Tafinlar®</u> Place this product preferred with similar quantity limits in the PDL class titled Oral Oncology Agents; however, only approve Tafinlar® for a diagnosis of unresectable or metastatic melanoma after confirmation that the BRAF V600E mutation has been detected by an FDA-approved test.</p>	<p>Tafinlar® will be added as preferred with similar quantity limits in the PDL class titled Oral Oncology Agents; however, Tafinlar® will only be approved for a diagnosis of unresectable or metastatic melanoma after confirmation that the BRAF V600E mutation has been detected by an FDA-approved test.</p>
<p><u>New Products to Market: Mekinist™</u> Place this product preferred with similar quantity limits in the PDL class titled Oral Oncology Agents; however, only approve Mekinist™ for a diagnosis of unresectable or metastatic melanoma after confirmation that the BRAF V600E or V600K mutation has been detected by an FDA-approved test.</p>	<p>Mekinist™ will be added as preferred with similar quantity limits in the PDL class titled Oral Oncology Agents; however, Mekinist™ will only be approved for a diagnosis of unresectable or metastatic melanoma after confirmation that the BRAF V600E or V600K mutation has been detected by an FDA-approved test.</p>
<p><u>New Products to Market: Cometriq™</u> Place this product non preferred with similar quantity limits in the PDL class titled Oral Oncology Agents.</p>	<p>Cometriq™ will be placed non preferred with similar quantity limits in the PDL class titled Oral Oncology Agents.</p>

Description of Recommendation	Final Decision (s)
<p><u>New Products to Market: Rescula®</u> Place this product non preferred with appropriate quantity limits in the PDL class titled Prostaglandin Agonists.</p>	<p>Rescula® will be placed non preferred with appropriate quantity limits in the PDL class titled Prostaglandin Agonists.</p>
<p><u>New Products to Market: Simbrinza™</u> Place this product preferred in the PDL class titled Ophthalmic Carbonic Anhydrase Inhibitors.</p>	<p>Simbrinza™ will be added as preferred in the PDL class titled Ophthalmic Carbonic Anhydrase Inhibitors.</p>
<p><u>New Products to Market: Fulyzaq™</u> Place this product non preferred with appropriate quantity limits in the PDL class titled Antidiarrheals. Approval of crofelemer will be granted as described below.</p> <ul style="list-style-type: none"> • For initial treatment, approve for 6 months if ALL of the following are true: <ul style="list-style-type: none"> ○ Patient has been diagnosed with human immunodeficiency virus; AND ○ Patient is experiencing diarrhea; AND ○ Active infection has been ruled out via fecal collection and microbiologic culture; AND ○ Patient has tried and failed the preferred antidiarrheals: loperamide, atropine-diphenoxylate. • For continuation of treatment, approve for one year if ALL of the following are true: <ul style="list-style-type: none"> ○ Documented reduction in the frequency and quantity of liquid stool volume for the previous 6 months; AND ○ Documented follow-up with patient that includes re-culture for microbiologic agents if breakthrough diarrhea occurs while on crofelemer therapy. 	<p>Fulyzaq™ will be placed non preferred with appropriate quantity limits in the PDL class titled Antidiarrheals. Approval of crofelemer will be granted as described below.</p> <ul style="list-style-type: none"> • For initial treatment, approve for 6 months if ALL of the following are true: <ul style="list-style-type: none"> ○ Patient has been diagnosed with human immunodeficiency virus; AND ○ Patient is experiencing diarrhea; AND ○ Active infection has been ruled out via fecal collection and microbiologic culture; AND ○ Patient has tried and failed the preferred antidiarrheals: loperamide, atropine-diphenoxylate. • For continuation of treatment, approve for one year if ALL of the following are true: <ul style="list-style-type: none"> ○ Documented reduction in the frequency and quantity of liquid stool volume for the previous 6 months; AND ○ Documented follow-up with patient that includes re-culture for microbiologic agents if breakthrough diarrhea occurs while on crofelemer therapy.
<p><u>New Products to Market: Suclear™ Bowel Prep Kit</u> Place this product as non preferred in the PDL class titled Laxative and Cathartics.</p>	<p>Suclear™ Bowel Prep Kit will be placed non preferred in the PDL class titled Laxative and Cathartics.</p>
<p><u>New Products to Market: Diclegis™</u> Place this product non preferred in the PDL class titled Oral Anti-emetics, Anticholinergics.</p>	<p>Diclegis™ will be placed non preferred in the PDL class titled Oral Anti-emetics, Anticholinergics.</p>

Description of Recommendation	Final Decision (s)
<p><u>New Products to Market: OspheTM</u> OspheTM (ospemifene) should only be approved for patients meeting ALL of the following criteria:</p> <ul style="list-style-type: none"> • Diagnosis of severe dyspareunia, due to vulvar and vaginal atrophy, in a post-menopausal woman; AND • Trial and failure of an over-the-counter vaginal lubricant; AND • Trial and failure of a prescription topical estrogen product, unless contraindicated. 	<p>OspheTM (ospemifene) will only be approved for patients meeting ALL of the following criteria:</p> <ul style="list-style-type: none"> • Diagnosis of severe dyspareunia, due to vulvar and vaginal atrophy, in a post-menopausal woman; AND • Trial and failure of an over-the-counter vaginal lubricant; AND • Trial and failure of a prescription topical estrogen product, unless contraindicated.
<p><u>New Products to Market: TecfideraTM</u> Place this product non preferred with appropriate quantity limits in the PDL class titled Multiple Sclerosis Agents.</p>	<p>TecfideraTM will be placed non preferred with appropriate quantity limits in the PDL class titled Multiple Sclerosis Agents.</p>
<p><u>New Products to Market: Breo ElliptaTM</u> Place this product non preferred with appropriate quantity limits in the PDL class titled Beta Agonists: Combination Products.</p>	<p>Breo ElliptaTM will be placed non preferred with appropriate quantity limits in the PDL class titled Beta Agonists: Combination Products.</p>
<p><u>New Products to Market: InvokanaTM</u> InvokanaTM (canagliflozin) should only be approved for patients with a diagnosis of type 2 diabetes who have tried and failed maximum tolerated doses of metformin.</p>	<p>InvokanaTM (canagliflozin) will only be approved for patients with a diagnosis of type 2 diabetes who have tried and failed maximum tolerated doses of metformin.</p>
<p><u>New Products to Market: Nesina[®]</u> Place this product non preferred with similar approval criteria and appropriate quantity limits in the PDL class titled DPP-4 Inhibitors.</p>	<p>Nesina[®] will be placed non preferred with similar approval criteria and appropriate quantity limits in the PDL class titled DPP-4 Inhibitors.</p>
<p><u>New Products to Market: Kazano[®]</u> Place this product non preferred with similar approval criteria and appropriate quantity limits in the PDL class titled DPP-4 Inhibitors.</p>	<p>Kazano[®] will be placed non preferred with similar approval criteria and appropriate quantity limits in the PDL class titled DPP-4 Inhibitors.</p>
<p><u>New Products to Market: Oseni[®]</u> Place this product preferred with similar approval criteria and appropriate quantity limits in the PDL class titled DPP-4 Inhibitors.</p>	<p>Oseni[®] will be placed preferred with similar approval criteria and appropriate quantity limits in the PDL class titled DPP-4 Inhibitors.</p>

Description of Recommendation	Final Decision (s)
<p><u>DPP-4 Inhibitors</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred. The combination alogliptin/pioglitazone should be among the preferred products. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the DPP4-Inhibitors class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s)</p> <p>Janumet™ Janumet XR™ Januvia™ Kombiglyze XR™ Onglyza™ Oseni®</p> <p>Non Preferred Agent (s)</p> <p>Jentadueto™ Juvisync™ Kazano® Nesina® Tradjenta™</p>
<p><u>DPP-4 Inhibitors Clinical Criteria</u></p> <p>DPP-4 Inhibitors will be approved for one of the following reasons:</p> <ul style="list-style-type: none"> • Metformin, insulin, a sulfonylurea or a TZD is seen in history within the past 90 days; OR • Diagnosis of Chronic Renal Insufficiency/Failure. 	<p>DPP-4 Inhibitors will be approved for one of the following reasons:</p> <ul style="list-style-type: none"> • Metformin, insulin, a sulfonylurea or a TZD is seen in history within the past 90 days; OR • Diagnosis of Chronic Renal Insufficiency/Failure.
<p><u>Thiazolidinediones</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least pioglitazone should be preferred. Based on safety concerns, rosiglitazone should be a non preferred product. 2. Continue quantity limits based on maximum recommended dose. 3. Agents not selected as preferred will be considered non preferred and require PA. 4. For any new chemical entity in the Diabetes: Thiazolidinediones class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s)</p> <p>pioglitazone</p> <p>Non Preferred Agent (s)</p> <p>Actos® ActoPlus Met® ActoPlus Met® XR Avandamet® Avandia® Avandaryl® Duetact™ pioglitazone/glimepiride pioglitazone/metformin</p>

Description of Recommendation	Final Decision (s)
<p><u>Oral Steroids</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however at least generic formulations of budesonide, dexamethasone, methylprednisolone, prednisolone and prednisone should be preferred. 2. The orally disintegrating formulation of prednisolone should be available for children < 12 years of age. 3. Agents not selected as preferred will be considered non preferred and require PA. 4. For any new chemical entity in the Oral Steroids class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s)</p> <p>cortisone dexamethasone solution, tablets Entocort EC® hydrocortisone methylprednisolone dose pack, tablets prednisolone solution prednisolone sodium phosphate prednisone dose pack, tablets, solution</p> <p>Non Preferred Agent (s)</p> <p>AsmalPred® Baycadron® budesonide EC Celestone® Celestone Soluspan® Cortef® dexamethasone elixir dexamethasone intensol DexPak® DexPak JR® Flo-Pred® Medrol® methylprednisolone 8 mg, 16 mg tablet Millipred® Orapred® Orapred ODT® prednisone intensol Prellone® Reyos® Uceris® Veripred 20®</p>

Description of Recommendation	Final Decision (s)
<p><u>Intranasal Steroids</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. Continue to maintain quantity limits based on maximum daily dose. 4. For any new chemical entity in the Corticosteroids, Intranasal class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s) fluticasone propionate Nasonex®</p> <p>Non Preferred Agent (s) Beconase AQ® Dymista® Flonase® flunisolide Nasacort AQ® Omnaris™ Qnasal™ Rhinocort Aqua® triamcinolone Veramyst® Zetonna™</p>
<p><u>Intranasal Antihistamines</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Intranasal Antihistamines class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s) Astepro®</p> <p>Non Preferred Agent (s) Astelin® azelastine Patanase™</p>
<p><u>Topical Steroids</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one agent in each of the potency categories (low, medium, high and very high) should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Topical Steroids class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s) betamethasone dipropionate ointment, cream, lotion betamethasone valerate cream, ointment clobetasol propionate ointment, cream, solution, gel Clobex® shampoo desonide cream, ointment fluocinolone acetonide fluocinonide fluocinonide emollient fluticasone propionate cream, ointment halobetasol propionate hydrocortisone cream, gel, ointment hydrocortisone butyrate ointment, solution hydrocortisone valerate mometasone furoate ointment, cream triamcinolone acetonide</p> <p>Non Preferred Agent (s) Aclovate®</p>

	alclometasone dipropionate Ala-Cort® Ala-Scalp® Aqua Glycolic HC® amcinonide ApexiCon®/ApexiCon E® Balneol for Her® betamethasone dipropionate gel betamethasone dipropionate augmented betamethasone valerate lotion, foam Caldecort® Capex® Shampoo clobetasol emollient clobetasol propionate foam, lotion, shampoo Clobex® lotion, spray Cloderm® Cordran® Cordran® Tape Cormax® Cutivate® Cyclocort® Derma-Smoothe/FS® Dermatop® Desonate® desonide lotion Desowen® desoximetasone diflorasone diacetate Diprolene AF® Elocon® fluticasone propionate lotion Halac Kit® Halog® Halonate® hydrocortisone-aloe hydrocortisone lotion hydrocortisone butyrate cream hydrocortisone-urea Kenalog® Lipocream® Locoid® Luxiq® mometasone furoate solution Momexin™ NuZon™ Olux®
--	---

	<p>Olux-E® Olux-Olux E® Complete Pack Pandel® Pediaderm HC™ Pediaderm TA™ prednicarbate Scalacort® Scalacort-DK® Kit Synalar® Temovate® Temovate E® Texacort® Topicort® Topicort® Topical Spray Triderm® Trianex® Ultravate® Ultravate® PAC Kit Ultravate® X Vanos™ Verdeso™ Westcort®</p>
<p><u>Topical Acne Agents</u> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least multiple generic formulations of benzoyl peroxide, one topical antibiotic agent for acne and tretinoin should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Topical Acne Agents class, require a PA until reviewed by the P&T Advisory Committee.</p>	<p>Selected Preferred Agent (s) benzoyl peroxide OTC BenzaClin® clindamycin solution, medicated swab, gel, lotion Differin® cream, gel erythromycin solution, gel sodium sulfacetamide/sulfur cleanser tretinoin tretinoin microspheres</p> <p>Non Preferred Agent (s) Acanya™ Acne Spot Treatment Aczone™ adapalene cream, gel Akne-Mycin® Atralin™ Avar™ Avar E™ Avar E LS™ Avar LS™ Avita® Azelex® Benzefoam™</p>

	<p> Benzefoam Ultra™ Benzamycin Pak® BenzePro Foam™ benzoyl peroxide cleanser, kit, microspheres, gel benzoyl peroxide/clindamycin benzoyl peroxide/erythromycin benzoyl peroxide/sulfur BP 10-1® BPO® BPO-5® BPO-10® BP Wash™ Cerisa™ Clarifoam® EF Cleocin-T® Clindacin PAC™ Clindagel® clindamycin foam Desquam-X® Differin® lotion Duac® Effaclar Duo® Epiduo™ erythromycin medicated swab Evoclin™ Inova™ Inova™ 4/1 Inova™ 8/2 Klaron® Lavoclen™ Pacnex® Panoxyl® Persa-Gel® Prascion® OC8® Ovace® Ovace Plus® Nu-Ox® Retin-A® Retin-A Micro® SE 10-5 SS® SE BPO® sodium sulfacetamide sodium sulfacetamide/sulfur cream, suspension, kit, medicated pad sodium sulfacetamide/sulfur/urea </p>
--	---

	SSS 10-4® SSS 10-5® Sumadan™ Sumaxin® Tazorac® Tretin-X™ tretinoin microspheres gel pump Vanoxide-HC® Veltin™ Zencia® Ziana™
<p><u>Growth Hormone</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agents based upon economic evaluation; however, one preferred agent should be supplied in a pediatric convenient dosing form. 2. Continue to require clinical PA for all agents, preferred or non-preferred. 3. For any new chemical entity in the Growth Hormone class, require a PA until reviewed by the P & T Advisory Committee. 	Selected Preferred Agent (s) Genotropin® Norditropin® Nutropin® Nutropin AQ® Non Preferred Agent (s) Humatrope® Omnitrope® Saizen® Serostim® Tev-Tropin™ Zorbtive®

Description of Recommendation	Final Decision (s)
<p><u>Growth Hormone Clinical Criteria</u></p> <ul style="list-style-type: none"> ● Growth Hormones will be approved for one of the following diagnoses: <ul style="list-style-type: none"> ○ Growth Hormone Deficiency or Pituitary dwarfism ○ Pituitary disease from known causes such as pituitary tumor, pituitary surgical damage, hypothalamic disease, irradiation, or trauma such as Panhypopituitarism, Iatrogenic pituitary disorders. Other disorders of the pituitary and other syndromes of diencephalohypophyseal origin. Other disorders of the pituitary gland and craniopharyngeal duct ○ Turner’s Syndrome ○ Chronic renal insufficiency & end-stage renal disease (pre transplant) ○ Prader-Willi Syndrome ○ Idiopathic Short Stature (meaning of unknown origin). Also called non-growth hormone deficient short stature ○ Small for gestational age ○ Short Stature Homeobox Gene ○ Noonan Syndrome ○ HIV wasting or cachexia ○ Short bowel syndrome ● Prefilled syringes will be approved in situations of inability to properly/reliable mix/measure dosage. ● Preservative free products will be approved in instances of intolerance/contraindication to preservatives in the preferred products. ● Non-preferred growth hormones require trial and failure of two preferred agents. 	<p>Growth Hormones will be approved for one of the following diagnoses:</p> <ul style="list-style-type: none"> ● Growth Hormone Deficiency or Pituitary dwarfism ● Pituitary disease from known causes such as pituitary tumor, pituitary surgical damage, hypothalamic disease, irradiation, or trauma such as Panhypopituitarism, Iatrogenic pituitary disorders. Other disorders of the pituitary and other syndromes of diencephalohypophyseal origin. Other disorders of the pituitary gland and craniopharyngeal duct ● Turner’s Syndrome ● Chronic renal insufficiency & end-stage renal disease (pre transplant) ● Prader-Willi Syndrome ● Idiopathic Short Stature (meaning of unknown origin). Also called non-growth hormone deficient short stature ● Small for gestational age ● Short Stature Homeobox Gene ● Noonan Syndrome ● HIV wasting or cachexia ● Short bowel syndrome ● Prefilled syringes will be approved in situations of inability to properly/reliable mix/measure dosage. ● Preservative free products will be approved in instances of intolerance/contraindication to preservatives in the preferred products. ● Non-preferred growth hormones require trial and failure of two preferred agents.
<p><u>Narcotic Agonists/Antagonists</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Narcotic Agonist / Antagonists class, require PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s) butorphanol NS pentazocine / naloxone</p> <p>Non Preferred Agent (s) pentazocine / acetaminophen</p>

Description of Recommendation	Final Decision (s)
<p><u>Fentanyl Buccal Products</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation. 2. Require prior approval for all of these agents to ensure utilization based on FDA-approved indication. 3. For any new chemical entity in the Narcotics: Fentanyl Buccal Products class, require PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s) N/A</p> <p>Non Preferred Agent (s) Abstral® Actiq® fentanyl oral transmucosal Fentora® Lazanda® Onsolis™ Subsys®</p>
<p><u>Fentanyl Buccal Products Clinical Criteria</u></p> <p>Fentanyl Buccal products will be approved if ALL of the following are true:</p> <ul style="list-style-type: none"> • Diagnosis of cancer pain; AND • Receiving and tolerant to opioid therapy, as evident by trial of opioid doses equal to, or greater than, morphine 60 mg daily or fentanyl patches 50 mcg/hr for at least one week without adequate pain control; AND • Unresponsive to therapy with three other immediate-released unique chemical entities utilized for breakthrough pain. 	<p>Fentanyl Buccal products will be approved if ALL of the following are true:</p> <ul style="list-style-type: none"> • Diagnosis of cancer pain; AND • Receiving and tolerant to opioid therapy, as evident by trial of opioid doses equal to, or greater than, morphine 60 mg daily or fentanyl patches 50 mcg/hr for at least one week without adequate pain control; AND • Unresponsive to therapy with three other immediate-released unique chemical entities utilized for breakthrough pain.
<p><u>GI Antibiotics</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based upon economic evaluation; however, at least metronidazole, oral vancomycin, paromomycin, nitazoxanide and rifaximin should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. For any new chemical entity in the GI Antibiotic class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s) Alinia® metronidazole paromomycin Vancocin® Xifaxan®</p> <p>Non Preferred Agent (s) Dificid® Flagyl® Flagyl® ER neomycin Tindamax® tinidazole vancomycin</p>

Description of Recommendation	Final Decision (s)
<p><u>1st Generation Cephalosporins</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent(s) based on economic evaluation; however, at least cephalixin should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the First Generation Cephalosporin class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s) cefadroxil capsule cephalixin</p> <p>Non Preferred Agent (s) cefadroxil tablet, suspension Duricef® Keflex®</p>
<p><u>2nd Generation Cephalosporins</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent(s) based on economic evaluation; however, at least cefuroxime should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Second Generation Cephalosporin class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s) cefuroxime axetil</p> <p>Non Preferred Agent (s) Ceclor® Ceclor CD® cefaclor cefaclor CD cefprozil Ceftin® Cefzil®</p>
<p><u>3rd Generation Cephalosporins</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent(s) based on economic evaluation; however, at least cefixime, cefpodoxime and cefdinir should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Third Generation Cephalosporin class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s) cefdinir cefpodoxime Suprax® suspension, tablets</p> <p>Non Preferred Agent (s) Cedax® cefditoren pivoxil Omnicef® Spectracef® Suprax® capsules, chewable tablets Vantin®</p>

Description of Recommendation	Final Decision (s)
<p><u>Penicillins</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent(s) based on economic evaluation; however, at least amoxicillin, amoxicillin/clavulanate, ampicillin, dicloxacillin and penicillin V should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Penicillin class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s)</p> <p>amoxicillin amoxicillin/clavulanate tablets, suspension ampicillin dicloxacillin penicillin V</p> <p>Non Preferred Agent (s)</p> <p>amoxicillin/clavulanate chewable tablets amoxicillin/clavulanate ER Augmentin® Augmentin XR® Moxatag™</p>
<p><u>Tetracyclines</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent(s) based on economic evaluation; however, at least generic formulations of doxycycline, minocycline, and tetracycline should be preferred. 2. If demeclocycline is selected as non preferred, allow for its use in SIADH only. 3. Agents not selected as preferred will be considered non preferred and require PA. 4. For any new chemical entity in the Tetracycline class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s)</p> <p>demeclocycline doxycycline hyclate doxycycline monohydrate 50 mg, 75 mg, 100 mg capsules, tablets, suspension minocycline capsules tetracycline</p> <p>Non Preferred Agent (s)</p> <p>Adoxa® Adoxa® Pak Alodox® Convenience Pak Avidoxy® Doryx® Doxy® doxycycline hyclate DR tablets doxycycline monohydrate 150 mg capsules Dynacin® Minocin® minocycline tablets minocycline ER Monodox® Morgidox® Ocudox® Oracea™ Oraxyl® Solodyn® Vibramycin®</p>

Description of Recommendation	Final Decision (s)
<p><u>Ketolides</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent(s) based on economic evaluation. 2. Maintain prior authorization criteria for telithromycin to ensure this product is being used for multi-drug resistant infections only. 3. Continue current quantity limit (10 days supply per month). 4. For any new chemical entity in the Antibiotics: Ketolide class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s) Ketek®</p> <p>Non Preferred Agent (s) N/A</p>
<p><u>Ketek® Clinical Criteria</u></p> <p>Telithromycin (Ketek®) should be approved for a diagnosis of community-acquired pneumonia (CAP) IF:</p> <ul style="list-style-type: none"> • There has been previous use (within the past 28 days) of ONE of the following: <ul style="list-style-type: none"> ○ Penicillin (e.g., amoxicillin, amoxicillin-clavulanate, ampicillin-sulbactam, or piperacillin-tazobactam); OR ○ 2nd or 3rd generation cephalosporins (e.g., cefuroxime, cefpodoxime, cefprozil, cefotaxime, ceftriaxone); OR ○ Macrolide (e.g., azithromycin, clarithromycin, erythromycin); OR ○ Fluoroquinolone (e.g., levofloxacin, gatifloxacin, moxifloxacin); OR ○ Tetracycline (e.g., doxycycline); OR ○ Trimethoprim/sulfamethoxazole (e.g., Bactrim); AND • Request is NOT for more than a 10-day supply <p>**If Ketek was initiated in the hospital, approve to complete the course of antibiotic therapy</p>	<p>Telithromycin (Ketek®) will be approved for a diagnosis of community-acquired pneumonia (CAP) IF:</p> <ul style="list-style-type: none"> • There has been previous use (within the past 28 days) of ONE of the following: <ul style="list-style-type: none"> ○ Penicillin (e.g., amoxicillin, amoxicillin-clavulanate, ampicillin-sulbactam, or piperacillin-tazobactam); OR ○ 2nd or 3rd generation cephalosporins (e.g., cefuroxime, cefpodoxime, cefprozil, cefotaxime, ceftriaxone); OR ○ Macrolide (e.g., azithromycin, clarithromycin, erythromycin); OR ○ Fluoroquinolone (e.g., levofloxacin, gatifloxacin, moxifloxacin); OR ○ Tetracycline (e.g., doxycycline); OR ○ Trimethoprim/sulfamethoxazole (e.g., Bactrim); AND • Request is NOT for more than a 10-day supply <p>**If Ketek was initiated in the hospital, approve to complete the course of antibiotic therapy</p>

Description of Recommendation	Final Decision (s)
<p><u>Macrolides</u></p> <ol style="list-style-type: none"> DMS to select preferred agent(s) based on economic evaluation; however, at least three unique chemical entities should be preferred. Azithromycin suspension should be among the preferred products. Agents not selected as preferred will be considered non preferred and require PA. For any new chemical entity in the Antibiotics: Macrolides class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s) azithromycin clarithromycin erythromycin base tablets</p> <p>Non Preferred Agent (s) Biaxin® Biaxin XL® clarithromycin ER erythromycin base capsule DR PCE® Zithromax® Zmax®</p>
<p><u>Oxazolidinones</u></p> <ol style="list-style-type: none"> DMS to select preferred agent(s) based on economic evaluation; however, at least linezolid should be preferred. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. Continue appropriate quantity limits. For any new chemical entity in the Oxazolidinones class, require a PA and quantity limit until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s) Zyvox®</p> <p>Non Preferred Agent (s) N/A</p>
<p><u>Zyvox® Clinical Criteria</u></p> <p>Diagnoses to approve:</p> <ul style="list-style-type: none"> Vancomycin-Resistant Gram Positive Infections (VRE) via current culture and sensitivity testing for Enterococcus faecium or Enterococcus faecalis Methicillin-Resistant S. aureus Infections (MRSA) via current culture and sensitivity testing Empiric management of suspected MRSA infection without culture confirmation if any of the following are true: <ul style="list-style-type: none"> Previously documented MRSA infection; OR Previous cellulitis caused by documented MRSA; OR Skin and soft tissue infection with abscess; OR Patient has: <ul style="list-style-type: none"> Failed antibiotic therapy within the past month with any of the following: <ul style="list-style-type: none"> Tetracycline, or Sulfamethoxazole/trimethoprim, or Fluoroquinolone, or Clindamycin; AND 	<p>Diagnoses to approve:</p> <ul style="list-style-type: none"> Vancomycin-Resistant Gram Positive Infections (VRE) via current culture and sensitivity testing for Enterococcus faecium or Enterococcus faecalis Methicillin-Resistant S. aureus Infections (MRSA) via current culture and sensitivity testing Empiric management of suspected MRSA infection without culture confirmation if any of the following are true: <ul style="list-style-type: none"> Previously documented MRSA infection; OR Previous cellulitis caused by documented MRSA; OR Skin and soft tissue infection with abscess; OR Patient has: <ul style="list-style-type: none"> Failed antibiotic therapy within the past month with any of the following: <ul style="list-style-type: none"> Tetracycline, or

<ul style="list-style-type: none"> ▪ Presents with any of the following risk factors: <ul style="list-style-type: none"> • Health facility stay/visit (current or within the past month); or • Surgery in the past month; or • Participation in team sports (current or past month); or • Jail/Prison (current or in past month); or • Military (current or in past month); or • History of “spider bite” within the past month; or • Pediatrics enrolled in daycare or school (current or in past month); or • Multiple areas of induration; or • HIV; or • Permanent indwelling catheters; or • Percutaneous implanted device; or • Previously colonized with multi-drug resistant pathogens including MRSA; or • Diabetic foot ulcer; or • End stage renal disease. 	<ul style="list-style-type: none"> • Sulfamethoxazole/trimethoprim, or • Fluoroquinolone, or • Clindamycin; AND ▪ Presents with any of the following risk factors: <ul style="list-style-type: none"> • Health facility stay/visit (current or within the past month); or • Surgery in the past month; or • Participation in team sports (current or past month); or • Jail/Prison (current or in past month); or • Military (current or in past month); or • History of “spider bite” within the past month; or • Pediatrics enrolled in daycare or school (current or in past month); or • Multiple areas of induration; or • HIV; or • Permanent indwelling catheters; or • Percutaneous implanted device; or • Previously colonized with multi-drug resistant pathogens including MRSA; or • Diabetic foot ulcer; or • End stage renal disease.
--	--