FINAL DETERMINATION OF THE SECRETARY
OF THE CABINET FOR HEALTH AND FAMILY SERVICES
ACCEPTING THE RECOMMENDATION
OF THE PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

Pursuant to KRS 205.564(9) and 907 KAR 1:019, Section 8, after reviewing the recommendations of the Pharmacy and Therapeutics Advisory Committee made as a result of its discussions and meeting conducted on May 19, 2011, in Frankfort, Kentucky, and in consultation with the Department for Medicaid Services and any exceptions filed thereto in accordance with the provision of 907 KAR 1:019:

I hereby **ACCEPT** and **ADOPT** the Pharmacy and Therapeutics Advisory Committee's May 19, 2011 recommendations, which are attached hereto, with the exception of the requirement that a patient have a prerequisite dose of oral naltrexone prior to being given the drug Vivitrol, the reason for which is to put minimal obstacles in front of the product.

This determination is final and appealable.

SO ORDERED this the 23rd day of June 2011.

Janie Miller, Secretary
Cabinet for Health and Family Services
Commonwealth of Kentucky

Secretary for Health and Family Services Selections for Preferred Products

This is a summary of the final Preferred Drug List (PDL) selections made by the Secretary for Health and Family Services based on the May 19, 2011 Pharmacy and Therapeutics Advisory Committee (PTAC) Meeting.

Description of Recommendation	Final Decision (s)
New Products to Market: Edarbi™ Place this product non preferred with similar approval criteria in the PDL class titled Angiotensin Receptor Blockers.	Edarbi™ will be placed non preferred with similar approval criteria in the PDL class titled Angiotensin Receptor Blockers.
Pancreatic Enzymes 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one pancreatic enzyme product 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 Pancreatic Enzyme class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) Creon® pancrelipase **Non Preferred** Agent (s) Pancreaze™ Zenpep®
Antiparasitics, Topical 1. DMS to select preferred agent (s) based on economic evaluation; however, at least permethrin 5% cream and malathion 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 Antiparasitics class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) Eurax® Ovide® permethrin 5% cream **Non Preferred** Agent (s) Acticin® Elimite® lindane malathion Ulesfia™
Androgenic Agents 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one gel formulation 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 Androgenic Agents class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) Androderm® Androgel® **Non Preferred** Agent (s) Axiron® Fortesta® Testim®

Description of Recommendation	Final Decision (s)
Oral Steroids 1. DMS to select preferred agent (s) based on economic evaluation; however at least budesonide and generic formulations of dexamethasone, methylprednisolone, prednisolone and prednisone should be preferred. 2. The orally disintegrating formulation of prednisolone should be available for children < 12 years of age, and branded Orapred® liquid should be available for children < 6 years of age as a step edit. 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.	Selected **Preferred** Agent (s) cortisone dexamethasone Entocort EC® hydrocortisone methylprednisolone prednisolone prednisolone sodium phosphate prednisone Zema-Pak® **Non Preferred** Agent (s) Baycadron® Celestone® Celestone Soluspan® Cortef® DexPak® DexPak JR® Millipred® Orapred® Orapred ODT® Pediapred® Prelone® Veripred 20®
Makena® Clinical Criteria Makena® will be approved for members with a singleton pregnancy who have a history of singleton spontaneous preterm birth if: • Patient has experienced an adverse reaction to the compounded formulation of 17P hydroxyprogesterone caproate; OR • Trial and failure (through previous miscarriage or pre-term birth) of the compounded formulation of 17P hydroxyprogesterone caproate; OR • No access to a pharmacy which can compound 17P hydroxyprogesterone caproate.	**Makena® Clinical Criteria** Makena® will be approved for members with a singleton pregnancy who have a history of singleton spontaneous preterm birth if: • Patient has experienced an adverse reaction to the compounded formulation of 17P hydroxyprogesterone caproate; OR • Trial and failure (through previous miscarriage or pre-term birth) of the compounded formulation of 17P hydroxyprogesterone caproate; OR • No access to a pharmacy which can compound 17P hydroxyprogesterone caproate.

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Vivitrol® Clinical Criteria Vivitrol® will be approved if both of the following are true: • Diagnosis of: o Alcohol dependence; or o Opioid dependence; AND • Patient has had a lead in dose of oral naltrexone.	**Vivitrol® Clinical Criteria** Vivitrol® will be approved for a diagnosis of alcohol dependence or opioid dependence.
Leukotriene Receptor Antagonists Clinical Criteria Leukotriene Receptor Antagonists will be approved if ONE of the following are true: • Diagnosis of Asthma; OR • Diagnosis of Allergic Rhinitis o After trial and failure of a nasal steroid + an oral antihistamine; or o Patient is < 2 years of age. **Additionally a quantity limit of 1 per day will be applied to Singulair®, and a 2 per day quantity limit will be applied to Accolate® and zafirlukast. **	**Leukotriene Receptor Antagonists Clinical Criteria** Leukotriene Receptor Antagonists will be approved if ONE of the following are true: • Diagnosis of Asthma; OR • Diagnosis of Allergic Rhinitis o After trial and failure of a nasal steroid + an oral antihistamine; or o Patient is < 2 years of age. **Additionally a quantity limit of 1 per day will be applied to Singulair®, and a 2 per day quantity limit will be applied to Accolate® and zafirlukast. **
Clonidine Patches Clinical Criteria Clonidine patches will be approved if any one of the following is true: • Patient is <15 years old; OR • Patient cannot tolerate/absorb PO.	**Clonidine Patches Clinical Criteria** Clonidine patches will be approved if any one of the following is true: • Patient is <15 years old; OR • Patient cannot tolerate/absorb PO.
Regranex® Clinical Criteria Regranex® will be approved for a diagnosis of lower extremity diabetic ulcers.	**Regranex® Clinical Criteria** Regranex® will be approved for a diagnosis of lower extremity diabetic ulcers.
Granulocyte Colony Stimulating Factors Clinical Criteria Granulocyte Colony Stimulating Factors (Leukine® [sargramostim], Neulasta® [pegfilgrastim], or Neupogen® [filgrastim]), will be approved for a diagnosis of: • Myelosuppressive chemotherapy; OR • Induction or consolidation chemotherapy in acute myeloid/myelogenous leukemia; OR • Bone marrow transplantation; OR • Bone marrow transplant failure or engraftment delay; OR • Peripheral blood progenitor cell collection and therapy; OR • Severe chronic neutropenia.	**Granulocyte Colony Stimulating Factors Clinical Criteria** Granulocyte Colony Stimulating Factors (Leukine® [sargramostim], Neulasta® [pegfilgrastim], or Neupogen® [filgrastim]), will be approved for a diagnosis of: • Myelosuppressive chemotherapy; OR • Induction or consolidation chemotherapy in acute myeloid/myelogenous leukemia; OR • Bone marrow transplantation; OR • Bone marrow transplant failure or engraftment delay; OR • Peripheral blood progenitor cell collection and therapy; OR • Severe chronic neutropenia.

Description of Recommendation	Final Decision (s)
Urinary Tract Antispasmodics 1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities should be preferred. One should be liquid oxybutynin IR and the other should be fesoterodine ER. 2. Only patients who are unable to swallow or tolerate oral medications should be approved for non-oral formulations of agents in this class. 3. Continue current quantity limits on all agents in this class. 4. Agents not selected as preferred will be considered non preferred and require PA. 5. For any new chemical entity in the Urinary Tract Antispasmodic Class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) flavoxate oxybutynin Toviaz™ VESIcare® **Non Preferred** Agent (s) Detrol® Detrol LA® Ditropan XL® Enablex® Gelnique™ oxybutynin ER Oxytrol™ Sanctura® Sanctura XR® Trospium
Progestins for Cachexia 1. DMS to select preferred agent (s) based upon economic evaluation; however, at least one unique chemical entity must 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 Progestins for Cachexia class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) megestrol acetate **Non Preferred** Agent (s) Megace® Megace ES®
Angiotensin Receptor Blockers 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 Angiotensin Receptor Blocker class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) Diovan® ST losartan **Non Preferred** Agent (s) Atacand® Avapro® Benicar® Cozaar® Edarbi™ Micardis® Teveten®

Description of Recommendation	Final Decision (s)
Angiotensin Receptor Blockers + Diuretics 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 Angiotensin Receptor Blocker + Diuretic class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) Diovan HCT® ST losartan/HCTZ **Non Preferred** Agent (s) Atacand HCT® Avalide® Benicar HCT® Hyzaar® Micardis HCT® Teveten HCT®
Angiotensin Receptor Blockers + CCB (DHP) 1. DMS to select preferred agent (s) based on economic evaluation. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Angiotensin Receptor Blocker + CCB (DHP) class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) Exforge® Exforge HCT® **Non Preferred** Agent (s) Azor™ Tribenzor® Twynsta®
Angiotensin Modulators + CCB Combinations 1. DMS to select preferred agent (s) based on economic evaluation. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Angiotensin Modulators + CCB Combinations class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) Lotrel® **Non Preferred** Agent (s) amlodipine / benazepril Tarka® verapamil SR / trandolapril
Direct Renin Inhibitors 1. DMS to select preferred agent (s) based upon economic evaluation. 2. Agents not selected as preferred will be considered non-preferred and require prior authorization. 3. For any new chemical entity in the Direct Renin Inhibitor Class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) Amturnide™ Tekturna® Tekturna HCT® Tekamlo® Valturna® **Non Preferred** Agent (s) N/A
Direct Renin Inhibitor Clinical Criteria Direct Renin Inhibitors will be approved after trial and failure of an ACE Inhibitor or an ARB.	**Direct Renin Inhibitor Clinical Criteria** Direct Renin Inhibitors will be approved after trial and failure of an ACE Inhibitor or an ARB.

Description of Recommendation	Final Decision (s)
Alpha/Beta Blockers 1. DMS to select preferred agent (s) based on economic evaluation; however, at least carvedilol 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 Alpha/Beta Blockers class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) carvedilol labetalol **Non Preferred** Agent (s) Coreg® Coreg CR® Trandate®
Beta Blockers 1. DMS to select preferred agent (s) based on economic evaluation. At least two non-selective beta blockers, at least one of which should have ISA, should be preferred on the PDL. At least two cardioselective beta blockers, one of which should be metoprolol succinate, should be preferred on the PDL. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Beta Blockers class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) acebutolol atenolol betaxolol bisoprolol metoprolol succinate ER metoprolol tartrate nadolol pindolol propranolol propranolol LA sotalol timolol **Non Preferred** Agent (s) Betapace® Betapace® AF Bystolic® Corgard® Inderal® LA Innopran XL® Kerlone® Levatol® Lopressor® Sectral® Sorine® Tenormin® Toprol XL® Zebeta®

Description of Recommendation	Final Decision (s)
Beta Blocker + Diuretics 1. DMS to select preferred agent (s) based on economic evaluation; however, at least three combination products, one of which should contain metoprolol, 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 Beta Blocker + Diuretic class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) atenolol / chlorthalidone bisoprolol / HCTZ metoprolol / HCTZ nadolol / bendroflumethiazide propranolol / HCTZ **Non Preferred** Agent (s) Corzide® Lopressor® HCT Tenoretic® Ziac®
Calcium Channel Blockers (non-DHP) 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 Calcium Channel Blockers (Non-DHP) class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) diltiazem diltiazem ER verapamil verapamil ER **Non Preferred** Agent (s) Calan® Calan SR® Cardizem® Cardizem CD® Cardizem LA® Cartia XT® Covera-HS® Dilacor XR® Dilt CD® Dilt XR® Diltia XT® Taztia XT® Tiazac® verapamil ER PM Verelan® Verelan PM®

Description of Recommendation	Final Decision (s)
Vasodilator + Nitrate Combinations 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 Vasodilator and Nitrate Combinations class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) BiDil® **Non Preferred** Agent (s) N/A
Agents for Pulmonary Hypertension 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one agent representing each of the three mechanisms of action (prostacyclin and prostacyclin analogs, oral endothelin receptor antagonists and phosphodiesterase 5 inhibitors) should be preferred. 2. Sildenafil and tadalafil should be subject to prior authorization criteria to ensure they are being used for PAH. 3. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 4. Allow continuation of therapy for non preferred single source branded products via a 90 day look back. 5. For any new chemical entity in the Agents for Pulmonary Hypertension class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) Adcirca™ Letairis™ Revatio™ Tracleer® Ventavis® **Non Preferred** Agent (s) Tyvaso™
Flolan® Clinical Criteria Flolan® (IV epoprostenol) will be approved for a diagnosis of World Health Organization (WHO) functional class (FC) III or IV Pulmonary Arterial Hypertension (PAH).	**Flolan® Clinical Criteria** Flolan® (IV epoprostenol) will be approved for a diagnosis of World Health Organization (WHO) functional class (FC) III or IV Pulmonary Arterial Hypertension (PAH).
Sildenafil and Tadalafil Clinical Criteria Sildenafil and tadalafil will be approved for a diagnosis of Pulmonary Arterial Hypertension only. Non oral dosage forms will only be approved for patients who cannot tolerate/absorb medications by mouth.	**Sildenafil and Tadalafil Clinical Criteria** Sildenafil and tadalafil will be approved for a diagnosis of Pulmonary Arterial Hypertension only. Non oral dosage forms will only be approved for patients who cannot tolerate/absorb medications by mouth.

Description of Recommendation	Final Decision (s)
Platelet Inhibitors 1. DMS to select preferred agent (s) based on economic evaluation; however, at least three unique chemical entities should be preferred. Based on the clinical merits, place in therapy and utilization of clopidogrel, it must be a preferred agent. Prasugrel should also be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Platelet Inhibitors class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) Aggrenox® cilostazol dipyridamole Effient™ Plavix® ticlopidine **Non Preferred** Agent (s) Persantine® Pletal®
Bile Acid Sequestrants 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 Bile Acid Sequestrants class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) cholestyramine cholestyramine light WelChol® **Non Preferred** Agent (s) Colestid® colestipol Prevalite® Questran® Questran Light®
Cholesterol Absorption Inhibitors 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 Cholesterol Absorption Inhibitor class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) Zetia® **Non Preferred** Agent (s) N/A

Description of Recommendation	Final Decision (s)
Fibric Acid Derivatives 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one fenofibrate product 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 Fibric Acid Derivatives class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) gemfibrozil Tricor® Trilipix™ **Non Preferred** Agent (s) Antara™ fenofibrate Fibricor™ Lipofen™ Lofibra® Triglide™
Omega-3 Fatty Acids 1. DMS to select preferred agent (s) based on economic evaluation. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Omega-3 Fatty Acids class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) Lovaza® **Non Preferred** Agent (s) N/A
Lovaza® Clinical Criteria Lovaza® will be approved after trial and failure of either of the following: • fibric acid derivative; OR • statin	**Lovaza® Clinical Criteria** Lovaza® will be approved after trial and failure of either of the following: • fibric acid derivative; OR • statin
Statins 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 current quantity limits on agents in the class. 4. For any new chemical entity in the Low Potency Statins class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) Lescol® Lescol XL® lovastatin pravastatin **Non Preferred** Agent (s) Advicor™ Altoprev® Mevacor® Pravachol®

Description of Recommendation	Final Decision (s)
Statin + CCB Combination 1. DMS to select preferred agent (s) based on economic evaluation. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Statins + CCB Combinations class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) Caduet® **Non Preferred** Agent (s) N/A
Caduet® Clinical Criteria Caduet® will be approved for patients currently taking amlodipine who have had a trial and failure of ALL of the following: • simvastatin; AND • simvastatin / ezetimibe OR rosuvastatin. **Additionally a quantity limit of 1 per day will be applied. **	**Caduet® Clinical Criteria** Caduet® will be approved for patients currently taking amlodipine who have had a trial and failure of ALL of the following: • simvastatin; AND • simvastatin / ezetimibe OR rosuvastatin. **Additionally a quantity limit of 1 per day will be applied. **