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 July 19, 2012 Pharmacy and Therapeutics Advisory Committee (PTAC) Meeting.

Description of Recommendation	Final Decision (s)
New Products to Market: Jentadueto™ Place this product preferred with similar approval criteria and quantity limits in the PDL class titled Diabetes: DPP-4 Inhibitors.	Jentadueto™ will be placed preferred with similar approval criteria and quantity limits in the PDL class titled Diabetes: DPP-4 Inhibitors.
New Products to Market: Janumet® XR Place this product preferred with similar approval criteria and quantity limits in the PDL class titled Diabetes: DPP-4 Inhibitors.	Janumet® XR will be placed preferred with similar approval criteria and quantity limits in the PDL class titled Diabetes: DPP-4 Inhibitors.
New Products to Market: Kalydeco™ Kalydeco™ should have a quantity limit of 2 per day and only be approved if BOTH of the following are true: • Presence of specific *G551D* mutation in the CFTR gene; AND • Absence of homozygous *F508del* mutation in the CFTR gene.	Kalydeco™ will have a quantity limit of 2 per day and only be approved if BOTH of the following are true: • Presence of specific *G551D* mutation in the CFTR gene; AND • Absence of homozygous *F508del* mutation in the CFTR gene.
New Products to Market: Inlyta® Place this product preferred with similar quantity limits in the PDL class titled Oral Oncology Agents; however, only approve Inlyta® after confirmation of a diagnosis of renal cell carcinoma (RCC) and trial/failure of at least one systemic therapy (e.g. bevacizumab plus interferon alpha, temsirolimus, or cytokines).	Inlyta® will be placed preferred with similar quantity limits in the PDL class titled Oral Oncology Agents; however, Inlyta® will only be approved after confirmation of a diagnosis of renal cell carcinoma (RCC) and trial/failure of at least one systemic therapy (e.g. bevacizumab plus interferon alpha, temsirolimus, or cytokines).
New Products to Market: Erivedge™ Place this product preferred with similar quantity limits in the PDL class titled Oral Oncology Agents; however, only approve Erivedge™ for one of the following diagnoses: • Metastatic basal cell carcinoma; OR • Locally advanced basal cell carcinoma if: o There is recurrence following surgery; OR o Patient is not a candidate for surgery; OR o Patient is not a candidate for radiation therapy.	Erivedge™ will be placed preferred with similar quantity limits in the PDL class titled Oral Oncology Agents; however, Erivedge™ will only be approved for one of the following diagnoses: • Metastatic basal cell carcinoma; OR • Locally advanced basal cell carcinoma if: o There is recurrence following surgery; OR o Patient is not a candidate for surgery; OR o Patient is not a candidate for radiation therapy.

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New Products to Market: Bydureon® Place this product non preferred in the PDL class titled Diabetes: Incretin Mimetics.	Bydureon® will be placed non preferred in the PDL class titled Diabetes: Incretin Mimetics.
New Products to Market: Zioptan® Place this product non preferred with similar quantity limits in the PDL class titled Ophthalmic Prostaglandin Agonists.	Zioptan® will be placed non preferred with similar quantity limits in the PDL class titled Ophthalmic Prostaglandin Agonists.
New Products to Market: Omontys® Place this product non preferred in the PDL class titled Hematopoietic Agents; however, only approve Omontys® for a diagnosis of Chronic Kidney Disease (CKD) in patients on dialysis.	Omontys® will be placed non preferred in the PDL class titled Hematopoietic Agents; however, Omontys® will only be approved for a diagnosis of Chronic Kidney Disease (CKD) in patients on dialysis.
New Products to Market: Qnasl™ Place this product non preferred with appropriate quantity limits in the PDL class titled Corticosteroids, Intranasal.	Qnasl™ will be placed non preferred with appropriate quantity limits in the PDL class titled Corticosteroids, Intranasal.
New Products to Market: Potiga™ Place this product non preferred in the PDL class titled Anticonvulsants: Second Generation.	Potiga™ will be placed non preferred in the PDL class titled Anticonvulsants: Second Generation.

Description of Recommendation	Final Decision (s)
Xolair® (omalizumab) Clinical Criteria Xolair® (omalizumab) should be approved for a diagnosis of moderate to severe asthma (step 5 or higher) if ALL of the following are true: • Positive skin test or in vitro reactivity (RAST test) to a perennial aeroallergen; AND • FEV_1 of <80% while on asthma controller medication; AND • Has had failure of or contraindication to inhaled corticosteroid in combination with a second controller agent (such as a long-acting inhaled $beta_2$-agonist, ipratropium, leukotriene modifier, or theophylline) for a 60-day trial. Xolair® (omalizumab) should be approved for continuation of therapy for a diagnosis of moderate to severe asthma (step 5 or higher) if one of the following is true: • During previous treatment with Xolair®, the patient experienced a reduction in asthma exacerbations (e.g., hospitalizations, urgent or emergent care visits, use of rescue medications, etc.) from their pre-Xolair® baseline, OR • The patient was receiving maintenance therapy with an oral corticosteroid prior to initiation of Xolair® and the patient has been able to reduce their oral corticosteroid dose to less than their pre-Xolair® baseline or to ≤ 5 mg daily, OR • The patient was receiving maintenance therapy with an inhaled corticosteroid prior to initiation of Xolair® and the patient has been able to reduce their inhaled corticosteroid dose to less than their pre-Xolair® baseline.	Xolair® (omalizumab) will be approved for a diagnosis of moderate to severe asthma (step 5 or higher) if ALL of the following are true: • Positive skin test or in vitro reactivity (RAST test) to a perennial aeroallergen; AND • FEV_1 of <80% while on asthma controller medication; AND • Has had failure of or contraindication to inhaled corticosteroid in combination with a second controller agent (such as a long-acting inhaled $beta_2$-agonist, ipratropium, leukotriene modifier, or theophylline) for a 60-day trial. Xolair® (omalizumab) will be approved for continuation of therapy for a diagnosis of moderate to severe asthma (step 5 or higher) if one of the following is true: • During previous treatment with Xolair®, the patient experienced a reduction in asthma exacerbations (e.g., hospitalizations, urgent or emergent care visits, use of rescue medications, etc.) from their pre-Xolair® baseline, OR • The patient was receiving maintenance therapy with an oral corticosteroid prior to initiation of Xolair® and the patient has been able to reduce their oral corticosteroid dose to less than their pre-Xolair® baseline or to ≤ 5 mg daily, OR • The patient was receiving maintenance therapy with an inhaled corticosteroid prior to initiation of Xolair® and the patient has been able to reduce their inhaled corticosteroid dose to less than their pre-Xolair® baseline.

Description of Recommendation	Final Decision (s)
Lipotropics: High Potency Statins 1. DMS to select preferred agent(s) based on economic evaluation; however, at least simvastatin and EITHER atorvastatin or rosuvastatin should be preferred. 2. Continue quantity limits on agents in this class 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 High Potency Statin class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** atorvastatin simvastatin **Non Preferred Agent (s)** Crestor® Lipitor® Livalo® Vytorin™ Zocor®
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™ Tracleer® Ventavis® **Non Preferred Agent (s)** Revatio™ Tyvaso™
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 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)
Proton Pump Inhibitors 1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities should be preferred. Additionally, at least one dosage form suitable for pediatric use should be preferred. 2. Continue current quantity limits on all agents in this class. 3. Agents not selected as preferred will be considered non preferred and require PA. 4. For any new chemical entity in the Proton Pump Inhibitors class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** Nexium® omeprazole pantoprazole **Non Preferred Agent (s)** Aciphex® Dexilant™ lansoprazole omeprazole OTC omeprazole/sodium bicarbonate Prevacid® Prevacid 24-HR® Prilosec® Prilosec OTC® Protonix® Zegerid® OTC
Sedative Hypnotic Agents 1. DMS to select preferred agent(s) based on economic evaluation; however, at least four unique chemical entities should be preferred. One non-benzodiazepine sedative hypnotic should be among the preferred products. 2. Place quantity limits on agents in the category according to the FDA recommended maximum dose. 3. If ramelteon is not selected as preferred, it should be approved for patients with history of drug/alcohol dependence. 4. Agents not selected as preferred should be considered non preferred and require PA. 5. For any new chemical entity in the Sedative Hypnotic class, require a PA and quantity limit until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** chloral hydrate estazolam flurazepam temazepam 15 mg, 30 mg triazolam zolpidem **Non Preferred Agent (s)** Ambien® Ambien® CR Doral® Edluar® Halcion® Intermezzo® Lunesta™ Restoril® Rozerem™ temazepam 22.5 mg, 7.5 mg Silenor® Somnote® Sonata® zaleplon zolpidem ER Zolpimist™

Description of Recommendation	Final Decision (s)
Antibiotics: Quinolones 1. DMS to select preferred agent (s) based on economic evaluation; however, at least two agents, including either levofloxacin, gemifloxacin or moxifloxacin and either ciprofloxacin or ofloxacin, 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 Antibiotics: Quinolones class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** ciprofloxacin levofloxacin tablets **Non Preferred Agent (s)** Avelox® ciprofloxacin ER Cipro® Cipro XR® Factive® Levaquin® levofloxacin solution Noroxin® ofloxacin
Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) 1. DMS to select preferred agent(s) based upon economic evaluation; however, at least six unique chemical entities should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. Any new chemical entity in the NSAIDs class should require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** Celebrex® diclofenac potassium etodolac flurbiprofen ibuprofen indomethacin ketoprofen ketorolac tromethamine meloxicam tablets naproxen sodium naproxen tablets piroxicam sulindac **Non Preferred Agent (s)** Anaprox® Anaprox® DS Ansaid® Arthrotec® Cataflam® Clinoril® Daypro® diclofenac sodium diclofenac SR diflunisal Duexis® etodolac SR Feldene® fenoprofen

	Flector® Indocin® indomethacin ER ketoprofen ER meclofenamate mefenamic acid meloxicam suspension Mobic® nabumetone Nalfon® Naprelan® EC Naprosyn® Naprosyn® EC naproxen suspension naproxen EC oxaprozin Pennsaid® Ponstel® Sprix™ tolmetin Vimovo™ Voltaren® Gel Voltaren® XR Zipsor™
Topical Diclofenac Clinical Criteria Topical diclofenac products will be approved if ONE of the following is true: • Patient is unable to tolerate, swallow, or absorb oral NSAIDs; OR • Patient has a contraindication to an oral NSAID (e.g., GI bleed)	**Topical Diclofenac Clinical Criteria** Topical diclofenac products will be approved if ONE of the following is true: • Patient is unable to tolerate, swallow, or absorb oral NSAIDs; OR • Patient has a contraindication to an oral NSAID (e.g., GI bleed)

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Narcotics: Short-Acting 1. DMS to select preferred agent (s) based on economic evaluation; however, at least generic formulations of hydrocodone, meperidine and oxycodone 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 Narcotics: Short Acting class, require PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** butalbital compound / codeine codeine / APAP dihydrocodeine bitartrate / APAP / caffeine hydrocodone / APAP hydrocodone / ibuprofen hydromorphone meperidine morphine immediate-release oxycodone oxycodone / APAP oxycodone / ibuprofen oxymorphone IR tramadol **Non Preferred Agent (s)** codeine Capital® Combunox® Dazidox® Demerol® Dilaudid® Endocet® Endodan® Hycet® Ibudone™ Lazanda® levorphanol Lorcet® Lortab® Magnacet® Margesic H® Maxidone® Norco® Nucynta™ Opana® Oxecta® oxycodone / ASA OxyIR® Panlor SS® Percocet® Percodan® Primlev® Reprexain™

	Rybix™ ODT Synalgos DC® tramadol/acetaminophen Trezix® Tylenol #3® Tylenol #4® Tylox® Ultracet® Ultram® Vicodin® Vicodin ES® Vicodin HP® Vicoprofen® Xodol® Xolox® Zamicet™ Zolvit™
Narcotics: Long-Acting 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one long acting form of morphine 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 Long-Acting Narcotics class, require PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** fentanyl transdermal Kadian® methadone morphine sulfate controlled release **Non Preferred Agent (s)** Avinza™ Butrans™ ConZip™ Dolophine® Duragesic® Embeda™ Exalgo™ methadone concentrate morphine sulfate extended release (Generic for Kadian®) MS Contin® Nucynta® ER Opana® ER Oramorph® SR oxycodone controlled release OxyContin® oxymorphone ER Ryzolt™ tramadol extended release Ultram® ER

Description of Recommendation	Final Decision (s)
Fentanyl Transdermal Clinical Criteria Fentanyl transdermal will be approved for a diagnosis of chronic pain after trial and failure of extended/controlled release morphine.	**Fentanyl Transdermal Clinical Criteria** Fentanyl transdermal will be approved for a diagnosis of chronic pain after trial and failure of extended/controlled release morphine.
Butrans™ (buprenorphine) Clinical Criteria Butrans™ will be approved if all of the following are true: • Diagnosis of chronic pain; AND • Trial and failure of extended/controlled release morphine (Of note: failure does not necessarily mean lack of efficacy. It could mean intolerance due to allergy or side effects.); AND • Patient does not have a history of opioid addiction.	**Butrans™ (buprenorphine) Clinical Criteria** Butrans™ will be approved if all of the following are true: • Diagnosis of chronic pain; AND • Trial and failure of extended/controlled release morphine (Of note: failure does not necessarily mean lack of efficacy. It could mean intolerance due to allergy or side effects.); AND • Patient does not have a history of opioid addiction.
Topical Immunomodulators 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 Topical Immunomodulators, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** Elidel® **Non Preferred Agent (s)** Protopic®
Dermatologics: Antibiotic Agents 1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities, one of which should be mupirocin ointment, 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 Dermatologics Antibiotics class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** bacitracin ointment bacitracin zinc ointment bacitracin zinc, neomycin, polymyxin B sulfate ointment bacitracin zinc, neomycin, polymyxin B sulfate, pramoxine ointment bacitracin zinc, polymyxin B ointment gentamicin 0.1% cream, ointment mupirocin neomycin, polymyxin, pramoxine **Non Preferred Agent (s)** Altabax™ Bactroban® Centany®

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Ophthalmic Antihistamines 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 Ophthalmic Antihistamines class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** Pataday™ **Non Preferred Agent (s)** azelastine Bepreve™ Elestat™ Emadine® epinastine Lastacaft™ Optivar® Patanol®
Ophthalmic Mast Cell Stabilizers 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 Ophthalmic Mast Cell Stabilizers class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** cromolyn **Non Preferred Agent (s)** Alamast® Alocril® Alomide® Crolom®
Ophthalmic Sympathomimetics 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 Ophthalmic Sympathomimetics class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** apraclonidine brimonidine **Non Preferred Agent (s)** Alphagan P® Iopidine®
Ophthalmic Prostaglandin Agonists 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. Continue current quantity limits on agents in this class. 4. For any new chemical entity in the Ophthalmic Prostaglandin Agonists class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** latanoprost **Non Preferred Agent (s)** Lumigan® Xalatan® Travatan Z® Zioptan®

Description of Recommendation	Final Decision (s)
Alpha Blockers for BPH 1. DMS to select preferred agent (s) based on economic evaluation; however, at least two agents, one of which should be highly selective for the alpha receptors in the genitourinary tract, 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 Blockers for BPH class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** alfuzosin doxazosin tamsulosin terazosin **Non Preferred Agent (s)** Cardura® Cardura XL® Flomax® Hytrin® Rapaflo™ Uroxatral®
Otic Anti-Infective & Anesthetic 1. DMS to select preferred agent (s) based on economic evaluation; however, at least three 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 Otic Anti-Infective & Anesthetic class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** acetic acid acetic acid in aluminum acetate antipyrine/benzocaine pramoxine/hydrocortisone **Non Preferred Agent (s)** acetic acid/hydrocortisone Aurax® Myoxin® Neotic® Otic Care® Otozin™ Pinnacaine® Pramotic® Pramotic® HC PR Otic® Treagan® Trioxin® Vosol® Vosol® HC Zinotic® Zinotic® ES

Description of Recommendation	Final Decision (s)
GI Antibiotics 1. DMS to select preferred agent (s) based upon economic evaluation; however, at least metronidazole, oral vancomycin and nitazoxanide 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.	**Selected Preferred Agent (s)** Alinia® tablets metronidazole tablets vancomycin **Non Preferred Agent (s)** Alinia® suspension Dificid® Flagyl® Flagyl® ER metronidazole capsules neomycin Neo-Fradin® Tindamax® tinidazole Xifaxan® Vancocin®
Xifaxan® Clinical Criteria Xifaxan® will be approved if ONE of the following is true: • Diagnosis of travelers diarrhea caused by non-invasive strains of E. coli after trial and failure of ciprofloxacin (three day course of therapy only); OR • Diagnosis of hepatic encephalopathy after trial and failure of lactulose OR neomycin.	Xifaxan® will be approved if ONE of the following is true: • Diagnosis of travelers diarrhea caused by non-invasive strains of E. coli after trial and failure of ciprofloxacin (three day course of therapy only); OR • Diagnosis of hepatic encephalopathy after trial and failure of lactulose OR neomycin.

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Oral Anti-Arrhythmics 1. DMS to select preferred agent (s) based on economic evaluation; however, at least five unique chemical entities 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 Oral Antiarrhythmics class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** amiodarone 200 mg disopyramide flecainide mexiletine procainamide propafenone quinidine gluconate quinidine sulfate quinidine sulfate CR Tikosyn® **Non Preferred Agent (s)** amiodarone 400 mg Cordarone® Multaq® Norpace® Norpace® CR Pacerone® Pronestyl® propafenone sustained-release Rythmol® Rythmol® SR Tambocor®