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 March 17, 2011 Pharmacy and Therapeutics Advisory Committee (PTAC) Meeting.

Description of Recommendation	Final Decision (s)
Branded Products with Generic Components Require prior authorization for the following products: • Nexiclon® XR • Millipred®	The following products will require prior authorization: • Nexiclon® XR • Millipred®
New Products to Market: Pradaxa® Dabigatran will be approved for a diagnosis of non valvular atrial fibrillation via an ICD-9 Override.	Pradaxa® will be approved for a diagnosis of atrial fibrillation.
New Products to Market: XGeva™ Denosumab (XGeva™) will be approved for a diagnosis of bone metastases resulting from solid tumors only.	XGeva™ will be approved for a diagnosis of bone metastases resulting from solid tumors only.
New Products to Market: Kombiglyze™ XR Place this product preferred with similar approval criteria and quantity limits in the PDL class titled Diabetes: DPP-4 Inhibitors.	Kombiglyze™ 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: Silenor® Place this product non preferred with similar quantity limits in the PDL class titled Sedative Hypnotic Agents.	Silenor® will be placed non preferred with similar quantity limits in the PDL class titled Sedative Hypnotic Agents.
New Products to Market: Latuda® Place this product non preferred with similar approval criteria and quantity limits in the PDL class titled Antipsychotic: Atypical.	Latuda® will be placed non preferred with similar approval criteria and quantity limits in the PDL class titled Antipsychotic: Atypical.
New Products to Market: Kapvay™ Place this product non preferred with similar approval criteria and quantity limits in the PDL class titled Antihyperkinesis Agents.	Kapvay™ will be placed non preferred with similar approval criteria and quantity limits in the PDL class titled Antihyperkinesis Agents.
New Products to Market: Butrans™ Place this product non preferred in the PDL class titled Narcotics: Long Acting.	Butrans™ will be placed non preferred in the PDL class titled Narcotics: Long Acting.
New Products to Market: Lastacaft® Place this product non preferred in the PDL class titled Ophthalmic Antihistamines.	Lastacaft® will be placed non preferred in the PDL class titled Ophthalmic Antihistamines.
New Products to Market: Amturnide™ Place this product preferred with similar approval criteria in the PDL class titled Direct Renin Inhibitors.	Amturnide™ will be placed preferred with similar approval criteria in the PDL class titled Direct Renin Inhibitors.

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Second Generation Anticonvulsants 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 require prior authorization. 3. Require therapeutic failure of one preferred agent prior to approval of a non-preferred agent. 4. Non preferred products will continue to require a tier 1 co-payment for generics and a tier 2 co-payment for branded products. 5. For any agent not selected as preferred, DMS to allow continuation of therapy if there is a paid claim in the past 90 days. 6. For any new chemical entity in the Anticonvulsants: Second Generation class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) Banzel® CC Felbatol® Gabitril® gabapentin lamotrigine levetiracetam Lyrica® CC Sabril® CC topiramate zonisamide **Non Preferred** Agent (s) Keppra™ Keppra XR™ Lamictal® Lamictal ODT® Lamictal XR® Neurontin® Topamax® Vimpat® Zonegran®
Banzel® Clinical Criteria Banzel® will be approved if: • Diagnosis of Lennox-Gastaut syndrome; OR • Trial and failure of one other anticonvulsant.	**Banzel® Clinical Criteria** Banzel® will be approved if: • Diagnosis of Lennox-Gastaut syndrome; OR • Trial and failure of one other anticonvulsant.
Lyrica® Clinical Criteria Lyrica® will be approved if any ONE of the following are true: • Diabetic Peripheral Neuropathy (DPN); OR • Postherpetic Neuralgia (PHN) AFTER adequate trial and failure of OR intolerance OR contraindication to at least one of these first-line agents o Tricyclic antidepressant (TCAs); or o Anticonvulsant: gabapentin; or o Topical: Lidocaine 5% patch. • Adjunct for partial onset seizure disorder; OR • Fibromyalgia.	**Lyrica® Clinical Criteria** Lyrica® will be approved if any ONE of the following are true: • Diabetic Peripheral Neuropathy (DPN); OR • Postherpetic Neuralgia (PHN) AFTER adequate trial and failure of OR intolerance OR contraindication to at least one of these first-line agents o Tricyclic antidepressant (TCAs); or o Anticonvulsant: gabapentin; or o Topical: Lidocaine 5% patch. • Adjunct for partial onset seizure disorder; OR • Fibromyalgia.
Sabril™ Clinical Criteria Sabril™ will be approved if: • Diagnosis of infantile spasms; OR • Trial and failure of one other anticonvulsant.	**Sabril™ Clinical Criteria** Sabril™ will be approved if: • Diagnosis of infantile spasms; OR • Trial and failure of one other anticonvulsant.

Description of Recommendation	Final Decision (s)
Anticonvulsants, Carbamazepine Derivatives 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 prior authorization. 3. Require therapeutic failure of one preferred agent prior to approval of a non-preferred agent. 4. Non preferred products will continue to require a tier 1 co-payment for generics and a tier 2 co-payment for branded products. 5. For any agent not selected as preferred, DMS to allow continuation of therapy if there is a paid claim in the past 90 days. 6. For any new chemical entity in the Anticonvulsants: Carbamazepine Derivatives class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) Carbatrol® carbamazepine carbamazepine XR Equetro™ oxcarbazepine **Non Preferred** Agent (s) Tegretol® Tegretol® XR Trileptal®
Oral Oncology Agents 1. Rename this class Oral Oncology Agents. 2. DMS to select preferred agent(s) based on economic evaluation; however, at least one oral agent representing a first-line recommendation by the NCCN for each cancer type should be preferred. Due to new data on the treatment of CML, both imatinib and EITHER dasatinib OR nilotinib should be preferred. 3. Continue quantity limits based on FDA-approved maximum dose. 4. Agents not selected as preferred will be considered non preferred and require PA. 5. All agents in the category will have no higher than a tier 2 copay regardless of PDL status. 6. DMS to allow continuation of therapy for existing users of non preferred single-source branded products via a 90 day look back. 7. For any new chemical entity in the Oral Oncology Agents class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) Gleevec® Iressa® Nexavar® Sprycel® Sutent® Tarceva® Tykerb® Xeloda® **Non Preferred** Agent (s) Afinitor® Tasigna® Votrient®

Description of Recommendation	Final Decision (s)
Anticoagulants 1. Rename this class Anticoagulants. 2. DMS to select preferred agent (s) based on economic evaluation; however, at least one low molecular weight heparin, one factor Xa inhibitor and warfarin should be preferred. 3. Agents not selected as preferred will be considered non preferred and require PA. 4. For any new chemical entity in the Anticoagulants class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) Arixtra™ Fragmin® Lovenox® Pradaxa® CC warfarin **Non Preferred** Agent (s) Coumadin® enoxaparin Innohep®
Oral Agents for Gout 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 Oral Agents for Gout class, require a PA until reviewed by the P&T Advisory Committee.	Selected **Preferred** Agent (s) allopurinol probenecid probenecid/colchicine **Non Preferred** Agent (s) Colcrys™ Uloric® Zyloprim®
Uloric® Clinical Criteria Uloric® will be approved after adequate trial (at least 3 months) of allopurinol without achievement of serum urate level below 6mg/dL **OR** intolerance **OR** contraindication to allopurinol.	**Uloric® Clinical Criteria** Uloric® will be approved after adequate trial (at least 3 months) of allopurinol without achievement of serum urate level below 6mg/dL **OR** intolerance **OR** contraindication to allopurinol.
Colcrys™ Clinical Criteria Colcrys™ will be approved if any one of the following is true: • Diagnosis of Familial Mediterranean Fever; OR • Trial and failure, via an electronic step edit, of one of the following: o NSAID (i.e., indomethacin, naproxen, ibuprofen, sulindac, ketoprofen) or o Corticosteroid.	**Colcrys™ Clinical Criteria** Colcrys™ will be approved if any one of the following is true: • Diagnosis of Familial Mediterranean Fever; OR • Trial and failure of one of the following: o NSAID (i.e., indomethacin, naproxen, ibuprofen, sulindac, ketoprofen) or o Corticosteroid.
Prenatal Vitamins Clinical Criteria Prenatal vitamins will be approved if one of the following is true: • Patient must be female and claim must be submitted with pregnancy indicator; OR • Patient is actively nursing; OR • Patient suffers from a chronic condition associated with wasting (i.e., HIV) or malabsorption.	**Prenatal Vitamins Clinical Criteria** Prenatal vitamins will be approved if one of the following is true: • Patient must be female and claim must be submitted with pregnancy indicator; OR • Patient is actively nursing; OR • Patient suffers from a chronic condition associated with wasting (i.e., HIV) or malabsorption.

Description of Recommendation	Final Decision (s)
Cymbalta® Clinical Criteria Cymbalta® will be authorized for the following diagnoses: • Depression/Major Depressive Disorder/Generalized Anxiety Disorder/Social Anxiety Disorder/Panic Disorder: Approval after trial and failure or intolerance or contraindication to one preferred SNRI. • Diabetic peripheral neuropathic pain via an ICD-9 Override • Fibromyalgia via an ICD-9 Override • Chronic musculoskeletal pain: Approval after trial and failure of or intolerance or contraindication to one NSAID.	**Cymbalta® Clinical Criteria** Cymbalta® will be authorized for the following diagnoses: • Depression/Major Depressive Disorder/Generalized Anxiety Disorder/Social Anxiety Disorder/Panic Disorder: Approval after trial and failure or intolerance or contraindication to one preferred SNRI. • Diabetic peripheral neuropathic pain • Fibromyalgia • Chronic musculoskeletal pain: Approval after trial and failure of or intolerance or contraindication to one NSAID.