



**CABINET FOR HEALTH AND FAMILY SERVICES
DEPARTMENT FOR MEDICAID SERVICES**

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May 24, 2013

Pharmacy and Therapeutics Advisory Committee (PTAC):

The Department has reviewed the PTAC recommendations as a result of the last meeting held on March 21, 2013. I have outlined the results of our review below:

Therapeutic Agents Class Review

Accepted 19 of 19 Therapeutic Class PTAC recommendations:

Accepted 14 of 14 Therapeutic Class PTAC recommendations where No Difference was noted from the Magellan Medicaid Administration (MMA) recommendation.

Accepted 5 of 5 Therapeutic Class PTAC recommendations where a Difference was noted from the MMA recommendation.

New Products to Market

Accepted 9 of 10 New Products to Market PTAC recommendations.

Declined 1 of 10 New Products to Market recommendations regarding Xeljanz (tofacitinib).

Xeljanz is the first Janase kinase inhibitor. Currently, Xeljanz is not considered by practice standards to be a first-line agent. There are a very limited number of peer reviewed studies regarding Xeljanz in comparison to the more commonly used immunomodulators. These limited studies indicate that Xeljanz works about as well as TNF inhibitors such as Humira and has many of the same risks like tuberculosis and other serious infections.

Due to its additional safety concerns Xeljanz will likely be used after TNF inhibitors. Of particular mention, Xeljanz can increase cholesterol and liver enzymes and lower blood cell counts. Thus, it is currently recommended with this product to conduct regular monitoring beyond those suggested with the use of Enbrel and Humira. In addition, at this time net cost appears to be greater for Xeljanz than other commonly used products having similar therapeutic indication.

We will adopt the MMA's recommendation to place Xeljanz as a Tier 3 non-preferred product choice. First line, the member must try a Disease Modifying Antirheumatic Drug (DMARD) such as methotrexate. Second line, after a 3 month DMARD trial, a member could be prescribed a Tier 2 medication, such as Enbrel or Humira. Third line, having failed a Tier 2 product, the member can be prescribed Xeljanz, a Tier 3 non-preferred product.

Again, we appreciate the efforts and insight of our PTAC members.

Kindest Regards,



Samantha McKinley, B.S., J.D., D.C., Pharm.D.

Department for Medicaid Services

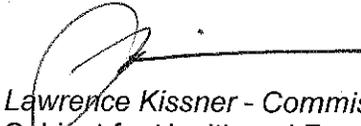
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Lawrence Kissner - Commissioner

Cabinet for Health and Family Services

Department for Medicaid Services

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**FINAL DETERMINATION OF THE COMMISSIONER OF THE DEPARTMENT FOR
MEDICAID SERVICES OF THE KENTUCKY CABINET FOR HEALTH AND FAMILY
SERVICES CONCERNING THE RECOMMENDATION OF THE
PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE FROM ITS
MARCH 21, 2013 ADVISORY MEETING**

Pursuant to KRS 205.564(9) and 907 KAR 1:019, Section 8, I have reviewed the following information: (1) the recommendations of the Pharmacy and Therapeutics Advisory Committee ("P&T Committee") made as a result of its discussions and meeting conducted on March 21, 2013 in Frankfort, Kentucky and in consultation the Department for Medicaid Services and any exceptions filed thereto in accordance with the provisions of 907 KAR 1:019. With the exception noted below, I hereby accept and adopt all recommendations of the Pharmacy and Therapeutics Advisory Committee made at its March 21, 2013 meeting as evidenced by the attachment hereto which is incorporated as though fully set out herein.

The Department advises that the P&T Committee recommendation to place the drug Xeljanz™ (manufactured by Pfizer) on the preferred list not be accepted. Based on the Department's recommendation, I do not accept the P&T Committee recommendation on Xeljanz. Rather, Xeljanz will be placed in the non preferred group with appropriate quantity limits and similar approval criteria in the PDL class titled Immunomodulators. Xeljanz will be approved after trial and failure of one preferred Immunomodulator. The reasoning for this is as follows:

1. Xeljanz is the first Janus kinase inhibitor. Currently, Xeljanz is not considered by practice standards to be a first-line agent.
2. There are a very limited number of peer reviewed studies regarding Xeljanz in comparison to the more commonly used immunomodulators. These limited studies

indicate that Xeljanz works about as well as TNF inhibitors such as Humira and has many of the same risks like tuberculosis and other serious infections.

3. Due to its additional safety concerns Xeljanz will likely be used after TNF inhibitors. Of particular mention, Xeljanz can increase cholesterol and liver enzymes, and lower blood cell counts. Thus, it is currently recommended with this product to conduct regular monitoring beyond those suggested with the use of Enbrel and Humira.
4. Further, a dose reduction is required for patients taking potent CYP3A4 inhibitors or drugs that are both moderate CYP3A4 inhibitors and potent CYP2C19 inhibitors, like fluconazole.
5. Also, at this time the net cost appears greater for Xeljanz as compared to cost per prescription for other commonly used products with similar therapeutic indication.

This determination is final and appealable.

SO ORDERED this the 31 day of May, 2013.



Lawrence Kissner, Commissioner
Cabinet for Health and Family Services
Department for Medicaid Services

**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 March 21, 2013 Pharmacy and Therapeutics Advisory Committee (PTAC) Meeting.

Description of Recommendation	Final Decision (s)
<p><u>New Products to Market: Stivarga®</u> Place this product preferred with similar quantity limits in the PDL class titled Oral Oncology Agents; however, only approve Stivarga® for:</p> <ul style="list-style-type: none"> • A diagnosis of metastatic colorectal cancer (mCRC) after trial and failure of all of the following: <ul style="list-style-type: none"> ○ Fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy; AND ○ An anti-VEGF therapy, AND ○ If KRAS wild type, an anti-EGFR therapy; OR • A diagnosis of gastrointestinal stromal tumors (GIST) after trial and failure of one preferred oral oncology agent that is FDA-approved for GIST. 	<p>Stivarga® will be placed preferred with similar quantity limits in the PDL class titled Oral Oncology Agents; however, Stivarga® will only be approved for:</p> <ul style="list-style-type: none"> • A diagnosis of metastatic colorectal cancer (mCRC) after trial and failure of all of the following: <ul style="list-style-type: none"> ○ Fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy; AND ○ An anti-VEGF therapy, AND ○ If KRAS wild type, an anti-EGFR therapy; OR • A diagnosis of gastrointestinal stromal tumors (GIST) after trial and failure of one preferred oral oncology agent that is FDA-approved for GIST.
<p><u>New Products to Market: Vascepa®</u> Place this product non preferred with similar approval criteria in the PDL class titled Lipotropics: Omega-3 Fatty Acids.</p>	<p>Vascepa® will be placed non preferred with similar approval criteria in the PDL class titled Lipotropics: Omega-3 Fatty Acids.</p>
<p><u>New Products to Market: Prepopik™</u> Place this product non preferred in the PDL class titled Laxative and Cathartics.</p>	<p>Prepopik™ will be placed non preferred in the PDL class titled Laxative and Cathartics.</p>
<p><u>New Products to Market: Linzess™</u> Place this product non preferred in the PDL class titled Laxatives and Cathartics.</p>	<p>Linzess™ will be placed non preferred in the PDL class titled Laxatives and Cathartics.</p>
<p><u>New Products to Market: Ultresa™</u> Place this product non preferred in the PDL class titled Pancreatic Enzymes.</p>	<p>Ultresa™ will be placed non preferred in the PDL class titled Pancreatic Enzymes.</p>
<p><u>New Products to Market: Xeljanz™</u> Place this product preferred with appropriate quantity limits and similar approval criteria in the PDL class titled Immunomodulators.</p>	<p>Xeljanz™ will be placed non preferred with appropriate quantity limits and similar approval criteria in the PDL class titled Immunomodulators.</p> <p>Xeljanz™ will be approved after trial and failure of one preferred Immunomodulator.</p>
<p><u>New Products to Market: Eliquis®</u> Place this product non preferred in the PDL class titled Anticoagulants.</p>	<p>Eliquis® will be placed non preferred in the PDL class titled Anticoagulants.</p>

Description of Recommendation	Final Decision (s)
<p><u>New Products to Market: Iclusig™</u> Place this product non preferred with similar quantity limits in the PDL class titled Oral Oncology Agents.</p>	<p>Iclusig™ will be placed non preferred with similar quantity limits in the PDL class titled Oral Oncology Agents.</p>
<p><u>New Products to Market: Aubagio®</u> Place this product non preferred with appropriate quantity limits in the PDL class titled Multiple Sclerosis Agents.</p>	<p>Aubagio® will be placed non preferred with appropriate quantity limits in the PDL class titled Multiple Sclerosis Agents.</p>
<p><u>Multiple Sclerosis Agents</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least glatiramer, one interferon β-1b and one interferon β-1a product should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. Place quantity limits on these products based on maximum recommended dose. 4. For any new chemical entity in the Multiple Sclerosis Agents class, require a PA and quantity limit until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s) Betaseron® Copaxone® Rebit®</p> <p>Non Preferred Agent (s) Avonex® Ampyra™ Aubagio® Extavia® Gilenya™</p>
<p><u>New Generation Antidepressants</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent(s) based upon economic evaluation; however, at least bupropion and trazodone 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 New Generation Antidepressants class should require a PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s) bupropion bupropion SR mirtazapine nefazodone trazodone</p> <p>Non Preferred Agent (s) Aplenzin™ bupropion ER/XL Forfivo XL® mirtazapine ODT Olepto™ Remeron® Wellbutrin® Wellbutrin® XL Wellbutrin® SR</p>

Description of Recommendation	Final Decision (s)
<p><u>Tricyclic Antidepressants</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent(s) based upon economic evaluation; however, at least four 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 Tricyclic Antidepressants class should require a PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s)</p> <ul style="list-style-type: none"> amitriptyline clomipramine desipramine imipramine maprotiline nortriptyline <p>Non Preferred Agent (s)</p> <ul style="list-style-type: none"> Anafranil[®] amoxapine doxepin imipramine pamoate Norpramin[®] Pamelor[®] protriptyline Tofranil[®] Tofranil-PM[®] trimipramine Surmontil[®] Vivactil[®]
<p><u>Antimigraine: 5-HT1 Receptor Agonists</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. At least one non-oral dosage form should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. Agents in this class should have quantity limits based on the FDA-approved maximum dose and duration. 4. As part of quantity limit override criteria, patients should be on concurrent migraine prophylaxis therapy (beta blocker, tricyclic antidepressant, calcium channel blocker, etc.) at a therapeutic dose. 5. For any new chemical entity in the Anti-Migraine: 5-HT1 Receptor Agonists class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s)</p> <ul style="list-style-type: none"> sumatriptan <p>Non Preferred Agent (s)</p> <ul style="list-style-type: none"> Alsuma[™] Amerge[®] Axert[®] Cambia[™] Frova[™] Imitrex[®] Maxalt[®] / Maxalt-MLT[®] naratriptan Relpax[™] Sumavel[™] Dosepro[™] Treximet[™] Zomig[®] / Zomig-ZMT[®]

Description of Recommendation	Final Decision (s)
<p><u>Anxiolytics</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent(s) based upon economic evaluation; however, at least five unique chemical entities, one of which is not a controlled substance, 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 Anxiolytics class should require a PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s)</p> <p>alprazolam buspirone chlordiazepoxide clorazepate diazepam lorazepam oxazepam</p> <p>Non Preferred Agent (s)</p> <p>alprazolam ER alprazolam ODT Ativan[®] meprobamate Niravam[®] Tranxene-T[®] Valium[®] Vistaril[®] Xanax[®] Xanax ER[®]</p>
<p><u>Anxiolytics Duration Edit</u></p> <p>Benzodiazepines, with the exception of clonazepam, should be available without requiring a prior authorization for the initial 60 days per a 365 day period. For therapy beyond 60 days, prior authorization should be required and approved if requested by the prescriber as follows:</p> <ul style="list-style-type: none"> • Approve for 6 months for the following diagnoses: <ul style="list-style-type: none"> ▪ Anxiety ▪ Anxiety disorder ▪ Panic attacks/disorder ▪ Agoraphobia ▪ Social phobia ▪ Depression ▪ Chemotherapy-induced nausea & vomiting ▪ Status epilepticus • Approve for 1 month for a diagnosis of acute alcohol withdrawal • Approve for 1 year for a diagnosis of seizures. 	<p><u>Anxiolytics Duration Edit</u></p> <p>Benzodiazepines, with the exception of clonazepam, will be available without requiring a prior authorization for the initial 60 days per a 365 day period. For therapy beyond 60 days, prior authorization will be required and approved if requested by the prescriber as follows:</p> <ul style="list-style-type: none"> • Approve for 6 months for the following diagnoses: <ul style="list-style-type: none"> ▪ Anxiety ▪ Anxiety disorder ▪ Panic attacks/disorder ▪ Agoraphobia ▪ Social phobia ▪ Depression ▪ Chemotherapy-induced nausea & vomiting ▪ Status epilepticus • Approve for 1 month for a diagnosis of acute alcohol withdrawal • Approve for 1 year for a diagnosis of seizures.

Description of Recommendation	Final Decision (s)
<p><u>Alzheimer's: Cholinesterase 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. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. Allow continuation of therapy for non preferred single-source branded products. 4. For any new chemical entity in the Alzheimer's: Cholinesterase Inhibitors class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s) donepezil Exelon[®] Patch galantamine rivastigmine</p> <p>Non Preferred Agent (s) Aricept[®] Aricept[®] ODT donepezil ODT Exelon[®] galantamine ER Razadyne[®] Razadyne ER[®]</p>
<p><u>Alzheimer's: NMDA Receptor Antagonists</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 will require Prior Authorization. 3. For any new chemical entity in the NMDA Receptor Antagonist class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s) Namenda[®]</p> <p>Non Preferred Agent (s) N/A</p>
<p><u>Antialcoholic Agents</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent(s) based upon economic evaluation; however, at least two unique chemical entities, one of which should be intramuscular naltrexone, 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 Antialcoholic Agents class should require a PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s) Campral[®] naltrexone Vivitrol[®]</p> <p>Non Preferred Agent (s) Antabuse[®] disulfiram Depade[®] ReVia[®]</p>

Description of Recommendation	Final Decision (s)
<p><u>Narcolepsy Agents</u></p> <ol style="list-style-type: none"> 1. Move modafinil and armodafinil products into this PDL class. 2. DMS to select preferred agent(s) based upon economic evaluation; however, at least one unique chemical entity should be preferred. 3. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 4. Continue current quantity limits on agents in this class. 5. Any new chemical entity in the Narcolepsy Agents class should require a PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s) Provigil[®]</p> <p>Non Preferred Agent (s) modafinil Nuvigil[®] Xyrem[®]</p>
<p><u>Skeletal Muscle Relaxants</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least four unique chemical entities, two typically used for spasticity and two typically used as an antispasmodic, should be preferred. Carisoprodol can be considered an inferior product in this category due to abuse potential; therefore, it should be non preferred and require PA. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. Continue current quantity limits on agents in this category based on FDA maximum recommended dose and duration. 4. For any new chemical entity in the Skeletal Muscle Relaxants class, require PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s) baclofen chlorzoxazone cyclobenzaprine dantrolene sodium methocarbamol orphenadrine citrate orphenadrine compound tizanidine tablets</p> <p>Non Preferred Agent (s) Amrix[®] carisoprodol carisoprodol compound cyclobenzaprine ER Dantrium[®] Fexmid[®] Flexeril[®] Lioresal[®] Lorzone[®] metaxalone methocarbamol / aspirin Parafon Forte DSC[®] Robaxin[®] Skelaxin[®] Soma[®] tizanidine capsules Zanaflex[®]</p>

Description of Recommendation	Final Decision (s)
<p><u>Tobacco Cessation</u></p> <ol style="list-style-type: none"> 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. Continue quantity limits on drugs in this class based on maximum FDA-approved dose. 4. For any new chemical entity in the Tobacco Cessation class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s)</p> <p>bupropion SR Chantix[®] nicotine buccal/gum nicotine lozenge nicotine transdermal</p> <p>Non Preferred Agent (s)</p> <p>Nicoderm CQ[®] Nicorette[®] Nicorette[®] lozenge Nicotrol[®] Inhaler Nicotrol[®] NS Zyban[®]</p>
<p><u>Dopamine Receptor Agonists</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 will require Prior Authorization. 3. For any new chemical entity in the Dopamine Receptor Agonists class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s)</p> <p>bromocriptine pramipexole ropinirole</p> <p>Non Preferred Agent (s)</p> <p>Mirapex[®] Mirapex[®] ER Neupro[®] Parlodel[®] Requip[®] Requip[®] XL ropinirole ER</p>
<p><u>Anticholinergics, Parkinson's</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least benztropine 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 Anticholinergics, Parkinson's disease class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s)</p> <p>benztropine trihexyphenidyl</p> <p>Non Preferred Agent (s)</p> <p>N/A</p>

Description of Recommendation	Final Decision (s)
<p><u>Catechol-O-Methyltransferase (COMT) Inhibitors</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least entacapone should be preferred. Tolcapone can be considered an inferior product in this category due to potential liver toxicity; therefore, it should be non preferred and require PA. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. For any new chemical entity in the Catechol-O-Methyltransferase (COMT) Inhibitors class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s) Comtan®</p> <p>Non Preferred Agent (s) entacapone Tasmar®</p>
<p><u>Dopamine Precursor/Dopa Decarboxylase 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. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. For any new chemical entity in the Dopamine Precursor/Dopa Decarboxylase Inhibitors class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s) levodopa/carbidopa ODT levodopa/carbidopa levodopa/carbidopa controlled release</p> <p>Non Preferred Agent (s) Parcopa™ Sinemet® Sinemet® CR</p>
<p><u>Dopamine Precursor/Dopa Decarboxylase Inhibitor/COMT Inhibitor</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. For any new chemical entity in the Dopamine Precursor / Dopa Decarboxylase Inhibitor / COMT Inhibitor class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s) N/A</p> <p>Non Preferred Agent (s) levodopa/carbidopa/entacapone Stalevo®</p>
<p><u>MAO-B 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. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. For any new chemical entity in the Monoamine Oxidase (MAO)-B Inhibitors class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s) selegiline tablets</p> <p>Non Preferred Agent (s) Azilect® selegiline capsules Zelapar™</p>

Description of Recommendation	Final Decision (s)
<p>MAOIs</p> <ol style="list-style-type: none"> 1. DMS to select preferred agent(s) based upon economic evaluation. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. Any new chemical entity in the Monoamine Oxidase Inhibitors class should require a PA until reviewed by the P&T Advisory Committee. 	<p>Selected Preferred Agent (s) N/A</p> <p>Non Preferred Agent (s) Emsam[®] Marplan[®] Nardil[®] Parnate[®] phenelzine tranylcypromine</p>