

Kentucky Department for Medicaid Services

Pharmacy and Therapeutics Advisory Committee Recommendations

November 19, 2009 Meeting

The following chart provides a summary of the recommendations that were made by the Pharmacy and Therapeutics Advisory Committee at the November 19, 2009 meeting. Review of the recommendations by the Secretary of the Cabinet for Health and Family Services and final decisions are pending.

	Description of Recommendation	P & T Vote
1	<p><u>Branded Products with Generic Components Clinical Criteria</u> Branded products with generic components will be approved if any of the following are true:</p> <ul style="list-style-type: none"> • Positive clinical response to the prescribed active ingredient, and the patient has an allergy to some component of the commercial product; OR • Therapeutic failure of: <ul style="list-style-type: none"> ○ At least three (if available) medications containing the same active ingredient; AND ○ The requested medication's corresponding generic (if a generic is available) has been attempted and failed or is contraindicated. • Of Note: Products in convenience packaging (i.e. dose packs) will not be approved if there is a generic equivalent available in a stock bottle. 	<p>Passed 10 For 0 Against</p>
2	<p><u>Branded Products with Generic Components</u> Require prior authorization for the following products:</p> <ul style="list-style-type: none"> • Terbinex Kit[®] • NuCort[®] 	<p>Passed 10 For 0 Against</p>
3	<p><u>New Drugs to Market: Multaq[®]</u> Allow this product to pay unrestricted until the entire class of antiarrhythmics can be reviewed for inclusion on the KY PDL.</p>	<p>Passed 9 For 0 Against 1 Abstention</p>
4	<p><u>New Drugs to Market: Effient[™]</u> Place this product preferred in the PDL category titled: Platelet Inhibitors.</p>	<p>Passed 9 For 0 Against 1 Abstention</p>

	Description of Recommendation	P & T Vote								
5	<p><u>New Drugs to Market: Sabril™</u> Place this product preferred in the PDL category titled: Anticonvulsants: Second Generation; however, only allow for its use in infantile spasms via an ICD-9 override.</p> <table border="1"> <thead> <tr> <th>Diagnosis</th> <th>ICD-9</th> </tr> </thead> <tbody> <tr> <td>Infantile Spasms</td> <td>345.6</td> </tr> <tr> <td></td> <td>345.60</td> </tr> <tr> <td></td> <td>345.61</td> </tr> </tbody> </table>	Diagnosis	ICD-9	Infantile Spasms	345.6		345.60		345.61	<p>Passed 10 For 0 Against</p>
Diagnosis	ICD-9									
Infantile Spasms	345.6									
	345.60									
	345.61									
6	<p><u>New Drugs to Market: Colcrlys®</u> Allow this product to pay after trial and failure of generic colchicine products.</p>	<p>Passed 10 For 0 Against</p>								
7	<p><u>New Drugs to Market: Onglyza™</u> Place this product non preferred in the PDL category titled: DPP4-Inhibitors.</p>	<p>Passed 10 For 0 Against</p>								
8	<p><u>New Drugs to Market: Saphris®</u> Place this product preferred in the PDL category titled: Antipsychotics: Atypical with the same diagnosis criteria as other agents in the class.</p>	<p>Passed 10 For 0 Against</p>								
9	<p><u>New Drugs to Market: Extavia®</u> Place this product non preferred in the PDL category titled: Multiple Sclerosis Agents.</p>	<p>Passed 10 For 0 Against</p>								
10	<p><u>New Drugs to Market: Embeda™</u> Place this product non preferred in the PDL category titled: Narcotics: Long-Acting.</p>	<p>Passed 6 For 4 Against</p>								
11	<p><u>New Drugs to Market: Invega®-Sustenna™</u> Place this product preferred in the PDL category titled: Antipsychotics: Atypical with the same diagnosis criteria as other agents in the class.</p>	<p>Passed 10 For 0 Against</p>								
12	<p><u>New Drugs to Market: Bepreve™</u> Place this product non preferred in the PDL category titled: Ophthalmic Antihistamines.</p>	<p>Passed 10 For 0 Against</p>								
13	<p><u>New Drugs to Market: Intuniv™</u> Place this product preferred with appropriate quantity limits and similar prior approval criteria in the PDL category titled: Antihyperkinesia Agents.</p>	<p>Passed 9 For 0 Against 1 Abstention</p>								
14	<p><u>New Drugs to Market: Valtorna®</u> Place this product preferred with similar approval criteria in the PDL category titled: Direct Renin Inhibitors if cost neutral to other agents in the category.</p>	<p>Passed 8 For 1 Against 1 Abstention</p>								

	Description of Recommendation	P & T Vote
15	<p><u>New Drugs to Market: Stelara™</u> Place this product non preferred in the PDL category titled: Immunomodulators with the following clinical criteria:</p> <p>Stelara™ will be approved if both of the following are true:</p> <ul style="list-style-type: none"> • Trial and failure of two of the following therapies: <ul style="list-style-type: none"> ○ Methotrexate ○ Cyclosporine ○ Oral retinoid ○ Topical corticosteroids ○ Phototherapy/UV light ○ Coal tar preparation • No less than a one month trial and failure of one preferred product that is indicated for psoriasis. 	<p>Passed 10 For 0 Against</p>
16	<p><u>New Drugs to Market: Onsolis™</u> Place this product non preferred in the PDL category titled: Narcotics: Fentanyl Buccal Products with similar prior approval criteria and quantity limits as other agents in the class.</p>	<p>Passed 10 For 0 Against</p>
17	<p><u>Immunomodulators</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least two self administrable products should be preferred. 2. Agents not selected as preferred will be considered non preferred and require trial and failure of preferred product (s) with a FDA-approved indication for the requested diagnosis. 3. All agents in the category should be approved for their FDA-approved indications only. 4. DMS to allow continuation of therapy if there is a paid claim in the past 90 days. 5. Maintain quantity limits on agents within the category according to their maximum recommended dose, taking into consideration any escalating doses needed during initial therapy. 6. For any new chemical entity in the Immunomodulator class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed 10 For 0 Against</p>

	Description of Recommendation	P & T Vote					
18	<u>Immunomodulator Clinical Criteria</u>	Passed 10 For 0 Against					
	<table border="1"> <thead> <tr> <th data-bbox="305 342 548 373">Drug</th> <th data-bbox="557 342 846 373">Diagnosis</th> <th data-bbox="854 342 1227 373">Prior Therapy</th> </tr> </thead> </table>		Drug	Diagnosis	Prior Therapy		
	Drug		Diagnosis	Prior Therapy			
	Orencia [®] (abatacept)		Rheumatoid arthritis	Trial and failure of 1 DMARD			
			Juvenile Idiopathic Arthritis (JIA)	Trial and failure of 1 DMARD			
	Humira [®] (adalimumab)		Rheumatoid Arthritis	Trial and failure of 1 DMARD			
			Juvenile Idiopathic Arthritis (JIA)	Trial and failure of 1 DMARD			
			Ankylosing Spondylitis	None			
			Plaque Psoriasis	Trial and failure of two of the following therapies: <ul style="list-style-type: none"> • Methotrexate • Cyclosporine • Oral retinoid • Topical corticosteroids • Phototherapy/UV light • Coal tar preparations 			
			Crohn's Disease	Failure of conventional therapy of at least one agent in at least 2 of the following classes (not all inclusive): <ul style="list-style-type: none"> • 5-ASA agents – examples: Mesalamine (Pentasa, Asacol, Rowasa) • Corticosteroids – examples: Cortenema, Prednisone • Immunosuppressives – examples: Azathioprine (Imuran), 6-Mercaptopurine (Purinethol) 			
	Psoriatic Arthritis	Trial and failure of one of the following treatment: <ul style="list-style-type: none"> • Oral NSAID • Methotrexate alone • Intra-articular 					

		corticosteroid	
Amevive [®] (alefacept)	Plaque Psoriasis	Trial and failure of two of the following therapies: <ul style="list-style-type: none"> • Methotrexate • Cyclosporine • Oral retinoid • Topical corticosteroids • Phototherapy/UV light • Coal tar preparations 	
Kineret [®] (anakinra)	Rheumatoid Arthritis	Trial and failure of 1 DMARD	
Cimzia [®] (certolizumab pegol)	Rheumatoid Arthritis	Trial and failure of 1 DMARD	
	Crohn's Disease	Failure of conventional therapy of at least one agent in at least 2 of the following classes (not all inclusive): <ul style="list-style-type: none"> • 5-ASA agents – examples: Mesalamine (Pentasa, Asacol, Rowasa) • Corticosteroids – examples: Cortenema, Prednisone • Immunosuppressives – examples: Azathioprine (Imuran), 6-Mercaptopurine (Purinethol) 	
Enbrel (etanercept)	Rheumatoid Arthritis	Trial and failure of 1 DMARD	
	Juvenile Idiopathic Arthritis (JIA)	Trial and failure of 1 DMARD	
	Ankylosing Spondylitis	None	
	Plaque Psoriasis	Trial and failure of two of the following therapies: <ul style="list-style-type: none"> • Methotrexate • Cyclosporine • Oral retinoid • Topical corticosteroids • Phototherapy/UV light • Coal tar preparations 	
	Psoriatic Arthritis	Trial and failure of one of	

		the following treatment: <ul style="list-style-type: none"> • Oral NSAID • Methotrexate alone • Intra-articular corticosteroid
Simponi™ (golimumab)	Rheumatoid Arthritis	Trial and failure of 1 DMARD
	Ankylosing Spondylitis	None
	Psoriatic Arthritis	Trial and failure of one of the following treatment: <ul style="list-style-type: none"> • Oral NSAID • Methotrexate alone • Intra-articular corticosteroid
Remicade® (infliximab)	Rheumatoid Arthritis	Trial and failure of 1 DMARD
	Ankylosing Spondylitis	None
	Plaque Psoriasis	Trial and failure of two of the following therapies: <ul style="list-style-type: none"> • Methotrexate • Cyclosporine • Oral retinoid • Topical corticosteroids • Phototherapy/UV light • Coal tar preparations
	Crohn's Disease	Failure of conventional therapy of at least one agent in at least 2 of the following classes (not all inclusive): <ul style="list-style-type: none"> • 5-ASA agents – examples: Mesalamine (Pentasa, Asacol, Rowasa) • Corticosteroids – examples: Cortenema, Prednisone • Immunosuppressives– examples: Azathioprine (Imuran), 6-Mercaptopurine (Purinethol)
	Ulcerative Colitis	Trial and failure of one of

			<p>the following treatments:</p> <ul style="list-style-type: none"> • Corticosteroid • Immunosuppressant 	
		Fistulizing Crohn's Disease	None	
		Psoriatic Arthritis	<p>Trial and failure of one of the following treatment:</p> <ul style="list-style-type: none"> • Oral NSAID • Methotrexate alone • Intra-articular corticosteroid 	
	Stelara™ (ustekinumab)	Plaque Psoriasis	<p>Trial and failure of two of the following therapies:</p> <ul style="list-style-type: none"> • Methotrexate • Cyclosporine • Oral retinoid • Topical corticosteroids • Phototherapy/UV light • Coal tar preparations 	
	<p>Non preferred products will require no less than a one month trial and failure of one preferred product which is approved for the same diagnosis.</p>			
19	<p><u>Topical Immunomodulator</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one topical immunomodulator 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. 			<p>Passed 10 For 0 Against</p>
20	<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. DMS to allow continuation of therapy if there is a paid claim in the past 90 days. 4. All agents in the category will have no higher than a tier 2 copay regardless of PDL status. 5. Place quantity limits on these products based on maximum recommended dose. 6. 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>Passed 9 For 0 Against 1 Abstention</p>

	Description of Recommendation	P & T Vote
21	<p><u>Calcium Channel Blockers (DHP)</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, one of which should be amlodipine, 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 Blocker (DHP) class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed</p> <p>9 For 1 Against</p>
22	<p><u>ACE Inhibitors</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. Lisinopril and ramipril must be among the preferred agents. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the ACE Inhibitor class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed</p> <p>10 For 0 Against</p>
23	<p><u>ACE Inhibitor + Diuretic Combinations</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. Lisinopril/HCTZ and ramipril/HCTZ must be among the preferred agents. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the ACEI + Diuretic Combination class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed</p> <p>10 For 0 Against</p>
24	<p><u>Antibiotic Agents for Acne</u></p> <ol style="list-style-type: none"> 1. Rename this category Miscellaneous Topical Treatments for Acne. 2. DMS to select preferred agent (s) based on economic evaluation; however, at least multiple generic formulations of benzoyl peroxide and one topical antibiotic agent for acne 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 Miscellaneous Topical Treatments for Acne class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed</p> <p>9 For 0 Against</p>
25	<p><u>Topical Retinoids</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least 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 Retinoid class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed</p> <p>9 For 0 Against</p>

	Description of Recommendation	P & T Vote
26	<p><u>Oral Retinoids</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least acitretin and isotretinoin 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 Retinoid class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed</p> <p>9 For 0 Against</p>
27	<p><u>Isotretinoin Clinical Criteria</u></p> <p>Since the iPLEDGE system already restricts the use of these products, allow them to be subject to the general PDL criteria if one is chosen to be preferred over another.</p>	<p>Passed</p> <p>9 For 0 Against</p>
28	<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 and rosiglitazone should be preferred. 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>Passed</p> <p>7 For 2 Against</p>
29	<p><u>Thiazolidinedione Combinations</u></p> <ol style="list-style-type: none"> 1. DMS to select preferred agent (s) based on economic evaluation; however, at least two combination products containing metformin should be preferred. 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 Combination class, require a PA until reviewed by the P&T Advisory Committee. 	<p>Passed</p> <p>9 For 0 Against</p>