

# Kentucky Department for Medicaid Services

## Drug Review Options

The following chart lists the agenda items scheduled and the options submitted for review at the November 19, 2009, meeting of the Pharmacy and Therapeutics Advisory Committee

Item	Options for Consideration						
<b><u>Branded Products with Generic components Clinical Criteria</u></b>	<p>Branded products with generic components will be approved if any of the following are true:</p> <ul style="list-style-type: none"> <li>• Positive clinical response to the prescribed active ingredient, and the patient has an allergy to some component of the commercial product; <b>OR</b></li> <li>• Therapeutic failure of:               <ul style="list-style-type: none"> <li>○ At least three (if available) medications containing the same active ingredient; <b>AND</b></li> <li>○ The requested medication's corresponding generic (if a generic is available) has been attempted and failed or is contraindicated.</li> </ul> </li> </ul> <p>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>						
<b><u>Branded Products with Generic components</u></b>	<p>Require prior authorization for the following products:</p> <ul style="list-style-type: none"> <li>• Terbinex Kit<sup>®</sup></li> <li>• NuCort<sup>®</sup></li> </ul>						
<b><u>New Drugs to Market: Multaq<sup>®</sup></u></b>	<p>Allow this product to pay unrestricted until the entire class of antiarrhythmics can be reviewed for inclusion on the KY PDL.</p>						
<b><u>New Drugs to Market: Effient<sup>™</sup></u></b>	<p>Place this product preferred in the PDL category titled: Platelet Inhibitors; however, only allow for its use in the following patient populations:</p> <p>Effient<sup>™</sup> will be approved if any of the following are true:</p> <ul style="list-style-type: none"> <li>○ Post stent placement via an ICD-9 override, OR</li> <li>○ Trial and failure of clopidogrel via a 90 day electronic look back, OR</li> <li>○ Concomitant use of a Proton Pump Inhibitor.</li> </ul>						
<b><u>New Drugs to Market: Sabril<sup>™</sup></u></b>	<p>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" style="width: 100%; margin-top: 10px;"> <thead> <tr> <th style="text-align: center;">Diagnosis</th> <th style="text-align: center;">ICD-9</th> </tr> </thead> <tbody> <tr> <td rowspan="3" style="text-align: center;">Infantile Spasms</td> <td style="text-align: center;">345.6</td> </tr> <tr> <td style="text-align: center;">345.60</td> </tr> <tr> <td style="text-align: center;">345.61</td> </tr> </tbody> </table>	Diagnosis	ICD-9	Infantile Spasms	345.6	345.60	345.61
Diagnosis	ICD-9						
Infantile Spasms	345.6						
	345.60						
	345.61						
<b><u>New Drugs to Market: Colcrys<sup>®</sup></u></b>	<p>Allow this product to pay after trial and failure of generic colchicine products.</p>						
<b><u>New Drugs to Market: Onglyza<sup>™</sup></u></b>	<p>Place this product non preferred in the PDL category titled: DPP4-Inhibitors.</p>						

Item	Options for Consideration
<b><u>New Drugs to Market:</u></b> <b><u>Saphris<sup>®</sup></u></b>	Place this product preferred in the PDL category titled: Antipsychotics: Atypical with the same diagnosis criteria as other agents in the class.
<b><u>New Drugs to Market:</u></b> <b><u>Extavia<sup>®</sup></u></b>	Place this product non preferred in the PDL category titled: Multiple Sclerosis Agents.
<b><u>New Drugs to Market:</u></b> <b><u>Embeda<sup>™</sup></u></b>	Place this product non preferred in the PDL category titled: Narcotics: Long-Acting.
<b><u>New Drugs to Market:</u></b> <b><u>Invega<sup>®</sup> Sustenna<sup>™</sup></u></b>	Place this product non preferred in the PDL category titled: Antipsychotics: Atypical with the same diagnosis criteria as other agents in the class and the following additional clinical criteria:  Invega <sup>®</sup> Sustenna <sup>™</sup> will be approved if one of the following criteria is met: <ul style="list-style-type: none"> <li>• Previous stabilization on oral paliperidone and continued issues with non compliance necessitating an injectable treatment regimen, OR</li> <li>• Trial and failure of risperidone injectable.</li> </ul>
<b><u>New Drugs to Market:</u></b> <b><u>Bepreve<sup>™</sup></u></b>	Place this product non preferred in the PDL category titled: Ophthalmic Antihistamines.
<b><u>New Drugs to Market:</u></b> <b><u>Intuniv<sup>™</sup></u></b>	Place this product non preferred with appropriate quantity limits and similar prior approval criteria in the PDL category titled: Antihyperkinesia Agents.
<b><u>New Drugs to Market:</u></b> <b><u>Valturna<sup>®</sup></u></b>	Place this product non preferred in the PDL category titled: Direct Renin Inhibitors.
<b><u>New Drugs to Market:</u></b> <b><u>Stelara<sup>™</sup></u></b>	Place this product non preferred in the PDL category titled: Immunomodulators with the following clinical criteria:  Stelara <sup>™</sup> will be approved if both of the following are true: <ul style="list-style-type: none"> <li>• Trial and failure of two of the following therapies: <ul style="list-style-type: none"> <li>○ Methotrexate</li> <li>○ Cyclosporine</li> <li>○ Oral retinoid</li> <li>○ Topical corticosteroids</li> <li>○ Phototherapy/UV light</li> <li>○ Coal tar preparation</li> </ul> </li> <li>• No less than a one month trial and failure of one preferred product that is indicated for psoriasis.</li> </ul>

Item	Options for Consideration																						
<p><b><u>New Drugs to Market:</u></b> <b><u>Onsolis™</u></b></p>	<p>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><b><u>Immunomodulators</u></b></p>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least two self administrable products should be preferred.</li> <li>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.</li> <li>3. All agents in the category should be approved for their FDA-approved indications only.</li> <li>4. Maintain quantity limits on agents within the category according to their maximum recommended dose, taking into consideration any escalating doses needed during initial therapy.</li> <li>5. For any new chemical entity in the Immunomodulator class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>																						
<p><b><u>Immunomodulator</u></b> <b><u>Clinical Criteria</u></b></p>	<table border="1"> <thead> <tr> <th data-bbox="456 770 745 800">Drug</th> <th data-bbox="745 770 1117 800">Diagnosis</th> <th data-bbox="1117 770 1511 800">Prior Therapy</th> </tr> </thead> <tbody> <tr> <td data-bbox="456 800 745 869" rowspan="2">Orencia® (abatacept)</td> <td data-bbox="745 800 1117 869">Rheumatoid arthritis</td> <td data-bbox="1117 800 1511 869">Trial and failure of 1 DMARD</td> </tr> <tr> <td data-bbox="745 869 1117 938">Juvenile Idiopathic Arthritis (JIA)</td> <td data-bbox="1117 869 1511 938">Trial and failure of 1 DMARD</td> </tr> <tr> <td data-bbox="456 938 745 1388" rowspan="4">Humira® (adalimumab)</td> <td data-bbox="745 938 1117 1005">Rheumatoid Arthritis</td> <td data-bbox="1117 938 1511 1005">Trial and failure of 1 DMARD</td> </tr> <tr> <td data-bbox="745 1005 1117 1075">Juvenile Idiopathic Arthritis (JIA)</td> <td data-bbox="1117 1005 1511 1075">Trial and failure of 1 DMARD</td> </tr> <tr> <td data-bbox="745 1075 1117 1104">Ankylosing Spondylitis</td> <td data-bbox="1117 1075 1511 1104">None</td> </tr> <tr> <td data-bbox="745 1104 1117 1388">Plaque Psoriasis</td> <td data-bbox="1117 1104 1511 1388">           Trial and failure of two of the following therapies:           <ul style="list-style-type: none"> <li>• Methotrexate</li> <li>• Cyclosporine</li> <li>• Oral retinoid</li> <li>• Topical corticosteroids</li> <li>• Phototherapy/UV light</li> <li>• Coal tar preparations</li> </ul> </td> </tr> <tr> <td data-bbox="456 1388 745 1896"></td> <td data-bbox="745 1388 1117 1896">Crohn's Disease</td> <td data-bbox="1117 1388 1511 1896">           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"> <li>• 5-ASA agents – examples: Mesalamine (Pentasa, Asacol, Rowasa)</li> <li>• Corticosteroids – examples: Cortenema, Prednisone</li> <li>• Immunosuppressives– examples: Azathioprine (Imuran), 6-</li> </ul> </td> </tr> </tbody> </table>	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"> <li>• Methotrexate</li> <li>• Cyclosporine</li> <li>• Oral retinoid</li> <li>• Topical corticosteroids</li> <li>• Phototherapy/UV light</li> <li>• Coal tar preparations</li> </ul>		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"> <li>• 5-ASA agents – examples: Mesalamine (Pentasa, Asacol, Rowasa)</li> <li>• Corticosteroids – examples: Cortenema, Prednisone</li> <li>• Immunosuppressives– examples: Azathioprine (Imuran), 6-</li> </ul>		
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			Mercaptopurine (Purinethol)
		Psoriatic Arthritis	Trial and failure of one of the following treatment: <ul style="list-style-type: none"> <li>• Oral NSAID</li> <li>• Methotrexate alone</li> <li>• Intra-articular corticosteroid</li> </ul>
	Amevive® (alefacept)	Plaque Psoriasis	Trial and failure of two of the following therapies: <ul style="list-style-type: none"> <li>• Methotrexate</li> <li>• Cyclosporine</li> <li>• Oral retinoid</li> <li>• Topical corticosteroids</li> <li>• Phototherapy/UV light</li> <li>• Coal tar preparations</li> </ul>
	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"> <li>• 5-ASA agents – examples: Mesalamine (Pentasa, Asacol, Rowasa)</li> <li>• Corticosteroids – examples: Cortenema, Prednisone</li> <li>• Immunosuppressives– examples: Azathioprine (Imuran), 6-Mercaptopurine (Purinethol)</li> </ul>
	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"> <li>• Methotrexate</li> <li>• Cyclosporine</li> <li>• Oral retinoid</li> <li>• Topical corticosteroids</li> <li>• Phototherapy/UV light</li> </ul>

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

		Disease	
		Psoriatic Arthritis	Trial and failure of one of the following treatment: <ul style="list-style-type: none"> <li>• Oral NSAID</li> <li>• Methotrexate alone</li> <li>• Intra-articular corticosteroid</li> </ul>
	Stelara™ (ustekinumab)	Plaque Psoriasis	Trial and failure of two of the following therapies: <ul style="list-style-type: none"> <li>• Methotrexate</li> <li>• Cyclosporine</li> <li>• Oral retinoid</li> <li>• Topical corticosteroids</li> <li>• Phototherapy/UV light</li> <li>• Coal tar preparations</li> </ul>
	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.		
<b><u>Topical Immunomodulator</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least one topical immunomodulator should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Topical Immunomodulators, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>		
<b><u>Multiple Sclerosis Agents</u></b>	<ol style="list-style-type: none"> <li>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.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. Place quantity limits on these products based on maximum recommended dose.</li> <li>4. For any new chemical entity in the Multiple Sclerosis Agents class, require a PA and quantity limit until reviewed by the P&amp;T Advisory Committee.</li> </ol>		
<b><u>Calcium Channel Blockers (DHP)</u></b>	<ol style="list-style-type: none"> <li>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.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Calcium Channel Blocker (DHP) class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>		
<b><u>ACE Inhibitors</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least three unique chemical entities, one of which should be lisinopril, should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the ACE Inhibitor class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>		
<b><u>ACE Inhibitor + Diuretic Combinations</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least three unique chemical entities, one of which should be lisinopril/HCTZ, should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the ACEI + Diuretic Combination class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>		

Item	Options for Consideration
<b><u>Antibiotic Agents for Acne</u></b>	<ol style="list-style-type: none"> <li>1. Rename this category Miscellaneous Topical Treatments for Acne.</li> <li>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.</li> <li>3. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>4. For any new chemical entity in the Miscellaneous Topical Treatments for Acne class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Topical Retinoids</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least tretinoin should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Topical Retinoid class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Oral Retinoids</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least acitretin and isotretinoin should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Oral Retinoid class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Isotretinoin Clinical Criteria</u></b>	<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>
<b><u>Thiazolidinediones</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least pioglitazone should be preferred.</li> <li>2. Continue quantity limits based on maximum recommended dose.</li> <li>3. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>4. For any new chemical entity in the Diabetes: Thiazolidinediones class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Thiazolidinedione Combinations</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least two combination products containing pioglitazone should be preferred.</li> <li>2. Continue quantity limits based on maximum recommended dose.</li> <li>3. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>4. For any new chemical entity in the Diabetes: Thiazolidinediones Combination class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Amylin Analog</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation.</li> <li>2. Allow for use of pramlintide with active insulin therapy only.</li> <li>3. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>4. For any new chemical entity in the Amylin Analog class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Symlin® Clinical Criteria</u></b>	<p>Symlin® will be approved if insulin is seen in history within the past 90 days.</p>

Item	Options for Consideration
<b><u>Incretin Mimetic</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least one agent should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. Continue step therapy for exenatide.</li> <li>4. For any new chemical entity in the Incretin Mimetics class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Byetta™ Clinical Criteria</u></b>	Byetta™ will be approved if metformin, a sulfonylurea or a TZD is seen in history within the past 90 days.
<b><u>DPP-4 Inhibitors</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least one agent should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the DPP4-Inhibitors class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>DPP-4 Inhibitors Clinical Criteria</u></b>	DPP-4 Inhibitors will be approved if insulin, a sulfonylurea or a TZD is seen in history within the past 90 days.
<b><u>Biguanides</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least metformin should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Diabetes: Biguanides class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Sulfonylureas and Combinations</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique second generation sulfonylureas and one combination product should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Sulfonylureas and Combination class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Alpha Glucosidase Inhibitors</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least one agent should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Alpha-Glucosidase Inhibitor class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Meglitinides</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least one agent should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Meglitinides class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Bone: Calcitonins</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least one product should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Bone: Calcitonins class, require a PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>
<b><u>Niacin Derivatives</u></b>	<ol style="list-style-type: none"> <li>1. DMS to select preferred agent (s) based on economic evaluation; however, at least one agent should be preferred.</li> <li>2. Agents not selected as preferred will be considered non preferred and require PA.</li> <li>3. For any new chemical entity in the Niacin Derivatives class, require PA until reviewed by the P&amp;T Advisory Committee.</li> </ol>

Item	Options for Consideration
<b><u>Skeletal Muscle Relaxants</u></b>	<ol style="list-style-type: none"><li data-bbox="358 262 1528 359">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.</li><li data-bbox="358 363 1451 392">2. Agents not selected as preferred will be considered non preferred and require PA.</li><li data-bbox="358 396 1516 457">3. Place quantity limits on agents in this category based on FDA maximum recommended dose and duration.</li><li data-bbox="358 462 1479 522">4. For any new chemical entity in the Skeletal Muscle Relaxants class, require PA until reviewed by the P&amp;T Advisory Committee.</li></ol>