



## Committee on Prescriptive Governance Updates May 10, 2010

### **New Drug Indications / Warnings May 2010**

(New Drug Indications/Black Box Warnings: FDA)

Generic Name	Trade Name	Indication(s)	CPG Action/Date
<b>January 2010</b>			
None			
<b>February 2010</b>			
Acetazolamide Oral  Formulary Pg. 13	Acetazolamide, Diamox Sequels	<i>Renal and Genitourinary Agents: Carbonic Anhydrase Inhibitors: Diuretics.</i> New black box warning. Indication for Acute mountain sickness, edema, glaucoma, seizures.	<i>Current: CTP MAY Prescribe</i>  May 10, 2010: CTP MAY prescribe
<b>March 2010</b>			
Bevacizumab Injection  Formulary Pg. 26	Avastin	<i>Antineoplastic Agents: Monoclonal Antibodies.</i> New indication for the treatment of metastatic renal cell carcinoma in combination with interferon alpha. Indication for glioblastoma, metastatic breast cancer, metastatic colorectal cancer, metastatic renal cell carcinoma, nonsquamous non-small cell lung cancer.	<i>Current: CTP MAY NOT prescribe</i>  May 10, 2010: CTP MAY NOT prescribe
<b>April 2010</b>			
<b>(Hemostatic)</b> Aprotinin Injection  Formulary Pg. 7	Trasylol	New Warning: Anaphylactic or anaphylactoid reactions	<i>Current: CTP May NOT Prescribe.</i>  May 10, 2010: CPT MAY NOT Prescribe.
Thrombin topical Formulary Pg. 7	Thrombin JMI, Thrombin, Recothrom	New Warning: (bovine) Must not be injected. Apply only to surface of	<i>Current CTP MAY prescribe:</i>

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Thrombin topical Formulary Pg. 7	Thrombin JMI, Thrombin, Recothrom	New Warning: (bovine) Must not be injected. Apply only to surface of bleeding tissue.	Current CTP MAY prescribe:  May 10, 2010: CTP MAY prescribe.
Teriparatide Injection  Formulary Pg.9	Forteo	<i>Treatment of glucocorticoid-induced osteoporosis</i>	Current CTP MAY prescribe  May 10, 2010: CTP MAY prescribe.
Olmesartan Medoxomil-Oral  Formulary Pg.12	Benicar	Warning change: When Pregnancy detced, discontinue drug as soon as possible.	Current: CTP MAY prescribe.  May 10, 2010: CTP MAY prescribe.
Aliskiren Hemifumarate- Oral  Formulary Pg. 12	Tekurna	Warning change: Use in pregnancy, can cause injury and death to developing fetus.	Current: CTP MAY prescribe.  May 10, 2010: CTP MAY prescribe.
Rosuvastatin Calcium Oral  Formulary Pg. 12	Crestor	Primary prevention of cardiovascular disease.	Current: CTP MAY prescribe.  May 10, 2010: CTP MAY prescribe.
Olanzapine Oral & Injectable  Formulary Pg.16	Zyprexa	Warning change: Increased mortality in elderly patients with dementia-related psychosis.	Current: CTP MAY prescribe.  May 10, 2010: CTP MAY prescribe.
Telbivudine-Oral	Tyzeka	Warning change: Lactic	Current: PI/PC

**New Drugs May 2010**

(Original New Drug Applications: FDA)

<b>Generic Name</b>	<b>Trade Name</b>	<b>Indication(s)</b>	<b>CPG Action/Date</b>
<b>January 2010</b>			
Human Papillomavirus (Types 16, 18) Bivalent Vaccine, Recombinant Injection  Formulary Pg. 22	Cervarix	<i>Biologic and Immunologic Agents: Agents for Active Immunization: Vaccines, Viral.</i> Indication for prevention of human papillomavirus.	May 10, 2010: CTP MAY prescribe
Ofatumumab Injection	Arzerra	<i>Antineoplastic Agents: Monoclonal Antibodies.</i>	May 10, 2010: CTP MAY NOT prescribe

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Formulary Pg. 26		Indication for chronic lymphocytic leukemia.	
Romidepsin Injection Formulary Pg. 26	Istodax	<i>Antineoplastic Agents: Histone Deacetylase Inhibitors.</i> Indication for cutaneous T-cell lymphoma.	May 10, 2010: CTP MAY NOT prescribe.
<b>February 2010</b>			
Ecallantide Formulary Pg. 7	Kalbitor	<i>Hematological Agents: Kallikrein Inhibitor.</i> Indication for hereditary angioedema.	May 10, 2010: PI/PC
Chenodiol Oral Formulary Pg. 19	Chenodal	<i>Gastrointestinal Agents: Gallstone solubilizing agents.</i> Indication for radiolucent gallstones.	May 10, 2010: PI/PC
<b>March 2010</b>			
Vigabatrin Oral Formulary Pg. 17	Sabril	<i>Central Nervous System Agents: Anticonvulsants.</i> Indication for infantile spasms and refractory complex partial seizures.	May 10, 2010: CTP MAY NOT prescribe.
<b>April 2010</b>			
<b>Potassium Channel Blocker/</b> Dalfampridine-Oral Formulary Pg. 18	Ampyra	Multiple sclerosis: TO improve walking inpatients with MS.	May 10, 2010: PI/PC.
<b>Antidiabetic Agent/</b> Liraglutide-Injection Formulary Pg. 8-9	Victoza	Type 2 diabetes mellitus	May 10, 2010: PI/PC
Tocilizumab-injection Formulary Pg. 22	Actemra	Treatment of moderately to severely active rheumatoid arthritis in adults	May 10, 2010: PI/PC.

**Formulary Revision Requests May 2010**

Generic Name	Trade Name	Indication(s)	CPG Action/Date
<b>Formulary Revision Request from Sarah Otto CNP, Ying Yang CNP (Initially discussed at January 2010 CPG)</b>			

<p>Isotretinoin Formulary Pg. 23</p>	<p>Accutane</p>	<p><i>Dermatologic Agents: Retinoids: First Generation Retinoids.</i> Indication for severe recalcitrant nodular acne.  Requesting Physician Initiated.</p>	<p>Current: CTP holder MAY NOT prescribe.  May 10, 2010: PI/PC for CTP Holder with SCA with physician in Dermatology practice ONLY</p>
<p><b>Formulary Revision Request from Lisa Miller CNP (Initially discussed at January 2010 CPG)</b></p>			
<p>Isotretinoin Formulary Pg. 23</p>	<p>Accutane, Claravis, Sotret, Amnesteem</p>	<p><i>Dermatologic Agents: Retinoids: First Generation Retinoids.</i> Indication for severe recalcitrant nodular acne.  Requesting Physician Initiated.</p>	<p>Current: CTP holder MAY NOT Prescribe.  May 10, 2010: PI/PC for CTP Holder with SCA with physician in Dermatology practice ONLY</p>
<p><b>Formulary Revision Request from Katherine Novotny</b></p>			
<p>Isotretinoin Formulary Pg. 23</p>	<p>Accutane, Claravis, Sotret, Amnesteem</p>	<p><i>Dermatologic Agents: Retinoids: First Generation Retinoids.</i> Indication for severe recalcitrant nodular acne.  Requesting Physician Initiated / Physician Consult.</p>	<p>Current: CTP holder MAY NOT Prescribe.  May 10, 2010: PI/PC for CTP Holder with SCA with physician in Dermatology practice ONLY</p>
<p><b>Formulary Revision Request from Jennifer Phillips, Sherry Grooms, Nancy Hogan, Darlene Bisgaard,</b></p>			
<p>Isotretinoin Formulary Pg. 23</p>	<p><b>Accutane</b></p>	<p><i>Dermatologic Agents: Retinoids: First Generation Retinoids.</i> Indication for severe recalcitrant nodular acne.  Requesting Physician</p>	<p>Current: CTP holder MAY NOT Prescribe.  May 10, 2010: PI/PC for CTP Holder with SCA with physician in Dermatology</p>

		Initiated/ Physician Consult.	practice ONLY
<b>Formulary Revision Requests from Michelle Angie, CNP</b>			
Leuprolide Acetate Formulary Pg. 25	Lupron	<i>Antineoplastic Agent:</i>	Current: CTP Holder w/ SCA w/ physician specializing in Hematology/ Oncology ONLY for prostate CA  May 10, 2010: CTP Holder w/ SCA with /physician specializing in Hematology/Oncology / or <b>Urology</b> ONLY for prostate CA.
Goserelin Acetate Formulary Pg. 25	Zoladex	<i>Antineoplastic Agent;</i>	Current: CTP Holder w/ SCA w/ physician specializing in Hematology/ Oncology ONLY for prostate CA  May 10, 2010: CTP Holder w/ SCA with /physician specializing in Hematology/Oncology /or <b>Urology</b> ONLY for prostate CA.
Phentolamine Formulary Pg 12	Regitine	<i>Cardiovasculars; Agents for Pheochromocytoma.</i> Indication for pheochromocytoma, dermal necrosis. Unlabeled use for hypertensive crises secondary to MAO inhibitor/ sympathomimetic amine interaction and rebound hypertension on withdrawal of clonidine,	Current: CTP holder MAY NOT prescribe.  May 10, 2010: Under continued review.

		<p>propranolol or other antihypertensives. It has also been used in combination with papaverine as an intracavernous injection for impotence.</p> <p>Requests change to CTP holder may prescribe, PI/PC for intracavernosal as impotence agent.</p>	
<p>Papaverine Solution Formulary Pg. 12</p>	<p>Papaverine</p>	<p><i>Cardiovasculars: Vasodilators: Peripheral Vasodilators.</i> Indication for ischemia.</p> <p>Request for change to CTP holder may prescribe, PI/PC intercavernosal only as an impotence agent.</p>	<p>Current: CTP holder may prescribe P.O. only.</p> <p>May 10, 2010: Under continued review.</p>
<p><b>Formulary Revision Request from Michelle Bagby</b></p>			
<p>Bosetan Formulary Pg. 11</p>	<p>Tracleer</p>	<p><i>Cardiovasculars: Vasodilators: Endothelin Receptor Antagonist.</i> Indication for pulmonary arterial hypertension.</p> <p>Request for change to CTP holder MAY prescribe.</p>	<p>Current: CTP holder MAY NOT prescribe.</p> <p>May 10, 2010: Changed to PI/PC.</p>
<p><b>Formulary Revision Requests from Christina Schultz</b></p>			
<p>Isotretinoin Formulary Pg. 23</p>	<p>Accutane, Claravis, Amnestein</p>	<p><i>Dermatologic Agents: Retinoids: First Generation Retinoids.</i> Indication for severe recalcitrant nodular acne.</p> <p>Requesting CTP Holder may prescribe</p>	<p>Current: CTP Holder may NOT Prescribe</p> <p>May 10, 2010: PI for CTP Holder with SCA with physician in Dermatology practice ONLY</p>
<p><b>Formulary Revision Request from Pamela Fletcher</b></p>			

<p>Isotretinoin Formulary Pg. 23</p>	<p><b>Accutane</b></p>	<p><i>Dermatologic Agents: Retinoids: First Generation Retinoids.</i> Indication for severe recalcitrant nodular acne.</p> <p><b>Requesting CTP Holder in Dermology practice MAY prescribe</b></p>	<p>Current: CTP Holder may NOT Prescribe</p> <p>May 10, 2010: PI for CTP Holder with SCA with physician in Dermatology practice ONLY</p>
<p><b>Formulary Revision Request from Anne M. McKee, Jodi Westfall, Mandi Fleming, Stephanie Russell, Katherine Novotny,</b></p>			
<p><b>Isotretinoin Formulary Pg. 3</b></p>	<p><b>Accutane</b></p>	<p><i>Dermatologic Agents: Retinoids: First Generation Retinoids.</i> Indication for severe recalcitrant nodular acne.</p> <p><b>Requesting physician initiated/Physician consult</b></p>	<p>Current: CTP Holder may NOT Prescribe</p> <p>May 10, 2010: PI for CTP Holder with SCA with physician in Dermatology practice ONLY</p>