



New Drug Indications / Warnings May 2009

(New Drug Indications/Black Box Warnings: FDA)

Generic Name	Trade Name	Indication(s)	CPG Action/Date
January 2009			
Ciprofloxacin Oral and Injection Formulary Page: 22	Cipro, Ciprofloxacin, Cipro XR, Proquin	Systemic Anti-Infectives: Antibiotics: Fluoroquinolones. <i>New Black Box Warning for increased risk of tendinitis and tendon rupture in all ages.</i>	Current: CTP holder may prescribe 5/11/09 No Change
Levofloxacin Oral and Injection Formulary Page: 22	Levaquin	Systemic Anti-Infectives: Antibiotics: Fluoroquinolones. <i>New Black Box Warning for increased risk of tendinitis and tendon rupture in all ages.</i>	Current: CTP holder may prescribe 5/11/09 No Change
Moxifloxacin Hydrochloride Oral and Injection Formulary Page: 22	Avelox	Systemic Anti-Infectives: Antibiotics: Fluoroquinolones. <i>New Black Box Warning for increased risk of tendinitis and tendon rupture in all ages.</i>	Current: CTP holder may prescribe 5/11/09 No Change
Gemifloxacin Mesylate Oral Formulary Page: 22	Factive	Systemic Anti-Infectives: Antibiotics: Fluoroquinolones. <i>New Black Box Warning for increased risk of tendinitis and tendon rupture in all ages.</i>	Current: CTP holder may prescribe 5/11/09 No Change
Norfloxacin Oral Formulary Page: 22	Noroxin	Systemic Anti-Infectives: Antibiotics: Fluoroquinolones. <i>New Black Box Warning for increased risk of tendinitis and tendon rupture in all ages.</i>	Current: CTP holder may prescribe 5/11/09 No Change

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<p>Entecavir Oral</p> <p>Formulary Page: 23</p>	<p>Baraclude</p>	<p>Systemic Anti-Infectives: Antivirals. <i>Changes to Black Box Warning to address patients co-infected with HIV and chronic Hepatitis B</i></p>	<p>Current: Physician Initiated.</p> <p>5/11/09 No Change</p>
<p>Tenofovir Disoproxil Fumarate Oral</p> <p>Formulary Page: 23</p>	<p>Viread</p>	<p>Systemic Anti-Infectives: Antiretroviral Agents: Nucleotide Analog Reverse Transcriptase Inhibitor. <i>New indication for chronic hepatitis B. Change to black box warning regarding exacerbation of hepatitis B in patients who discontinue anti-hepatitis B therapy.</i></p>	<p>Current: Physician Consult for Post-Exposure Prophylaxis.</p> <p>Physician Initiated for all other indications.</p> <p>5/11/09 No Change</p>
<p>February 2009</p>			
<p>Miscellaneous Estrogens, Vaginal</p> <p>Formulary Pg. 9</p>	<p>Premarin Vaginal</p>	<p>Endocrine/Metabolic: Sex Hormones: Estrogens. <i>New indication for Premarin for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy caused by menopause.</i></p>	<p>Current: CTP holder may prescribe.</p> <p>5/11/09 No Change</p>
<p>Abacavir Sulfate, Oral</p> <p>Formulary Pg. 23</p>		<p>Anti-infective Agents: Antiretroviral Agents: Nucleoside Reverse Transcriptase Inhibitors. <i>Revised Black Box Warning to include suggestion to screen for HLA-B*5701 allele prior to initiating treatment. Patients who carry this allele are at high risk for experiencing a hypersensitivity reaction.</i></p>	<p>Current: Physician Consult only for post-exposure prophylaxis.</p> <p>Physician Initiated for all other indications.</p> <p>5/11/09 No Change</p>

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March 2009			
Rosuvastatin Injection Formulary Pg. 14		Cardiovascular Agents: Antihyperlipidemic Agents: HMG-CoA Reductase Inhibitors. <i>New indication for primary dysbetalipoproteinemia.</i>	Current: CTP holder may prescribe. Physician Initiated for Pediatric Dosing. 5/11/09 No Change
Fenofibrate Oral Formulary Pg. 14		Cardiovascular Agents: Antihyperlipidemic Agents: Fibric Acid Derivatives. <i>New indication to include combination therapy with statins for mixed dyslipidemia.</i>	Current: CTP holder may prescribe. 5/11/09 No Change
Thiothixene Oral Formulary Pg. 18	Thioridazine HCL	Central Nervous System Agents: Antipsychotic Agents: Phenothiazine Derivatives. <i>New black box warning related to prolonged QTc interval in a dose related manner. Drugs with this potential have been associated with torsade de pointes-type arrhythmias and sudden death.</i>	Current: Psych CTP holder may prescribe. Physician Initiated for CTP holders other than Psych. Initial 90 day review. 5/11/09 No Change
Dexmedetomidine Hydrochloride Injection Formulary Pg. 19	Precedex	Central Nervous System Agents: Sedatives and Hypnotics, Nonbarbiturate. <i>New indication for procedural sedation.</i>	Current: CTP holder may not prescribe. 5/11/09 No Change
Immune Globulin (Human) Intravenous (Gamunex) Formulary Pg. 24		Biological and Immunologic Agents: Immune Globulins. <i>New indication for chronic inflammatory demyelinating polyneuropathy.</i>	Current: CTP holder may prescribe 5/11/09 No Change

New Drug Indications/Black Box Warnings May 2009

<p>Efalizumab Injection</p> <p>Formulary Pg. 24</p>	<p>Raptiva</p>	<p>Biological and Immunologic Agents: Immunosuppressives. <i>New black box warning for infections, including serious infections leading to hospitalizations or death.</i></p>	<p>Current: Physician Initiated.</p> <p>5/11/09 No Change</p>
<p>April 2009</p>			
<p>None</p>			



New Drugs May 2009

(Original New Drug Applications: FDA)

Generic Name	Trade Name	Indication(s)	CPG Action/Date
January 2009			
Eltrombopag Oral Formulary Pg. 7	Promacta	Hematological Agents: Hematopoietic Agents: Thrombopoietin Receptor Agonist: <i>Indication for thrombocytopenia in patients with chronic immune thrombocytopenic purpura who have had an insufficient response to corticosteroids, immunoglobulins or splenectomy.</i>	5/11/09 CTP holder MAY NOT prescribe
Fesoterodine Fumarate Oral Formulary Pg. 15	Toviaz	Renal and Genitourinary Agents: Anticholinergics: <i>Indication for overactive bladder.</i>	5/11/09 CTP holder may prescribe
Lacosamide Oral and Injection Formulary pg. 20	Vimpat	Central Nervous System Agents: Anticonvulsants: <i>Indication for partial onset seizures</i>	5/11/09 CTP holder may prescribe
Rufinamide Oral Formulary pg. 20	Banzel	Central Nervous System Agents: Anticonvulsants: <i>Indication for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome.</i>	5/11/09 CTP holder may prescribe
February 2009			
Silodosin Oral Formulary pg. 14	Rapaflo	Cardiovascular Agents: Antiadrenergics/ Sympatholytics: Antiadrenergic Agents- Peripherally Acting: <i>Indication for benign prostatic hyperplasia.</i>	5/11/09 CTP holder may prescribe
Fospropofol Formulary pg. 20	Lusedra	Central Nervous System Agents: General Anesthetics: <i>Indication for monitored anesthesia care.</i>	5/11/09 CTP holder MAY NOT prescribe

March 2009			
Plerixafor Injection Formulary Pg. 7	Mozobil	Hematopoietic Agents: Stem Cell Mobilizers. <i>Indication for peripheral stem cell collection and transplantation.</i>	5/11/09 Physician Initiated
Fibrinogen Concentrate Formulary Pg. 8	RiaSTAP	Hematopoietic Agents: Hemostatics: Systemic. <i>Indication for fibrinogen deficiency.</i>	5/11/09 CTP holder MAY NOT prescribe
April 2009			
Febuxostat Oral Formulary Pg. 11	Uloric	Endocrine/Metabolic Agents: Agents for Gout: Uricosurics. <i>Indication for the chronic management of hyperuricemia in patients with gout.</i>	5/11/09 CTP holder may prescribe
Milnacipran Hydrochloride Oral Formulary Pg. 18	Savella	Central Nervous System Agents: Antidepressants: Serotonin and Norepinephrine Reuptake Inhibitors. <i>Indication is for fibromyalgia.</i>	5/11/09 CTP holder may prescribe
Dexlansoprazole Oral Formulary Pg. 21	Kapidex	Gastrointestinal Agents: Proton Pump Inhibitors. <i>Indication for gastroesophageal disease.</i>	5/11/09 CTP holder may prescribe

			and as stated in the standard care arrangement.
Review/ Revision Request from Theresa L. Mason CRNP and Melanie Lint CNS			
Lithium Carbonate Formulary pg 18	Eskalith	Central Nervous System Agents: Antipsychotic Agents. <i>Indication for mania.</i>	Current: Psych CTP holder may prescribe. CTP Holder other than Psych is Physician Initiated. Initial 30 day review. 5/11/09 No change. See revised review requirement comment Formulary pg. 4
Olanzapine Formulary Page 18	Zyprexa	Central Nervous System Agents: Antipsychotic Agents: Dibenzapine Derivatives. <i>Indications for bipolar disorder and schizophrenia.</i>	Current: Psych CTP holder may prescribe. CTP Holder other than Psych Physician Initiated. Initial 90 day review. 5/11/09 No change. See revised review requirement comment Formulary pg. 4
Quetiapine Quetiapine Fumarate Formulary Page 18	Seroquel	Central Nervous System Agents: Antipsychotic Agents: Dibenzapine Derivatives. <i>Indications for bipolar disorder and schizophrenia.</i>	Current: Psych CTP holder may prescribe. CTP Holder other than Psych is Physician Initiated. Initial 90 day review. 5/11/09 No

			change. See revised review requirement comment Formulary pg. 4
Paliperidone Formulary Page 18	Invega	Central Nervous System Agents: Antipsychotic Agents: Dibenzapine Derivatives. <i>Indication for schizophrenia.</i>	Current: Psych CTP holder may prescribe. CTP Holder other than Psych is Physician Initiated. Initial 90 day review. 5/11/09 No change. See revised review requirement comment Formulary pg. 4
Risperidone Formulary Page 18	Risperdal	Central Nervous System Agents: Antipsychotic Agents: Benzisoxazole Derivatives. <i>Indication for bipolar mania, irritability associated with autistic disorder and schizophrenia.</i>	Current: Psych CTP holder may prescribe. CTP Holder other than Psych is Physician Initiated. Initial 90 day review. 5/11/09 No change. See revised review requirement comment Formulary pg. 4
Ziprasidone Formulary Page 18	Geodon	Central Nervous System Agents: Antipsychotic Agents: Benzisoxazole Derivatives. <i>Indication for bipolar mania and schizophrenia.</i>	Current: Psych CTP holder may prescribe. CTP Holder other than Psych is Physician Initiated. Initial 90 day 5/11/09 No change. See

			revised review requirement comment Formulary pg. 4
Atomoxetine Formulary Page 19	Strattera	Central Nervous System Agents: Miscellaneous Psychotherapeutic Agents. <i>Indication for attention deficit disorder.</i>	Current: Psych CTP holder may prescribe. CTP Holder other than Psych is Physician Consult. Initial 60 day 5/11/09 No change. See revised review requirement comment Formulary pg. 4
Review / Revision Request from Belinda Brown, DNP, AACRN, Adriana Whelan, ND, CNP; Janet Briggs, MSN, RN, ANP, AACRN			
Saquinavir, Ritonavir, Indinavir, Nelfinavir, Amprenavir, Lopinavir, Atazanavir, Fosamprenavir, Tipranavir, Darunavir Formulary Page 23	Invirase, Norvir, Crixivan, Viracept, Kaletra, Reyataz, Lexiva, Telzir, Aptivus, Prezista, Reyataz, Kaletra	Anti-Infectives, Systemic: Antiretroviral Agents: Protease Inhibitors. <i>Indication for HIV.</i>	Current: Physician Consult for post-exposure prophylaxis only. Physician Initiated for all other indications. 5/11/09 Change to Physician Consult for CTP holders with a standard care arrangement with a collaborating physician who specializes in HIV or infectious diseases.
Zidovudine, Didanosine, Zalcitabine, Stavudine, Lamivudine, Zidovudine/Lamivudine, Abacavir, Zidovudine/Lamidvu	Retrovir, Videx, Hivid, Zerit, Epivir, Combivir, Ziagen, Trizivir, Viread, Emtriva, Epzicom, Truvada	Anti-Infectives, Systemic: Antiretroviral Agents: Nucleoside reverse transcriptase inhibitors & combinations. <i>Indication for HIV. Epivir (Lamivudine)</i>	Current: Physician Consult for post-exposure prophylaxis only. Physician Initiated for all other indications.

<p>dine/abacavir, Tenofovir, Emtricitabine, Abacavir/lamivudine, Tenofovir/emtricitabine</p> <p>Formulary Page 23</p>		<p><i>also has an indication for chronic hepatitis B.</i></p>	<p>5/11/09 Change to Physician Consult for CTP holders with a standard care arrangement with a collaborating physician who specializes in HIV or infectious diseases.</p>
<p>Nevirapine, Delavirdine, Efavirenz, Etravirine</p> <p>Formulary Page 23</p>	<p>Viramune, Rescriptor, Sustiva, Intelence</p>	<p>Anti-Infectives, Systemic: Antiretroviral Agents: Non-Nucleoside Reverse Transcriptase Inhibitors. <i>Indication for HIV.</i></p>	<p>Current: Physician Consult for post-exposure prophylaxis only. Physician Initiated for all other indications.</p> <p>5/11/09 Change to Physician Consult for CTP holders with a standard care arrangement with a collaborating physician who specializes in HIV or infectious diseases.</p>
<p>Review / Revision Request from Anne McKee CNP , Margaret Bobonich CNP, Kathleen Chohaney CNP, Sherry Grooms, Virginia Guillen CNP, Mandi Fleming CNP, Sally Steiber CNP, Pamela Fletcher CNP, Jodi Westfall</p>			
<p>Flurouracil- Topical</p> <p>Formulary Page 25</p>	<p>Efudex, Carac</p>	<p>Dermatologic Agents: Pyrimidine antagonist, topical. <i>Indication Actinic or solar keratoses, superficial basal cell carcinomas.</i></p>	<p>Current: Physician Initiated.</p> <p>5/11/09 Change to CTP holder may prescribe for those with a standard care arrangement with a physician specializing in dermatology.</p>