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New Drugs October 2010

(Original New Drug Applications: FDA)

Generic Name	Trade Name	Indication(s)	CPG Action/Date
		2010	
Velaglucerase Alfa Injection Formulary Pg. 10	VPRIV	Endocrine and Metablic Agents: Gaucher disease: Long term enzyme replacement therapy.	10/18/10 CTP Holder may prescribe.
Collagenase Clostridium Histolyticum Injection Formulary Pg. 22	Xiaflex	Dermatologic Agents: Enzyme Preparations. Treatment of adult patients with Dupuytren contracture with a palpable cord.	10/18/10 CTP Holder MAY NOT prescribe.
Gadofosveset Trisodium Injection Formulary Pg. 26	Ablavar	Diagnostic Aids: In Vivo Diagnostic Aids. Contrast agent for magnetic resonance angiography.	10/18/10 CTP Holder may prescribe.
	June	2010	T
None			
None	July	2010	
		st 2010	
Denosumab Injection Formulary Pg. 22	Prolia	Biologic and Immunologic Agents: Monoclonal Antibodies. Indication for treatment of osteoporosis.	10/18/10 Physician Initiated/ Physician Consult.
Sipuleucel-T Injection Formulary Pg. 26	Provenge	Antineoplastic Agents: Miscellaneous Antineoplastics. Indication for treatment of prostate cancer.	10/18/10 CTP Holder MAY NOT prescribe.
Hexaminolevulinate Hydrochloride Intrevesical	Cysview	Diagnostic Aids: In Vivo Diagnostic Aids. Indication for detection of bladder cancer.	10/18/10 CTP Holder may prescribe.
Formulary Pg. 26			
September 2010			
Cabazitaxel Injection Formulary Pg. 24	Jevtana	Antineoplastic Agents: Antimitotic Agents. Indication for treatment of prostate cancer.	10/18/10 CTP Holder MAY NOT prescribe.

New Drugs Indications/ Warnings October 2010

(New Drug Indications/ Black Box Warnings: FDA

Generic Name	Trade Name	Indication(s)	CPG Action/Date
	May	2010	
Tiotropium Bromide Inhalation	Spiriva	Respiratory Agents: Bronchodilators. New indication to reduce	Current: CTP Holder MAY prescribe.
Formulary Pg. 13		exacerbations in COPD patients.	10/18/10 No Change.
Varenicline Tartrate Oral	Chantix	Central Nervous System Agents: Smoking Deterrants. New black	Current: CTP Holder MAY prescribe.
Formulary Pg. 18		box warning regarding potential for serious neuropsychiatric events	10/18/10 No Change.
	June		
Deferasirox Oral Formulary Pg. 10	Exjade	Endocrine and Metabolic Agents: Detoxification Agents. New black box warning indicating my cause renal impairment and failure, hepatic impairment and failure, and GI hermorrhage.	Current: CTP Holder MAY NOT prescribe. 10/18/10 No Change.
Hydromorphone Hydrochloride Oral Formulary Pg. 15	Dilaudid	Central Nervous System Agents: Opioid Analgesics: Schedule II Opioids. New black box warning regarding potential for abuse and risk of fatal overdose.	Current: CTP Holder MAY prescribe. Schedule II restrictions apply. 10/18/10 No Change.
Rho (D) Immune Globulin (Human) (Rho[D] IGIV) Injection Formulary Pg. 22	WinRho SDF	Biologic and Immunologic Agents: Immune Globulins. New black box warning regarding potential to develop intravascular hemolysis leading to	Current: CTP Holder MAY prescribe. 10/18/10 Change to Physician Initiated/ Physician Consult.
<u> </u>	July	death. 2010	<u> </u>
Clopidogrel Bisulfate Oral Formulary Pg. 6	Plavix	HematologicalAgents: Antiplatelet Agents: Aggregation Inhibitors. New black box warning indicating diminished effectiveness in poor metabolizers.	Current: CTP Holder MAY prescribe. 10/18/10 No Change.

Rifaximin Oral	Xifaxan	Anti-Infectives,	Current:
		Systemic:	/ 0 / GTTD
Formulary Pg. 22		New indication for	10/18/10 CTP
		reduction in risk of	Holder may
		hepatic encephalopathy recurrence	prescribe.
Human	Gardisil	Biologic/Immunologic	Current:
Papillomavirus	Gui G 1312	Agents: Agents For	CTP Holder MAY
Quadrivalent		Active Immunizations.	prescribe.
Vaccine,		New indication for	preserioe.
Recombinant		prevention of genital	10/10/10 N
Injection		warts in boys and men 9	10/18/10 No
		through 26 years of age.	Change.
Formulary Pg, 22			
		st 2010	
Propylthiouracil Oral	Propylthiouracil	Endocrine and	Current:
		Metabolic Agents:	CTP Holder MAY
Formulary Pg. 9		Thyroid Drugs: Anti-	prescribe.
		thyroid Agents.	
		New black box warning	10/18/10 No
		indicating risk for	Change.
		hepatotoxicity.	Change.
September 2010			
Iodine Products Oral	Iosat, ThyroSafe,	Endocrin and Metabolic	Current:
	ThyroShield	Agents: Thyroid Drugs.	/ 0 / GTTD
Formulary Pg. 9		New black box warning	10/18/10 CTP
		indicating that this drug	Holder may
		should only be used	prescribe.
		during nuclear radiation	
		when recommended by a	
		public official.	

Formulary Revision Request October 2010

(Original New Drug Applications: FDA)

Generic Name	Trade Name	Indication(s)	CPG Action/Date	
Formulary Review Revision Request from Michelle Bagby NP				
Treprostinil Formulary Pg. 6	Remodulin	Cardiovascular Agents: Vasodilators: Peripheral Vasodilators. Indication for treatment	Current: CTP Holder MAY NOT prescribe.	
		of pulmonary artery hypertension.	10/18/10 Change to Physician Initiated/ Physician Consult in	
		Requesting Physician Consult.	specialty clinic.	
Epoprostenol Formulary Pg. 12	Flolan	Cardiovascular Agents: Vasodilators: Peripheral Vasodilators. Indication for treatment of pulmonary	Current: IV: Acute Care CTP Holder MAY prescribe.	
		hypertension. Requesting Physician Consult.	10/18/10 Change to Physician Initiated/ Physician Consult in specialty clinic.	
Formulary	Formulary Review Revision Request from Amber S. Lanich ACNP			
Treprostinil Formulary Pg. 6	Remodulin	Cardiovascular Agents: Vasodilators: Peripheal Vasodilators. Indication for treatment of pulmonary artery	Current: CTP Holder MAY NOT prescribe.	
		hypertension. Requesting Physician Consult.	Physician Initiated/ Physician Consult in specialty clinic.	
Formulary Re	Formulary Review Revision Request from Christine Dombroski RNC NP			
Tranexamic Acid	Lysteda	Hematologic Agent: Hemostatics.	Current: CTP Holder MAY NOT	
Formulary Pg. 7		Indication for heavy menstrual bleeding.	prescribe.	
		Requesting CTP Holder May Prescribe.	10/18/10 Change to Physician Initiated/ Physician Consult.	
Formulary Review Revision Request from Teresa J. Lampe NP-C				

Tranexamic Acid	Lysteda	Hematologic Agent: Hemostatics.	Current: CTP Holder MAY NOT
Formulary Pg. 7		Indication for heavy menstrual bleeding.	prescribe.
		Requesting CTP Holder May Prescribe.	10/18/10 Change to Physician Initiated/ Physician Consult.
Formulary Review Revision Request from Joyce Perry CNP, Kellie Hoffman CNP, Donna Owen CNP			
Phentolamine Solution	Regitine, Oraverse	Cardiovascular Agents: Agents for Pheochromocytoma.	Current: CTP Holder MAY NOT prescribe.
Formulary Pg.12		Indication for pheochromocytoma, dermal necrosis. Unlabeled used for hypertensive crises. It has also been used in combination with papaverine as an intracavernous injection for impotence. Requesting CTP Holder	10/18/10 No Change.
		May Prescribe ICI- Intracavernous Injection.	
Papaverine	Papacon, Para-Time SR, Pavacot	Cardiovascular Agents: Vasodilators:	Current: PO: CTP Holder
Formulary Pg. 12		Peripheral Vasodilators. Indication for ischemia.	MAY Prescribe.
		Requesting CTP Holder May Prescribe ICI- Intracavernous Injection.	Change.