Pharmacy and Therapeutics Committee Approvals, February 2007

P&T Date: February 6, 2007

AGENDA ITEM	P&T COMMITTEE DECISION	COMMENTS
• **LUBIPROSTONE (AMITIZA®)**	**NOT ADDED TO FORMULARY.**	• ***Indication:*** Chronic idiopathic constipation • ***Mechanism of Action:*** Activation of chloride channels in the apical membrane of the gastrointestinal epithelium causing fluid secretion into the abdominal lumen resulting in an increase in intestinal fluid secretion and motility • ***Adverse effects:*** most commonly nausea (31.1%) and diarrhea (13.2%). Other adverse events include: syncope, edema, respiratory difficulty, rash, nervousness, flushing, palpitations, and vertigo.
• **PANITUMUMAB (VECTIBIX®)**	**NOT ADDED TO FORMULARY.**	• ***Indication:*** Treatment of EGFR-expressing, metastatic colorectal carcinoma with disease progression on or following fluoropyrimidine-, oxaliplatin-, and irinotecan- containing chemotherapy regimens. • ***Mechanism of Action:*** Binds to EGFR expressing cells, resulting in inhibition of cell growth, induction of apoptosis, and decreased pro-inflammatory cytokine and vascular growth factor production. • ***Warnings:*** **BLACK BOX - Severe dermatologic toxicities** (NCI-CTC grade ≥3) in 12% of patients **and anaphylactic infusion reactions.** • ***Adverse effects:*** Most commonly skin rashes/toxicities (89%), hypomagnesemia, paronychia, fatigue, abdominal pain, nausea, and diarrhea. The most serious adverse events were pulmonary fibrosis, severe dermatologic toxicity complicated by infectious sequelae and septic death. • ***Contraindications:*** None known, however, the combination of panitumumab plus IFL (ironotecan, fluorouracil, leucovorin) is not recommended due to the high incidence of grade 3-4 diarrhea.
• **CONIVAPTAN (VAPRISOL®)** • **GUIDELINES**	**ADDED TO FORMULARY & GUIDELINES APPROVED** *Restricted to adults with euvolemic hyponatremia (serum sodium ≤ 120 or severe symptomatic hyponatremia) after other potential causes have been excluded.*	• ***Indication:*** Treatment of euvolemic hyponatremia in hospitalized patients. • ***Mechanism of Action***: V_{1A} and V_2 selective receptor antagonist, causing an increase in electrolyte-free water excretion. • ***Dosage and Administration:*** The recommended dose is 20 mg IV x 1 over 30 minutes, followed by a continuous infusion of 20 mg over 24 hours. The continuous infusion of 20mg/day is recommended for 1 to 3 days but total duration of infusion should not exceed 4 days. • ***Adverse effects:*** The most common adverse events were: infusion site reactions, phlebitis, headache, hypokalemia, and hypomagnesemia. • ***Drug interactions:*** Substrate and potent inhibitor of CYP_{3A4}. Substrates of CYP_{3A4} include amlodipine, atorvastatin, digoxin, midazolam, and simvastatin. Other CYP_{3A4} inhibitors include ketoconazole, itraconazole, clarithromycin, and ritonavir (increase conivaptan plasma concentrations)
• **FLUTAMIDE (EULEXIN®)**	**APPROVED**	• ***Automatically substitute*** orders for flutamide (Eulexin®) 250mg PO TID to bicalutamide (Casodex®) 50mg daily.
• **ONDANSETRON (ZOFRAN®)**	**APPROVED**	• ***Automatically substitute*** orders for ondansetron injection >4mg to 4mg in non-chemotherapy related nausea & vomiting. • ***Automatically substitute*** orders for ondansetron ODT to tablets. • ***Remove automatic substitution*** of ondansetron to droperidol.
• **INFLIXIMAB (REMICADE®)**	**APPROVED**	• All orders for inpatient administration require approval by the Attending Physician; if unavailable, the order will be processed the next working day.

Requests for full monographs or questions regarding this listing may be addressed to the Drug Information Center at **(310) 423-3784.**

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