

## NEW DRUG CLASSIFICATION

November 15, 2005

Drug	Approval	Indication	Cost (AWP)	Alternatives	Classification	Notes
<b>Arranon®</b> (Nelarabine 650 mg ) Injection GlaxoSmithKline RX	10/28/2005	For the treatment of patients with T-cell acute lymphoblastic leukemia (T-ALL) and T-cell lymphoblastic lymphoma (T-LBL) whose disease has not responded to or has relapsed following treatment with at least two chemotherapy regimens.	Not available (N/A)	<p><b>Induction</b></p> <p>Vincristine (Oncovin®) Dexamethasone (Decadron®) Anthracycline Cyclophosphamide (Cytosan®)</p> <p>Asparaginase</p> <p><b>Maintenance</b></p> <p>Cytarabine (ara-C®) Mitoxantrone (Novantrone®) Daunorubicin (Cerubidine®) Methotrexate (Trexall®) 6-Mercaptopurine (Purinethol®)</p>	1V:1.4	Nelarabine is a pro-drug for arabinosylguanine (Ara-G). Ara-G is a nucleoside analog that has shown to be successful in the treatment of hairy cell leukemia, acute myelogenous leukemia, and chronic myelogenous leukemia. Other potential mechanisms of action include RNA synthesis inhibition and ribonucleotide reductase inhibition. During clinical trials the adverse events were dose dependent of which somnolence, malaise, and fatigue were the most common. Nelarabine is a pregnancy category D medication.
<b>Clobex®</b> (Clobetasol 0.05%) Non-aerosol spray	10/27/05	For the treatment of moderate-to-severe plaque psoriasis	\$162.50	Coal Tar Anthralin Calcipotriene Acitretin Tazarotene	3S:2.3	Clobetasol is now available as a non-aerosol spray formulation. It was demonstrated to be safe and effective in two multi-centers, randomized, double-blind

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**RX:** 1.1=review within 3 months, 1.2=review within 6 months, 1.3=review as a class only, 1.4=no review planned, 2.1=review within 6 months, 2.2=review as class only, 2.3=no review planned

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Galderma Labs Rx				Ultraviolet A and topical psoralens (topical PUVA)		studies. Clobetasol is also available as a cream, gel, ointment, and solution. Clobetasol is a pregnancy category C medication.
<b>Havrix®</b> (Hepatitis A vaccine) 720 EL.U./0.5ml Injection GlaxoSmithKline Rx	10/17/05	This formulation has a new indication of the Hepatitis A vaccine for use in children aged 12 months or older	N/A	VAQTA	5S:2.3	Hepatitis A vaccine is supplied as a sterile suspension for intramuscular administration. Hepatitis A vaccine is contraindicated in patients allergic to any component of the vaccine, including Neomycin. The tip cap and the rubber plunger of the needleless syringe contain latex rubber that may cause an allergic reaction. This is a pregnancy category C medication.
<b>Levemir®</b> (Insulin detemir {rDNA origin}) Injection Novo Nordisk Rx	10/19/05	Indicated for once or twice-daily subcutaneous administration in the treatment of adult patients with Type 1 or Type 2 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia.	N/A	Humilin-R Novolin-R NPH Humalog Novolog Lantus	3S:2.1	This is a long-acting insulin made by recombinant DNA technology as opposed to human insulin. It should be administered by subcutaneous injection in the thigh, abdominal wall, or upper arm. Injection sites should be rotated within the same region. Insulin detemir is a pregnancy category C drug.
<b>Soltamox®</b> (Tamoxifen)	10/29/05	For the treatment of Metastatic breast cancer,	N/A	Toremifene citrate (Fareston)	3S:2.2	This product provides an oral solution of tamoxifen.

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citrate) 10mg/5ml Oral solution Savient Pharmaceuticals Inc. Rx		and breast cancer incidence reduction in high-risk women. It's also indicated for the treatment of node-positive breast cancer in postmenopausal women following total mastectomy or segmental mastectomy, axillary dissection, and breast irradiation.		Fulvestrant (Faslodex)		Tamoxifen is associated with the following warning: serious and life-threatening, including uterine malignancies, stroke and pulmonary embolism, can occur when used in the risk reduction setting. This is a pregnancy category D medication.
<b>Exjade®</b> (Deferasirox 125, 250, 500mg) Tablets Novartis Rx	11/02/05	For the treatment of chronic iron overload due to blood transfusions in adults and children, administered as a once-daily drink after tablet(s) are dispersed in a glass of water or orange juice.	N/A	Deferoxamine mesylate (Desferal)	1P:1.1	This new iron chelator is administered orally as a drink (the tablets are dispersed in a glass of orange juice, apple juice or water). The current standard of care often requires a subcutaneous infusion lasting eight to 12 hours per night, for five to seven nights a week for as long as the patient continues to receive blood transfusions or has excess iron within the body. Defarasirox is a pregnancy category B medication.

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