

**TREATMENT INVESTIGATIONAL NEW DRUGS (INDS)
ALLOWED TO PROCEED
JUNE 22, 1987 – FEBRUARY 19, 2002**

<u>DRUG</u>	<u>SPONSOR</u>	<u>EFFECTIVE DATE</u>
Cytomegalovirus Immune Globulin <u>Indication</u> - To prevent cytomegalovirus infections in certain renal transplant patients. [Charges]	Commonwealth of Massachusetts Department of Public Health	10-19-87
Ifosfamide & Mesna <u>Indication</u> - Refractory germ cell carcinoma (mesna protects the bladder from toxicity associated with ifosfamide treatment).	National Cancer Institute	12-24-87
Trimetrexate <u>Indication</u> - Pneumocystis carinii pneumoinia in AIDS patients who cannot tolerate standard forms of treatment.	National Institute of Allergy & Infectious Diseases	02-18-88
Anafranil (Clomipramine HCl) <u>Indication</u> - Treatment of severe obsessive compulsive disorder.	Ciba-Geigy	06-03-88
Eldepryl (Selegiline HCl) <u>Indication</u> - Treatment of severe Parkinson-s disease unresponsive to standard therapy. [Charges]	Somerset Pharmaceuticals	06-16-88
Pentostatin <u>Indication</u> - Treatment of hairy cell leukemia refractory to alpha interferon.	National Cancer Institute	07-28-88

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Teniposide	National Cancer Institute	10-07-88
<u>Indication</u> - Treatment of relapsed or refractory acute lymphoblastic leukemia.		
Ganciclovir	National Institute of Allergy & Infectious Diseases	11-28-88
<u>Indication</u> - Treatment of cytomegalovirus retinitis in AIDS patients.		
Pentamidine Isethionate Aerosolized	LyphoMed Inc.	02-03-89
<u>Indication</u> - Prevention of Pneumocystis carinii pneumonia in AIDS patients. [Charges]		
Levamisole hydrochloride	National Cancer Institute	05-04-89
<u>Indication</u> - For use (with 5-fluorouracil) as an adjuvant treatment for Dukes C adenocarcinoma of the colon.		
Erythropoietin (EPO)	Ortho	06-27-89
<u>Indication</u> - Treatment of zidovudine (AZT) related anemia in HIV positive patients.		
Exosurf (synthetic pulmonary surfactant)	Burroughs Wellcome	07-26-89
<u>Indication</u> - Prevention and treatment of Respiratory Distress Syndrome (RDS) in premature infants.		

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Dideoxyinosine (ddl)	Bristol-Myers	09-28-89
<u>Indication</u> - Treatment of patients with AIDS or AIDS Related Complex who are intolerant to zidovudine (AZT).		
Survanta (bovine pulmonary surfactant)	Ross Laboratories	09-29-89
<u>Indication</u> - Prevention and treatment of Respiratory Distress Syndrome (RDS) in premature infants.		
Retrovir (zidovudine)	Burroughs Wellcome	10-26-89
<u>Indication</u> - Treatment of pediatric patients with HIV disease.		
Ceredase (beta-glucocerebrosidase)	Genzyme Corporation	11-07-89
<u>Indication</u> - Chronic enzyme replacement therapy in the management of patients with Gaucher's disease (Type 1). [Charges]		
Fludarabine phosphate	National Cancer Institute	11-24-89
<u>Indication</u> - Chronic lymphocytic leukemia.		
Baclofen Intrathecal	Medtronic, Inc.	03-07-90
<u>Indication</u> - Spasticity in patients with multiple sclerosis or spinal cord injury who are intolerant to or unresponsive to oral baclofen (03/90) and spasticity of cerebral origin (12/94).		and 12-12-94

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Granulocyte Macrophage Colony Stimulating Factor (GMCSF)	Immunex Corp.	09-24-90
<u>Indication</u> - Bone-marrow transplantation graft delay or failure.		
Dideoxycytidine (ddC)	Hoffmann-LaRoche	05-30-91
<u>Indication</u> - Treatment of patients with AIDS or advanced ARC who cannot be maintained on zidovudine (AZT).		
4-Hydroperoxycyclophosphamide (4HC)	Nova Pharmaceutical	06-14-91
<u>Indication</u> - Bone marrow purging. [Charges]		
Oxandrolone	Gynex, Inc.	10-17-91 and 10-21-91
<u>Indication</u> - Clinical management of boys with constitutional delay of growth and puberty (10/91) and in girls with Turners Synodrome (10/92). [Charges]		
Mepron (Atovaquone)	Burroughs Wellcome	11-08-91
<u>Indication</u> - Treatment of AIDS patients with Pneumocystis carinii pneumonia who are intolerant to or unresponsive to trimethoprim/sulfamethoxazole.		
Cognex (Tacrine) (THA)	Parke-Davis	12-02-91
<u>Indication</u> - Treatment of patients with Alzheimer's dementia. [Charges]		

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Mycobutin (Rifabutin)	Adria Laboratories	03-06-92
<u>Indication</u> - Prophylaxis against Mycobacterium Avium Complex bacteremia in HIV-infected patients.		
2-Chlorodeoxyadenosine (2-CdA)	National Cancer Institute	03-06-92
<u>Indication</u> - Treatment of active Hairy Cell Leukemia.		
Taxol	National Cancer Institute	07-15-92
<u>Indication</u> - Treatment of advanced refractory epithelial ovarian cancer.		
Copolymer-1 (COP-1)	Teva/Lemmon	01-05-93
<u>Indication</u> - Treatment of exacerbating-remitting Multiple Sclerosis. [Charges]		
Glucophage (Metformin HCl)	Lipha	09-10-93
<u>Indication</u> - Non-insulin dependent Diabetes Mellitus. [Charges]		
Navelbine (Vinorelbine tartrate)	Burroughs Wellcome	04-14-94
<u>Indication</u> - Non-small cell lung cancer.		
Somatropin	Serono	12-20-94
<u>Indication</u> - Treatment of AIDS-associated catabolism/weight loss. [Charges]		

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Gemcitabine Hydrochloride	Lilly	01-27-95
<u>Indication</u> - Locally advanced or metastatic pancreatic cancer.		
Atorvastatin	Parke-Davis	02-09-95
<u>Indication</u> - Homozygous familial hypercholesterolemia or severe refractory hypercholesterolemia.		
Riluzole	Rhone-Poulenc Rorer	06-20-95
<u>Indication</u> - Amyotrophic Lateral Sclerosis (ALS).		
Vistide (Cidofovir)	Gilead Sciences, Inc.	09-01-95
<u>Indication</u> - Treatment of CMV Retinitis		
Autologous Peripheral Blood Lymphocytes Activated Ex Vivo with OKT3 Monoclonal Antibody	Cellcor	09-15-95
<u>Indication</u> - Treatment of Metastatic (Stage IV) Renal Cell Carcinoma. [Charges]		
Carmustine Wafer	Guilford Pharmaceuticals	10-27-95
<u>Indication</u> - Recurrent malignant glioma. [Charges]		
Myotrophin	Cephalon, Inc.	06-19-96
<u>Indication</u> - Amyotrophic Lateral Sclerosis (ALS).		

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Progesterone Gel <u>Indication</u> - Invitro Fertilization (IVF).	Columbia Research, Inc.	02-07-97
Xyrem (sodium oxybate) <u>Indication</u> - Treatment of narcolepsy. [Charges]	Orphan Medical, Inc.	11-16-98
Visudyne (verteporfin) <u>Indication</u> - For the treatment of subfoveal choroidal neovascularization secondary to age-related macular degeneration (AMD)	QLT Photo Therapeutics	07-08-99
Synthetic Porcine Secretin <u>Indication</u> - 1) Evaluation of exocrine pancreatic function in patients for whom other diagnostic tests are not suitable and /or feasible, and 2) Diagnosis of gastrinoma [Charges]	Chi Rho Clin	11-01-00
Activated Protein C (human, recombinant, human kidney cells) <u>Indication</u> - Treatment of severe sepsis	Eli Lilly	01-08-01

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Ziconotide	Elan Pharmaceuticals	01-18-02

Indication – Management of severe, chronic pain in patients who are not adequately controlled and/or are tolerant to systemic opioids and for whom intrathecal therapy is warranted.