

Acute Health Division

Hospital Circular

Human
Services



Peoplefirst

Distribution: Public Hospitals

Subject: Highly Specialised Drugs Program - New indication for Cyclosporin (Neoral) and Disodium Pamidronate, revised indication for HIV/AIDS drugs and advance notice of listing of Octreotide.

Purpose: The purpose of this circular is to advise hospitals involved with the Highly Specialised Drugs Program of several changes to the Program.

We have had recent advice from the Commonwealth regarding an additional indications for Cyclosporin (Neoral) and Disodium Pamidronate (Aredia), revision of the indications for a range of HIV/AIDS drugs and advance notice for inclusion of Octreotide on the Highly Specialised Drugs Program.

NEW INDICATION

Drug: Cyclosporin (Neoral)
Indication: Treatment by dermatologists of patients with severe atopic dermatitis in whom other systematic therapy is ineffective or inappropriate.

Drug: Disodium Pamidronate (Aredia)
Indication: Treatment of predominantly lytic bone disease due to breast cancer.

Drugs: Didanosine (DDI), Indinavir Sulphate (Crixivan), Lamivudine (3TC), Nevirapine (Viramune), Ritonavir (Norvir), Saquinavir Mesylate (Invirase), Stavudine (Zerit), Zalcitabine/DDC (Hivid), and Zidovudine/AZT (Retrovir).

Indication: amend existing indication to read....

“ the treatment of HIV infection in patients with CD4 cell counts of less than 500 per mm³, or viral load greater than 10,000 copies per mL.”

EFFECTIVE SUBSIDY DATE: 1 January 1998

ADVANCE NOTICE

Octreotide (Sandostatin)

Octreotide will be subsidised from 1 February 1998 for the following indication as approved by the PBAC:

Active acromegaly in patients with persistent elevation of mean growth hormone levels of greater than 2.5 microgram/Litre and

- a. after failure of other therapy including dopamine agonists; or*
- b. as interim treatment in patients awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or*
- c. where surgery and radiotherapy are contraindicated.*

Treatment is to cease in patients previously treated with radiotherapy where there is biochemical evidence of remission (normal IGF1) after Octreotide withdrawal for at least four weeks. Octreotide should be withdrawn for assessment of remission every two years in the ten years after radiotherapy.

Treatment is to cease if there has been a failure to lower IGF1 after three months of treatment at a dose of 100 micrograms three times daily.

PRICE

Injection,	50mcg in 1 mL ampoule	\$ 41.76
Injection,	100mcg in 1 mL ampoule	\$ 83.50
Injection,	500mcg in 1 mL ampoule	\$417.96

EFFECTIVE SUBSIDY DATE: 1 February 1998

Please find attached the relevant pages to revise Appendix 2 (pages: 1, 6-8); Appendix 3 (pages: 2-3) and Appendix 8 (New Claim Form for Octreotide) of the Commonwealth/State Highly Specialised Drugs Program Guidelines, August 1997. You should update your guidelines with the attached pages.



DR C W BROOK
DIRECTOR
ACUTE HEALTH

Appendix 2: Drugs Covered by the Program

Note: Drugs funded under the Highly Specialised Drugs Program provide a subsidy for community patients only. Inpatients remain the responsibility of the treating hospital.

Drug	Date Subsidised	PBAC Clinical indications and other restrictions
Apomorphine Hydrochloride	1 Mar 1996	Parkinson's disease in patients severely disabled by motor fluctuations which do not respond to other therapy.
Azithromycin (Zithromax)	1 December 1997	Prophylaxis against Mycobacterium avium complex infections in HIV positive patients with CD4 cell counts of less than 75mm ³ .
Clarithromycin (Klacid)	1 May 1996	Treatment of Mycobacterium avium complex infections in HIV positive patients.
Clozapine (Clozaril)	1 Sep 1993 Note: indication modified 1 February 1995.	Hospital must be participating in the National Clozapine Patient Monitoring System (based at the Mental Health Research Institute of Victoria) For the treatment of Schizophrenia in patients who are non-responsive to, or intolerant of, other neuroleptic agents.
Cyclosporin (Sandimmun)	1 Jan 1991	Patients with an organ or tissue transplant.
Desferrioxamine (Desferal)	Revised indication effective from 1 July 1995.	Disorders of erythropoiesis associated with treatment related chronic iron overload.
Didanosine (DDI)	1 July 1992 Revised indication to be effective from 1 January 1998.	Treatment of HIV infection in patients with CD4 counts of less than 500 per mm ³ , or viral load greater than 10,000 copies per mL.
Disodium Pamidronate (Aredia)	1 November 1997 1 January 1998	Predominantly lytic bone disease due to advanced multiple myeloma. Predominantly lytic bone disease due to breast cancer.

<p>Interferon Alfa 2B (Intron A) <i>Continued from previous page</i></p>	<p>Revised in September 1997</p> <p>1 October 1997</p>	<ul style="list-style-type: none"> · do not have cirrhosis or other liver disease, · do not have HIV infection, · are not pregnant, not lactating, or are practising an adequate form of birth control, · have no history of significant psychiatric illness, · would be likely to attend regularly for treatment and follow-up, · have an alcohol usage of no more than 7 standard drinks per week, and · have not used illicit injectable drugs within the previous 12 months. <p>The course of treatment is limited to 3 million units subcutaneously three times weekly for up to 52 weeks. If the ALT remains greater than the upper limit of the laboratory reference range after twelve weeks, treatment is to cease. The course of treatment must be continuous and excludes re-treatment of non-responders or patients who relapse and thus patients eligible for the 12 months' course will be new patients and current responding patients who have had less than 12 months continuous interferon treatment.</p> <p>Adjunctive therapy of malignant melanoma following surgery in patients with nodal involvement.</p>
<p>Interferon Gamma 1B (Imukin)</p>	<p>1 February 1995</p>	<p>For the treatment of chronic granulomatous disease in patients with frequent and severe infections despite adequate prophylaxis with antimicrobial agents.</p>
<p>Lamivudine (3TC)</p>	<p>1 July 1996 Indication revised to be effective from 1 January 1998.</p>	<p>Combination therapy for the treatment of HIV infection in patients 12 years and older with CD4 counts of less than 500 per mm³, or viral load greater than 10,000 copies per mL.</p>
<p>Lenograstim (Granocyte)</p>	<p>1 July 1994</p> <p>Revised effective * 1 March 1996. ♦ 1 August 1997</p> <p>1 March 1996</p>	<p>For use in patients with non-myeloid malignancies receiving marrow ablative chemotherapy and subsequent bone marrow transplantation.</p> <p>Patients being treated with aggressive chemotherapy with the intention of achieving a cure or substantial remission in;</p> <ul style="list-style-type: none"> · non-Hodgkin's lymphoma (intermediate or high grade), · relapsed Hodgkin's disease, · germ cell tumours, · acute lymphoblastic leukaemia, · Ewing's sarcoma, · rhabdomyosarcoma, · neuroblastoma, · *infants and children with CNS tumours, and · ♦osteosarcoma. <p>Patients with breast cancer receiving standard dose adjuvant chemotherapy and patients receiving first line chemotherapy for Hodgkin's disease;</p> <ul style="list-style-type: none"> · who have had a prior episode of severe febrile neutropenia or prolonged severe neutropenia (neutrophil count below 1 x 10⁹ per litre), · for whom there is clinical justification for wishing to continue therapy with the same drug combination, dosage and treatment schedule, and · for whom a good response to treatment is anticipated providing chemotherapy can be delivered as planned.

Mycophenolate Mofetil (CellCept)	15 May 1997	Prophylaxis of renal allograft rejection.
Neoral (Cyclosporin)	1 March 1996 1 January 1998 Amended to be effective as at 1 October 1997	<p>Organ Transplant For use by organ or tissue transplant recipients</p> <p>Psoriasis Treatment by dermatologists of patients with severe psoriasis for whom other systemic therapies are ineffective or inappropriate and in whom the disease has caused significant interference with quality of life.</p> <p>Atopic Dermatitis <i>Treatment by dermatologists of patients with severe atopic dermatitis in whom other systematic therapy is ineffective or inappropriate.</i></p> <p>Rheumatoid Arthritis Treatment by rheumatologists and clinical immunologists of patients with severe active rheumatoid arthritis for whom classical slow-acting anti-rheumatic agents (including methotrexate) are ineffective or inappropriate.</p> <p>Condition of funding Rheumatoid Arthritis <i>The Commonwealth requires patient numbers specific to this indication as a condition of funding.</i></p>
Nevirapine (Viramune)	1 October 1997 Indication revised to be effective from 1 January 1998	Combination therapy with nucleoside analogues for the treatment of HIV infection in patients with CD4 cell counts of less than 500 per mm ³ , or viral load greater than 10 000 copies per mL.
Octreotide (Sandostatin)	1 February 1998	<p>Active acromegaly in patients with persistent elevation of mean growth hormone levels of greater than 2.5 microgram/Litre and</p> <p>(a) after failure of other therapy including dopamine agonists; or</p> <p>(b) as interim treatment in patients awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; or</p> <p>(c) where surgery and radiotherapy are contraindicated.</p> <p>Treatment is to cease in patients previously treated with radiotherapy where there is biochemical evidence of remission (normal IGF1) after octreotide withdrawal for at least four weeks. Octreotide should be withdrawn for assessment of remission every two years in the ten years after radiotherapy.</p> <p>Treatment is to cease if there has been a failure to lower IGF1 after three months of treatment at a dose of 100 micrograms three times daily.</p>
Rifabutin (Mycobutin)	1 February 1995 Revised to be effective 1 October 1997	<p>Treatment of Mycobacterium avium complex infections in HIV positive patients.</p> <p>Prophylaxis against Mycobacterium avium complex infections in HIV positive patients with CD4 cell counts of less than 75 per mm³</p>

Ritonavir (Norvir)	1 December 1996 Indication revised to be effective from 1 January 1998	Treatment of HIV infection in patients with CD4 cell counts of less than 500 per mm ³ , or viral load of greater than 10 000 copies per mL.
Saquinavir Mesylate (Invirase)	1 August 1996 Indication revised to be effective from 1 January 1998	Combination therapy for the treatment of HIV infection in patients 12 years and older with CD4 cell counts of less than 500 per mm ³ , or viral load greater than 10,000 copies per mL.
Sodium Foscarnet (Foscavir)	1 March 1994 1 July 1996	Treatment of sight-threatening cytomegalovirus retinitis in AIDs patients. Treatment of aciclovir resistant herpes simplex virus infection in immunocompromised patients with HIV infection.
Stavudine (Zerit)	1 July 1996 Indication revised to be effective from 1 January 1998	Treatment of HIV infection with CD4 cell counts of less than 500 per mm ³ , who have received prior therapy with zidovudine, or viral load of greater than 10 000 copies per mL.
Tacrolimus (Prograf)	1 November 1997	Prevention and treatment of rejection in primary liver transplant recipients.
Zalcitabine (DDC) (Hivid)	1 September 1993 Indications revised to be effective from 1 January 1998.	Combination therapy for the treatment of HIV infection in patients with CD4 cell counts of less than 500 per mm ³ , or viral load of greater than 10 000 copies per mL.
Zidovudine (AZT) (Retrovir)	1 July 1992 Indication revised to be effective from 1 January 1998.	Treatment of HIV infection in patients with CD4 cell counts of less than 500 CD4 cells per mm ³ , or viral load greater than 10,000 copies per mL.

Appendix 3: Agreed Prices

Drug & dose form information	Pack size	Agreed Price	
		1997/98	
		Per Pack	Per Item
Filgrastim			
Vial 300mcg/ml 1ml	10	\$1,504.00	\$150.4000
Vial 480mcg/ml 1.6ml	10	\$2,407.00	\$240.7000
Inj. 300mcg/1mL single dose pre-filled	10	\$1,504.00	\$150.4000
Inj. 480mcg/1.6mL single dose pre-filled	10	\$2,407.00	\$240.7000
Ganciclovir			
Powder, 500mg	1	\$57.71	\$57.7100
Capsule, 250mg	84	\$540.00	\$6.4286
Indinavir Sulphate (Crixivan)			
Capsule, 200 mg (base)	360	\$455.00	\$1.2639
Capsule, 400mg (base)	180	\$455.00	\$2.5278
Interferon Alpha 2A			
Sol for inj. 3,000,000 iu/mL sin use	3	\$78.73	\$26.2433
Sol for inj. 4,500,000 iu/mL sin use	3	\$118.10	\$39.3667
Sol for inj. 6,000,000 iu/mL sin use	3	\$157.46	\$52.4867
Sol for inj. 9,000,000 iu/mL sin use	3	\$236.20	\$78.7333
Sol for inj. 18,000,000 iu/mL sin use	3	\$472.39	\$157.4633
Vials, 18,000,000iu	5	\$787.32	\$157.4640
Inj. 3,000,000iu in 0.5mL single dose pre-filled	1	\$26.24	\$26.2400
Inj. 4,500,000iu in 0.5mL single dose pre-filled	1	\$39.37	\$39.3700
Inj. 6,000,000iu in 0.5mL single dose pre-filled	1	\$52.49	\$52.4900
Inj. 9,000,000iu in 0.5mL single dose pre-filled	1	\$78.73	\$78.7300
Interferon Alpha 2B			
Vials, 3,000,000iu	5	\$131.22	\$26.2440
Vials, 5,000,000iu	5	\$218.70	\$43.7400
Vials, 9,000,000iu	5	\$393.66	\$78.7320
Vials, 10,000,000iu	5	\$437.40	\$87.4800
Sol for inj, 10,000,000iu/ml	5	\$437.40	\$87.4800
Sol for inj, 25,000,000iu/5ml	5	\$1,093.50	\$218.7000
Sol for inj, 18,000,000iu in 3mL multi-dose vial	5	\$787.32	\$157.4640
Sol for inj, 25,000,000iu in 2.5mL multi-dose vial	5	\$1,093.50	\$218.7000
Interferon Gamma 1B			
Soln for subcut inj. 3,000,000iu 100 micrograms/0.5mL	6	\$1,052.00	\$175.3333
Lamivudine (3TC)			
Tablet, 150mg	60	\$282.00	\$4.7000
Oral solution 10mg/mL, 240mL	1	\$75.20	\$75.2000
Lenograstim			
Powder for inj. 13.4M units (105 micrograms)	5	\$256.25	\$51.2500
Powder for inj. 33.6M units (263 micrograms)	5	\$641.80	\$128.3600

Appendix 3: Agreed Prices

Drug & dose form information	Pack size	Agreed Price	
		Per Pack	Per Item
1997/98			
Mycophenolate Mofetil (CellCept)			
Capsule, 250mg	300	\$548.00	\$1.8267
Tablet, 500mg	150	\$548.00	\$3.6533
Nevirapine (Viramune)			
Tablet, 200mg	60	\$271.58	\$4.5263
Octreotide (Sandostatin)			
Injection, 50mcg in 1 mL ampoule	1	\$41.76	\$41.7600
Injection, 100mcg in 1 mL ampoule	1	\$83.50	\$83.5000
Injection, 500mcg in 1 mL ampoule	1	\$417.96	\$417.9600
Rifabutin			
Capsule, 150mg	30	\$147.00	\$4.9000
Ritonavir (Norvir)			
Capsule, 100mg	84	\$106.17	\$1.2639
Saquinavir Mesylate (Invirase)			
Capsule, 200mg	270	\$455.00	\$1.6852
Sodium Foscarnet			
Infusion, 2.4%, 250ml	6	\$395.00	\$65.8333
Infusion, 2.4%, 500ml	6	\$660.00	\$110.0000
Stavudine (Zerit)			
Capsule, 15mg	60	\$250.00	\$4.1667
Capsule, 20mg	60	\$280.00	\$4.6667
Capsule, 30mg	60	\$333.68	\$5.5613
Capsule, 40mg	60	\$444.90	\$7.4150
Tacrolimus (Prograf)			
Capsule, 1mg	100	\$405.00	\$4.0500
Capsule, 5mg	50	\$1,010.00	\$20.2000
Zalcitabine (DDC)			
Tablet 375 microgram	100	\$193.75	\$1.9375
Tablet 750 microgram	100	\$242.18	\$2.4218
Zidovudine (AZT)			
Capsule, 100mg	100	\$205.46	\$2.0546
Capsule, 250mg	40	\$205.46	\$5.1365
Syrup, 200ml	1	\$41.09	\$41.0900

HIGHLY SPECIALISED DRUGS PROGRAM

Claim Form
For the Period from to

Octreotide (Sandostatin)

Patient Information	Number of Patients*
Community Patients	

Dispensing Information			
Dosage Form, Strength	Number of Items Dispensed	Cost per Item	Expenditure
Injection, 50mcg in 1 mL amp		\$41.7600	
Injection, 100mcg in 1 mL amp		\$83.5000	
Injection, 500mcg in 1 mL amp		\$417.9600	
	Total Expenditure		

I certify that the Octreotide claimed was dispensed to patients who met the Highly Specialised Drugs Program's criteria, including PBAC indications and that the amount claimed is correct.

AUTHORISING SIGNATURE: _____ DATE: _____

NAME OF SIGNATORY: _____

CONTACT PHONE NO: _____

POSITION: _____

HOSPITAL: _____ CAMPUS: _____

*Number of patients represents total number of individual patients who received supply of highly specialised drugs in quarter, NOT number of occasions of dispensing.