THE HIGHLY SPECIALISED DRUGS PROGRAM

Program overview

In addition to the drugs available under usual PBS arrangements, a number of drugs are also made available under alternative arrangements that are clinically appropriate.

These alternative arrangements are provided for under Section 100 (s100) of the *National Health Act 1953*. One of the programs under s100 is the Highly Specialised Drugs (HSD) Program. The Australian Government provides funding for specialised medicines under the HSD Program.

Highly Specialised Drugs are for the treatment of chronic conditions which, because of their clinical use or other specialist requirements, are restricted to supply through public and private hospitals that have appropriate specialist facilities. To prescribe these drugs as pharmaceutical benefit items, medical practitioners are required to be affiliated with these specialist hospital units.

The HSD Program is administered by the Access and Systems Branch, of the Pharmaceutical Benefits Division, while the process of selecting and reviewing drugs and procedures is the responsibility of the Highly Specialised Drugs Working Party.

Subsidy for drugs under this program commences following recommendation by the Pharmaceutical Benefits Advisory Committee (PBAC), approval by the Australian Government, and the States and Territories accepting the offer of subsidy.

To gain access to a Government funded drug under this program, a patient must attend a participating hospital and be a day admitted patient, a non-admitted patient or a patient on discharge. Government subsidy is not available for hospital in-patients and funding for any in-patient use is provided by the state in public hospitals. Patients must also be under appropriate specialist medical care, meet the specific medical criteria and be an Australian resident in Australia (or other eligible person).

A patient will be required to pay a contribution for each supply of a Highly Specialised Drug at a similar rate to the PBS.

Highly Specialised Drugs Working Party

The Australian Health Ministers' Advisory Council established the Highly Specialised Drugs Working Party in 1991. The Working Party consists of representatives from the Health Department of each of the States and Territories, the Australian Private Hospitals Association and the Commonwealth as chair.

The Working Party's terms of reference are:

- selecting drugs proposed for inclusion in the funding arrangements for highly specialised drugs;
- referring proposed drugs with supporting information to the PBAC for consideration for listing as pharmaceutical benefits under section 100 supply arrangements;
- monitoring information on potential new highly specialised drugs which might come under the funding arrangements;
- monitoring the quality use of drugs supplied under these arrangements; and
- investigating and making recommendations on procedures to monitor drugs supplied by public hospitals under the section 100 arrangements to patients in community settings.

Utilisation Based Government Expenditure on Highly Specialised Drugs

During 2007-2008 there were 78 drugs subsidised under the HSD Program, compared to 2006-2007 when 71 were subsidised. The new drug listings are:

1. Ibandronate Sodium
2. Abatacept
3. Sevelamer
4. Sitaxentan Sodium
5. Tipranavir
6. Darunavir
7. Rituximab

The Government[1] expenditure based on utilisation for 2007-2008 amounted to $663,702,029. Drugs were categorised as follows:

Indications Grouping	*Number of Drugs*	*Public Hospital*	*Private Hospital*	*Combined*
Acromegaly Agents	2	$14,276,151	$7,157,581	$21,433,732
Antiarthritic Agents	4	$7,108,480	$29,489,280	$36,597,760
Bisphosphonate Agents	3	$12,110,094	$10,055,755	$22,165,849
Haemopoietic Agents	4	$94,362,386	$27,863,888	$122,226,274
Hepatitis B or C Agents	9	$58,976,446	$15,960,344	$74,936,790
HIV/AIDS Antiretroviral Agents	23	$124,640,964	$1,292,851	$125,933,815
Immunocompromised Conditions	10	$8,788,695	$1,290,358	$10,079,053
Immunosuppressive Agents	7	$58,900,273	$5,152,447	$64,052,720
Iron Overload Agents	3	$10,880,717	$2,852,222	$13,732,936
Malignancy Agents	5	$54,213,707	$37,549,921	$91,763,627
Other Conditions	3	$50,296,895	$4,322,892	$54,619,787
Pulmonary Arterial Hypertension Agents	5	$3,529,715	$22,629,967	$26,159,682
Grand Total	**78**	**$498,084,523**	**$165,617,506**	**$663,702,029**

NB: Repatriation patients have been removed from Private hospital expenditure but cannot be removed from Public hospital expenditure as repatriation patients cannot be identified by public hospitals.

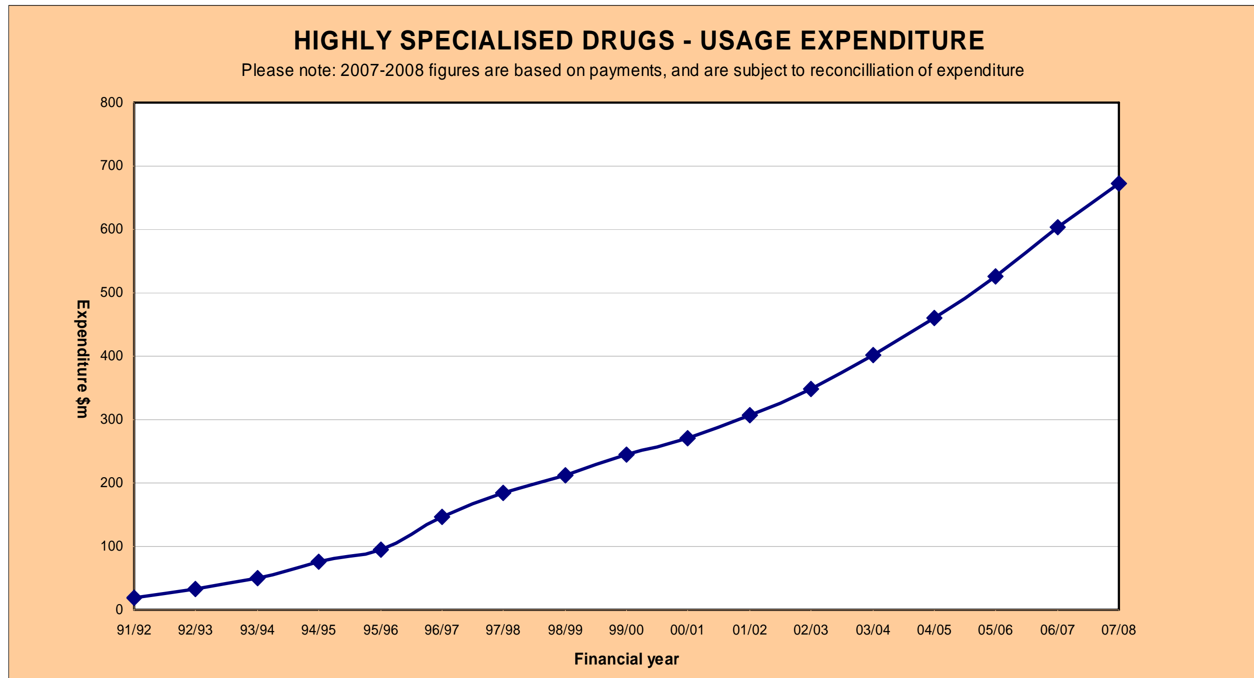
Government expenditure based on utilisation through the HSD program in 2006-2007 was $588.4 million. In 2007-2008 utilisation costs totalled $663.7 million, an increase of 12.8% from 2006-2007. At the end of the financial year, payments made to public hospitals via grants to the States and Territories are reconciled against the actual drug usage.

Australian Government expenditure for HSDs is processed through two avenues; a grant process for public hospitals and a claims payment arrangement through Medicare Australia for private hospitals. For 2007-2008 the expenditure based on utilisation in public hospitals was $498.1 million, an increase of 7.3% from the 2006-2007 expenditure of $464.3 million. HSD expenditure processed through Medicare Australia showed an increase of 33.4% from the $124.1 million in 2006-2007 to $165.6 million in 2007-2008.

The HSD Program continues to increase at a steady rate across both public and private hospitals. The increase in expenditure over the last few years is due to the increase in the number of drugs listed on the program and the increase of new private hospitals participating in the program.

[1] All usage figures quoted in table refer to Government expenditure only and exclude the patient co-payment.

Highly Specialised Drugs – Utilisation Government[2] Expenditure Chart
- outlines the program Government expenditure from 1991-1992 to 2007-2008 financial years.



[2] All expenditure figures quoted in chart refer to Government expenditure only and exclude the patient co-payment.