

## Highly Specialised Drugs Program Funding Requirements - June 2008

**Document Number** PD2008\_036

**Publication date** 04-Jul-2008

**Functional Sub group** Population Health - Pharmaceutical

**Summary** The Policy Directive outlines the Commonwealth and NSW Department of Health requirements for Area Health Services and hospitals involved with the Highly Specialised Drugs Program and the Complex Authority Required Highly Specialised Drugs Program. The policy has been updated to include changes to requirements for accredited medical practitioners prescribing hepatitis C drugs for maintenance therapy which came into effect 1 March 2008.

**Replaces Doc. No.** Highly Specialised Drugs Program Funding Requirements [PD2008\_007]

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**Applies to** Area Health Services/Chief Executive Governed Statutory Health Corporation, Board Governed Statutory Health Corporations, Affiliated Health Organisations - Non Declared, Affiliated Health Organisations - Declared, Public Hospitals

**Audience** Directors of Pharmacy, Finance, Inter-Govt Funding Strategies Branch

**Distributed to** Public Health System, NSW Department of Health, Public Hospitals

**Review date** 04-Jul-2013

**File No.** 99/9486-8

**Status** Active

### Director-General

This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is **mandatory** for NSW Health and is a condition of subsidy for public health organisations.

**COMMONWEALTH/STATE HIGHLY SPECIALISED DRUGS  
PROGRAM FUNDING REQUIREMENTS**

June 2008

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## 1 SUMMARY

This Policy Directive replaces PD2008\_007. The Policy Directive outlines the Commonwealth and NSW Department of Health requirements for Area Health Services and hospitals involved with the Highly Specialised Drugs Program and the Complex Authority Required Highly Specialised Drugs Program.

The Commonwealth/State Highly Specialised Drugs (HSD) Program was established under Section 100 of the National Health Act 1953 through an initiative of the Australian Health Ministers' Advisory Council in 1991, as a result of concerns raised by the States and Territories about the rapid growth in the use of high cost drugs provided through the public hospital system.

Section 100 of the National Health Act 1953 allows special funding arrangements for the supply of drugs where the usual Pharmaceutical Benefits Scheme (PBS) process is considered inappropriate.

In 2004 the Commonwealth introduced the Complex Authority Required Highly Specialised Drugs (CAR HSD) Program. This provides funding for a separate range of highly specialised drugs with complex restrictions where prescribers must obtain prior written approval from Medicare Australia. In addition, other restrictions may apply.

Under these programs the Commonwealth funds an agreed list of highly specialised drugs for listed clinical indications for use by outpatients and those attending day services in a hospital. Funding is not available for hospital inpatients.

Drugs are included in the HSD and CAR HSD Programs because of their clinical use or other special features and are prescribed by specialist hospital units, authorised HIV prescribers or accredited medical practitioners for hepatitis C maintenance treatment. Highly Specialised Drugs must be dispensed through a hospital pharmacy while Complex Authority Required Highly Specialised Drugs may be dispensed through hospital or community pharmacies.

A current list of drugs funded under the Highly Specialised Drugs Program and the Complex Authority Required Highly Specialised Drugs Program is available from the NSW Health Pharmaceutical Services Branch website. Highly Specialised Drugs Program declaration forms may also be obtained from this website. <http://www.health.nsw.gov.au/publichealth/pharmaceutical>. Information Bulletins are issued by the Department to advise of changes to the drugs funded under the program, including eligibility criteria.

The current restriction for each drug including indication and agreed prices is available on the Australian Department of Health and Ageing website. <http://www.pbs.gov.au/html/healthpro/home>

## **2 POLICY AND PROGRAM DEVELOPMENT**

### **2.1 Highly Specialised Drugs Working Party (HSDWP)**

The Highly Specialised Drugs Working Party was established by the Australian Health Ministers' Advisory Council (AHMAC) in 1991 to oversee the policy and administrative aspects of the Highly Specialised Drugs Program.

The HSDWP consists of representatives from the Health Departments of each of the States and Territories, the Australian Private Hospitals Association (APHA) and the Australian Government as Chair.

The HSDWP makes recommendations to the Pharmaceutical Benefits Advisory Committee (PBAC) on the suitability of supplying drugs via hospital outpatient departments under section 100 of the National Health Act 1953.

The HSDWP 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 Pharmaceutical Benefits Advisory Committee (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.

### **2.2 Pharmaceutical Benefits Advisory Committee (PBAC)**

The Pharmaceutical Benefits Advisory Committee is an independent statutory body established under section 101 of the National Health Act 1953 to make recommendations and give advice to the Commonwealth Minister of Health about which drugs should be made available as pharmaceutical benefits. The Committee is required by the Act to consider the effectiveness and cost of a proposed benefit compared to alternative therapies.

The PBAC considers submissions from interested parties, such as the Highly Specialised Drugs Working Party or pharmaceutical manufacturers, for inclusion of drugs under the special funding arrangements of Section 100 of the National Health Act.

When the PBAC recommends a drug for inclusion in the Highly Specialised Drugs Program or the Complex Authority Required Highly Specialised Drugs Program it also defines the clinical indications which the Commonwealth will subsidise. The Committee is obliged to make recommendations about a product that are consistent with the uses approved for marketing by the Commonwealth Therapeutic Goods Administration.

## **2.3 Selection Criteria**

For any drug to be considered for subsidy under the Highly Specialised Drugs Program and the Complex Authority Required Highly Specialised Drugs Program, it must:

- require ongoing specialised medical supervision,
- be for the treatment of chronic medical conditions, not episodes of inpatient treatment or treatment of acute conditions,
- be highly specialised and used in an identifiable patient target group,
- be subject to marketing approval by the Therapeutic Goods Administration (TGA) and specific indications covered by the terms of the marketing letter from the TGA, and
- have a high unit cost.

## **2.4 Submissions**

Applications for inclusion of a new drug or a variation in current listing of a drug under the Highly Specialised Drugs Program may be made either directly to the Pharmaceutical Benefits Advisory Committee (PBAC) or through the Highly Specialised Drugs Working Party (HSDWP).

Hospitals seeking NSW Department of Health's support for an application to the HSDWP should initially send a written submission to the NSW Therapeutic Advisory Group (TAG), who will assess the submission and provide advice to the Department. The submission should outline how the drug meets the selection criteria, clinical advantages over existing treatments, cost effectiveness in comparison to these treatments and projected level of use and cost. Submissions should be forwarded to:

The Executive Officer  
NSW Therapeutic Advisory Group  
PO Box 766  
DARLINGHURST NSW 2010  
Telephone: (02) 8382-2852  
Facsimile: (02) 8382 3529

## 3 PROGRAM PRINCIPLES AND REQUIREMENTS

The following principles and requirements form the basis of the funding agreement between the Commonwealth and the States and Territories for the supply of highly specialised drugs under Section 100 of the National Health Act.

### 3.1 Definition

“Highly Specialised Drugs” are medicines for the treatment of chronic conditions, which, because of their clinical use or other special features, are restricted to supply arranged through hospitals having access to appropriate specialist facilities.

“Complex Authority Required Highly Specialised Drugs” (CAR HSD) are a group of medicines that have additional specific requirements including prior written approval by Medicare Australia.

### 3.2 Funding

3.2.1 The Commonwealth is responsible for funding the cost of drugs included in the Highly Specialised Drugs Program and the Complex Authority Required Highly Specialised Drugs Program which are supplied in accordance with Pharmaceutical Benefits Advisory Committee (PBAC) criteria to community patients.

For the purposes of this Program the term *community patients* means outpatients and patients receiving day services in a hospital. Patients must also meet certain “eligibility” criteria set down in the Health Insurance Act. (Refer to Section 3.3)

3.2.2 Hospitals are responsible for funding the cost of drugs for overnight stay patients and inpatients, and for outpatient use not in accordance with the PBAC criteria.

3.2.3 The Commonwealth only reimburses to the agreed price of drugs supplied ex manufacturer. The States and Territories must therefore meet any administrative and other flow-on costs associated with the Program from their own budgets.

3.2.4 The Commonwealth only subsidises specific agreed forms and strengths of each drug. The cost of a form or strength of a drug which is not listed will not be reimbursed.

3.2.5 The Commonwealth requires the States and Territories to provide by the beginning of March each year an annual projected estimate for the forthcoming financial year for each drug form subsidised under the

Program. Payments by the Commonwealth are contingent on the provision of these forward estimates.

Area Health Services will therefore be required to provide projected annual usage estimates for all drugs supplied by their hospitals for the next financial year in January of each year. Areas/hospitals will also be required to provide forward estimates of usage of new drugs proposed for listing under the Program. (Additional Area/hospital responsibilities are listed under *Financial Reporting Requirements*, section 3.9)

- 3.2.6 A condition of funding for the treatment of hepatitis C is the requirement for the States and Territories to adhere to the following specific requirements regarding the facility for the selection of treatment centres.

Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

- (a) a nurse educator/counsellor for patients; and
- (b) 24 hour access by patients to medical advice; and
- (c) an established liver clinic; and
- (d) facilities for safe liver biopsy.

Hospitals wishing to become treatment centres for hepatitis C may lodge a submission based on above guidelines for treatment centres to:

Chief Health Officer  
NSW Health  
Locked Mail Bag 961  
NORTH SYDNEY NSW 2059

Further information and a current list of authorised treatment centres in New South Wales is available from AIDS and Infectious Diseases Unit, Department of Health (Telephone: (02) 9391 9234).

### **3.3 Patient Eligibility**

It is the responsibility of hospitals accessing the Highly Specialised Drugs Program and the Complex Authority Required Highly Specialised Drugs Program to ensure that supply is to eligible patients only.

To qualify for Commonwealth subsidy of drugs supplied under the Program a person must be:

- a community patient, which is defined for the purposes of the Program as an outpatient or a patient receiving day services in a hospital; and

- an Australian resident entitled to hold a Medicare Card, an eligible overseas representative, or other eligible person as defined in the *Health Insurance Act 1973*.

**Note:** Where a patient is entitled to be treated as an eligible person under Section 7 of the *Health Insurance Act* (i.e. a visitor from a country with which Australia has entered into a Reciprocal Health Care Agreement), the supply will be limited to the original prescription only, with no repeats.

### **3.4 Prescribing Requirements- Highly Specialised Drugs Program**

- 3.4.1 Drug treatment subsidised under the Highly Specialised Drugs Program must be initiated by specialists affiliated with hospitals having appropriate specialised facilities.

In cases where a specialist wishes an eligible patient to access a drug through a hospital with which the specialist has no affiliation, he/she should contact that hospital's management to see if an arrangement for supply of the drug can be made through the hospital pharmacy.

In the case of oral agents for the treatment of HIV/AIDS, these may also be prescribed by individually authorised prescribers who may be either hospital-based or in general practice. (Refer to section 3.4.2 below)

In addition, accredited medical practitioners may prescribe hepatitis C drug treatment for **maintenance** therapy in a shared care arrangement with agreement of the treating specialist associated with an authorised public health service Hepatitis C Treatment Centre. (Refer to section 3.4.3 below)

- 3.4.2 Authorisation to prescribe oral HIV/AIDS drugs other than by specialists is granted on an individual prescriber basis by NSW Department of Health. Among other requirements, authorised prescribers must maintain a link with a designated HIV/AIDS Unit and participate in a program of continuing medical education.

Further information on eligibility criteria and application procedures is available from:

The Project Coordinator  
HIV/HCV Continuing Medical Education Project  
Australasian Society for HIV Medicine Inc  
Locked Mail Bag 5057  
DARLINGHURST NSW 1300  
Telephone: (02) 8204 0700  
Facsimile: (02) 9212 2382

- 3.4.3 The **initiation** of prescribing of Highly Specialised Drugs for the treatment of hepatitis C is restricted to specialists associated with an authorised hepatitis C centre i.e. they may prescribe initiation and maintenance drug treatment for hepatitis C for outpatients who meet the specific indication and criteria for each individual drug.

However, medical practitioners who undertake training and are accredited by the NSW Department of Health may prescribe hepatitis C drug treatment for **maintenance** therapy in a shared care arrangement with the agreement of the treating specialist associated with an authorised public health service Hepatitis C Treatment Centre. Accredited medical practitioners may not initiate therapy. Accredited medical practitioners must nominate and maintain a link to an authorised public health service Hepatitis C Treatment Centre. Accredited medical practitioners and their patients must have full access to the services that the Authorised Hepatitis C Treatment Centre provides to their patients. (Refer to section 3.2.6) Prescriptions must be dispensed by the public hospital pharmacy.

For further information on training contact:

The Project Coordinator  
HIV/HCV Continuing Medical Education Project  
Australasian Society for HIV Medicine Inc  
Locked Mail Bag 5057  
DARLINGHURST NSW 1300  
Telephone: (02) 8204 0700  
Facsimile: (02) 9212 2382

For a list of Accredited Prescribers and Authorised Hepatitis C Treatment Centres contact AIDS/Infectious Diseases Branch, NSW Health. Telephone: (02) 9391 9249

- 3.4.4 The prescribing and supply of clozapine must involve participation in a patient monitoring system, in addition to all other requirements of the Program.
- 3.4.5 A signed declaration form which certifies that the patient meets the criteria approved by the Pharmaceutical Benefits Advisory Committee for the drug prescribed must be provided by the specialist or authorised prescriber for each patient on initiation of therapy. Current declaration forms are available from the NSW Health Pharmaceutical Services website.  
<http://www.health.nsw.gov.au/publichealth/pharmaceutical/hsd.asp>.

A separate signed declaration form must be provided for each patient and for each drug prescribed, and should accompany the original prescription to the hospital pharmacy where it must be retained for audit

purposes. There is no requirement for a subsequent declaration forms for the patient/drug, except where indicated in the criteria for specific drugs.

- 3.4.6 Ongoing specialist medical supervision is a requirement of the programs. In cases where a patient resides in a rural area where specialist services are not available, the specialist who initiates treatment may need to refer the patient to a medical officer at the local hospital or, if this is not possible, to a local general practitioner, for ongoing care between specialist visits. Specialist review should occur every six months as a minimum.

It would be preferable in such cases for the specialist to provide a six month prescription to cover the period between specialist reviews, together with a signed declaration form. However, where this is not possible, the local doctor to whom the patient has been referred by the specialist may, with the specialist's agreement, write a prescription for supply at the local hospital Pharmacy Department. If the doctor does not have an affiliation with the hospital, an arrangement will need to be made with the hospital management and Pharmacy Department for supply of the drug.

In cases where drugs are supplied to a patient through a hospital other than the hospital where treatment is initiated, it is essential for audit purposes that the supplying hospital obtains either a new signed declaration form from the specialist or a copy of the original signed declaration form from the hospital where treatment was initiated.

The requirement for specialist review does not apply to:

- to patients prescribed oral HIV/AIDS drugs by authorised hospital and community prescribers, who are required to undertake continuing medical education and to maintain a link with a designated HIV/AIDS unit. (Refer to section 3.4.2); or
  - to patients prescribed hepatitis c maintenance drug therapy by accredited medical practitioners, who are required to undertake continuing medical education and to nominate and maintain a link to an authorised public health service Hepatitis C Treatment Centre. (Refer to section 3.4.3)
- 3.4.7 Hospital pharmacies should not issue more than one month's supply of a drug at a time to avoid wastage, unless exceptional circumstances exist, when with the agreement of the hospital administration and/or the Drug Committee, greater quantities may be supplied. A patient co-payment should be collected for each month's supply of a drug provided under the Program. (Refer to Section 3.7)

### **3.5 Prescribing Requirements- Complex Authority Required Highly Specialised Drugs Program**

3.5.1 An application for authorisation to prescribe these drugs must be made in writing to Medicare Australia and must contain an authority prescription and written relevant supporting information.

Only prescriptions approved by Medicare Australia may be dispensed under the Program.

A declaration form is not required as prior written approval from Medicare Australia is required for these drugs.

3.5.2 Pulmonary Arterial Hypertension (PAH) Agents may only be prescribed by Pulmonary Arterial Hypertension (PAH) Designated Prescribing Centres. A list of Designated Prescribing Centres is available on the NSW Health Pharmaceutical Services Branch website.  
<http://www.health.nsw.gov.au/publichealth/pharmaceutical>.

### **3.6 National Drug Price**

Standard national prices for drugs included in the Highly Specialised Drugs Program and Complex Authority Required Highly Specialised Drugs Program are established through direct negotiations between the Commonwealth and suppliers, based on forward estimates of usage provided by the States and Territories. This price is referred to as the “agreed price”. Hospitals should not purchase drugs at a higher price.

### **3.7 Patient Co-payment**

The Commonwealth expects that all community patients will make a financial contribution for each month’s supply of a drug under the Program comparable to that made in the community under the Pharmaceutical Benefits Scheme, and in accordance with their status under the Commonwealth/State Joint Pharmaceutical Safety Net Scheme. The level of co-payment will be the same as the hospital outpatient rate for prescriptions applicable at the time. An amount which represents the estimated co-payments collected by hospitals is deducted by the Commonwealth from the annual grant.

### **3.8 Audit Requirements**

It is a condition of funding by the Commonwealth that adequate and auditable systems are in place which ensure that supply is to eligible community patients and that prescribing is in accordance with the criteria laid down by the Pharmaceutical Benefits Advisory Committee (PBAC) for the supply of the drug.

To comply with the above condition, hospitals must have available the following documentation, to enable claims to be audited on a patient basis:

- a prescription written by an eligible prescriber;
- a declaration form, or a copy of a declaration form, signed by the prescriber certifying that the patient meets the PBAC criteria a (NOTE: This does not apply to drugs on the Complex Authority Required Highly Specialised Drugs Program);
- the patient's Medicare Card number or other evidence of the patient's entitlement to hold a Medicare Card or other eligibility criteria as appropriate, (refer to Section 3.3); and
- a medical record.

Where the patient's medical record is held outside the hospital, for example in a specialist's consulting rooms or by a general practitioner who is authorised to prescribe oral HIV/AIDS drugs, or a medical practitioner who is accredited to prescribe hepatitis c maintenance drug therapy the accepted audit trail will consist of a prescription and a declaration form signed by the eligible prescriber. An internal audit program developed by NSW Department of Health Audit Branch for the Highly Specialised Drugs Program is included in Area Health Service audit schedules.

Officers of NSW Department of Health have the authority to review and audit compliance with the requirements of the Program in hospitals making claims for reimbursement through the Department. Documentation should be retained for seven years.

### **3.9 Financial Reporting Requirements**

For each drug supplied under the Highly Specialised Drugs Program and the Complex Authority Required Highly Specialised Drugs Program hospitals are required to report quarterly to the Department, through the Department of Health Reporting System (DOHRS), the following information:

- number of patients treated during the quarter,
- number of standard packs issued for each form of the drug in the quarter, and
- total cost claimed for each form of the drug for the quarter

Additional information is required to be submitted on a spreadsheet when claiming some drugs on the Complex Authority Required Highly Specialised Drugs Program.

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**Note:** Number of patients represents the total number of individual patients who received the drug in the quarter, not the number of occasions of dispensing.

For further information regarding financial matters contact from Finance and Business Management Branch, NSW Department of Health, (Telephone: (02) 9391 9175).

Professor Debora Picone AM  
**Director-General**