Accreditation of Community Prescribers - s100 Highly Specialised Drugs for HIV and Hepatitis B

Summary
This Policy Directive (PD) gives effect to sections of the National Health Act 1953 (Cth) and the Health Insurance Act 1973 (Cth) relating to special arrangements to be made for the supply of Highly Specialised Drugs and that patients must be under appropriate medical care. The PD sets out the criteria and requirements for general practitioners to become accredited as community prescribers of s100 Highly Specialised Drugs for HIV and Hepatitis B.

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Governed Statutory Health Corporations, Affiliated Health Organisations, NSW Health
Pathology, Public Health System Support Division, Government Medical Officers,
Community Health Centres, Public Hospitals, Private Hospitals and day Procedure
Centres

Distributed to Ministry of Health, Public Health System, Divisions of General Practice, Government
Medical Officers, NSW Ambulance Service, Private Hospitals and Day Procedure
Centres, Tertiary Education Institutes

Audience General Practitioners, Clinical and Allied Health Services
ACCREDITATION OF COMMUNITY PRESCRIBERS – S100 HIGHLY SPECIALISED DRUGS FOR HIV AND HEPATITIS B

PURPOSE

The purpose of this Policy Directive is to detail the NSW Health requirements for the accreditation and authorisation of non-affiliated medical practitioners or nurse practitioners to prescribe Highly Specialised Drugs (HSD) under section 100 (s100) of the Commonwealth National Health Act 1953 for the treatment of Hepatitis B (HBV) and Human Immunodeficiency Virus (HIV). S100 HSD are medicines for the treatment of conditions, which, because of their clinical use or other features, may generally only be prescribed by specialist medical practitioners affiliated with public or private hospitals with appropriate specialist facilities. As it is important that people living with HBV and HIV have access to high quality health care in primary care settings, the s100 HSD Program also provides for non-affiliated medical practitioners and nurse practitioners to be accredited to prescribe s100 HSD used in the treatment of HBV and HIV. With the introduction of new direct acting antiviral (DAA) treatments for Hepatitis C, it is now out of scope for inclusion as an s100 Highly Specialised Drug requiring accreditation and authorisation of community prescribers. In March 2016 the new DAAs for Hepatitis C were listed on the Pharmaceutical Benefits Scheme. The DAAs are now available on both the General Schedule (S85) and under the HSD Program (S100). Medical practitioners or nurse practitioners experienced in treating Hepatitis C, or in consultation with a specialist experienced in treating Hepatitis C, can now prescribe DAAs under General Schedule (S85) and prescriptions can be dispensed through community pharmacies.

MANDATORY REQUIREMENTS

A non-affiliated medical practitioner or nurse practitioner may only prescribe HSDs for HBV and HIV if they are authorised as a community prescriber as outlined in this policy.

IMPLEMENTATION

1. The Ministry of Health will appoint approved clinical authorities who will:

   1.1 Convene a Clinical Advisory Committee/s with sufficient specialist experience and knowledge to adjudicate applications for community prescribing accreditation in the areas of HBV and/or HIV.
   1.2 Recommend to the Ministry of Health applicants the Clinical Advisory Committee/s have assessed as having suitable grounding and experience for community prescribing with reference to any relevant clinical standards, treatment guidelines, models of care and government directives.
   1.3 Periodically adjudicate community prescribers’ ongoing suitability for community prescribing accreditation, with reference to recent clinical practice, continuing professional development (CPD), and links with...
appropriate specialists and specialist treatment facilities.
1.4 Annually, or on request, provide the Ministry of Health with a copy of the register of community prescribers who continue to be suitable for community prescribing accreditation in accordance with item 1.3. The register shall include at least the following fields: Title, First Name, Last Name, Practice Address, Post Code, Phone, Email, Provider Type, Affiliated Specialist and Specialist Treatment Facility.
1.5 Maintain a register of accredited community prescribers.

2. The Ministry of Health is required to:

2.1 Provide a mechanism for community prescriber and training programs that reflect relevant clinical standards, treatment guidelines, models of care and government directives.
2.2 On the basis of recommendations made by an approved clinical authority (per items 1.2 and 1.4 above), authorise community prescribers to prescribe s100 HSD.
2.3 Notify community prescriber applicants of the outcome of their applications.
2.4 Oversight execution of a declaration that outlines the terms of the community prescriber program.
2.5 Annually issue a list of authorised HBV and HIV community prescribers to NSW public hospital pharmacy departments.

3. Local Health Districts are required to:

3.1 Ensure that all HSD prescribing, dispensing and claiming is done in line with Commonwealth and State requirements for the HSD Program, including establishing appropriate audit processes.

**REVISION HISTORY**

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<th>Version</th>
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<td>January 2019</td>
<td>Deputy Secretary, Population and Public Health</td>
<td>This PD updates changes to community prescribing of s100 HSD for hepatitis C. Community prescribing of hepatitis C is no longer under the shared care arrangements in PD2013_55. GPs can now prescribe direct acting antiviral treatments for hepatitis C to patients under General Schedule (S85) without having a specialist referral. Prescriptions can be dispensed through community pharmacies.</td>
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<tr>
<td>December 2013</td>
<td>Deputy Director General, Population and Public Health</td>
<td>Replaces section 3.4 of PD2008-036 and IB2013_016. This PD also updates arrangements for accreditation of community providers to include Hepatitis B (HBV) community prescribing</td>
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<td>July 2008</td>
<td>Director General</td>
<td>Updates to PD2008_007</td>
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<td>January 2008</td>
<td>Director General</td>
<td>Updates to PD2005_183</td>
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<td>January 2005</td>
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ATTACHMENTS

1. Accreditation and Authorisation of Community Prescribers – Section 100 Highly Specialised Drugs for the Treatment of HIV and Hepatitis B: Procedures.
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1 BACKGROUND

1.1 About this document

Highly Specialised Drugs (HSD) are medicines for the treatment of conditions, which, because of their clinical use or other features, may generally only be prescribed by specialist medical practitioners affiliated with public or private hospitals with appropriate specialist facilities. As it is important that people living with HBV and HIV have access to high quality health care in primary care settings, the HSD Program also provides for non-specialist medical practitioners and nurse practitioners to be accredited to prescribe s100 HSDs used in the treatment of HBV and or HIV for dispensing at a public hospital pharmacy department.

1.2 Key definitions

Affiliated medical practitioner: refers to a staff hospital specialist or visiting or consulting specialist of a hospital with HBV or HIV facilities.

Approved clinical authority: refers to a committee or organisation recognised by the Ministry of Health under this policy as having sufficient medical expertise to assess community prescribing accreditation applications.

Community prescriber: refers to a medical practitioner or nurse practitioner accredited and authorised to prescribe HSDs in accordance with this policy.

1.3 Legal and legislative framework

The HSD Program is a joint initiative of the Australian Government and the states and territory governments. The Program operates under section 100 of the National Health Act 1953 (Cth). Section 100 allows for special arrangements to be made for the supply of drugs that, because of their clinical use or other special features, are restricted to supply through public and private hospitals that have appropriate specialist facilities.

A medical practitioner or nurse practitioner, who is not affiliated with an appropriate specialist unit at a public or private hospital, may only prescribe HSDs with the approval of the state or territory.

Patients must be under appropriate medical care. They must also be an eligible person under the Health Insurance Act 1973 (Cth). An eligible person must be:

- an Australian resident
- a person covered by a Reciprocal Health Care Agreement, or
- an eligible overseas representative.
2 PRESCRIBING

2.1 HSD Prescribing for HBV or HIV Medications

To write HSD prescriptions, a prescriber must be a medical practitioner issued with a PBS prescriber number and meet at least one of the following:

2.1.1 A visiting or consulting hospital medical specialist practitioner affiliated with a recognised specialist treatment facility

2.1.2 An accredited community prescriber authorised by the Ministry of Health to prescribe HBV medication as outlined in Section 2.2 of this policy

2.1.3 An accredited community prescriber authorised by the Ministry of Health to prescribe oral HIV medication as outlined in Section 2.3 of this policy

2.1.4 A hospital medical practitioner or community general practitioner in exceptional situations where it is impractical to obtain a prescription for HBV or HIV medication from the treating specialist and where that specialist medical practitioner has provided written agreement for the prescription to be issued.

2.2 HBV Community Prescribing (Shared Care)

Authorisation to prescribe drug treatment for HBV may be granted on an individual basis by the Ministry of Health to non-affiliated medical practitioners or nurse practitioners where the approved clinical authority is satisfied:

2.2.1 The applicant has:

a) completed appropriate training and assessment requirements OR
b) demonstrated equivalent prior experience OR
c) current authorisation as a HBV community prescriber by another Australian State or Territory participating in the HSD Program

2.2.2 The applicant demonstrates preparedness to participate in relevant continuing professional development (CPD)

2.2.3 There is evidence of an agreement to participate in shared care with a treating specialist associated with a recognised hospital viral hepatitis treatment facility. The applicant and his/her patients have full and timely access to the services of a nominated public hospital viral hepatitis treatment facility.
2.3 HIV Community Prescribing

Authorisation to prescribe oral agents for the treatment of HIV other than by specialists may be granted on an individual basis by the Ministry of Health to non-affiliated medical practitioners or nurse practitioners where the approved clinical authority is satisfied:

2.3.1 The applicant has:
   a) completed appropriate training and assessment requirements OR
   b) demonstrated equivalent prior experience OR
   c) current authorisation as a HIV community prescriber by another Australian State or Territory participating in the HSD Program

2.3.2 The applicant demonstrates preparedness to participate in relevant CPD

2.3.3 The applicant can demonstrate an established link with a specialist in HIV, located within a recognised specialist HIV treatment facility approved by the Ministry of Health.

3 FURTHER INFORMATION

Further information on training courses, eligibility criteria and application procedures are available from approved clinical authorities. At the time of publication, the approved clinical authority for HBV and HIV community prescribing is:

Australasian Society for HIV, Viral Hepatitis and Sexual Health
Locked Mail Bag 5057
DARLINGHURST NSW 1300
Telephone: (02) 8204 0700
Facsimile: (02) 9212 2382
ashm.org.au

Further information about the HSD Program is available from Medicare Australia at: medicareaustralia.gov.au/provider/pbs/highly-specialised-drugs/

4 LIST OF ATTACHMENTS

1. Implementation Checklist
Attachment 1: Implementation checklist

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