Health
Justice Health &
Forensic Mental Health Network

Justice Health & Forensic Mental Health Network
PO BOX 150 Matraville NSW 2036
Tel (02) 9700 3000
http://www.justicehealth.nsw.gov.au

Management and Treatment of Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV)

Policy Number 1.241

Policy Function Continuum of Care

Issue Date 6 December 2017

Summary This policy provides guidance for the screening, assessment and treatment of patients who are at risk or who are living with hepatitis B virus and hepatitis C virus

Responsible Officer ED Clinical Operations

Applicable Sites

- ☐ Administration Centres
- ☒ Community Sites (e.g. Court Liaison Service, Community Integration Team, etc.)
- ☒ Health Centres (Adult Correctional Centres or Police Cells)
- ☒ Health Centres (Juvenile Justice Centres)
- ☒ Long Bay Hospital
- ☒ Forensic Hospital

Previous Issue(s) Policy 1.241 (Dec 2013);
Policy 2.023 (Aug 2010)

Change Summary

- New direct-acting antiviral treatments are available for all patients with hepatitis C infection and subsequent change in service delivery
- New antiviral treatments for selected patients with hepatitis B infection and subsequent change in service delivery
- Increasing incidence of cirrhosis, liver failure and hepatocellular carcinoma as a consequence of hepatitis B and hepatitis C and subsequent change in service delivery for screening, monitoring and management.
- Provide guidance for clinicians receiving patients into custody on hepatitis treatment and discharging patents on treatment into the community

TRIM Reference POLJH/1241

Authorised by Chief Executive, Justice Health & Forensic Mental Health Network

1. Preface

Australia has a large and growing burden of disease attributable to chronic hepatitis B Virus (HBV) and chronic hepatitis C Virus (HCV) infection.

It is estimated that more than 77,000 NSW residents have chronic HBV infection. People living with chronic HBV are at risk of progressive liver fibrosis leading to cirrhosis, liver failure and/or hepatocellular carcinoma (HCC). People living with chronic HBV require regular monitoring to assess liver health and the need for antiviral therapy. Lifelong viral suppression with anti-viral medication is indicated for selected patients with active chronic HBV infection. Without intervention 15-25% of people with chronic hepatitis B will experience serious complications in their lifetime and a significant proportion will die from liver cancer or liver failure as a result of the infection.

Chronic HCV affects approximately 90,000 people in NSW. People living with chronic HCV are at risk of progressive liver fibrosis leading to cirrhosis, liver failure and/or hepatocellular carcinoma (HCC). Direct-acting antiviral (DAA) therapies were introduced in 2016 for the treatment of HCV. These medications are simple oral well tolerated and highly curative which means that all Australians living with HCV should receive antiviral therapy.

The goals and the supporting targets and priorities for NSW are articulated in the *NSW HBV Strategy 2014-2020* and the *NSW HCV Strategy 2014-2020*.

The effectiveness and efficiency of the Early Detection Program (EDP) is measured through a number of HBV, HCV testing and treatment key performance indicators (KPIs) in the Service Level Agreement between JH&FMHN and the NSW Ministry of Health (MoH).

2. Policy Content

2.1 Mandatory Requirements

All clinical staff must comply with this policy which:

- provides guidance for the testing of patients who have been or are at risk of acquiring HBV or HCV;
- ensures patients affected by HBV and HCV receive appropriate information relating to their condition;
- provides clinical guidelines for management of patients newly diagnosed with HBV or HCV;
- provides clinical guidelines for monitoring of patients with HBV and HCV;
- ensures patients living with HBV and HCV receive ongoing clinical care including antiviral therapy, if appropriate; and
- ensures continuation of treatment and care when patients receiving antiviral therapy enter the correctional system, move within the correctional system, or are released from the correctional system.

2.2 Implementation - Roles & Responsibilities

It is the responsibility of all clinical staff within JH&FMHN to provide care and treatment to patients at risk of, or living with HBV and HCV.

Patients undergoing assessment for HBV or HCV treatment must be referred to the JH&FMHN Hepatitis Nurse Led Model of Care. The only exceptions are those patients that are receiving HCV treatment and monitoring through a clinical research study.

Patients with chronic HCV who choose not to be treated or if treatment is delayed due to other co morbidities, and patients with chronic HBV, are to be referred to the JH&FMHN Hepatitis Nurse Led Model of Care (NLMC), for regular monitoring by the Primary Health Nurse (PHN), Public/Sexual Health Nurses (PSHN) or for review by a General Practitioner (GP), Specialist VMO and/or Nurse Practitioner (NP), Transitional Nurse Practitioner (TNP), Clinical Nurse Consultant (CNC) Hepatology depending on clinical status. Refer to JH&FMHN *Hepatitis B Clinical Management Guidelines* and/ or *Hepatitis C Clinical Management Guidelines*.

3. Procedure Content

3.1 Testing for HBV and HCV

Patients who are identified as being at risk of having acquired a blood borne virus (BBV) or sexually transmittable infection (STI) must be offered testing as per Policy 1.363 *Early Detection Program for Blood Borne Viruses and Sexually Transmissible Infections*.

Patients, who disclose current and likely ongoing risk behaviours at the initial EDP test, should be re-tested according to the appropriate window period: HBV and HCV re-test in 6 months. A wait list entry for rescreening should then be made at this initial appointment.

The NHMRC recognises that all people in custody and particularly people who inject drugs, are at high risk of acquiring and transmitting HBV infection, which is vaccine preventable. Therefore as per Policy 1.245 *Immunisation of Patients*, HBV immunisation of patients must be a priority for all clinical staff in JH&FMHN. All patients must be offered, and where possible, complete a three-dose course of HBV vaccine over 4 months. The HBV immunisation can be commenced at the initial screening appointment opportunistically.

3.2 Results of HBV and HCV testing

All results of HBV and HCV testing must be interpreted by the Public Sexual Health Nurse (PSHN) and provided to the patient. There is a PSHN linked to all health centres. When patients are screened by PCN's a corresponding wait list entry must be made on the PSHN list for the results to be interpreted. At centres where the PSHN is not on site a wait list entry in iPM PAS must be made for the population health at that centre, so the linked PSHN can follow these results up.

For negative results, the PSHN must complete the JH&FMHN *Results Letter* informing the patient of their results. This letter must be scanned and emailed to the Nursing Unit Manager (NUM) for distribution by the NUM (or delegate) at health centres that do not have a PSHN on site. At all health centres the results letter must be placed in an official JH&FMHN envelope marked confidential and addressed to the patient. A copy of the letter must be filed in the patient's health record.

The PSHN will make a Primary Health Nurse (PHN) wait list entry for any patients who are non-immune (anti-HBsAb negative and anti-HBcAb negative), so that HBV immunisation can be offered, or continued if they have their first dose at the initial EDP. If the HBV results from the EDP reflect immunity to (HBcAb positive or HBsAb greater than 10 IU/ml) further immunisation is not required and any further scheduled appointments

for HBV immunisation must be cancelled. The results of HBV immunity must be recorded on the immunisation record in the patient's medical record.

For HIV positive adults, immunocompromised adults and other special groups refer to The Australian Immunisation Handbook.

Patients with a negative result for HBV or HCV, who disclose risk behaviours since the initial EDP test, should be re-tested according to the appropriate window period HBV and HCV retest in 6 months.

For results indicative of acute or chronic HBV or HCV infection, the PSHN must complete JUS060.309 *Population Health Early Detection Programme Registration Form*. Positive results should be returned to the patient face-to-face (if at the same centre/inpatient unit) or via teleconference if at another centre. (Inpatient unit comprises of the Forensic Hospital or Long Bay Hospital).

When negative and positive results are returned to the patient, clinical notes must be recorded, the iPM PAS appointment entries made (as appropriate) and the appointment must be coded. If the consultation is by teleconference, this will include the scanning and emailing of progress notes to the relevant centre for filing as required and posting of the original notes.

For further information refer to Policy 1.363 *Early Detection Program for Blood Borne Viruses and Sexually Transmissible Infections*.

3.3 History and Clinical Assessment for HBV and HCV

Where the result is HBsAg detected and/or HCV PCR detected, the JUS030.303 *Nurse Led Model of Care (NLMC) Hepatitis Clinical Assessment Form* must be completed by the PSHN or the PHN (in consultation with the PSHN).

Where the result is HBsAg detected, the patient must be assessed and referred as detailed below for continued monitoring and/or treatment consideration.

Where the result is HCV PCR detected, the patient must be offered antiviral therapy, or re-tested in 3-6 months for spontaneous clearance if acute infection is suspected. If the patient consents to treatment, further work up for treatment is then to be performed by the PSHN or the PHN (in consultation with the PSHN) if at a health centre where there is no on site PSHN.

In both cases, the JUS030.303 *NLMC Hepatitis Clinical Assessment Form* must be emailed to the NP/TNP/CNC Hepatology, filed in the patient's health record, a progress note entry made, and an iPM/PAS referral made to the JH&FMHN Hepatitis Nurse Led Model of Care team under the HepCare.

For those with chronic HBV or HCV, the NP/TNP/CNC Hepatology, PSHN or the PHN (in consultation with the PSHN) will:

1. Undertake a history and further clinical assessment using the JUS060.341 *NLMC Hepatitis B Clinical Assessment Form* and/or complete the JUS060.342 *NLMC Hepatitis C Clinical Assessment Form*.
2. Complete a FibroScan (Transient Elastography) test, if clinically indicated and report the result using the JUS100.300 *FibroScan Report* which will be uploaded to JHeHS.
3. In addition the NP/TNP/CNC Hepatology will complete a drug interaction check (refer to http://www.hep-druginteractions.org/).

The specialist consult/review is undertaken between the NP/TNP/CNC Hepatology, or the PSHN (when assessed as competent) VMO and patient as required, either by case presentation, teleconference or face-to-face, using the JUS060.345 *Specialist Review Form*. The most recent pathology results must be reviewed at this time on JHeHS. The result of this consultation may include prescription for antiviral therapy and/or alternative follow-up plans.

For health centres/inpatient units utilising external specialist Visiting Medical Officers (VMO), appropriate documentation and iPM/PAS appointments must be completed.

3.4 Treatment Initiation for HBV and HCV

All patients prescribed Highly Specialised Drug (HSD) medication are required to complete JUS020.125 *Consent for JH&FMHN Staff to Obtain Patient Medicare Number*. The completed form should be faxed to the Population Health Secure Fax (02) 9700 3747 so that the required information can be obtained from Medicare Australia. A patient who's Medicare number has expired or unable to be found on the Australian Government Department of Human Services Provider Digital Access Portal will be required to re-apply. Patients who are Medicare ineligible will not be denied treatment on this basis and funding will be sort through compassionate or other means.

On the Long Bay Campus, once written by the Specialist VMO the original Auxiliary Regular Medicine Order (ARMO) and the original HSD script must be sent, by the NP/TNP/CNC Hepatology, to the JH&FMHN Pharmacy Department for review and dispensing. At sites other than Long Bay Campus once written by the Specialist VMO a copy of the ARMO and the original HSD script must be sent to the JH&FMHN Pharmacy Department.

Once antiviral medication for HCV treatment is received at a health centre, the NUM is to be notified by the PHN. The NUM must acknowledge the receipt of the medication on the Hepatitis C Data Base, Trim document DG20711/17.

The receiving clinician must not commence treatment with the patient until approval from PSHN and/or NP/TNP/CNC Hepatology has been obtained. The clinician initiating treatment must confirm the patient's release date and whether any new medications have commenced since completion of the JUS060.342 *NLMC Hepatitis C Clinical Assessment Form*. If new medications have commenced, discussion must occur with the NP/TNP/CNC Hepatology for a repeat drug interaction check (refer to http://www.hep-druginteractions.org/).

A discussion with the patient regarding side effects must occur utilising the product information booklet supplied with the medication. The importance of taking the medication at a similar time of the day and not to miss any doses must be reinforced to the patient. Information should also be provided on what to do if any doses are missed. The patient must be educated about being responsible for the safe keeping of the medication if approved for self medication due to the high cost and difficult nature of replacing the medication.

iPM/PAS coding and an appointment comment must be completed by the clinician commencing treatment stating that treatment has been commenced. Further an Alert must be entered in iPM/PAS: Clinical > Essential Medication. The alert must include the start date and end date of the treatment course. A progress note entry must be made in the patient's health record.

The Population Health Surveillance Officer must be notified of all patients commencing treatment for HCV or HBV for reporting and data quality. JUS060.320 *The Viral Hepatitis Data Collection Form* must be completed by the clinician who commences treatment and faxed to the Population Health Secure Fax (02) 9700 3747.

The JUS110.304 *Schedule of Investigations – Hepatitis C treatment with Direct Acting Antivirals (DAAs)* must be initiated and emailed to the NP/TNP/CNC Hepatology.

Patients with cirrhosis, and whose treatment will include Ribavirin medication must also have the JUS110.301 *Hepatitis Treatment Record* initiated.

The above three forms must be filed in the Observation section of the patient's health record while on treatment and then filed in number order at completion of treatment.

3.5 Monitoring

3.5.1 Monitoring for HBV and HCV (on treatment)

Monitoring of patients on HBV treatment must be consistent with the JH&FMHN *Hepatitis B – Clinical Management Guidelines*. This must include at least 6-monthly FBC, LFT, UEC, INR, and HBV DNA, and annual HBV serology (anti-HBsAb, anti-HBsAg, anti-HBeAg, anti-HBeAb) and may also include a 6-monthly abdominal ultrasound for HCC for higher risk groups, as determined by the clinical plan in conjunction with the NP/TNP/CNC Hepatology and/or VMO. For further information refer to *ASHM – Decision Making in HBV*.

Monitoring of patients on HCV treatment must be consistent with the JUS110.304 *Schedule of Investigations – Hepatitis C treatment with Direct Acting Antivirals (DAAs)*. During treatment, these follow-up intervals need to be reviewed on a case-by-case basis by the PSHN. At each appointment the PHN or PSHN must discuss adherence to treatment, and assess adverse events and potential drug–drug interactions. Blood test results must be monitored when results are available for patient safety (GESA, 2017). If any MO's are planning to commence new medications whilst the patient is on HCV treatment a drug interaction check must be completed (refer to http://www.hep-druginteractions.org). For further information on treatment monitoring refer to *GESA - Clinical guidance for treating hepatitis C virus infection*: a summary and *GESA - The Australian recommendations for the management of hepatitis C virus infection: a consensus statement 2017*.

When pathology is taken as per the schedule of investigations a iPM/PAS wait list entry must then be made for PSHN in your centre or PSHN linked to your health centre (POP-CL-GAOL-TELE) so the results can be assessed and signed off. A further wait list entry must be made for the PHN wait list for the next date of treatment monitoring as per the JUS110.304 *Schedule of Investigations – Hepatitis C treatment with Direct Acting Antivirals (DAAs)*.

Monitoring of patients on HCV and HBV treatments is the responsibility of the health centre/inpatient unit where the patient is located. Staff should liaise with the PSHN or NP/TNP/CNC Hepatology for any questions or concerns.

3.5.2 Monitoring for chronic HBV and HCV (not on treatment)

Monitoring of patients, by the PHN/PSHN, with chronic HBV and HCV (not on treatment) must be consistent with the JUS110.300 *Chronic Hepatitis Routine Monitoring*. This should include 6-monthly FBC, LFT, UEC, and INR for patients with chronic HBV and HCV. A base line FibroScan should be attended and then yearly to second yearly depending on the previous FibroScan result. For those patients with chronic HBV, HBV DNA, anti-HBsAg, anti-HBeAb and anti-HBeAg must be included. At each appointment a follow up wait list for continued routine monitoring must be made. Patients with chronic HBV and/or HCV who have cirrhosis or

are otherwise at higher risk of HCC refer to Policy 1.175 *Management of Advanced Liver Disease and Hepatocellular Carcinoma*.

3.5.3 Screening for Hepatocellular Carcinoma (HCC)

Health centres/inpatient units must consult with the NP/TNP/CNC Hepatology regarding frequency of screening for HCC for all patients identified with:

- chronic HBV and HCV, and/or;
- advanced liver disease, and/or;
- cirrhosis (F4) detected by FibroScan, and/or;
- higher risk groups with chronic HBV:
    - Asian males over 40 years.
    - Asian females over 50 years.
    - African males over age 20 years.
    - Those with a family history of HCC.

3.6 Continuity of Care

3.6.1 New patients entering custody on treatment

New patients entering custody or inpatient unit whilst on HBV or HCV treatment must continue their treatment without interruption due to the clinical risks associated with missed doses. The NP/TNP/CNC Hepatology and the JH&FMHN Pharmacy Department must be contacted at the earliest possible time of the day so that the process of facilitating continuity of treatment can occur, and replacement medication can be couriered to the Health Centre/inpatient unit if required.

For patients on HCV treatment, the receiving health centre/inpatient unit or police cells clinical staff must verify with the patient:

- When treatment was commenced.
- How many tablets have been taken to date?
- Whether the current medications can be retrieved from the community? Staff must exhaust all options through liaison with friend/family members and/or external providers to have it delivered or brought to the Health Centre if possible. In some circumstances JH&FMHN Pharmacy Department will courier the medications from the patient's home.
- If the patient has their own unopened medication and the medication meets the requirements contained in the JH&FMHN *Medication Guidelines* per section 5.10.2 *The Use of Patient's-Own Medication* then they may be used. Any opened containers of medication must be sent to the JH&FMHN Pharmacy Department for quality assurance.
- If the HCV medication is unable to be sourced from the community, staff should note that strict controls exist from the Federal Government regarding the re-supply of HCV medication and further supply may not be possible if existing tablets cannot be located. The NP/TNP/CNC Hepatology must be made aware the patient is in custody and there is no likelihood of the medication being obtained from the community, so an alternate option can be considered.

The receiving Health Centre/inpatient unit or Police Cells clinical staff must obtain a signed Release of Information (ROI) request from the patient, to be sent to their treatment providers through the JH&FMHN Health Information and Records Service (HIRS). More than one ROI may be required, for example to contact the:

- specialist clinic
- community or hospital pharmacy who dispenses the patient's medication
- GP
- Laboratory where blood tests were done pre-treatment and during treatment.

ROIs must be marked URGENT and sent to JH&FMHN HIRS via Fax: (02) 9289 5107. The ROIs must include the following request:

- Copy of the Pharmaceutical Benefits Scheme (PBS) script from the dispensing pharmacy
- Copy of pre-treatment pathology results from the prescribing doctor e.g. HCV genotype, HCV Viral load, or HBsAg and HBV DNA (if on HBV treatment)
- Copy of the most recent pathology results
- FibroScan score from the prescribing doctor
- Starting date of treatment
- Planned duration of treatment
- Any additional medications the patient may be currently prescribed

Once the external provider's information is received by HIRS, it is uploaded into JHeHS and HIRS will create a waitlist entry in iPM/PAS notifying the Health Centre that the information is now available. A telephone order script must then be arranged with the Remote On Call After Hours Medical Service (ROAMS) primary health doctor (13000 ROAMS or 13000 76267). The script must be sent to the JH&FMHN Pharmacy Department to arrange urgent ongoing supply. If out-of-hours, staff must contact the After Hours Nurse Manager (AHNM). Following this, staff must liaise with NP/TNP/CNC Hepatology and PSHN, Long Bay Correctional Complex (LBCC) as soon as possible to facilitate an ongoing prescription and an Auxiliary Medication Chart.

On Sundays (HIRS not available), staff must send an ROI request directly to the external dispensing pharmacy to confirm the patient's current treatment regimen.

The receiving centre must undertake baseline pathology testing as soon as possible as per JH&FMHN *Hepatitis B – Clinical Management Guidelines* – JH&FMHN *Hepatitis C-Clinical Management Guidelines*.

When a new reception/admission enters custody/inpatient unit on treatment with their medication, the receiving centre should use the medication if it meets the requirements outlined in the JH&FMHN *Medication Guidelines* under 5.10.2 *The Use of Patient's-Own Medication*.

3.6.2 Patients transferred between health centre/inpatient units on treatment

It is imperative that all patients on HBV and HCV treatment transfer accompanied by their medication. On transfer into a centre the receiving nurse should check the patients LSMC if it is identified that the medication has not been sent with the patient the NUM or AHNM must be notified immediately. Every effort must be made to locate the patient's medication. This could include:

- Liaison with CSNSW to see if the medication is in the patients' property or carry on.
- Contact the patient's previous health centre to locate the medication.
- If the medication is found at the previous centre a courier must be organised by the previous centre to deliver the medication so there are no missed doses.
- If the medication is not located the NP/TNP/CNC Hepatology or if out of hours the AHNM must be notified in order to plan for replacement medication through the JH&FMHN Pharmacy Department.
- An IIMS must be initiated to report this incident.

To provide continuity of care, patients that have been commenced on HCV treatment transferring from custodial settings where the health care is provided by a non JH&FMN health-care provider, e.g. a private operator (e.g. Global Expert Outsourcing (GEO)) or a Clinical Research Study (Stop C), the PHN must refer patients at transfer to the NLMC on iMS PAS. The PCN must check there are follow up appointments for treatment monitoring as per the JUS110.304 *Schedule of Investigations – Hepatitis C treatment with Direct Acting Antivirals (DAAs)* and a wait list entry for the PSHN.

3.6.3 Patients leaving custody/inpatient unit on treatment

Patients leaving custody on HBV or HCV treatment must continue their treatment without interruption due to the clinical risks associated with missed doses.

Prior to the patient's departure, health centre/inpatient unit staff must liaise with the JH&FMHN Pharmacy Department regarding discharge medications and repeat prescriptions. Staff must also ensure the patient is provided with appropriate follow up information.

Staff handing over care of the patient must endeavour to connect the patient with a GP, specialist MO and/or hospital pharmacy, and make arrangements with the patient for the required information below to be sent to the nominated address or service. The information may also be provided to the patient on release. N.B. The *Hepatitis NSW Directory* provides a listing of available services by postcode. Staff must check patient's contact details for the community have been recorded and updated on the JUS 030.303 *NLMC Clinical Assessment form* in the event that follow-up post-release is required. All clinical staff should liaise with a PSHN as required.

The required release documents include

- JHeHS Transfer of Care summary
- FibroScan report
- Viral Hepatitis Data Collection Form.
- A copy of the original HSD prescription may be found in the patient's health record or may be obtained by contacting the JH&FMHN Pharmacy Department.
- Template letters of introduction for the receiving health professional are available on JH&FMHN intranet /Forms/Population Health.

Discharge Letters for Receiving Health Professional:

  - HBV Discharge Letter MO.
  - HCV Discharge Letter MO.

- HCV Discharge Letter Public Hospital Pharmacy.

Patients leaving custody/inpatient unit at short notice may be given the JH&FMHN phone number (02) 9700 3000. Attempts must be made by the health centre to contact the patient to make arrangements for continuity of care where possible.

4. Definitions

Must

Indicates a mandatory action to be complied with.

Should

Indicates a recommended action to be complied with unless there are sound reasons for taking a different course of action.

5. Legislation and Related Document

JH&FMHN Policies and Procedures	1.175 *Management of Advanced Liver Disease and Hepatocellular Carcinoma*
	1.245 *Immunisation of Patients*
	1.363 *Early Detection Program for Blood Borne Viruses and Sexually Transmissible Infections*
	Hepatitis Clinical Management Guidelines
	Medication Guidelines
	Supplement to Hepatitis Clinical Management Guidelines - Hepatitis B
JH&FMHN Forms	*HBV Discharge Letter*
	HCV Discharge Letter
	HCV Discharge Letter Public Hospital Pharmacy
	JUS020.125 *Consent for JH&FMHN Staff to Obtain Patient Medicare Number*
	JUS030.303 *Hepatitis Clinical Assessment Form*
	JUS060.320 *Viral Hepatitis Data Collection Form*
	JUS060.341 *NLMC Hepatitis B Clinical Assessment Form*
	JUS060.342 *NLMC Hepatitis C Clinical Assessment Form*
	JUS060.345 *Specialist Review Form*
	JUS100.300 *FibroScan Report*
	JUS110.300 *Chronic Hepatitis Routine Monitoring*
	JUS110.301 *Hepatitis Treatment Record*
	JUS110.304 *Schedule of Investigations – Hepatitis C treatment with Direct Acting*

	Antivirals *Results Letter*
NSW MoH Policy Directives, and Guidelines	*NSW Hepatitis C Strategy 2014-2020* *NSW Hepatitis B Strategy 2014-2020*
Others	*The Australian Immunisation Handbook* *ASHM – Decision Making in HBV* *GESA - The Australian recommendations for the management of hepatitis C virus infection: a consensus statement 2017* *Hepatitis NSW Directory* *HEP Drug Interactions Website* *ASHM – HCV New Treatment Quick Reference Tool*