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Management of Advanced Liver Disease Hepatocellular Carcinoma Screening

Policy Number 1.175

Policy Function Continuum of Care

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Summary This policy provides guidance for the screening, assessment, treatment and monitoring of patients who are at risk of, or who are living with, advanced liver disease and/or hepatocellular carcinoma.

Responsible Officer Executive Director 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 (Youth Justice NSW)
- ☒ Long Bay Hospital
- ☒ Forensic Hospital

Previous Issue(s) Policy 1.175 (January 2018; March 2014; 1.241 December 2012; 2.023 August 2010)

Change Summary

- Ensure document reflects current best practice and evidenced based medicine
- Clarification of housing management for ALD patients
- Update links to current policies

HPRM Reference POLJH/1175

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

1. Preface

Advanced Liver Disease (ALD) is a disease process that involves progressive destruction, attempted regeneration and replacement of the functioning liver by fibrous tissue culminating in cirrhosis. Portal venous flow into the liver decreases due to the process of fibrosis, leading to elevated portal pressures (portal hypertension) and expansion of portal-systemic venous communication pathways manifesting as varices. Portal hypertension also leads to splenomegaly, causing anaemia and thrombocytopenia. The most commonly recognised complications of ALD include ascites, peripheral oedema, variceal bleeding, and hepatic encephalopathy. In addition, cirrhosis is associated with a markedly increased risk of hepatocellular carcinoma (HCC).

Patients with established cirrhosis may have stable liver function for long periods of time. An acute insult such as variceal bleeding or sepsis in the presence of advanced fibrosis and decreased functional reserve may lead to hepatic decompensation, or liver failure may develop insidiously as a result of the progressive clinical course of ALD.

This policy describes an integrated approach to screening, assessment and management of patients with ALD and HCC.

There is a close nexus between hepatitis B (HBV), hepatitis C (HCV) and imprisonment, as injecting drug use is a key risk factor for transmission of both of these viruses, and also a major driver of criminal activity. Although unrestricted access to testing and highly effective antiviral therapy is available for both of these chronic viral infections, less than half of those diagnosed in Australia are currently receiving treatment. Left undiagnosed and untreated, these infections will continue to drive a rapidly growing disease burden on the Australian health care system via the insidious progression of hepatic fibrosis leading to cirrhosis, liver failure and HCC with the attendant high levels of morbidity and mortality.

The NSW Ministry of Health has committed to at least doubling the number of people receiving treatment for chronic HCV and tripling the number of people on treatment for chronic HBV, in order to avert the personal, social and health care costs of the burgeoning epidemic of ALD and its complications. The goals and the supporting targets and priorities for NSW are articulated in the NSW HCV Strategy 2014 - 2020 and the NSW HBV Strategy 2014 - 2020.

Data collected during 2012-2014 in Justice Health and Forensic Mental Health Network (the Network) from staging the degree of hepatic fibrosis by transient elastography (Fibroscan™) revealed that 12% of patients with chronic HCV have cirrhosis (fibrosis stage 4, or F4), indicating the substantive burden of ALD due to HCV alone in the NSW custodial system (Kelly 2018)

Cirrhosis of the liver is the greatest risk factor for HCC in Australia. HCC is the fastest rising cause of cancer death in Australia (MacLachlan 2012) with a reported 200% increase in liver cancer mortality from 1982-2017 (AIHW 2017).

Other causes of ALD include alcohol; metabolic associated liver disease (MAFLD) previously called non-alcoholic fatty liver disease (NAFLD), primary sclerosing cholangitis, primary biliary cirrhosis, autoimmune hepatitis, and genetic causes including haemochromatosis and Wilson's disease.

2. Policy Content

2.1. Mandatory Requirements

Staff must comply with this policy which:

- provides guidance for the holistic management of patients who have ALD and/or HCC;
- ensures patients affected by ALD and HCC receive appropriate information relating to the condition;
- provides clinical guidelines for management of new patients with ALD and/or HCC;
- provides clinical guidelines for monitoring of patients with ALD and/or HCC;
- provides guidelines for accommodation requirements for people living with ALD and/or HCC
- ensures patients living with ALD and/or HCC receive ongoing clinical care including antiviral therapy if appropriate; and
- ensures continuation of treatment when patients ALD and/or HCC 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 the Network to provide care and treatment to patients living with ALD and/or HCC. It is the role of the Network Population Health HepCare Team (Nurse Practitioners (NP), and Clinical Nurse Consultant (CNC, Hepatology) to coordinate and support primary prevention (clinical and laboratory monitoring, endoscopy) and secondary prevention (ongoing clinical and laboratory surveillance, endoscopic surveillance, medication for complications).

Patients who are living with hepatitis, ALD and/or HCC must be referred to the HepCare Team Nurse Led Model of Care (NLMC). They must be regularly monitored and managed by the Primary Health Care Nurses (PHN) and the Public Sexual Health Nurses (PSHN) in consultation with the HepCare team, including those with cirrhosis (F4) detected by FibroScan and also those with an increased risk of HCC without cirrhosis due to chronic hepatitis B.

Further detail on staff roles and responsibilities and the processes for each of the above is provided in this policy in Section 3 Procedure Content.

3. Procedure Content

3.1. Identification of patients with ALD and HCC

The identification component of the clinical pathway for ALD and HCC must be commenced by the PHNs at the Reception Screening Assessment (RSA) or at the Early Detection Program Screening (EDP). Those patients who report, or are known or suspected to have ALD, must be referred through the Patient Administration System (PAS) / iPM to the PSHN who must undertake an initial ALD assessment including clinical observations and measurements as well as laboratory investigations as per the JHFMHN Protocol for Management of ALD and HCC. The patients must then be referred by the PSHNs to the Network

HepCare team who will manage the patients via the Nurse Led Model of Care (NLMC) program. There is an increased likelihood of fulminant hepatitis in patients with existing cirrhosis if they become newly infected with viral hepatitis (due to the reduced reserve of hepatic synthetic function). Therefore as per the Network Policy 1.245 *Immunisation of Patients*, a two dose hepatitis A immunisation (0, 6-12 months) must be offered to these patients if they are non-immune (hepatitis A IgG antibody negative), either as a monovalent vaccine, or combined with HBV immunisation (Twinrix 720/20) if the patient is non-immune to HBV (hepatitis B surface antibody negative), in accordance with the Australian Immunisation Handbook.

3.2 Laboratory Monitoring

Laboratory monitoring must be consistent with the

Protocol for Management of ALD and HCC.

3.3 History and Clinical Assessment for ALD and HCC Screening

The HepCare team will undertake a detailed medical history assessment including a clinical history, examination, and laboratory investigations, as well as a Fibroscan using the *NLMC Advanced Liver Disease (ALD) Clinical Assessment Form* JUS060.340. For those patients with ALD and/or HCC who are also living with chronic HCV or chronic HBV, the HepCare team will also undertake further targeted assessments and complete the *NLMC Hepatitis C Clinical Assessment Form* JUS060.342 or the *NLMC Hepatitis B Clinical Assessment Form* JUS060.341 where appropriate. Upon completion of the form or forms, a specialist consultation between the HepCare nurse and the Specialist should be undertaken. This consultation is to determine whether a person to person consultation with the specialist and patient is required, and to designate ongoing monitoring, management and treatment requirements.

Patients with stable ALD may then be managed in a shared care arrangement with the HepCare NP/CNC Hepatology in conjunction with Primary Care GP/NP and the Infectious Diseases (ID) Specialist or Hepatologist and ID Registrar. The shared care arrangements are communicated by the relevant waitlist entries in PAS and documented in the patient's health record via JHeHs. The recommended review intervals for the HepCare NP/ CNC, Primary Care GP/NP and Specialists as well as the clinical and laboratory monitoring parameters will be directed by the outcome of the clinical consultation with the HepCare team and Specialists. Typical follow-up periods range from six monthly for stable patients with no evidence of decompensation and on no medications, to quarterly for those requiring medications or with active problems. More frequent review is indicated for unstable patients. Suggested medical interventions for patients with ALD and stable liver function, are outlined in the *Protocol for Management of ALD and HCC*. The management plan must be documented in the patient's health record utilising the *NLMC Advanced Liver Disease (ALD) Clinical Assessment Form* JUS060.340 on JHeHs and the next consultation waitlisted. The relevant NLMC forms are signed off by the reviewing specialist and/or nurse practitioner.

Patients with stable ALD including compensated cirrhosis may be housed in a centre with or without 24 hour nursing presence.

Patients with unstable ALD requiring immediate intervention must be transferred to the local hospital's Emergency Department. Refer to policy 1.252 *Access to Local Public Health Services*. Patients with unstable ALD who have a recent history of bleeding, encephalopathy, ascites and/or

spontaneous bacterial peritonitis (SBP) must be housed in a Centre where there is 24 hour nursing presence.

Resuscitation of patients with proven or suspected variceal bleeding must be done in accordance with *Adult Emergency Response Guidelines* and the *Protocol for Management of ALD and HCC*. Proven or suspected SBP must be managed according to the *Protocol for Management of ALD and HCC*.

3.4 Screening for HCC

Regular screening for HCC is facilitated by the PSHNs in consultation with the HepCare team, for all those identified with cirrhosis (F4) detected by Fibroscan, and also those with an increased risk of HCC without cirrhosis due to chronic HBV (Asian males over 40 years, Asian females over 50 years, Africans aged over 20 years, a family history of HCC and Aboriginal and Torres Strait Islander People ≥50 years). In addition to those with chronic HBV or HCV, patients with cirrhosis secondary to alcohol, haemochromatosis, and auto-immune liver diseases are at an increased risk for HCC and must be screened.

The screening consists of six monthly alpha feto-protein (AFP) blood test and upper abdominal ultrasound.

If AFP is elevated and abdominal ultrasound does not identify a lesion then repeat the AFP at one month. If still raised then notify the HepCare team who will refer for a triple phase CT or MRI, followed by specialist review.

If a suspicious lesion is identified on the abdominal ultrasound, the patient must be referred for further imaging such as a triple phase CT or MRI scan, followed by specialist review.

3.5 Monitoring of ALD

Regular monitoring (at least six monthly) of ALD must be undertaken in all those with cirrhosis (F4) detected by FibroScan, or suspected on the basis of clinical or laboratory findings. The *NLMC Advanced Liver Disease (ALD) Clinical Assessment Form* JUS060.340 must be completed for these patients. Upon completion of the form, a specialist consultation should be undertaken (by discussion only or face-to-face) to determine whether a face-to-face consultation with the patient is required and to designate ongoing management and monitoring requirements.

Clinical evidence of liver failure (decompensated cirrhosis) may commonly include:

- ascites
- peripheral oedema
- encephalopathy
- bruising
- jaundice

Laboratory evidence of liver failure (decompensated cirrhosis) may commonly include:

- thrombocytopenia

- increased prothrombin time or INR
- increased bilirubin
- lowered albumin

Important acute complications of ALD may commonly include:

- bleeding gastro-oesophageal varices
- spontaneous bacterial peritonitis
- worsening encephalopathy
- intractable ascites (i.e. unresponsive to diuretic therapy

For patients with ALD the PSHN or PHN will undertake monitoring at a frequency determined by HepCare NP/CNC and the Specialist. This monitoring will also generally include:

- temperature, pulse, blood pressure, star and handwriting charts, in addition to weight and girth;
- FBC, LFTs, UECs, INR and AFP testing;
- six monthly HCC screening by abdominal ultrasound

Patients with compensated ALD should be referred for endoscopic screening for varices using the revised Baveno VI criteria for identification of high risk varices. Patients who have a platelet count >110,000/μL and liver stiffness measurement (Fibroscan) <25kPa do not need to be referred for endoscopy screening. The requirement for endoscopic screening should be reviewed at each six monthly NLMC assessment, or when there is a change in the patients' disease status. Patients' whose results are close to the referral cutoff levels will be assessed for possible endoscopic screening based on factors including the patients medical history, clinical presentation and co-morbidities via an individualized decision making process.

In patients with compensated cirrhosis who have small varices, the endoscopy should be repeated in 1-2 years. In the presence of decompensated cirrhosis, the endoscopy should be repeated at yearly intervals.

3.6 Lifestyle

Patients must be given information regarding management of their ALD including an explanation of what cirrhosis is and why it is a problem. They must be educated regarding the signs and symptoms of cirrhosis and also the signs and symptoms of decompensation. Information needs to be given about appropriate dietary management including protein supplementation for those with poor muscle bulk or hypoalbuminaemia but without encephalopathy. Fluid restriction and reduced salt intake should be implemented for those with severe ascites and/or peripheral oedema. The Justice Health Network Dietician should be contacted to discuss referral of the patient for education and review.

3.7 Continuity of Care

Ensuring continuity of care is a high priority for patients who are released to freedom whilst living with ALD and/or HCC. Patients must continue their treatment in the community without interruption due to the clinical risks associated with missing medications and receive regular reviews and support. To facilitate continuity of care patients should be referred to the Integrated Care Service (ICS) prior to release.

Prior to the patient's release, health centre staff must liaise with Pharmacy regarding discharge medications. Staff must also ensure the patient is provided with all appropriate follow up information including, but not limited to the JHeHS Release Summary and Transfer of Care summary (including medications and follow up appointments) and all FibroScan and medical imaging reports.

In consultation with ICS, staff handing over care of the patient must endeavor to connect the patient with a community GP or specialist medical officer (MO) and make arrangements with the patient for the required information to be sent to the nominated service/address or to be provided to the patient upon release, or both. The Hepatitis NSW Directory provides a listing of available services by postcode. Staff must obtain contact details in the community for the patient and record this information in the patient's health record via JHeHs. All clinical staff should liaise with a PSHN for clarification of this process as required.

3.8 Palliative Care and End of Life Choices

Appropriate palliative care measures must be considered for patients with ALD. The HepCare Team, ID Specialist or Hepatologist will consult with the patient regarding if and when the patient is to be referred to Palliative Care Services such as with the advent or progression of HCC or worsening liver failure. These should include, but not be limited to, a referral from the ID Specialist or Hepatologist to a palliative care specialist, a pain management team, CNS 2 Cancer Care Coordinator, NP Palliative Care and Integrated Care and include details about hospital or hospice placement. Early release for health-related reasons should be considered and managed according to policy 1.170 *Early Release for Health-Related Reasons*. End of life treatment decisions must be made in consultation with the patient, his/her family, the treating medical team and the Legal Advisor, Governance Unit in accordance with the NSW Ministry of Health Guidelines GL2005_057 *End of Life Care and Decision Making Guidelines*, and PD2014_030 *Using Resuscitation Plans in End of Life Decisions* and policy 1.174 *End of Life Care, Resuscitation Plans and Advanced Care Directives*. Deaths associated with ALD must be managed in accordance with policy 1.120 *Management of a Death*.

3.9 Documents and Alerts

Information relating to patient care is to be documented in the patient's Health Record and an alert must be placed in iPM/ PAS e.g. Clinical/Gastrointestinal/Advanced Liver Disease

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 Documents

The Network Policies and Procedures	1.037*Long Bay Hospital Admission Policy (Referral, Admission and Assessment)* 1.120 *Management of a Death* 1.170 *Early Release for Health-Related Reasons* 1.141 *Release Planning and Transfer of Care Policy - Adult to External Providers* 1.142 *Discharge Planning - Medical Subacute Unit and Aged Care & Rehabilitation Unit, Long Bay Hospital* 1.174 *End of Life Care, Resuscitation Plans and Advance Care Directives –* 1.231 *Health Problem Notification Form (Adults)* 1.235 *Health Problem Notification and Escorts Form (Adolescents)* 1.241 *Hepatitis C and B Care Management and Treatment* 1.245 *Immunisation of Patients* 1.252 *Access to Local Public Hospitals* *Adult Emergency Response Guidelines* *Protocol for Management of Advanced Liver Disease and Hepatocellular Carcinoma*
The Network Forms	JUS005.001 *Health Problem Notification Form* JUS005.002 *Health Problem Notification and Escort form (Adolescents)* JUS030.303 *NLMC HEPATITIS INITIAL ASSESSMENT FORM* JUS060.341 *NLMC HEPATITIS B CLINICAL ASSESSMENT FORM* JUS060.342 *NLMC HEPATITIS C CLINICAL ASSESSMENT FORM* JUS060.340 *NLMC ADVANCED LIVER DISEASE (ALD) CLINICAL ASSESSMENT FORM* JUS110.306 *Star and Handwriting Chart*

NSW Health Policy Directives, and Guidelines	*NSW HCV Strategy 2014 - 2020* *NSW HBV Strategy 2014 - 2020* GL2005_057 *End of Life Care and Decision Making Guidelines* PD2014_030 *Using Resuscitation Plans in End of Life Decisions*
Other Guidelines	Hepatitis NSW Directory *Gastroenterological Society of Australia: Clinical Guidelines and Updates:* *American Association for The Study of Liver Diseases: Practice Guidelines* *European Association for the Study of The Liver: Clinical Practice Guidelines* Australasian Hepatology Association Consensus- Based Guidelines: www.hepatologyassociation.com.au