

Hepatitis B and immigration

This template has been developed to support clinicians who have patients with chronic hepatitis B applying for a permanent visa.

Summary

Patients with chronic hepatitis B (CHB) can be denied a permanent visa because they fail to meet the health requirements set by the Department of Home Affairs. The main reasons for failing the health assessment are related to the significant health services and/or community care costs, or prejudice to access of Australians to some health services, access to organ transplants. Depending on the type of visa the applicant has applied for, they can be provided a 'natural justice' opportunity that will allow the applicant to apply for a health waiver (see table 2). The provision of a 'positive' medical report in a migration case is very important, and can contribute to a favourable outcome for the patient. In addition, the range of other discretionary issues, such as cost mitigation or strongly compassionate and compelling other reasons can contribute to whether or not a health waiver will be granted. These issues should be made by the applicant and his/her migration advisors. Policy changes in 2019 have improved the prospects for many chronic hepatitis B patients in not having permanent residence visa applications rejected because of these health requirements.

It is often important that a medical report is provided prior to the appointment with the Medical Officer of the Commonwealth (MOC)

In this report it is important that the following is included:

- contribution to the Australian community (e.g. via paid or volunteer work) despite having CHB,
- whether it is likely that the patient will develop liver disease including significant fibrosis, cirrhosis, or hepatocellular carcinoma; and whether they will develop end stage liver disease and require liver transplantation.
- whether or not the applicant is likely to need treatment, or at which stage it is likely that medication will be needed. For example, if the applicant is in the immune control phase they will not need antiviral therapy and are most likely to never need it.
- information regarding the impact of treatment including how the applicant's ability to work will be influenced by them being on medication, and how this will influence the likelihood of developing liver diseases.

From 1 October 2019 the CHOICE of medication, if required, will be an essential factor to be considered.

Introduction

This template has been developed as a source of information to clinicians with patients who have chronic hepatitis B (CHB) and are in the process of applying for a permanent visa. Patients can be denied a permanent visa due to their hepatitis B status. To be eligible for a permanent visa the applicant has to meet the health criteria set by the Department of Home Affairs. This template can be used by health professionals to help support patients who are undergoing this process.

a. Hepatitis B

Hepatitis B virus (HBV) is a DNA virus that may cause inflammation of the liver, cirrhosis, liver failure and hepatocellular carcinoma (HCC). The virus is transmitted by contact with infected blood or some body fluids. The infection is vaccine preventable. If the initial infection persists for six months the patient has CHB. The risk of developing CHB is much higher in infants via perinatal transmission and in young children compared to adults (see table 1). The great majority of people living with CHB

were infected at birth or in early childhood, including in Australia where most people living with CHB were born overseas in endemic areas, or are Aboriginal or Torres Strait Islander people.

Antiviral treatment for CHB is used to suppress the virus and to prevent, halt or even reverse liver damage including fibrosis and cirrhosis, and preventing HCC. The decision to initiate treatment depends on serum HBV DNA viral load, ALT levels, which phase of CHB the patient is in, and a range of other patient factors.

b. Health assessment for visa applicants

When applying for a permanent visa the applicant must undergo a health examination conducted in Australia by a Bupa panel physician. After the examination a Medical Officer of the Commonwealth (MOC) will assess and form an opinion whether the applicant meets the relevant health requirement. Currently MOCs are employed by the private multinational healthcare company, Bupa. MOCs are required to determine whether the health status of the applicant could affect their visa application. Australian migration law provides two distinct types of health-related Public Interest Criteria (PIC), see table 2.

Table 1: Risk of progression, by age at infection

	Perinatal	Childhood	Adult
Risk of development of chronic infection (%)	80–90	30	<5
Risk of advanced liver disease (% exposed to HBV)	20-30	5-10	1-2

¹ Edith Cowan University. Hepatitis Education Project. 2014; Available from: <http://hepatitis.edu>.

Table 2: Health PICs categorised by visa type and health waiver

Health PIC	Visa type	Health waiver available, when failing the health assessment
PIC 4005	Majority of visas	No
PIC 4007	Most family stream, all humanitarian and a limited number of skilled visas, including temporary employer nominated work visas.	Yes * within the family stream, a health waiver is available for: partner/fiancée/de facto/spouse and child visas. Not available for parent, carer or adoptive child visas.

Note: meeting the relevant health requirement is required for temporary visa applications as well, but for most temporary visas, CHB — even if there is a need for medication — will not result in failure to meet the requirement. However, under Policy, it should be noted that some temporary visas are expected to lead to permanent visa applications later (for example partner, skilled or business skills and temporary parent visas) and applicants for these visas are tested at the PERMANENT health standard when applying for the related temporary visa.

Health assessment criteria

There are different outcomes for each applicable PIC if the MOC finds that the applicant fails the health assessment. This could lead to a visa refusal.

The MOC will assess if the applicant meets the following criteria:

- a) free from tuberculosis,
- b) free from any disease that is a threat to the public health in Australia or a danger to the Australian community (e.g. Ebola),
- c) free from any disease or condition that would be likely to require the applicant to:
 - i. receive healthcare or community services, or
 - ii. meet the medical criteria for the provision of a community service,

and the provision of those healthcare and community services are likely to result in 'significant costs*' to the Australian community, prejudice the access of an Australian citizen or permanent resident to healthcare or community services [Under Department Policy this is currently set at a threshold of \$49,000 over a 10 year period for permanent visa applicants.].

It is recommended that the applicant seeks advice from a migration agent/lawyer

The health requirements are regardless of whether the healthcare or community services would actually be used in connection with the applicant. This means that the MOC's opinion is not based upon the particular visa applicant but upon a hypothetical person with the same condition and severity.

What if the applicant fails the criteria? Who is eligible for a health waiver?

If an applicant is found by the MOC to not meet the health criteria, there will be a different outcome for each applicable category of PIC (see table 2). **Visas where PIC**

4005 applies do not have the possibility to apply for a health waiver. (Where the estimated 'significant costs' are found by the MOC to be under \$49,000 over a 10-year period, the person WILL HAVE MET THE HEALTH CRITERIA whether or not a waiver is available in that case i.e. a waiver is not 'needed' to meet the health requirement.)

In the case of permanent visa applicants where PIC 4007 applies, an opportunity is given for them to apply for a 'waiver' of the health requirement. Due to the complex process it is recommended that the applicant seeks advice from a migration agent/lawyer.

Moreover, a health waiver can be granted under PIC 4007 (provided the applicant meets all other criteria for granting the visa) if the health costs or prejudice are not 'undue'. In this case the applicant has the capacity to 'mitigate' the costs or prejudice. Or when there are particularly compelling or compassionate circumstances, a health waiver can be granted.

In particular, a MOC must assess and provide an opinion as to whether or not a 'hypothetical' person is likely to require the provision of healthcare or community services over a ten year period (for applications from 1 July 2019). The Migration Regulations require that the MOC's opinion must be accepted as correct by the Department. Based on that opinion (unless there is a legal error in the opinion) a decision is made as to whether a hypothetical person like the applicant will be likely to incur significant costs or prejudice access of others to healthcare and/or community services.

c. Why is hepatitis B an issue for immigration?

The main reason for applicants with living with CHB to be denied a permanent visa is due to the expected healthcare costs. Depending on what phase of the disease the patient is in, they will make use of health services in different degrees and some CHB patients are therefore likely to exceed the threshold of \$49,000 over the 10-year period

*Although the legal provision above has not changed from July 1 2019 there has been a significant shift in Departmental Policy that may have significant implications for some visa applicants with CHB. Policy now 'defines' the phrase 'significant cost' to be \$49,000 (previously \$40,000) over the life of a visa. For permanent visa applicants with a chronic lifetime condition such as CHB a MOC estimate of health care or community services costs is to be limited to 10 years, rather than over a 'lifetime'. It may be that these two Policy changes may mean that even some applicants on medication for CHB (or where the MOC has an opinion that they are likely to require medication in the future) may meet the health requirement without the need to obtain a waiver where this is available, as explained in the following section. The medical report of the clinician on behalf of the visa applicant may be crucial in advising the MOC on the prognosis of a particular patient and thus whether a person will meet the 'new' health test Policy, whether or not the visa subclass is one where a health waiver is available.

for calculation of costs, despite the Policy changes noted above.

Patients living with CHB with no evidence of progressive liver disease and who are not receiving antiviral therapy are required to have a check-up every six to twelve months. Patients who are on treatment may need tests more frequently. Patients with CHB with an elevated risk of HCC should undergo liver ultrasound surveillance every six months.

d. Critical change from 1 October 2019 in antiviral medication costings

If required, the cost of antiviral therapy contributes significantly to the expected overall healthcare costs. The Department periodically reviews its Policy Guidelines for MOC's for various diseases and conditions. New Guidelines for viral hepatitis were released on 1 October 2019. The new Guidelines for CHB note that the two 'preferred first line therapies' for CHB are ENTECAVIR and TENOFOVIR and Policy is that administration of either will be 'lifelong'. In coming to cost estimates over 10 years MOC's are asked to factor in the indicated costs of the medications set out in the Guidelines. Those medication costs in turn reflect the Pharmaceutical Benefits Scheme 'price' of both entecavir and tenofovir.

From 1 October 2019 the ANNUAL COST of the recommended daily dose of entecavir set out in the Guidelines (500mg) has been \$2,330, meaning that over the new 10-year period the health costs for those on entecavir should be UNDER the 'significant cost' threshold (even after the other required health services costs — mainly periodic tests also listed in the Guidelines — are added to the cost of entecavir). This means that those visa applicants measured on the permanent visa health standards and receiving entecavir therapy only **WILL MEET THE HEALTH REQUIREMENT**, without any consideration of a health waiver i.e. a health waiver will not be needed.

On the other hand, those patients who are receiving or whom the MOC considers to a person likely to require tenofovir — a 300mg dosage daily — (rather than entecavir) will still incur an estimate of health costs OVER the 10-year 'significant cost' threshold of \$49,000, because the annual PBS cost of tenofovir in the Guidelines is \$5,260 to which other required health services costs will be added.

Thus, from 1 October 2019 the clinician choice of appropriate antiviral medication will have a critical impact on the migration visa outcomes for their CHB patients. There will always be overriding clinical considerations affecting choice of prescribed medication, but the implications for prescription of either entecavir or tenofovir for visa applicants are now a factor that needs to be appreciated.

One drug — entecavir — is likely to result in a 'positive' health requirement decision by the MOC. The other drug — tenofovir — will result in a 'negative' MOC decision, resulting in either visa refusal or the need for the visa applicant to seek a health waiver (if available for that application) to succeed in their application.

The majority of patients in Australia are treated with entecavir, one of 2 first line therapies used for the management of chronic hepatitis B. Whilst the treatments are largely interchangeable, with many patients able to initiate either treatment, safety of entecavir has not been established for use in pregnant women. However, **outside of established contraindications, entecavir or tenofovir can be used.**

e. What other reasons may cause a patient to be denied?

End stage liver disease associated with CHB is an indication for liver transplantation. If this applies to an applicant the issue is not only 'significant cost' but also prejudice of access of Australians to scarce medical resources, i.e. transplants from deceased donors. Although a health waiver can be applied for where the relevant visa subclass allows it in these cases, it is most unlikely that it will ever be granted under current policy.

Hepatitis B is not considered a public health threat to the Australian community. However, it might be considered a threat when the applicant intends to work in healthcare and undertake exposure-prone procedures where there is a risk of contact between the worker's blood and a patient's open tissue. If this is a consideration, it is advisable that the applicant consults a viral hepatitis specialist experienced in the management of infected health care workers. The Department will seek a report from a prospective employer or institution about whether a person would be involved in exposure-prone procedures before a visa decision is made.

f. How can clinicians support their patients?

This section explains the role of a report written by the patient's medical advisors. An appropriate report may prevent a visa refusal even when it is not possible to apply for a health waiver (visas with PIC 4005). A medical report will be essential in cases where a clinician is of the opinion that there is unlikely to ever be significant costs or prejudice to access healthcare because antiviral medication is not indicated for the patient, or where the patient has been prescribed entecavir or where it is appropriate that entecavir therapy commence. If the MOC agrees with such an assessment and prognosis, it will increase the chance that they will meet the health criteria.

It is often important that a medical report is provided prior to the visa applicant's appointment with a MOC

It is often important that a medical report is provided prior to the visa applicant's appointment with the BUPA physician. The MOC must take this report into account in forming his/her opinion as to whether the health status of the applicant is likely to be a significant cost or prejudice to access healthcare. A medical report in relation to an applicant with CHB provided to the MOC may persuade the MOC that it is unlikely there will be significant cost in that case. It is recommended that the patient's previous history and test results be provided in the medical report.

For example:

"An adult with CHB in the immune control phase with, low HBV viral load and no evidence of significant fibrosis will require regular investigations and clinical review, but is not likely to be found a 'significant cost' by the MOC. This is because the patient is at low risk of developing liver disease and related complications and anti-viral drugs are not likely to be required."

A report by the patient's doctor in a case like this, may, at an early stage, assist in preventing the issue of the migration health 'significant cost' from being raised.

It is recommended that this report be provided by a clinician with:

1) expertise in the management of CHB, and

2) knowledge of CHB as related to migration laws and ideally with experience providing medical reports for the purposes of migration assessments.

Many physicians writing medical reports find it beneficial to outline their credentials at the beginning the report. We would recommend clinicians define how they meet the above criteria before providing recommendations pertaining to the patient.

It should be stressed that all permanent visa applicants must disclose to the MOC in writing whether they have or ever had hepatitis, even if they are symptom free and are not receiving therapy.

What should be included in a medical report?

In all cases a medical report should deal with the nature and degree of severity of CHB in the patient/visa applicant and the prognosis. The issues to address could include:

- whether the patient is likely to be able to work or contribute to the Australian community (e.g. via paid or volunteer work) despite having CHB.
- whether the patient is **able to receive care in a community/primary care setting**
- whether it is **likely that the patient will develop liver disease** including significant fibrosis, cirrhosis, or HCC; and whether they will develop end stage liver disease and require liver transplantation
- information regarding the impact of treatment, including when the patient is on medication, whether this will influence his/her ability to work, and how this will influence the likelihood of developing liver diseases.
- whether or not the patient is likely to need antiviral treatment, or when it is likely that medication will be needed. For example, if the applicant is in the immune control phase they will not need immediate treatment and are most likely to never need it.

- NB: The Medical Policy advice of the Department to MOCs is that **only 10-20% of subjects in the immune control phase may have subsequent reactivation of HBV with immune escape**, even after many years. If medication has commenced or is likely to be needed, the report should specify what antiviral treatment is appropriate. **If that is specified as being entecavir, that should now be**

enough to satisfy the MOC that there is not likely to be 'significant cost' in that antiviral therapy.

The provision of a 'positive' medical report in a migration case is very important — and can contribute to a favourable outcome for the patient. The issues to address should be confined to MEDICAL issues and not deal with other issues such as the non-medical personal circumstances of a patient, or special or non-medical compassionate issues.

In addition, the range of other discretionary issues, such as cost mitigation or strongly compassionate and compelling other reasons can contribute to whether or not a health waiver will be granted. **These issues should be made by the visa applicant and his/her migration advisors.**

For more information on hepatitis B, including treatment options, [please visit B Positive.](#)

f. Resources

[Australian Government Department of Health 'Meeting our health requirement'](#)

This website outlines the health examination process in more detail, as well as role of the Medical Officer of the Commonwealth in determining whether an applicant meets the health requirement.

[B Positive | Hepatitis B for Primary Care](#)

This online resource developed for health professionals outlines hepatitis B in extensive detail, covering clinical assessment, treatment and management of chronic hepatitis B, liver disease – including hepatocellular carcinoma (liver cancer) – and more.

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