

# **Cardiovascular Conditions**

**Version One December 2018** 

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#### **BACKGROUND**

The following document contains basic information on how to manage a variety of common and/or significant cardiovascular conditions. As with many medical conditions the presentation, clinical course and management of cardiovascular conditions can vary greatly and the recommendations in this document should be adapted as needed, to suit each individual case. However, NOT ASH outcomes relating to cardiovascular conditions can be particularly difficult to document correctly and where a specific NOT ASH reason has been provided, it is strongly recommended that you use these as this will aid in preventing confusion among applicants and LIAs, as well as prevention of complaints and IPT involvement in Residence applications.

If you are unsure of the correct outcome for any cardiovascular condition, please contact the Medical Officers for their advice.

#### Note: Terminology of Cardiovascular conditions

It is useful to remember that different countries use different terminology for various conditions and tests. In particular, an Exercise Tolerance Test (ETT) may be called a Treadmill Test (TMT) in some countries. For this reason, it is important to avoid using abbreviations that may be misunderstood when requesting FIR. For example, Exercise ECG is a suitable alternative for ETT that is easily understood internationally.

Also be aware of the use of Coronary Artery Disease and Ischaemic Heart Disease, as these are not the same thing.

- Coronary Artery Disease (CAD) can be used when the applicant has proven occlusions of the Coronary Arteries on imaging (e.g.angiogram), but does not have any symptoms or clinical disease.
- Ischaemic Heart Disease can be used when the applicant has symptoms or clinical evidence of heart disease +/- abnormalities on imaging.

Appendix One contains background information about CVD Risk assessments.

Appendix Two contains a link to background information about Atrial Fibrillation and management of this condition.



#### ABNORMAL ECG

Depending on the abnormality, a formal Cardiologist assessment should be considered. The information requested should always relate to the specific abnormality. If the abnormality is suggestive of Coronary Artery Disease then a formal Cardiologist assessment should be requested.

#### For example:

ECG shows ST changes in the inferior leads:

 A Cardiologist assessment should be requested which includes an ECHO and Exercise ECG to assess for ischaemic heart disease.

#### ECG shows AF:

• A Cardiologist assessment should be requested which includes an ECHO and a request for a CHA<sub>2</sub>DS<sub>2</sub>-VASc score and information regarding the applicant's risk of stroke.

#### **HYPERTENSION**

All applicants with Hypertension should have their CVD Risk calculated (see the following section on how to do this). A formal Cardiologist assessment should be requested for all applicants with:

- Uncontrolled Hypertension (BP >160/90)
- CVD Risk >20%
- CVD Risk >15% and any CVD high risk markers

This should always include a request for ECG, ECHO and Exercise ECG. It is worth noting that some countries in the pacific do not have cardiologist or ECHOs available.

#### FIR/ AWC outcomes:

The following information is useful to include when requesting FIR or providing AWC outcomes relating to hypertension:

- Creatinine, eGFR, protein: creatinine ratio, cholesterol profile, blood pressure, smoking history and a medication list.
- Consider also adding HBA1c if the applicant is high risk for Diabetes.

If any of this information has already been provided, **do not** include it in a new FIR request unless it has the potential to alter the case outcome.

#### **CVD RISK CALCULATORS**

If an applicant has a known history of Hypertension, Hyperlipidaemia or Diabetes then their CVD Risk should be calculated. New NZ specific CVD Risk assessment guidelines were released in 2018, but at present this is not relevant to Immigration medical assessments as no new risk calculators have been developed or released yet.



#### If the applicant has a history of Diabetes:

The NZSSD online calculator should be used: <a href="https://www.nzssd.org.nz/cvd/">https://www.nzssd.org.nz/cvd/</a>

#### If the applicant has NO history of Diabetes:

The QRisk online calculator should be used: <a href="https://qrisk.org/2017/">https://qrisk.org/2017/</a>

# It is not necessary to request any additional information before calculating the applicant's CVD Risk.

The applicant's age, ethnicity, height, weight and blood pressure will be recorded in the examination findings. The MA should then assume the lowest possible risk for any information that they do not have. i.e. assume that the applicant:

- has never smoked;
- total cholesterol = 4, HDL = 1.2;
- ACR is normal.

#### If the applicant has a CVD Risk ≥20%, or has any ECG changes consistent with CAD:

 A Cardiologist assessment is required and should include a request for an ECG, ECHO, Exercise ECG.

#### If the applicant has a CVD Risk between 15 - 20%

 Consider requesting a Cardiologist assessment if the applicant has any high risk markers\*

#### \*High risk markers indicating significant increased cardiovascular risk include:\*\*

- Uncontrolled hypertension,
- Uncontrolled hyperlipidaemia;
- LV impairment of any sort;
- Regional Wall Apnormalities (RWMAs);
- Peripheral vascular disease;
- Cerebrovascular disease;
- DM II with complications;
- Multiple or recurrent previous cardiac events;
- Implantable Cardioverter Defibrillators (ICD);
- Atrial fibrillation (AF);
- High calcium score on CT.

#### \*\* as per9(2)(b)(ii)

#### Note:

When assessing CVD Risk for a Fijian Indian please use "Indian" ethnicity not "Pacific".



#### CARDIOMEGALY

Any applicant with cardiomegaly (CTR ≥55% for Temp visa, or CTR ≥50% for residence visa), or marked LVH type appearances on CXR should be referred for an ECG (reported) and ECHO. If this is an incidental finding, with no other medical history of note – these can be requested by themselves, without a formal Cardiology assessment.

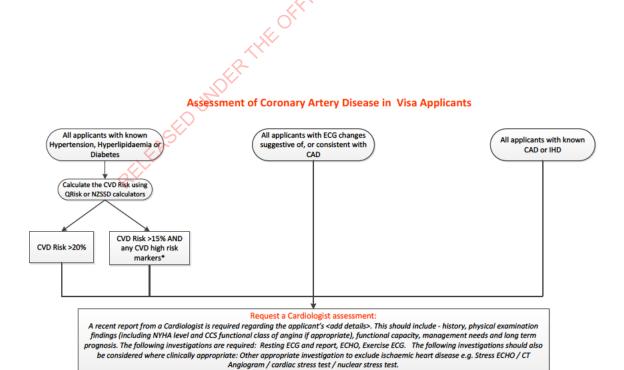
However, if the applicant has any known cardiac conditions or other high risk markers\* then a formal Cardiology assessment, including ECG, ECHO and an Exercise ECG should be requested.

## **CAD / IHD ASSESSMENTS**

A formal Cardiologist assessment should always be considered for all applicants with:

- Known CAD or IHD
- ECG changes suggestive of, or consistent with CAD
- CVD Risk >20%
- CVD Risk >15% and any CVD high risk markers\*

This should always include a request for ECG, ECHO and Exercise ECG.





#### \*High risk markers indicating significant increased cardiovascular risk include:

- Uncontrolled hypertension;
- Uncontrolled hyperlipidaemia;
- LV impairment of any sort;
- Regional Wall Abnormalities (RWMAs);
- Peripheral vascular disease;
- Cerebrovascular disease;
- DM II with complications;
- Multiple or recurrent previous cardiac events;
- Implantable Cardioverter Defibrillators (ICD);
- Atrial fibrillation (AF);
- High calcium score on CT.

#### **Cardiac Investigations:**

The initial investigation should always include an ECG, ECHO and Exercise ECG. Exercise ECG - the applicant needs to achieve a minimum of 85% maximum heart rate (MHR) otherwise this is considered non-diagnostic. If the test is non-diagnostic, then CAD is not excluded and further assessment is required.

If an applicant is unable to do an Exercise ECG, or if the Exercise ECG is non-diagnostic or reported as equivocal, then an equivalent test can be requested by an MA. For example a minimally invasive test such as a CT angiography/calcium score. It can be useful to always include this option in the proforma wording (see below).

Invasive screening e.g. coronary angiogram **should not** be requested by an MA because of the risks associated with these tests. However, if a Cardiologist has recommended further assessment with an angiogram, then it is ok for the MA to request this information.

# The proforma Cardiologist FIR request should be used and should be modified as needed, for example: include the following:

A recent report from a Cardiologist is required regarding the applicant's CVD Risk. This should include - history, physical examination findings (including NYHA level and CCS functional class of angina if appropriate), functional capacity, management needs and long term prognosis. The following investigations are required: Resting ECG and report, ECHO, Exercise ECG. The following investigations should also be considered where clinically appropriate: Other appropriate investigation to exclude ischaemic heart disease e.g. Stress ECHO / CT Angiogram / cardiac stress test / nuclear stress test.

If the applicant has other related abnormalities, such as Hypertension or an abnormal creatinine and eGFR, then additional information can be added to this FIR request. For example a cholesterol profile or protein: creatinine ratio.



#### **Old Coronary Angiogram reports:**

It can be really useful to ask for a copy of any previous angiogram reports. This can be a simple way of identifying whether people are at risk of progression of pre-existing disease. If an applicant had an MI and is reported to have had a stent, always consider requesting a copy of the angiogram report as part of the new Cardiologist FIR.

Requesting the previous angiogram report allows you to review the old information and identify if there were other stenoses that might now be considered clinically significant. For example, the applicant may have had a stent placed for a 90% stenosis, but the angiogram report shows that there were 4 other 50% stenoses that were not stented at the time. Depending on the time frame, these could now have progressed to being a significant risk. In this scenario it would be important to then ask the Cardiologist to comment on the applicant's risk of a further event.

Alternatively, there might have been 2 other 20% lesions which are not likely to have progressed over time and can safely be managed with medical treatment only. Assuming all the rest of the FIR information is normal (i.e. ECG, ECHO and Exercise ECG), there would be no need further cardiac investigation at this point in time.

# CAD / IHD OUTCOMES

#### **Positive Exercise ECG:**

- If the applicant has had a positive Exercise ECG as part of this assessment (or a recent medical assessment) they are most likely to be NOT ASH.
- It is then the applicant's responsibility to provide further information that supports an ASH outcome.

#### Residence Visa:

#### NOT ASH Reason:

Chronic recurring medical condition(s) likely to impose significant costs in excess of NZ\$41,000 over the predicted course of the Condition(s)

#### Please make it clear that:

The applicant has had a positive exercise ECG result, consistent with Coronary Artery Disease. It is highly likely that the applicant will also require cardiac intervention such as cardiac stenting or bypass surgery. The applicant's suspected Coronary Artery Disease is a chronic, recurring condition considered likely to impose significant costs in excess of \$41,000 over the course of the applicant's condition.

- Please **only** use the A4.10.1 condition when you have specific evidence that the applicant has a 'severe ischaemic heart disease' such as a cardiologist letter stating this.
- You do not need to include costs as part of your NOT ASH reason.



#### **Temporary Visa:**

NOT ASH Reason:

Likely to impose significant health costs OR demands

#### Please make it clear that:

The applicant has had a positive exercise ECG result, consistent with Coronary Artery Disease. It is highly likely that the applicant will require cardiac intervention such as cardiac stenting or bypass surgery. The applicant's suspected Coronary Artery Disease is considered likely to impose significant costs and demands on the New Zealand health system.

• You do not need to include costs as part of your NOT ASH reason.

#### Positive Exercise ECG with recent stenting or a bypass:

If the applicant has had a positive Exercise ECG as part of this assessment (or a recent medical assessment) they may also provide evidence of subsequent cardiac stenting or bypass surgery.

If the applicant has been successfully treated and the time since intervention is sufficient to confirm this (usually 3 months post intervention), it may be appropriate to give them an ASH or AWC outcome. However, it is important to ensure that you have all the relevant information before providing an outcome.

If the applicant has not provided a new full Cardiologist report, including current examination findings, a copy of the angiogram report, details of what intervention has occurred and when, as well as a follow up assessment post intervention (including a new ECHO and Exercise ECG, or suitable alternative), then further information is required. A new Cardiologist FIR should be requested.

#### **Residence Visa:**

If necessary, the applicant can be deferred for up to 3 months to allow for recovery and a new Cardiologist assessment post intervention. This new Cardiologist assessment must include: current examination findings, a copy of the angiogram report, details of what intervention has occurred and when, as well a new ECHO and Exercise ECG, or suitable alternative. The outcome will depend on the information provided post intervention.

#### **Temporary Visa:**

This should be approached in the same way as a Residence case and the same information will be required before an outcome can be determined. However, Temporary visas CANNOT be deferred.



#### **POTENTIAL OUTCOMES:**

#### An applicant could be considered ASH if:

- They have had successful intervention; and
  - They are asymptomatic; and
  - o They have no residual abnormalities on ECG, ECHO, Exercise ECG; and
  - They have no other medical reasons why they might be considered NOT ASH.\*\*

#### \*\*Other medical reasons that might warrant a NOT ASH outcome:

- Poor compliance with medication;
- Unfavourable Cardiologist report;
- Other NOT ASH medical conditions.

#### An applicant should be considered NOT ASH if:

o They do not meet the ASH criteria above.

#### **Residence NOT ASH Reason:**

Chronic recurring medical condition(s) likely to impose significant costs in excess of NZ\$41,000 over the predicted course of the Condition(s)

#### **Temporary NOT ASH Reason:**

Likely to impose significant health costs OR demands

#### **NOT ASH wording:**

- Please acknowledge the recent intervention, but make it clear why the applicant still does not meet the ASH criteria.
- Please **DO NOT** use the A4.10.1 condition for Residence visas, as it can be difficult to justify that the applicant has a 'severe ischaemic heart disease'.
- Please **DO NOT** include costs as part of your NOT ASH reason for either visa type.

If you have any reservations or concerns about what outcome to provide, or how to word the outcome, please discuss the case with a Medical Officer.



#### **MURMURS**

All applicants with a murmur need to provide a new, or a recent echocardiogram. This is because we have no way of knowing what degree of valve abnormality they have without imaging. An ECHO dated within the past year is considered acceptable.

**Always** check whether the applicant has any previous cases under Client History before requesting a new assessment. If they do, have a look to see what the most recent ECHO showed and whether there was any advice from a Cardiologist regarding when they would next need a follow up ECHO.

This applies to all visa types. Even an applicant applying for a short 3 month visitor visa may become unwell and need a valve replacement during that time. They may be too sick to send home and may need an immediate valve replacement in New Zealand.

This is a high cost and high demand health condition. If an applicant declines to get an ECHO please discuss this with the Medical Officers, as we cannot be sure they will not impose significant costs and demands on the NZ health system during their visa period.

#### **VALVE DISEASE**

Any applicant with known cardiac valve disease needs a recent ECHO to confirm that their valve disease is not significant and does not require surgical repair in the near future.

Always check whether the applicant has any previous cases under Client History before requesting a new assessment. If they do, have a look to see what the most recent ECHO showed and whether there was any advice from a Cardiologist regarding when they would next need a follow up ECHO.

Depending on the information provided:

- You may not need any further information at this point in time and can provide an outcome;
- You may be able to simply request a new ECHO;
- You may need to request a new Cardiologist assessment with new specialist advice around the need for future valve replacement.

FIR example: Cardiologist Assessment

A new Cardiologist assessment is required regarding the applicant's known Mitral Valve Regurgitation. This should include – history, management to date, current examination findings, ECG, ECHO, ongoing management needs and long term prognosis. In particular, please comment on whether the applicant is likely to require cardiac valve surgery in the future and if so, when.



#### **MA Outcomes:**

#### **Residence Visa applicants:**

- The A4.10.1 INZ Listed NOT ASH conditions include:
  - Valve disease with a high probability of surgical and/or other procedural intervention in the next 5 years.
- Valve replacements may also be considered a chronic, recurring medical condition:
  - For example if the applicant is likely to require several valve replacements over the course of their lifetime.
  - However, please discuss each case with a Medical Officer before providing a final outcome under chronic, recurring medical condition.

#### **Temporary Visa applicants:**

Depending on the degree of valve disease, the applicant may require further assessment when they next apply for a visa.

- A trivial or mild valve abnormality is not generally considered significant and does not need follow up. The applicant can be given an ASH outcome.
- A moderate valve abnormality should be considered significant and an AWC outcome might be given depending on the visa length and any advice from the Cardiologist as to when a replacement is likely to be needed:
  - The applicant has known cardiac valve disease. The next visa application will require a new Cardiologist assessment regarding the applicant's Mitral Valve Regurgitation. This should include – history, management to date, current examination, ECG, ECHO, ongoing management needs and long term prognosis. In particular, please comment on whether the applicant is likely to require cardiac valve surgery in the future and if so, when.
- Any applicant with a severe valve abnormality must have a Cardiologist assessment, including requesting the following information:
  - Please comment on whether the applicant is likely to require cardiac valve surgery in the future and if so, when.
- If an applicant may require surgery within the timeframe of their visa, they should be considered NOT ASH.

#### For example:

- An applicant applying for a 2 year visa who is reported to be likely to require a Mitral Valve replacement in 3 years time may be considered NOT ASH as their valve disease may progress faster than expected.
- An applicant applying for a 2 year visa who is reported to be likely to require a Mitral Valve replacement in 5 years time should be considered AWC.



#### **EP STUDIES**

The following information was provided in a NZ Cardiologist report in 2016.

The cost of a screening EP study in private would be \$15,330.00, and a separate later ablation \$25,130.00. However, if this procedure was performed in the public system they would be combined and the cost would be under \$15,000.00. The short term and long term prognosis is excellent and your WPW condition should not affect the quality of your future life.

This would be considered NOT ASH for a Temporary Visa, however does not meet the \$41,000 cost level for a Residence visa.

#### **PACEMAKERS**

Pacemakers and Implantable Cardioverter Defibrillators (ICD) may be considered high cost, depending on the visa type and time frame. If the applicant is reported to have a Pacemaker or ICD, then further information is required. A Cardiologist assessment should be requested, including the following information:

 Please comment specifically on the ongoing management needs relating to the ICD including – how often this needs to be checked, how often it needs replacing, whether it is the batteries or the entire unit that is replaced and the cost of repairing / replacing it.

Depending on when the unit needs replacing and the cost of this, versus the visa length – the applicant may be ASH, AWC or NOT ASH.

#### CARDIOMYOPATHY

Cardiomyopathy is usually progressive and is associated with progressive heart failures, requiring recurrent hospital admissions. Depending on the cause of the Cardiomyopathy, various cardiac interventions may also be required.

#### Residence Visas:

Cardiomyopathy is an A4.10.1 INZ Listed Condition for Residence visa applications. You will need a cardiologist report outlining the diagnosis and the likely management and treatment.

#### **Temporary Visas:**

Temporary visa assessments are less straightforward than the Residence visas. As with many of the cardiac conditions, the applicant's current health status, as well as the rate of progression needs to be considered in relation to the visa length. The type of visa application also needs to be considered, i.e. are they fit for purpose, or are they unable to perform their expected duties due to their cardiac symptoms.



It is therefore important to ensure that you have a Cardiologist assessment which provides all of this information: For example:

#### FIR: Cardiologist

A recent report from a Cardiologist is required regarding the applicant's known Cardiomyopathy. This should include - history, physical examination findings (including NYHA level), functional capacity, management needs and long term prognosis. The following investigations are required: Resting ECG and report, ECHO, Exercise ECG. Please specifically comment on the underlying cause of the applicant's Cardiomyopathy, the impact on the applicant's daily functioning and ability to work, as well as the expected rate of progression over time.



# APPENDIX ONE: CVD RISK SCREENING – A GUIDE FOR MEDICAL ASSESSORS

Written by Dr Rob Kofoed (Medical Officer), 2016

#### **Background:**

Even though the government has announced a decrease in the total number of permanent residents, there will still be 45-50,000 per annum new permanent residents of which about 10-15% would be over 55 years of age (the majority from UK, India, China, SE Asia and the pacific).

If we didn't screen any of these applicants, then the cost to our health services would be significant. Hypothetically, if we estimate that 20% of these applicants have diabetes and/or CVD and if the cost per annum for each individual with CVD and/or diabetes is an extra \$2400 (this figure is based on a study from CMDHB in 2008 estimating that on average, each person with CVD and/or diabetes is associated with \$2,400 more health care costs compared to a person without CVD or diabetes.- see: <a href="www.cmdhb.org.nz/About CMDHB/Planning/Health-Status/Health-Status.htm">www.cmdhb.org.nz/About CMDHB/Planning/Health-Status/Health-Status.htm</a>) then the annual cost of not screening for this cohort is approximately an extra \$2,500,000 on our health services; and as 45-50,000 new residents arrive in each year this will increase by \$2,500,000 each year during the lifetime of all these new residents.

As MAs our role is to assess cardiovascular risk to reduce the average health cost per person (knowing that we won't be able to reduce this to zero) by screening out the highest risk applicants. By screening for the highest risk applicants and NOT ASHng those who do not meet the current ASH criteria as described in the Immigration Instructions, this should significantly reduce the average cost per person as individuals in higher risk groups are likely to incur the highest health costs.

#### **CVD Risk assessment:**

The cardiovascular risk calculators and tools we currently use are population based calculators designed primarily to determine when cost effective targeted intervention is recommended at each level of risk.

As MAs we are using these calculators to determine if an individual is at a high level of risk and form an opinion on whether the applicant's condition will likely result in high cost health services for that individual.

#### What Calculators?

To get consistency we should all be using the same cardiovascular risk calculators. During a discussion with Professor Rod Jackson from the University of Auckland in 2016, his comments were:

'We have developed new CVD risk prediction equations, which will be available shortly, but they are designed for people already living in NZ. They will include an option to predict risk for Pacific peoples, which no other risk calculators have, so that would be useful for screening people from the pacific Islands. It will also include options for predicting risk for Indians and



Chinese. As far as I am aware only the UK QRISK calculator also includes these ethnicities (https://grisk.org/2016/)

If people already have a personal history of CVD, then their risk is probably over 20% in 5 years. However it is really difficult to know if any of these calculators would apply to people from other countries, particularly low and middle income countries and also those with multimorbidities. They may have very different risks and there is no good data available. I really wouldn't know how to estimate risk in these groups and your guess would be as good as mine.'

Following this discussion it was decided to use the QRisk calculator for non-diabetics and the NZSSD calculator for diabetics or applicants with HBA1c >50: <a href="http://www.nzssd.org.nz/cvd/">http://www.nzssd.org.nz/cvd/</a>



#### APPENDIX TWO: ATRIAL FIBRILLATION AND ABLATION

The following link is for a NZ Ministry of Health report from 2012 regarding "Catheter Ablation for the Treatment of Atrial Fibrillation". It contains background information on Atrial Fibrillation, including NZ specific information and may be of interest in better understanding the significance of Atrial Fibrillation in our immigration applicants.

http://www.moh.govt.nz/notebook/nbbooks.nsf/0/69B1EE7B091E66E8CC257F7F00789C2E/\$f <u>ile/catheter-ablation-technology-note-jul2013.pdf</u>

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# **Background**

The following document contains basic information on how to manage a variety of common and/or significant Diabetic cases. As with many medical conditions the presentation, clinical course and management of Diabetes can vary greatly and the recommendations in this document should be adapted as needed, to suit each individual case. However, NOT ASH outcomes relating to Diabetes can be particularly difficult to document correctly and where a specific NOT ASH reason has been provided, it is strongly recommended that you use these as this will aid in preventing confusion among applicants and LIAs, as well as prevention of complaints and IPT involvement in Residence applications.

If you are unsure of the correct outcome for any Diabetic case, please contact the Medical Officers for their advice.

#### Note: Terminology relating to Diabetes

It is useful to remember that different countries use different terminology for various conditions and tests. For example: microalbumin:creatinine ratio can be written as MAU or ACR. For this reason, it is important to avoid using abbreviations that may be misunderstood when requesting FIR.



# Type I Diabetes

This should be assessed and managed the same as Type II Diabetes (see the rest of this document).

#### **ADDITIONAL CONSIDERATIONS**

Many Type I Diabetics have Insulin Pumps and while these are potentially high cost (approximately \$6,000 per year for monitoring, medication and the pump through Pharmac), this cost shouldn't be taken into consideration when assessing the medical.

If the applicant is well controlled, with no complications, they should be considered AWC for Temp, or ASH for Residence. However, if the applicant is poorly controlled, or has significant complications, then they should be considered as likely NOT ASH.

If the applicant is borderline and it is not clear whether an AWC, ASH or NOT ASH outcome is most appropriate – please contact The Auckland based Medical Officers to discuss this.

# **Type II Diabetes**

#### **DIABETES AND HBA1C**

#### HBA1c <60 +/- medication:

- Is considered well controlled for Immigration purposes and is not of concern.
- The applicant's 5y CVD Risk should still be calculated and recorded in the MA comments.
- Assuming the 5y CVD Risk is <15% and there are no associated diabetic complications and no other abnormalities on the medical:

Residence: ASH

Temp: AWC or ASH

- If the 5y CVD Risk is ≥20% a Cardiologist assessment is recommended. This should always include a request for an ECG, ECHO and Exercise ECG.
- If there are any other associated diabetic complications, consider requesting further information from the relevant specialist (e.g. Opthalmologist, Neprhologist).

#### HBA1c >80 +/- medication:

Also consider for

#### HBA1c ≥ 60 with comorbidities OR if this is a new diagnosis of Diabetes

- An Endocrinologist assessment should be requested.
  - The proforma wording for this should be used and includes all the additional tests that are needed: retinal screening report, peripheral vascular exam, smoking history, reported ECG, creatinine, eGFR, microalbumin:creatinine ratio (ACR).



- A Cardiovascular Risk Assessment (CVD Risk) should also be calculated.
- There is no need to wait until the Endocrinologist assessment report comes back to calculate the CVD Risk.
- If the applicant has a CVD Risk between 15 20%, consider requesting a Cardiologist assessment if the applicant has any associated significant risk factors (e.g. poorly controlled BP / high cholesterol) or any known complications (e.g. proteinuria, diabetic retinopathy, peripheral neurovascular disease).
- If the applicant has a CVD Risk ≥20%, or has any ECG changes consistent with CAD, then a Cardiologist assessment is recommended. This should always include a request for an ECG, ECHO and Exercise ECG.

#### VISA OUTCOMES

Visa applicants with Diabetes will have different outcomes depending on their overall Diabetes control and associated complications.

#### **ASH Outcome:**

If an applicant has well controlled Diabetes with: HBA1c ≤60, no associated complications and a 5y CVD Risk <15% then an ASH outcome should be considered for any visa type.

#### ASH with Conditions (AWC) Outcome: <

If an applicant has poorly controlled Diabetes and/or any associated minor complications and/or a 5y CVD Risk ≥15% +/- a favourable Cardiologist assessment, then an AWC outcome should be considered for a temp visa:

- The applicant has Diabetes. The next visa application will require a new HBA1c, creatinine, eGFR, microalbumin:creatinine ratio, lipid profile, Blood Pressure, smoking history and a medication list.
- Consider also adding:
  - An ECG if the applicant is >40years +/- higher risk for CAD.
  - A retinal screening report.

#### **NOT ASH Outcome:**

If an applicant has uncontrolled Diabetes and/or severe diabetic complications and/or a significantly abnormal Cardiologist assessment, then a NOT ASH outcome should be considered.

#### **Newly Diagnosed Diabetics:**

If the applicant is a newly diagnosed diabetic with uncontrolled HBA1c (≥75), consider requesting an Endocrinologist assessment. This allows for a full assessment, with appropriate advice and management to be given. Alternatively, if the applicant is in New Zealand, you could request the same information from a General Practitioner.



If the applicant has been started on appropriate treatment and there are no associated complications and/or a 5y CVD Risk <15%, the following outcomes should be considered:

• Temp Visa: AWC

Residence Visa: Deferral for 3 months to allow for further assessment on

treatment.

#### **ADDITIONAL TESTS**

The panel physician should have provided a microalbumin:creatinine ratio (aka: MAU or ACR) result as a routine additional test for any applicant with Diabetes. However, if this has not been provided, you do not need to do a specific request just to obtain this result.

The same applies to Lipid / Cholesterol profiles – it is not necessary to do a separate request to obtain this information. The 5y CVD Risk can be calculated without these (see below).

Instead, the microalbumin:creatinine ratio and a lipid profile should be included in any request for Further Information – e.g. if you are requesting a Cardiologist or Endocrinologist assessment, or alternatively included in any future conditions for Temp visas.

#### CARDIOVASCULAR RISK IN DIABETICS

If an applicant has Diabetes, you should **ALWAYS** calculate their 5y CVD Risk using the NZSSD online calculator: <a href="https://www.nzssd.org.nz/cvd/">https://www.nzssd.org.nz/cvd/</a> and then record this result in the MA comments section.

#### It is not necessary to request any additional information before calculating their CVD Risk.

The applicant's age, ethnicity, height, weight and blood pressure will be recorded in the examination findings.

The MA should assume the lowest possible risk for any information that they do not have. I.e. assume that the applicant:

- has never smoked;
- total cholesterol = 4, HDL = 1.2;
- ACR is normal.

#### If the applicant has a CVD Risk ≥20%, or has any ECG changes consistent with CAD:

- A Cardiologist assessment is recommended.
- This should include a request for an ECG, ECHO, Exercise ECG.

#### If the applicant has a CVD Risk between 15 - 20%:

- Consider requesting a Cardiologist assessment if the applicant has:
  - any associated significant risk factors\*
  - o any known complications of their Hypertension (e.g. proteinuria).



\*High risk markers indicating significant increased cardiovascular risk include:

- Uncontrolled hypertension;
- Uncontrolled hyperlipidaemia;
- LV impairment of any sort;
- Peripheral vascular disease;
- Cerebrovascular disease;
- DM II with complications;
- Multiple or recurrent previous cardiac events;
- Implantable Cardioverter Defibrillators (ICD);
- Atrial fibrillation (AF);
- High calcium score on CT.

#### Note:

When assessing CVD Risk for a Fijian Indian please use "Indian" ethnicity not "Pacific".

#### Hepatitis B Assessments – HAT Update Sept 2018

As you all know, some of the anti-viral medications used for the treatment of Hepatitis B changed to generics in July 2018. This means that the majority of the anti-virals that are used in NZ for Hepatitis B are no longer considered high cost. As a result, we need to rethink our Hepatitis B assessment outcomes. IHT are working with 9(2)(q)(ii)

, to develop new formal guidelines, but in the meantime we have developed the following interim guidelines.

#### **HAT assessment of Hepatitis B:**

All applicants who are Hep B positive applicant require the following information to determine an outcome:

- HBeAg
- HBV DNA
- LFTs
- AFP
- a new Liver ultrasound
- Liver Fibroscan report (dated within 3 years of the current medical assessment)

ALL of this information is required to be able to determine the applicant's current standard of health. Each result provides essential information about whether the applicant needs anti-viral medication, has fibrosis / cirrhosis, has HCC or any other complications relating to their Hepatitis B.

### **HAT to request:**

For every Hepatitis B applicant, please request the following information BEFORE referring the case to an MA:

#### FIR: Hepatitis B Tests:

Please provide an HBeAg, HBV DNA, LFTs, AFP, a recent Liver Ultrasound report, a Liver Fibroscan report (dated within 3 years of the current medical assessment) and a current medication list.

#### Note:

**Liver Ultrasound** – this should be a recent report. **Liver Fibroscan** – this can be dated within the past 3 years.

Remember – not every country can do Fibroscans (e.g. Tonga) – if they state they cannot provide one, please discuss the case with Danielle / Rob.

## **Summary of likely MA Outcomes:**

#### **Hep B Temporary Visas:**

Hep B, no meds,no complications	AWC
Hep B, on meds, no complications	AWC
Hep B +/- meds, with complications : the outcome will depend on visa length + exact complications	NOT ASH <i>or</i> Discuss with Danielle / Rob

Note: complications include HCC, undetermined liver lesions, cirrhosis, Fibroscan >8.5kPA, varices etc

#### **Hep B Residence Visas:**

Hep B, no meds, no complications	ASH EORWAN
Hep B, on meds, no complications	NOT ASH – A4.10.1 Listed Condition: Hepatitis B surface antigen positive and meeting criteria for anti-viral treatment in NZ
Hep B +/- meds, with complications OR at high risk of complications	NOT ASH – A410.1 Listed Condition: Severe, chronic or progressive renal or hepatic disorders

Note: complications include HCC, undetermined liver lesions, cirrhosis, Fibroscan >8.5kPA, varices etc

Recommended NOT ASH Wording: A4.10.1 INZ Listed condition – Hep B on medication.

The applicant has Hepatitis B and is currently taking (name of medication) for this. The applicant's Hepatitis B with the associated medication is an A4.10.1 INZ Listed condition.

#### **Recommended AWC Wording:**

AWC Box notes:

• The applicant has Hepatitis B and is on anti-viral medication for this. The next visa application will require the following information:

Conditional FIR: 'Hepatitis B Test'

• Please provide the following information – HbeAg, HBV DNA, LFTs, AFP, a new Liver Ultrasound scan, Liver Fibroscan report (dated within 3 years of this visa application), current examination findings, a medical diagnosis list and a current medication list.

# Background information for those who are interested: Temporary Visas:

#### **AWC outcome:**

Anti-viral medications are no longer high cost for temporary visas.

Applicants who are currently taking, or are likely to need anti-viral medications can be given an AWC outcome.

#### AWC Box notes:

• The applicant has Hepatitis B and is on anti-viral medication for this. The next visa application will require the following information:

#### Conditional FIR: 'Hepatitis B Test'

 Please provide the following information – HbeAg, HBV DNA, LFTs, AFP, a new Liver Ultrasound scan, Liver Fibroscan report (dated within 3 years of this visa application), current examination findings, a medical diagnosis list and a current medication list.

#### **NOT ASH outcome:**

Applicants who have cirrhosis / HCC or other complications secondary to their Hepatitis B are likely to be considered NOT ASH.

However, occasionally, these applicants may be stable and considered suitable for a short visa period.

#### **Residence Visas:**

IHT have been in contact with the MOH to discuss Hepatitis B, the Immigration Instructions and our current legal requirements. Until we have any further information / advice from the MOH, we must continue to follow the Immigration Instructions, as they are written.

#### The A4.10.1 INZ Listed Conditions include:

- Hepatitis B surface antigen positive and meeting criteria for anti-viral treatment in New Zealand.
- Severe, chronic or progressive renal or hepatic disorders.

#### **ASH Outcomes:**

No medications or complications secondary to their Hepatitis B.

#### **NOT ASH Outcomes:**

These are unchanged and the MAs should continue to follow the current Hepatitis B guidelines for Residence visa applications.

#### **Anti-viral medication:**

Applicants who are currently on, or are recommended to start anti-viral medications are NOT ASH under the A4.10.1 Listed condition of Hepatitis B.

As per the 2016 Hep B Guidelines, this includes any applicant who is:

- HBeAg positive and ALT ≥40 for at least 6 months;
- HeAg negative and HBV DNA ≥2000IU/mL and at least moderate liver fibrosis (Biopsy ≥F2; Liver Stiffness ≥6kPA);
- Hep B positive and is currently on, or is recommended to start anti-viral medication.

#### **Recommended NOT ASH Wording:**

- A4.10.1 INZ Listed condition Hep B on medication.
  - The applicant has Hepatitis B and is currently taking (name of medication) for this.
     The applicants Hepatitis B with the associated medication is an A4.10.1 INZ Listed condition.

#### **Liver related complications:**

Applicants who currently have, or are considered high risk for future liver related complications (irrespective of the need for anti-viral medication) are NOT ASH under:

A4.10.1 Listed condition of a severe, chronic or progressive hepatic disorder; or

A4.10.1 Cancer condition (if they have HCC or suspected HCC).

As per the 2016 Hep B Guidelines, this includes any applicant who is:

- Hep B positive and has severe fibrosis (biopsy stage F3 or F4, OR fibroscan reading of ≥8.5kPA, OR any clinical, laboratory or radiologic evidence of cirrhosis);
- Previous or suspected HCC;
- Known Cirrhosis +/- complications such as varices.

#### **Recommended NOT ASH Wording:**

- A410.1 INZ Listed Condition severe, chronic or progressive hepatic disorder OR cancer depending on the specific issue.
  - o The MA can write this as they normally would. No specific wording needs to be used.
  - However, the NOT ASH reasoning should focus on the liver related complication, not on any medication they may be taking.
  - This indicates to the Branch IO that the applicant has a significant long term condition and that they should NOT be considering a waiver simply because the medication is no longer high cost.



# **Hepatitis C Guidelines for Immigration New Zealand Medical Assessors**

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#### WHY HAVE THESE GUIDELINES BEEN DEVELOPED?

The management of Hepatitis C within New Zealand changed in July 2016, when Pharmac introduced funding for some of the newer Directly Acting Anti-virals (DAAs) to be used for the treatment of Hepatitis C. This resulted in General Practitioners (GPs) becoming directly involved in the treatment of Hepatitis C for the first time. New guidelines have therefore been developed for GPs and Gastroenterologists to allow for the appropriate and correct management of Hepatitis C positive patients<sup>1</sup> (Hep C treatment has changed).

New INZ Guidelines for the assessment of Hepatitis C positive visa applicants have therefore been developed.

#### **BACKGROUND OF HEPATITIS C IN NEW ZEALAND**

Hepatitis C (HCV) is a virus that is contracted through direct exposure to blood or body fluids which, if not cleared or treated, causes inflammation of the liver. Most newly acquired HCV infections within NZ are from injectable drug use. Other risk factors include:

- exposure to contaminated blood products (prior to July 1992);
- incarceration (high rate of HCV in prison, where tattooing is common);
- antenatal transmission (5% of new-borns of an HCV positive mother are infected despite best precautions) and;
- infection through a medical or dental procedure or a blood transfusion in a HCV high risk country (Eastern-Europe, Middle East, North Africa, Western and Central Sub-Saharan Africa, Central Asia and the Indian Subcontinent).<sup>1</sup>

It is estimated that only 50% of the 50,000 New Zealanders who are infected are aware they have  $HCV^2$ . When people become infected only 25 -30% of people experience non-specific and often mild symptoms. Approximately 20 -25% of people clear the virus spontaneously, usually within 12 weeks. Around 75 – 80% of people will therefore develop chronic HCV and may not be aware of the fact until later in life, when they already have complications such as cirrhosis.<sup>1</sup> Of those with chronic HCV, 2 – 4% of people will develop Hepatocellular Carcinoma (HCC).<sup>1</sup> There is no vaccine available to prevent HCV.

Active Hepatitis C or HCV related complications (such as fibrosis, cirrhosis or HCC) are considered high cost health conditions within the INZ Immigration Instructions.<sup>3</sup> See Appendix One for detailed Immigration Instructions.

#### COSTS OF HEPATITIS C IN NEW ZEALAND

Hepatitis C Drug Treatment: approximately \$80k per treatment

Liver transplant process: \$180k Cost of HCC Surveillance \$2k pa

Resection only of an HCC: \$30k Cost of treating a small HCC \$50-200k

NOTE: These costs are based on personal communication with 9(2)(q)(ii)



# **Medical Management of Hepatitis C**

#### **HCV DIAGNOSIS**

The Diagnosis of Active Hepatitis C usually involves three steps: 1,4

#### **Hepatitis C Virus Serology**

Anti-HCV or HCV Ab Indicates HCV exposure (screening test)

HCV RNA level (viral load) → Confirms active HCV infection

HCV genotyping → Determines the treatment regime

#### Screening = Anti-HCV or HCV Ab

The Immigration Health Team (IHT) had a positive rate of 0.4%, or 399 individual applicants, in 2016.

Clinic Country		Birth Country
New Zealand	171 P	
India	66	124
Cambodia	39	49
China	28	67
Philippines	9	14
Rest of the world	86	145
Grand total	399	399

- Positive: An HCV RNA is required to confirm active HCV infection.
- Negative: If active HCV is suspected or the person is known to have current or previous HCV, then the screening HCV serology should be repeated in 3 months.

Note: A person can be re-infected with HCV following treatment — anyone who continues to have high risk behaviours such as IV Drug use, should have their HCV RNA repeated.

#### Confirmation of active HCV = HCV RNA level

- Positive: the person needs genotyping and treatment.
- Negative: with no history of previous HCV treatment the person may have spontaneously cleared the virus.



Note: HCV RNA can have brief periods where it is not detected despite the person having active HCV. So if there is no history of previous HCV treatment, the HCV RNA should always be repeated in 3 months.

#### Genotyping

Genotyping is required for all active HCV to assist in determining the most appropriate treatment regime. Approximately 55% of the HCV cases diagnosed in New Zealand are Genotype Ia or Ib.

#### PRE-TREATMENT ASSESSMENT<sup>1,4</sup>

Routine investigations recommended prior to starting treatment include:1

- Liver elastography (Fibroscan or Shear Wave Elastography)
- FBC
- LFTs, including AST
- INR
- Renal Function
- Hepatitis B (risk of reactivation of Hepatitis B with co-infection)
- HIV (ARVs and DAAs can have serious interactions)
- Pregnancy test (Ribavirin is a potent teratogen)
- Physical examination

#### **FIBROSCAN**

The NZ Society of Gastroenterologists strongly recommends a fibroscan is performed in all people with Active HCV prior to starting treatment.<sup>4</sup>

- The fibroscan result can alter the Drug Treatment Regime and may mean the person requires active supervision by a Gastroenterologist (rather than a GP).
- A fibroscan result performed post-treatment when Sustained Viral Response (SVR) has been achieved will be markedly lower than a pre-treatment result due to reduced inflammation post treatment and cannot be used to determine cirrhosis status.

Pre-treatment fibroscan results indicate:4

#### Either:

■ <10.5kPA 

→excludes cirrhosis
</p>

■ 10.5 – 12.5kPA → bridging fibrosis / transition to cirrhosis

>12.5kPA → likely cirrhosis

Or:

■ F0-F2 → no cirrhosis

F3-4 → suggests cirrhosis



#### **LIVER BIOPSY**

Liver Biopsy does not have a routine role in staging, but may be useful if:4

- There is diagnostic uncertainty regarding the
  - A. degree of fibrosis vs cirrhosis, or
  - B. the cause of the person's Liver Disease.
- If a fibroscan was not performed pre-treatment then a liver biopsy is the only way to determine cirrhosis status after SVR.

Aen d result Action Act The following investigations are only recommended if there is evidence of Decompensated Chronic Liver Disease (as determined by history, examination, blood results).4

- Abdominal Ultrasound scan
- AFP



# **Treatment Regimes**

## **NEWLY FUNDED ORAL DIRECT ACTING ANTIVIRALS (DAAS)**

The Genotype variant and the results of the pre-treatment investigations determine the drug treatment regime. Three new oral DAAs have been approved by Pharmac, in addition to the pre-existing funded drug treatment regimes.

Treatment is usually 12 weeks long, with Sustained Viral Response (SVR) **ALWAYS** confirmed at 12 weeks post completion of treatment.

Note: The following Treatment Regimes are current as of April 2017; however, these are likely to change over time. An applicant may also choose to import drugs from overseas, where newer treatment regimens may be available. If a Specialist states that a treatment regime is appropriate for the applicant's genotype, then this should be considered as an acceptable treatment.

Genotype I Drug Treatment Regimes <sup>4</sup>		
Viekira Pak <sup>A</sup>	= Paritaprevir, Ritonavir, Ombitasvir and Dasabuvir	Genotype Ib  SVR = 12 weeks post completion of treatment
Viekira Pak-RBV <sup>A</sup>	= Paritaprevir, Ritonavir, Ombitasvir and Dasabuvir PLUS Ribavirin (RBV)	Genotype la  SVR = 12 weeks post completion of treatment
HARVONI	= Ledipasvir with Sofosbuvir	Only funded in NZ if there is already cirrhosis.
SOVALDI	= Sofosbuvir + peg-INF/RBV OR Sofosbuvir + RBV	Under specialist supervision only

<sup>&</sup>lt;sup>A</sup>Viekira Pak and Viekira Pak-RBV should NEVER be used for treatment of Genotypes 2, 3, 5 and 6 as the treatment will not be effective and could result in increased viral resistance.



Genotypes 2, 3, 4, 5 and 6 Drug Treatment Regimes <sup>4</sup>		
Require Specialist Supervision		
Pegylated Interferon (Peg-INF) <sup>B</sup>		Compensated cirrhosis
HARVONI <sup>B</sup>	= Ledipasvir with Sofosbuvir	Decompensated cirrhosis
Sofosbuvir + Daclatasvir for 12 weeks <sup>c</sup>		Not funded
Sofosbuvir + Ledipasvir for 12 weeks (+ RBV if Genotype 3) <sup>C</sup>		Not funded
Sofosbuvir + peg-INF/RBV for 12 weeks <sup>c</sup>	RIN	Not funded
Sofosbuvir + RBV for 12 0r 24 weeks <sup>c</sup>	, al MFO	Not funded

BPHARMAC FUNDED Drug Treatment Regimes

- PEG-INF based therapy is the only funded therapy for compensated patients with these Genotypes.
- HARVONI may be funded for these Genotypes in certain situations for example decompensated cirrhosis.

<sup>c</sup>These Drug Treatment Regimes are NOT FUNDED for these Genotypes in New Zealand, but can be considered approved treatment regimes.

These unfunded Drug Treatments can be obtained by:

- self-funding and importing a 12 week supply of the medication, or
- self-funding HARVONI, or
- by participating in a Clinical Trial being conducted within New Zealand.

Note: New Drug Treatments are constantly being developed and trialled – if the Specialist reports the client is on a treatment appropriate for their genotype, which is not on this list, it should be considered an acceptable treatment. However, SVR should ALWAYS be determined at 12 weeks post completion of treatment.



#### MONITORING DURING TREATMENT

HCV RNA levels should not be repeated during treatment because the response on treatment does not predict the final treatment outcome and does not predict relapse.<sup>4</sup>

#### **POST TREATMENT TESTS**

#### **Sustained Viral Response (SVR)**

Non detectable HCV RNA level at a specific time period post completion of treatment:

- This will always be 12 weeks, no matter which Drug Treatment Regime is used.
- SVR cannot be confirmed during treatment, or at a time period earlier than 12 weeks post completion of treatment.
- Approximately 5% of people will relapse and will have a positive HCV RNA level at 12 weeks post completion of treatment.
- Most relapse occurs within the first 4 weeks. At present there are no effective medications to treat people who relapse, however some are under development.

#### **Liver Function Tests**

- Should be performed routinely post treatment, at or after the expected SVR time period.
- This allows for:
  - Detection of other chronic conditions that can affect liver function including:
    - Fatty Liver / Metabolic Syndrome;
    - Hepatitis B;
    - Alcohol use;
    - Drugs.
  - An indication of risk of HCC long term:
    - The degree of pre-existing fibrosis determines the ongoing risk, not the specific level of the LFTs.

# Relevance of these changes to Immigration New Zealand

INZ process and assessment outcomes should be consistent with "Best Medical Practice" within New Zealand for all high cost health conditions. Active Hepatitis C or HCV related complications (such as fibrosis, cirrhosis or HCC) are considered high cost health conditions within the Immigration Instructions<sup>3</sup> (Appendix One).

The following updated Guidelines are therefore recommended for the Assessment of Hepatitis C in INZ visa applicants.

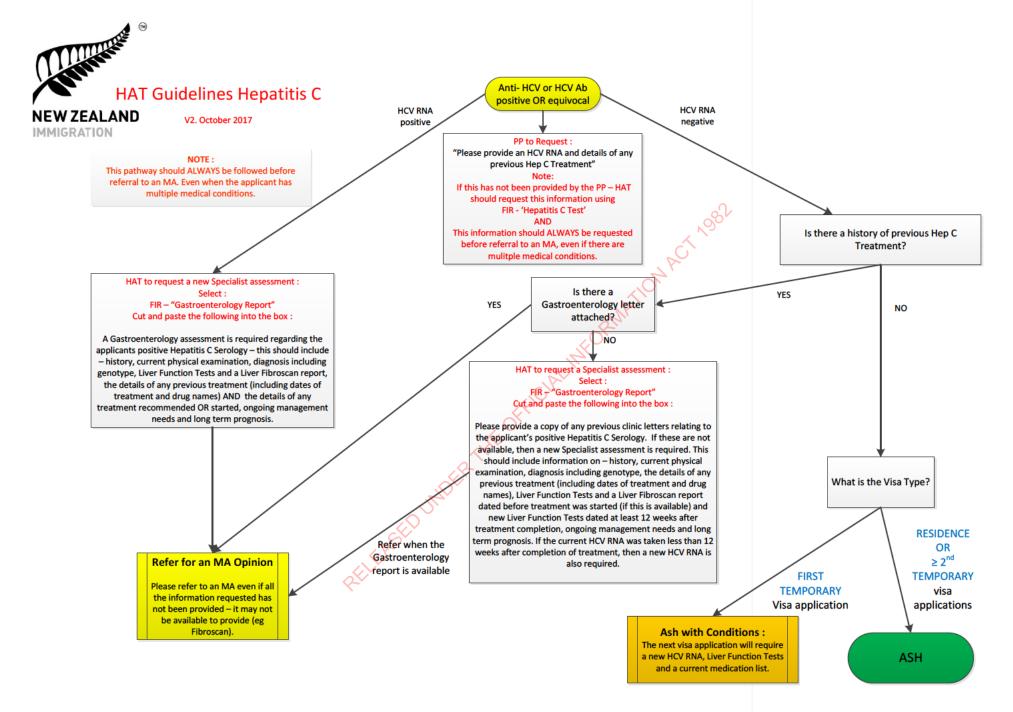


# **Flowcharts**

The management and assessment process of Hepatitis C Positive applicants, for the Health Assessment Team (HAT) and Medical Assessors (MAs) can be found in the following Flowcharts:

- HAT Guidelines Hepatitis C
- MA Guidelines Hepatitis C Flowchart A
- RELEASED INDERTHE OFFICIAL INFORMATION ACT 19892 • MA Guidelines Hepatitis C Flowchart A – Appendix
- MA Guidelines Hepatitis C Flowchart B
- MA Guidelines Hepatitis C Flowchart C

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MA Guidelines Hepatitis C –
AND Flowchart A

V2.October 2017

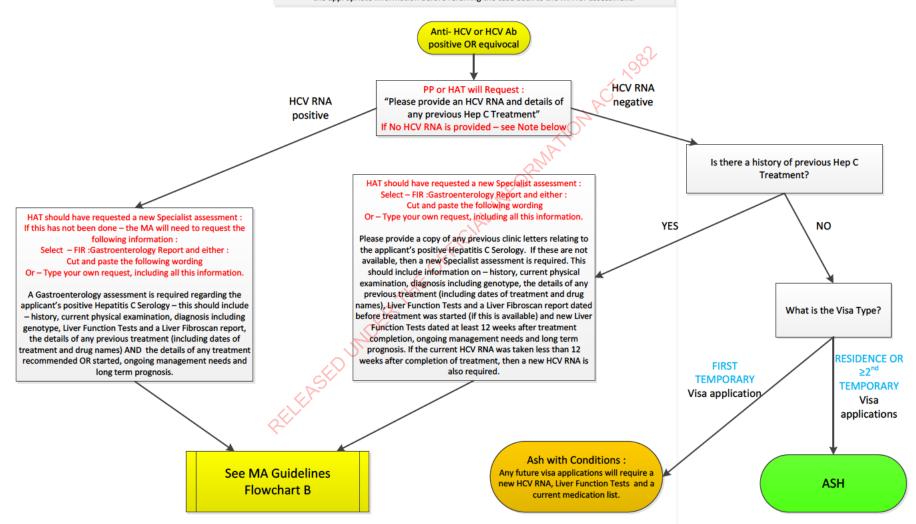
#### If no HCV RNA has been provided by the PP or HAT:

Do two separate requests:

FIR- Hepatitis C Test: A new HCV RNA level is required. Please also provide details of any previous Hepatitis C Treatment.

AND ·

FIR: Other: Dear HAT – if the HCV RNA is positive – please follow the HAT Hep C Flowchart and request the appropriate information before referring the case back to the MA for assessment.





## Appendix A

### **Appropriate Treatment by Genotype**

Genotype I Drug Treatment Regimes :			
Viekira Pak¹	= Paritaprevir, Ritonavir, Ombitasvir and Dasabuvir	Genotype Ib SVR = 12 weeks post completion of treatment	
Viekira Pak-RBV <sup>1</sup>	= Paritaprevir, Ritonavir, Ombitasvir and Dasabuvir PLUS Ribavirin (RBV)	Genotype Ia SVR = 12 weeks post completion of treatment	
HARVONI	= Ledipasvir with Sofosbuvir	Only funded in NZ if there is already cirrhosis.	
SOVALDI	= Sofosbuvir + peg-INF/RBV OR Sofosbuvir + RBV	0	

<sup>&</sup>lt;sup>1</sup>Viekira Pak and Viekira Pak-RBV should NEVER be used for treatment of Genotypes 2,3,5 and 6 - as the treatment will not be effective and could result in increased viral resistance.

Genotypes 2, 3, 4, 5 and 6 Drug Treatment Regimes			
Pegylated Interferon (Peg-INF) <sup>2</sup>	SIA INT	Compensated cirrhosis	
HARVONI <sup>2</sup>	= Ledipasvir with Sofosbuvir	Decompensated cirrhosis	
Sofosbuvir + Daclatasvir for 12 weeks <sup>3</sup>	K OK	Not funded	
Sofosbuvir + Ledipasvir for 12 weeks (+ RBV if Genotype 3) <sup>3</sup>	SEP THE	Not funded	
Sofosbuvir + peg-INF/RBV for 12 weeks <sup>3</sup>		Not funded	
Sofosbuvir + RBV for 12 0r 24 weeks <sup>3</sup>		Not funded	

<sup>&</sup>lt;sup>2</sup>PHARMAC FUNDED Drug Treatment Regimes :

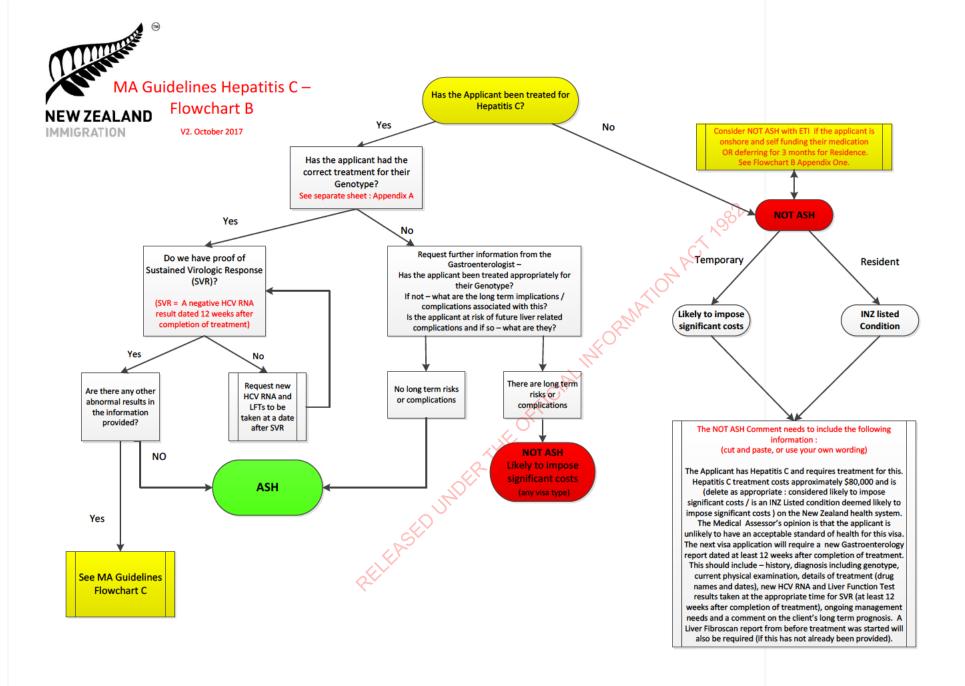
PEG-INF - based therapy is the only funded therapy for compensated patients with these Genotypes. HARVONI - may be funded for these Genotypes in certain situations – for example decompensated cirrhosis.

These unfunded Drug Treatments can be obtained by :

- self funding and importing a 12 week supply of the medication, or
- · self funding HARVONI, or
- by participating in a Clinical Trial being conducted within New Zealand.

Note: New Drug Treatments are constantly being developed and trialled – if the Specialist reports the client is on a treatment appropriate for their genotype, which is not on this list, it should be considered an acceptable treatment.

<sup>&</sup>lt;sup>3</sup>These Drug Treatment Regimes are NOT FUNDED for these Genotypes in New Zealand, but can be considered approved treatment regimes.





# MA Guidelines Hepatitis C – Flowchart B. Appendix One

V2. October 2017

When providing a NOT ASH Outcome AND :

The applicant is Onshore and is reported to be self funding their treatment.

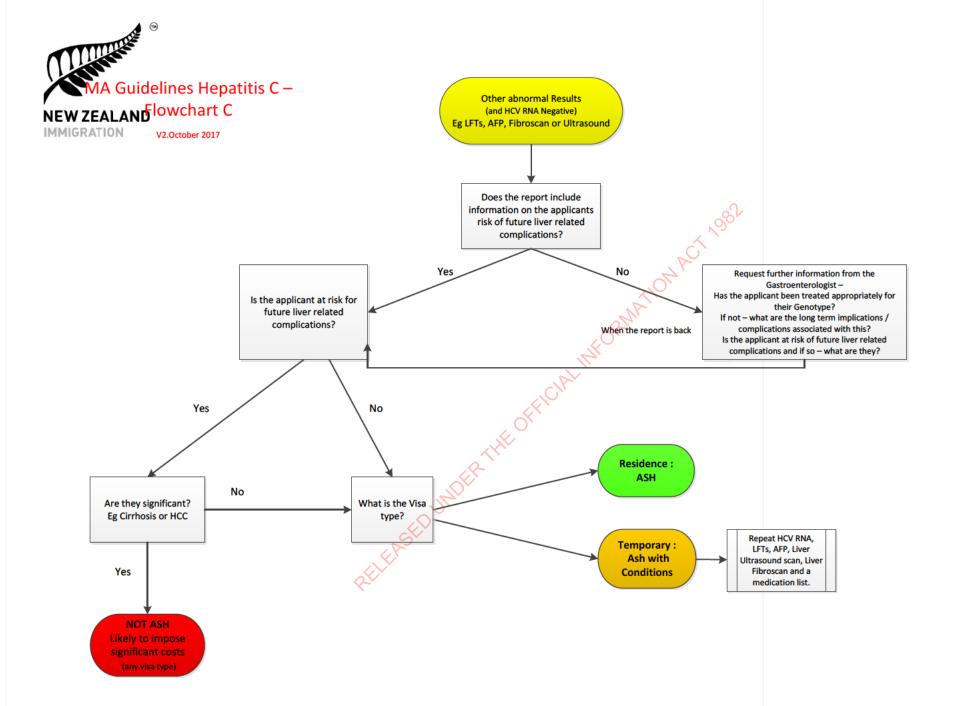
#### NOT ASH with ETI Wording:

The applicant has Hepatitis C and is currently undergoing treatment for this in New Zealand. The applicant is reported to be self funding their treatment, which is due to be completed on (add date) and confirmation of cure will be determined on (add date). Hepatitis C treatment costs approximately \$80k per treatment. The Medical Assessor's opinion is that the applicant is unlikely to have an acceptable standard of health for this visa. However, if the applicant meets all other visa requirements, the Branch IO could consider an Exception to Instructions, as in line with A4.15(b) the applicant is not infectious, is not imposing significant costs on New Zealand's health system and is able to undertake the study/work on the basis of which they are applying for a visa in line with. We would support INZ granting a visa until (add date 1 month after SVR) to allow for completion of Hepatitis C treatment and confirmation of cure. The next visa application will require a new Gastroenterology Specialist assessment with regards to their Hepatitis C - this should include - history, diagnosis including genotype, current physical examination, details of treatment (drug names and dates), new HCV RNA and LFTs results taken at the appropriate time for SVR (at least 12 weeks after completion of treatment - end of April 2018), on going management needs and a comment on the applicants long term prognosis.

Residence visa application

Consider Deferring for 3 months, if the applicant will have completed their treatment by the end of the deferral period.

The applicant has Hepatitis C and is currently undergoing treatment for this. Their treatment is due to be completed on (add date) and confirmation of cure will be determined on (add date). In 3 months time, the applicant will need to provide a new Gastroenterology Specialist assessment with regards to their Hepatitis C - this should include - history, diagnosis including genotype, current physical examination, details of treatment (drug names and dates), new HCV RNA and LFTs results taken at the appropriate time for SVR (at least 12 weeks after completion of treatment – add date), on going management needs and a comment on the applicants long term prognosis.





## **References**

- 1. Best Practice Issue 77 SE September 2016 – The treatment of Hepatitis C has changed.
- 2. www.hepatitisfoundation.org.nz
- 3. http://onlineservices.immigration.govt.nz/opsmanual/index.htm
- 4. NZ Society of Gastroenterology HCV Treatment Guidelines. November 2016 update.

AELERSED UNDER THE OFFICIAL INFORMATION ACT 1988

RELERSED UNDER THE OFFICIAL INFORMATION ACT 19



#### APPENDIX ONE

#### **Residence Applications**

#### A4.10 Acceptable standard of health (applicants for residence)

- a. Applicants for residence class visas must have an acceptable standard of health unless they have been granted a medical waiver or (f), below, applies. An application for a residence class visa must be declined if any person included in that application is assessed as not having an acceptable standard of health and a medical waiver is not granted (see A4.60).
- b. Applicants for residence class visas are considered to have an acceptable standard of health if they are:
  - i.unlikely to be a danger to public health; and
  - ii.unlikely to impose significant costs or demands on New Zealand's health services or special education services; and
  - iii.able to undertake the work on the basis of which they are applying for a visa, or which is a requirement for the grant of the visa.
- c. The conditions listed in A4.10.1 are considered to impose significant costs and/or demands on New Zealand's health and/or special education services. Where an immigration officer is satisfied (as a result of advice from an Immigration New Zealand medical assessor) that an applicant has one of the listed conditions, that applicant will be assessed as not having an acceptable standard of health.
- d. If an immigration officer is not satisfied that an applicant for a residence class visa has an acceptable standard of health, they must refer the matter for assessment to an Immigration New Zealand medical assessor (or the Ministry of Education as appropriate).
- e. Despite (d) above, referral to an Immigration New Zealand medical assessor (or the Ministry of Education) is not required where the applicant is the partner or dependent child of a New Zealand citizen or residence class visa holder, unless the provisions of A4.60(a) or A4.60(b) apply.
- f. Mandated refugees (see <u>S3.5(a)(i)</u>) and Refugee Quota Family Reunification Category applicants (see <u>S4.20</u>) are exempt from the requirement to have an acceptable standard of health, except where they have any of the conditions set out at <u>A4.74</u>.

## A4.10.1 Medical conditions deemed to impose significant costs and/or demands on New Zealand's health and/or education services

- HIV infection
- Hepatitis B-surface antigen positive and meeting criteria for anti-viral treatment in New Zealand
- Hepatitis C-RNA positive and meeting criteria for anti-viral treatment in New Zealand



- Malignancies of organs, skin (such as melanoma) and haematopoietic tissue, including past history of, or currently under treatment. Exceptions are:
  - treated minor skin malignancies
  - malignancies where the interval since treatment is such that the probability of recurrence is <10 percent</li>
- Requirement for organ transplants (with the exclusion of corneal grafts), or following organ transplant when immune suppression is required (with the exclusion of corneal grafts)
- Severe, chronic or progressive renal or hepatic disorders
- Musculoskeletal diseases or disorders such as osteoarthritis with a high probability of surgery in the next five years
- Severe, chronic or progressive neurological disorders, including but not exclusive to:
  - any dementia including Alzheimer's disease
  - poorly controlled epilepsy
  - complex seizure disorder
  - cerebrovascular disease
  - cerebral palsy
  - paraplegia, quadriplegia
  - poliomyelitis
  - Parkinson's disease
  - motor neurone disease, Huntington's disease, muscular dystrophy
  - prion disease
  - relapsing and/or progressive multiple sclerosis
- Cardiac diseases, including but not exclusive to:
  - severe ischaemic heart disease
  - cardiomyopathy
  - valve disease with a high probability of surgical and/or other procedural intervention in the next five years
  - aortic aneurysm with a high probability of surgical and/or other procedural intervention in the next five years
- Chronic respiratory disease, including but not exclusive to:
  - severe and/or progressive restrictive (including interstitial) lung disease
  - severe and/or progressive obstructive lung disease
  - cystic fibrosis
- Significant or disabling hereditary disorders, including but not exclusive to:



- hereditary anaemias and coagulation disorders
- primary immuno-deficiencies
- Gaucher's disease
- Severe autoimmune disease which may require treatment in New Zealand with immunesuppressant medications other than Prednisone, Methotrexate, Azathioprine or Salazopyrin
- Severe (71-90 decibels) hearing loss or profound bilateral sensori-neural hearing loss after best possible correction at country of origin, where significant support is required, including cochlear implants
- Severe vision impairment with visual acuity of 6/36 or beyond after best possible correction at country of origin, or a loss restricting the field of vision to 15-20 degrees where significant support is required
- Severe developmental disorders or severe cognitive impairments where significant support is required, including but not exclusive to:
  - physical disability
  - intellectual disability
  - autistic spectrum disorders
  - brain injury
- Major psychiatric illness and/or addiction including any psychiatric condition that has required hospitalisation and/or where significant support is required
- Those with a history, diagnostic findings or treatment for MDR-TB or XDR-TB, unless they have been cleared by a New Zealand Respiratory or Infectious Diseases specialist upon review of their file or review of the applicant according to the New Zealand Guidelines for Tuberculosis Treatment

#### **Temporary Applications**

#### A4.15 Acceptable standard of health (applicants for temporary entry class visas)

- a. Applicants for temporary entry class visas must have an acceptable standard of health, unless they have been granted a visitor visa for the purpose of obtaining medical treatment (see  $\underline{V3.40}$ ) or have been granted a medical waiver (see  $\underline{A4.65}$ ).
- b. Applicants for temporary entry class visas to New Zealand are considered to have an acceptable standard of health if they are:
  - i.unlikely to be a danger to public health; and
  - ii.unlikely to impose significant costs or demands on New Zealand's health services during their period of intended stay in New Zealand; and



iii.(if they are under 21 years of age and are applying for a student visa) unlikely to qualify for Ongoing Resourcing Schemes (ORS) funding during their period of intended stay in New Zealand; and

iv.able to undertake the work or study on the basis of which they are applying for a visa, or which is a requirement for the grant of the visa.

## A4.15.1 Assessment of whether an applicant for a temporary entry class visa is unlikely to impose significant costs or demands on New Zealand's health services

- a. Assessment of whether an applicant for a temporary entry class visa is likely to impose significant costs or demands on New Zealand's health services will take into account whether there is a relatively high probability that the applicant will need publicly funded health services during their period of stay in New Zealand including, but not limited to:
  - hospitalisation;
  - residential care;
  - high cost pharmaceuticals;
  - high cost disability services.
- b. The following factors have no bearing on whether an applicant is unlikely to impose significant costs or demands on health services:
  - The ability of a person of organisation to pay for health services, pharmaceuticals, or residential care which may be required.
  - The ability of an applicant to gain access to the private health system.
  - The applicant's possession of health insurance.
  - The capacity of family, friends, or a charitable organisation to provide care for an applicant.



### **Renal Failure**

### **BACKGROUND INFORMATION**

It is important to note that renal failure / dialysis remains a high demand condition and one that we don't have enough resources for here in New Zealand and, on this basis, it is also a non waiverable condition.

Here is some previous work done by the Immigration Health team on costing dialysis.

**Hospital haemodialysis** –An estimated figure would be \$80,000 pa. (In 2002 - 4 the estimated cost was \$ 64,318 and in 2007 it was estimated to be around \$70,000. Australia estimated \$72,000 in 2012).

This cost would include equipment, consumables, and nursing staff time but would not include money spent by other departments like surgery for dialysis related procedures. The first year would carry a higher cost as this year would include other services and procedures e.g. radiology, surgery that are needed to get dialysis established.

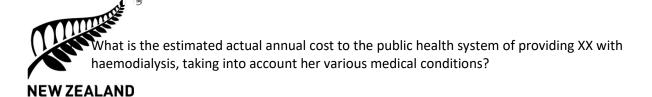
**Peritoneal dialysis (PD)** – An estimate figure would be \$40,000 p.a. for continuous automated PD and about \$50,000 for automated PD (in 2002/3 the estimate was \$36,615).

This is primarily the cost of the fluids used. In the first year there is an additional cost of having the catheter inserted surgically and training the patient to do it which would add about \$10,000 to the cost of the first year. This does not take into account hospital admissions for complications like peritonitis which occur about once every 2 years and might mean needing to replace the catheter and a switch to haemodialysis for a few months which incurs additional cost.

**Home haemodialysis** – This is significantly cheaper in the longer term at about \$30,000 per year (in 2002 – 4 estimated to be \$33,584)

The cost is for consumables and depreciation on the dialysis machine. It is cheaper because there are fewer staff to pay. However, the first year is more expensive because they would need surgery to form vascular access (a fistula) and they need a period of training usually 3-6 months with a very high nursing input (usually 1:1 nursing), purchasing the machine and installing it in the home. So the first year of home HD would cost about \$50-60,000. Home dialysis is cheaper than PD after 3 years, once the costs associated with training and setup are 'paid off'.

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From reviewing the bills that are available it appears that the applicant is consuming around \$12 – 13,000 per month in hospital costs. This is a higher cost than the expected \$8,000 per month and is likely due to the other health issues the individual has. Doctors I have spoken to have stated that there are other costs that should be anticipated. For example, most dialysis patients have other admissions to hospital for their heart disease, diabetes, etc. The public renal specialist who I contacted stated that 'if you are talking about the overall cost to the NZ taxpayer of having a person on dialysis because in reality very few dialysis patients hold down jobs and many will need assistance with other things like housing and transport also.' The data from Australia also indicates a stable cost model if the same treatment is maintained.

There are other options available to those that are New Zealanders including renal transplant. The operation costs about \$50,000, however, the workup and planning of a transplant is very expensive. I understand that a private hospital in Auckland charges around \$150,000 which includes all care leading up to the surgery as well. After the first year the ongoing cost is really just the cost of the drugs which is \$20,000 per year. While people are being worked up for kidney transplantation they are usually also receiving dialysis so the year of their transplant is very expensive but long term this is the most cost effective treatment and allows many to go back to work, etc.

So unless the type of dialysis is changed then it would be reasonable to assume that the current rate of consumption of public health care dollars would continue at around \$12 - 13,000 per month.

Ashton, T. & Marshall, M.R. 'The organization and financing of dialysis and kidney transplantation services in New Zealand' Int J Health Care Finance Econ (2007) 7: 233. doi:10.1007/s10754-007-9023-x

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**IMMIGRATION** 



#### RENAL ASSESSMENTS

Renal related medical assessments can be very complicated, simply because of the unpredictable nature of renal disease / Chronic Kidney Disease (CKD) and the impact that a single acute renal insult can have on longstanding renal disease.

It is therefore not possible to determine a specific eGFR that should be of concern for all visa types. This will depend entirely on the medical scenario for each applicant. If you are unsure whether a specific applicant is likely to be of concern and needs further assessment, please contact the Medical Officers for advice. One tip is to check client history for any previous eGFR and past history.

An eGFR of <30 is always a significant concern and indicates that the applicant may need renal replacement therapy in the near future. A Nephrologist assessment should always be requested for these applicants.

#### **RENAL OUTCOMES**

#### Non Waiverable Condition: Dialysis

 The applicant requires dialysis treatment, or will require treatment within five years of the date of their medical assessment.

An applicant who meets these criteria are NOT ASH for both GMC and LMC.

It is essential to determine if the applicant is likely to require renal replacement therapy (dialysis or transplant) in the future and if so, when. The Nephrologist proforma has good wording around this, or you can use your own. But it is important that this information is obtained when considering a NOT ASH outcome for renal abnormalities.

If it is not clear how the applicant's renal disease will progress, remember that you can Defer for Residence visas to allow for further assessment of renal function over time.

#### **Renal Transplants:**

Renal Transplant is not technically a Non Waiverable condition in itself.

However, if the applicant needs dialysis while waiting for a transplant, then the applicant is Non Waiverable because of the dialysis and this should be clearly stated.

Renal Transplants are not always NOT ASH and the specific scenario needs to be considered for each applicant, including whether the applicant needs a transplant, or already has one.

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#### **Residence: NOT ASH**

- A4.10.1 INZ Listed Condition: Requirement for organ transplants (with the exclusion of corneal grafts), or following organ transplant when immune suppression is required (with the exclusion of corneal grafts).
- If they are currently receiving or need dialysis, the MA should state: *Requiring / Receiving Dialysis is a Non Waiverable Condition*.

#### Temporary:

#### Needs a renal transplant: NOT ASH

• Likely to impose significant costs and demands.

#### Has a renal transplant:

- The outcome depends on the applicant's current health status and visa type:
  - o Are they stable?
  - What medications are they on? What are the cost of these?
  - What ongoing assessments do they need and how often? What are the costs of these?
  - O What is the visa length?
- An applicant may be NOT ASH or AWC depending on the answers to the above questions.

If you are not sure of an appropriate outcome for a renal condition, please contact the Medical Officers to discuss the case.



## **Urinalysis**

The information below is general advice, but each applicant's abnormalities obviously need to be considered in relation to their other medical information and conditions.

#### **GENERAL ADVICE**

If the applicant has:

- One abnormal dipstick urinalysis, and the second is normal: ASH
- Two abnormal dipstick urinalysis, check if there is a formal laboratory report provided.
  - If this is normal: ASH
  - If this is abnormal, check the dates. If they were all done on the same day and the abnormality is thought to be significant, then you should consider a FIR or AWC (see below sections).

#### **GLUCOSURIA**

If there is a good reason e.g. the applicant has uncontrolled Diabetes, the glucosuria is not significant in itself and does not need follow up. The Diabetes is significant however.

If there is no obvious reason for this and the applicant is otherwise well, with no other medical conditions:

 Consider AWC – the next visa application will require a new urinalysis, HBA1c and medication list.

#### **HAEMATURIA**

If there is a good reason provided and the applicant is low risk with no red flags, consider either ASH or AWC outcome.

However, if there are any red flags, e.g. persistent haematuria, older person, male: consider requesting another urinalysis. If this remains positive for haematuria then further information is



required. Depending on the applicant and the specific scenario, you might just want to ask for a renal tract ultrasound, or you may require a Urologist assessment.

#### **PROTEINURIA**

If the applicant has proteinuria, but normal Creatinine, eGFR and no known medical condition or other abnormality on their medical assessment consider an ASH or AWC outcome.

If there is a good reason for the proteinuria, e.g. the applicant has known Diabetes or Hypertension, then it may be of use to determine the degree of proteinuria as part of any further assessments being requested.

Microalbumin: creatinine ratio

aka: ACR or MAU

This should be used for diabetics.

**Protein: creatinine ratio** 

aka: PCR

This should be used for all non-diabetics.

#### HAEMATURIA AND PROTEINURIA

Many of our visa applicants are high risk for renal conditions such as IgA Nephropathies, because of their ethnicity.

Haematuria and Proteinuria in an applicant should always be investigated further. A Nephrologist assessment should be requested.



## Guidelines for Medical Assessors: Blood test results 3 October 2022

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#### PURPOSE OF THIS DOCUMENT

This document offers information and guidance about blood disorders and how to interpret blood test results when assessing a visa applicant's standard of health.

#### **BACKGROUND**

Applicants for residence or temporary entry visas provide medical certificates which include the results from blood tests.

For a General Medical Certificate (GMC), the results show:

- Full Blood Count (FBC)
- Creatinine (Cr)
- HBA1c
- HIV
- hepatitis B (HBsAg)
- hepatitis C (Anti-HCV or HCV Ab), and
- syphilis.

For a Limited Medical Certificate (LMC) the results are only for a FBC and Cr.

## ASSESSING BLOOD TEST RESULTS FOR ASH REQUIREMENTS

#### Note

If you are unsure whether blood tests results are likely to be of concern or may need further investigation, contact the MOs for advice.

#### Haemoglobin

In general, elevated haemoglobin is not considered significant, for any visa type unless the applicant has a confirmed medical diagnosis for a significant medical condition related to elevated haemoglobin – for example, sickle cell disease.

Decreased haemoglobin can be a sign of anaemia which is common amongst visa applicants, especially women and girls from developing countries who are vegetarian.

Hb ≥100 and microcytosis

If the applicant has Hb ≥100 and microcytosis, this is most likely anaemia caused by an iron deficiency which is common in vegetarians and pregnant women. If you have no other concerns about the applicant's health, they are likely to meet ASH requirements.

If you do have a concern – for example, the applicant is male and not vegetarian, they have Beta Thalassemia Major or another blood disorder – consider making a FIR for a haematologist's assessment, including the ferritin level to confirm this.



Hb ≥100 and normocytic

If the applicant has Hb ≥100 and normocytic this may indicate age-related anaemia or anaemia caused by chronic disease. If no obvious cause has been identified and you have a concern about the result, then consider investigating further.

Hb ≥100 and macrocytic

Possible causes for macrocytosis include B12 or folate deficiency, and ETOH use. Consider making a FIR to a haematologist for ferritin, B12 and folate tests. Always check the platelet level, as some visa applicants are so deficient in B12 that their platelets have been affected.

Hb ≥80 and ≤ 100

If there is a reasonable explanation for the haemoglobin level and you have no other concerns, then the applicant is likely to meet ASH requirements. Otherwise, consider making a FIR for a haematologist's assessment to exclude thalassemia or haemagloblinopathies, gastrointestinal and gynaecologic anaemia. Ask them to comment on the applicant's:

- medical history
- examination and diagnosis
- their management needs, and
- the long term prognosis.

#### White cell count (WCC)

If the applicant's total white cell count is significantly abnormal, then investigate further:

- If the appearances are of a viral infection, then this would not be considered significant.
- In pregnancy the WCC normal range increases due to an increase in neutrophils.
- If a repeat FBC has been provided and the WCC is improving, this is unlikely to be considered significant.
- If the WCC is moderately abnormal, then consider asking for a repeat FBC to review this abnormality.
- If the WCC is under 3 or over 18, or you have any concerns that may suggest an underlying haematologic disorder, then make a FIR for a haematologist's assessment.

Allergies and parasitic infections are common amongst visa applicants, so mild to moderate eosinophilia is not a significant concern.

#### **Platelets**

Some applicants' platelet levels are very low – between 10 and 20. This is often caused by a B12 deficiency which is common in vegetarians.

If an applicant has platelets <100, this may be caused by:

- a B12 or folate deficiency
- liver disease or cirrhosis especially if they have Hepatitis B or C
- ETOH use, or



a malignancy.

If the platelet level is between 80 and 100, consider making a FIR for:

- a repeat FBC, and
- tests for ferritin, folate, B12 and liver function.

If the platelet level is <80 and there is no obvious cause, consider making a FIR for a haematologist's assessment.

#### Haemophilia

If an applicant is confirmed to have haemophilia refer to the separate guidance available for this medical condition.

#### **Beta Thalassemia**

Beta Thalassemia is an inherited blood disorder affecting the production of haemoglobin and causing anaemia. The anaemia can range from minor, which is managed with oral medication, to major, where the person needs lifelong monthly blood transfusions.

The cost of treating Beta Thalassaemia Major can be in the millions and patients who are well managed can live well into to old age. Children with the disorder can risk brain damage if they do not receive transfusions and so may have bone marrow transplants instead, although there are risks associated with this.

Beta Thalassemia Major

Applicants for residence or temporary entry with Beta Thalassemia Major do not meet ASH requirements. For residence visa applicants, Beta Thalassemia Major is on the list of conditions in A4.10.1 of Immigration Instructions.

Beta Thalassemia Minor

In general Beta Thalassemia Minor is not always considered to be significant. Your opinion may depend on whether the applicant has a significant anaemia which results in regular blood transfusions.

# WORDING FURTHER INFORMATION REQUESTS (FIRS) TO APPLICANTS FOR BLOOD TESTS

Each of the following blood tests can be the subject of a FIR either as a stand alone request or as the FIR heading for a group of blood tests related to a particular medical condition:

- Liver Function Test (LFT)
- Repeat urinalysis
- Serum Creatinine (eGFR)
- HIV test



- Full blood count
- HBA1c
- Hepatitis B test
- Hepatitis C test.

If you have multiple requests for tests and medication lists, separate the test headings into the different medical conditions and use the appropriate headings for each condition.

#### **Examples**

If you request HBA1c, creatinine, eGFR, microalbumin:creatinine ratio, cholesterol profile, blood pressure, a medication list, FBC and a ferritin level, use the headings as follows.

**HBA1c** – an HBA1c, creatinine, eGFR, microalbumin: creatinine ratio, cholesterol profile, Blood Pressure and a medication list are required.

**Full Blood Count** – A Full Blood Count and a ferritin level are required.

If you request HBeAg, HBV DNA, LFTs, AFP, liver ultrasound and a liver Fibroscan (dated within the past 3 years), use the heading as follows.

**Hepatitis B test** – An HBeAg, HBV DNA, LFTs, AFP, Liver ultrasound and a Liver Fibroscan (dated within the past 3 years) are required please.

#### ASH OUTCOMES FOR APPLICANTS WITH ABNORMAL BLOOD TESTS

#### Haemoglobin levels

If an applicant for residence or temporary visa has no other health concerns and:

Hb ≥100 and microcytosis, then your opinion can be likely ASH.

Hb ≥100 and macrocytic, then your opinion can be likely ASH for residence visas and likely ASH or AWC for a temporary visa

Hb over 80 and under 100, and a reasonable explanation for the haemoglobin level then your opinion can be likely ASH.

#### **Beta Thalassemia Major**

Nearly all applicants with Beta Thalassemia Major are NOT ASH.

In your opinion for a residence visa applicant, note the condition from A4.10.1:

Severe or disabling hereditary disorders, including but not exclusive to: hereditary anaemias and coagulation disorders.

In your opinion for a temporary visa applicant, note:

Likely to impose significant costs and demands.



The exception is an applicant with a Limited Medical Certificate. Your opinion for these applicants is that they are likely to meet ASH requirements.

#### **REFERENCES**

Complete Blood Count in Primary Care - bpacNZ

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