PHARMAC
Pharmaceutical Management Agency

NOTIFICATION

Decision to fund a new hepatitis C treatment (Maviret) and to widen access to adalimumab (Humira) for psoriasis

17 December 2018

What we're doing

We are pleased to announce a decision to fund a new treatment for chronic hepatitis C infection, glecaprevir and pibrentasvir (Maviret) from 1 February 2019, and to widen access to adalimumab (Humira) for patients with psoriasis from 1 July 2019, through an agreement with AbbVie Ltd.

In summary, this decision will result in the following:

On 1 February 2019:

- Glecaprevir with pibrentasvir (Maviret) tablets will be funded in the community and DHB hospitals without restrictions for patients with chronic hepatitis C. Maviret treats all genotypes of hepatitis C.

- Maviret will replace the currently funded open-listed hepatitis C treatment, Viekira Pak (+/- RBV), which will be delisted on the same day. Viekira Pak can only be used to treat patients with genotype 1 hepatitis C.

On 1 July 2019:

- The funding restrictions for adalimumab (Humira) for the treatment of plaque psoriasis will be widened via the lowering of the Psoriasis Area and Severity Index (PASI) entry score and the addition of the Dermatology Quality of Life Index (DLQI) assessment.

Distribution arrangements for Maviret:

- Maviret will be listed 'XPHARM' in the Pharmaceutical Schedule and only pharmacies registered as a 'Maviret AbbVie Care Pharmacy' will be able dispense funded Maviret.

- Patients will present a prescription for Maviret directly to the pharmacy. Pharmacies will order stock through Healthcare Logistics (HCL) and process the prescription through dispensing software.

Contractual arrangements:

- A confidential rebate will apply to Maviret and Maviret will have protection from subsidy reduction and delisting until 1 February 2022.

- The confidential net price of Humira will be amended and Humira will have protection from subsidy reduction and delisting until 30 June 2020.

Further details about the decision can be found on the following pages.

Any changes to the original proposal?

This proposal was the subject of a consultation letter dated 20 July 2018, with further updates provided on 27 August 2018 and 24 October 2018. Having carefully considered consultation feedback, we have made the following changes:

- Maviret will be funded from 1 February 2019.
- Funded access to adalimumab (Humira) for the indication of plaque psoriasis will be widened from 1 July 2019.
- The commercial arrangement with AbbVie for Humira has been changed to include an amendment to the confidential net price and an extension of subsidy and delisting protection for Humira until 30 June 2020.

Who we think will be most interested

- People with chronic hepatitis C infection.
- People with chronic plaque psoriasis.
- Gastroenterologists, infectious disease specialists, general practitioners, nurses, dermatologists.
- Organisations that support people at risk of chronic hepatitis C infection.
- Hospital and community pharmacists, DHBs, suppliers and wholesalers.
- Pharmacy software vendors.

What will the effect of the Maviret decision be?

For people starting treatment

All treatment-naive people with chronic hepatitis C will be able to access a funded treatment, regardless of disease genotype. There will be no prescription co-payment for Maviret.

Maviret may be an option for people who have previously been unsuccessfully treated for hepatitis C with other treatments. These people should discuss their treatment options with their doctor.

People who are not able to take Maviret, for example because their liver disease is too advanced, may be eligible for funded ledipasvir with sofosbuvir (Harvoni – see below).

For people already on treatment

People who have already started a treatment course of Viekira Pak +/- RBV or Harvoni will be able to complete their course and will not need to switch therapies. Their pharmacy will have their complete funded course.

For people with hepatic impairment

Maviret is not recommended for people with moderate hepatic (liver) impairment (Child-Pugh B) and it is contraindicated in those with severe hepatic impairment (Child-Pugh C). Ledipasvir with sofosbuvir (Harvoni) remains a funded treatment option for these people via current access criteria and distribution arrangements through the Hepatitis C Treatment Panel.

For community pharmacies

A slightly different distribution mechanism to the current system in place for Viekira Pak +/- RBV will be used for Maviret. This is to align distribution with standard pharmacy processes as much as possible. More details on this mechanism are outlined in the 'Detail of the decision' section.

For hospital pharmacies

Maviret will be listed in Section H of the Pharmaceutical Schedule subject to supply being sourced through PHARMAC's approved distribution mechanism. Hospital pharmacies will need to process any usage through community dispensing software and be registered with the Maviret AbbVie Care Pharmacy Programme in order to be provided with stock and receive the professional fee-for-service.

For prescribers

Prescribers will be able to prescribe Maviret for all people with chronic hepatitis C, as clinically appropriate. For those with moderate to severe hepatic impairment, Harvoni remains a funded treatment option.

Prescriptions for Maviret should be provided to the patient, who will need to present it at a Maviret AbbVie Care registered pharmacy. A list of these pharmacies will be available at www.maviret.co.nz from 1 February 2019. This differs from the current Viekira Pak arrangement where prescribers provide a distribution request directly to PHARMAC.

Where a Maviret AbbVie Care pharmacy is not accessible, the prescriber can request an 'alternative distribution form' to arrange medication counselling and delivery; these forms can be accessed via the 'find a pharmacy' feature at www.maviret.co.nz from 1 February 2019.

The 'health pathways', or a DHB's equivalent clinical support platform, will be updated by the Ministry of Health to reflect these changes.

For DHBs

Funding of this new treatment may lead to an increase in demand for related services such as liver elastography scans (eg Fibroscan®).

In the long term, treatment of hepatitis C with Maviret is expected to reduce demand for services such as late stage liver care, hepatocellular carcinoma support and liver transplantation.

What will the effect of the Humira decision be?

From 1 July 2019, relevant prescribers will be able to consider treatment with funded Humira in patients with chronic plaque psoriasis who have a PASI score of greater than 10 (previously the PASI score had to be greater than 15). The amendments to the funding criteria will also allow for the DLQI to be used as an alternative assessment of treatment response.

All other criterion relating to the use of Humira for chronic plaque psoriasis remain unchanged and there are no changes to the criteria for other funded indications of Humira.

Details of this decision

Listing of glecaprevir with pibrentasvir (Maviret)

Maviret will be listed without restrictions in Section B (the Community) and Part II of Section H (the Hospital Medicines List) of the Pharmaceutical Schedule on 1 February 2019 as follows:

Chemical	Presentation	Brand	Pack size	Price and subsidy
glecaprevir with pibrentasvir	Tab 100 mg with pibrentasvir 40 mg (84 tablets)	Maviret	84 OP	$24,750

- Maviret will have subsidy and delisting protection until 1 February 2022.
- A confidential rebate will apply to Maviret, reducing the net price to the Funder.
- The Section H listing will direct hospital pharmacies to use the community based claiming and distribution process described below.

Distribution

An alternative distribution mechanism for Maviret, that does not utilise the Community Pharmacy Services Agreement (CPSA), will be in place by 1 February 2019. This will be similar to the way Viekira Pak is currently distributed. Only pharmacies registered as a Maviret AbbVie Care Pharmacy can provide funded Maviret.

Further detail on the processes and requirements for pharmacies is detailed below:

- Maviret will be listed in the Pharmaceutical Schedule as 'XPHARM' meaning no claim will be made through the normal pharmacy claiming process.
- Pharmacies will need to complete the 'Maviret online Quality Use of Medicines training' and agree to the terms and conditions for the Maviret AbbVie Care Pharmacy Programme to become a Maviret AbbVie Care Pharmacy. All existing Viekira Pak AbbVie Care pharmacies would also need to complete the training. The training will take approximately 2 hours to complete and pharmacies can go to www.abbviecarepharmacy.co.nz to start their registration.
- Pharmacies will need a current Healthcare Logistics trading account to order Maviret stock via their dispensing software. This functionality will only be activated once registration as a Maviret AbbVie Care pharmacy is complete.
- Maviret will be provided to Maviret AbbVie Care Pharmacies free of charge. This means pharmacies will not be left with the liability of expensive stock.
- Pharmacies will receive stock for the complete course of treatment per order and dispense to the patient monthly.
- Patients will present their prescription for Maviret to a Maviret AbbVie Care registered pharmacy; a list of these pharmacies will be available at www.maviret.co.nz from 1 February 2019.
- Pharmacies will dispense the prescription with an 'NS' patient code.
- Pharmacy software vendors (Toniq and RxOne) have made necessary changes and tested their systems to enable dispensing data capture with the proposed mechanism of dispensing using the NS patient code.
- Pharmacies will receive a professional fee-for-service for the training, ordering, dispensing, administration and patient services related to Maviret.

Delisting of Viekira Pak and Viekira Pak-RBV

On 1 February 2019, Viekira Pak and Viekira Pak-RBV will be delisted from Section B and Part II of Section H of the Pharmaceutical Schedule.

Pharmacies with people who have already commenced on Viekira Pak +/- RBV therapy will have received the full subsidised treatment course. The delisting will not affect these people currently taking Viekira Pak +/- RBV and pharmacies will be expected to provide these people with the complete treatment course as per the prescribed regimen.

Adalimumab (Humira and HumiraPen) restriction and contractual changes

The price and subsidy of Humira/HumiraPen will remain unchanged. The confidential net price of Humira has been amended and Humira/HumiraPen will have subsidy and delisting protection to 30 June 2020.

On 1 July 2019, the funding restrictions for adalimumab for the indication of severe chronic plaque psoriasis will be amended in Section B of the Pharmaceutical Schedule as detailed below (additions in bold, deletions in strikethrough). Similar amendments will be made to the Hospital Restrictions for adalimumab in Part II of Section H. There are no other changes to the funding restrictions for adalimumab.

Initial application — (severe chronic plaque psoriasis) only from a dermatologist. Approvals valid for 4 months for applications meeting the following criteria:
Either:
1 Both:
1.1 The patient has had an initial Special Authority approval for etanercept for severe chronic plaque psoriasis; and
1.2 Either:
1.2.1 The patient has experienced intolerable side effects from etanercept; or
1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for severe chronic plaque psoriasis; or
2 All of the following:
2.1 Either:
2.1.1 Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than ~~15~~ **10**, where lesions have been present for at least 6 months from the time of initial diagnosis; or
2.1.2 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis; and
2.2 Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin; and
2.3 A PASI assessment **or Dermatology Quality of Life Index (DLQI) assessment** has been completed for at least the most recent prior treatment course (but preferably all prior treatment courses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course; and
2.4 The most recent PASI **or DLQI** assessment is no more than 1 month old at the time of application.
Note: "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than ~~15~~**10**, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior

treatment; for severe chronic plaque psoriasis of the face, hand or foot, at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe, and the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment.

Renewal — (severe chronic plaque psoriasis) only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

1 Either:

1.1 Applicant is a dermatologist; or

1.2 Applicant is a Practitioner and confirms that a dermatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and

2 Either:

2.1 Both:

2.1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and

2.1.2 **Either**

2.1.2.1 Following each prior adalimumab treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-treatment baseline value; or

2.1.2.2 Following each prior adalimumab treatment course the patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, when compared with the pre-treatment baseline value; or

2.2 Both:

2.2.1 Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment; and

2.2.2 Either:

2.2.2.1 Following each prior adalimumab treatment course the patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values; or

2.2.2.2 Following each prior adalimumab treatment course the patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value; and

3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Note: A treatment course is defined as a minimum of 12 weeks of adalimumab treatment

Our response to what you told us

We're really grateful for the time people took to respond to this consultation. All consultation responses received by 13 August 2018 were considered in their entirety when making a decision. Most responses were fully supportive of the proposal. The table below summarises the main themes raised in feedback, along with any changes we have made after listening to you, and our comments on the feedback.

If you have any questions, you can email us at enquiry@pharmac.govt.nz or call our toll-free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.

Theme	PHARMAC Comment
Feedback regarding Maviret dispensing and distribution arrangements	
Queries/concerns about the distribution mechanism, including location of pharmacies, number of pharmacies, and accessibility of information about pharmacies that would be able to dispense Maviret.	Any pharmacy can be part of the AbbVie Care Pharmacy programme. Details of pharmacies that choose to be part of the programme will be available on the following website www.maviret.co.nz from 1 February 2019. The programme is very similar to the current arrangement for Viekira Pak. We will work with AbbVie and pharmacies to ensure appropriate locations and numbers of pharmacies.
How would prisons be serviced?	Prisons will be served as per current arrangements. Pharmacies that provide medication to prisons can provide Maviret as long as they are registered with AbbVie to do so.
How is the handling fee being paid?	Any fee for service paid to pharmacies will be processed by Healthcare Logistics (HCL) on behalf of AbbVie.
Prescribing and patient management	
Nurse prescribers should be able to prescribe funded Maviret.	Maviret will be funded without restrictions. Funded Maviret will be dispensed to any patient with a prescription written by any person (including nurse prescribers) lawfully able to prescribe it.
Treatment of treatment-experienced patients with hepatitis C should be done in secondary care.	The Ministry of Health is updating 'Health Pathways' and similar clinical decision-making tools to guide clinicians about how and when patients should be treated in primary care vs secondary care.
Uncertainty about which patients would be considered unsuitable for Marivet, noting that Maviret is not contraindicated in patients with cirrhosis.	Maviret will be open-listed; however, as noted in the prescribing information on the Medsafe website, it is not recommended in patients with moderate hepatic impairment and is contraindicated in patients with severe hepatic impairment. We are aware that cirrhotic patients are currently referred to secondary services for treatment. These patients may be treated with either Maviret or Harvoni, at the treating specialist's discretion, depending on clinical circumstance.
Further treatments should be funded for groups of people with hepatitis C who would still have suboptimal or no treatment options despite the funding of Maviret; specifically, patients for whom a direct acting antiviral (DAA) treatment has failed should receive Maviret plus sofosbuvir (and possibly with ribavirin), or sofosbuvir / velpatasvir / voxilaprevir (Vosevi).	We acknowledge that there is a small subgroup of patients with remaining unmet clinical need. This decision will not prevent us from considering funding of other hepatitis C treatments for these patients and we continue to work with potential suppliers of these products. We intend to seek further advice on this at the next Anti-infective Subcommittee of the Pharmacology and Therapeutics Advisory Committee (PTAC) meeting.
Patients with decompensated cirrhosis should receive sofosbuvir / velpatasvir (Epclusa) in place of Harvoni as responders consider this would be cheaper due to treatment duration and higher efficacy.	See above.

Theme	PHARMAC Comment
Considered that the goal should be elimination of hepatitis C and suggested a 'test and treat' campaign.	Elimination strategies are the responsibility of the Ministry of Health. We continue to work closely with the Ministry and note that funding of a pangenotypic treatment is a direct contribution to any elimination strategy that the Ministry of Health may lead.
Concerns that GPs are underfunded for the extended visits that hepatitis C support requires.	We will pass this feedback onto the Ministry of Health, which is responsible for the funding of DHB Services. We note that Maviret is more straightforward than current treatments to prescribe and monitor in primary care.
Concerns about inequity of access for Māori and disadvantaged groups and requests for better funding to allow such patients to see GPs.	PHARMAC is considering how we can optimally work with partners, including Ministry of Health, DHBs and Work and Income, to develop strategies to prevent inequities in access occurring. We note that there will be no pharmacy co-payments incurred by patients as part of the distribution arrangements for this treatment.
On discontinuing Viekira Pak simultaneously: most who commented on this were supportive. One responder asked to delay the delisting of Viekira Pak for 2-4 weeks to allow for any delays in presenting with a prescription.	AbbVie has agreed to supply Viekira Pak to pharmacies in the circumstance where a patient presents with a prescription post 1 February 2019. Viekira Pak will be made available up until 30 April 2019.
Summary of consultation feedback on Maviret implementation and education	
Various consultation feedback indicated that the following should be considered to support any implementation: • Presentations at national primary care meetings. • Presentations at regional primary care CME meetings. • Provision of training sessions/webinars for the primary care team about treating hepatitis C. • Provision of education materials, such as guidelines and written materials, on the place of Maviret in treatment. • Updated National Pathways. • National awareness campaign.	Our implementation programme includes the following elements: • Educational materials. • Updating of National Pathways. • A range of opportunities and methods for people to get information about Maviret, including at conferences and regional meetings. We also note that a national hepatitis C awareness campaign is in development, led by the Ministry of Health and the Health Promotion Agency.