Health New Zealand
Te Whatu Ora

Standard Operating Procedures for Nurse Direct Supply for Maviret

This includes the approval process and obtaining initial stock, procedure for storage and procedure for supply to patients.

Background

The combination of glecaprivir and pibrentasvir (Maviret) is prescription only except when provided:

> in a manufacturer's original pack that has received consent from the Minister of Health or Director General for treatment of chronic hepatitis C virus infection to people who meet the clinical and eligibility criteria of an approved training programme, when provided by nurses who meet the requirements of the Nursing Council or pharmacists who meet the requirements of the Pharmacy Council.

A small number of nurses will be working in outreach, e.g. in a mobile van or with homeless people, to diagnose and manage people with chronic hepatitis C virus (HCV). To provide Maviret directly to people with HCV, these nurses need to meet the requirements of the Nursing Council **and** the additional approval below.

The company (AbbVie) provides the following information:

"Maviret shows good stability at 30ºC/75% Relative Humidity (RH), hence the absence of including a specific storage temperature in the Datasheet, in line with ICH requirements. In the Consumer Medicines Information (CMI) and the approved outer carton, we recommend that consumers store the product below 30ºC. In practice, small deviations, no greater than 5ºC, for a few hours, above 30ºC and below 15ºC may occur and are covered by the stability data on the product."

Note that vehicles can get very hot quickly in summer which could compromise the shelf-life of Maviret (as well as point-of-care test kits). Temperature drops can also be significant over winter in some areas. **Maviret stock is expensive and we want to avoid temperature excursion and stock wastage.**

Maviret also needs to be kept out of the reach of children and secure from being taken without authority.

Procedure for approval of nurses for direct supply to patients

Nurses able to supply Maviret directly to patients are those who have been authorised by the Nursing Council in hepatitis C management **and** have documented approval from their local Regional Hepatitis C Programme Lead and Hepatitis C Clinical Lead to supply Maviret directly. This will be a small number of nurses meeting all of the following requirements:

- authorised with the Nursing Council for hepatitis C management
- experienced in hepatitis C diagnosis and management
- capable of assessing the patient for hepatitis C treatment
- has appropriate links to secondary care for advice
- approved by the Hepatitis C Clinical Lead at a regional/local level to provide Maviret by direct supply
- approved by the Regional Hepatitis C Programme Manager to provide Maviret by direct supply
- working in an outreach/remote role.

Documentation needs to be kept regionally (for nurses in the region this applies to). At a national level a list of all nurses authorised to work with Direct Supply is to be kept along with their region and their contact details (phone and email). This list will be shared with Pharmac in consultation with Regional Hepatitis C Programme Managers. Any changes, e.g. a nurse leaving the role or no longer needing to directly supply Maviret needs to be documented at the regional and national level and be notified to Pharmac.

Information about direct supply to patients by nurses needs to be kept at a regional and national level (number of supplies, age, gender and ethnicity) and shared with Pharmac annually.

Procedure for storage of Maviret used for direct supply to patients

1. Planned storage locations should be tested in advance for temperature variations before the stock is acquired.
2. A thermometer with an ability to show current temperature and minimum and maximum temperatures is needed, or an electronic temperature device with alerts for a deviation needs to be kept with the stock for wherever it is stored.
3. Temperatures should be recorded weekly and checked for any out-of-range temperatures before providing to a patient.
4. Maviret stock must be stored out of sunlight and secure from being taken without authority, e.g. locked cupboard or locked box. Do not store in the fridge.
5. Maviret stock must be removed from a vehicle for periods when the **temperature in the vehicle** might rise above 30°C or drop below 15°C. NB: the temperature in the vehicle will often be higher than outside and can get very low during winter. This will include weekends, overnight and days and times when the vehicle is not being used. Stock can be stored temporarily at a pharmacy, at the workplace, at a home or at accommodation. It needs to be stored out of the reach of children and unavailable to be taken without authority. It must be kept securely when off-site e.g. in a locked box.
6. Any temperature excursion shown on the thermometer above 30°C or below 15°C for more than a short time when the stock is on-board needs to be checked with

the manufacturer of Maviret. Such stock is to be quarantined until confirmed if it is safe to use or not.

7. Any temperature excursion and actions taken needs to be documented.
8. The nurse who supplies Maviret is responsible for ensuring the stock integrity is maintained.

Procedure for direct supply to patients – where an assessment by the approved nurse confirms Maviret supply is appropriate for that patient

1. Keep a stock record and update it when stock comes in or goes out.
2. Oldest stock is used first.
3. Check the stock is in date (i.e. not expired).
4. Check the amount of stock tallies with the stock record before supply or entering incoming stock.
5. Write the patient name, date of supply, dose to take (take three tablets once a day with food) and the nurse's name and contact number onto a label for the medicine.
6. Record the supply (**without** patient name), quantity provided, date and nurse name in the stock record notebook.
7. Provide Maviret to the patient with appropriate counselling.
8. Contact a pharmacy that is approved for Maviret supply to inform of supply providing patient details and arrange the replacement stock. It is recommended that the pharmacy be contacted in advance with information about the nurse direct supply classification and action required. The pharmacy needs to dispense the Maviret for the name of the patient who has had the direct supply with the following information written under instructions in the dispensing software: "Given to nurse".
9. Collect Maviret from the pharmacy to replace that used and enter in the stock record.

Procedure for getting Maviret stock

1. Initial stock will be arranged for nurses who meet the criteria for supply (see background above) by the Regional Hepatitis C Programme Manager.
2. The Regional Hepatitis C Programme Manager provides to the appropriate Therapeutic Group Manager at Pharmac:
    a. the name of the nurse
    b. that the nurse has completed training and been signed off by the Regional Hepatitis C Programme Manager and Hepatitis C Clinical Lead*
    c. the AbbVie Care pharmacy for delivery of initial stock.
3. Pharmac will arrange the delivery of up to two eight-week courses of Maviret (currently 4 packs of 84 tablets) through AbbVie to the nominated pharmacy.

4. Replenishment of stock used can be undertaken through any AbbVie Care Pharmacy by the nurse contacting the pharmacy with the details of the patient/s to whom packs were supplied.
5. Any AbbVie Care Pharmacy used for delivery of initial stock or stock replenishment needs to be provided with the Model Flowchart: Nurse Direct Supply, Outreach, this document and the name and contact details of the nurse who has been signed off by the Regional Hepatitis C Programme Manager and Hepatitis C Clinical Lead. Note the pharmacist does not need to have become credentialled to provide Maviret to the nurse under the Nurse Direct Supply, Outreach model. Credentialling for the pharmacist is only required for the Collaborative Care Models.
6. The pharmacist and nurse need to follow the Model Flowchart: Nurse Direct Supply, Outreach.

*Documentation is kept by the Regional Hepatitis C Programme Manager and shared with the National Lead for Hepatitis C. This includes notification if the nurse is no longer providing direct supply services in that area for removal from the nationally held list and advice to Pharmac.

Note: In the absence of a Regional Hepatitis C Programme Manager, a regional lead for hepatitis C or the National Lead for Hepatitis C may carry out these functions.