NATIONAL BLOOD AUTHORITY
AUSTRALIA

Hemlibra: Implementation, Distribution and Transition Arrangements

Hemlibra (emicizumab) has been added to the national supply arrangements for blood products administered by the National Blood Authority (NBA), from 2 November 2020.

General information on the availability of Hemlibra is available here. Key points include:

- Hemlibra will be available through specialist clinicians at Haemophilia Treatment Centres, to prevent or reduce the frequency of bleeding in severe or moderate haemophilia A patients, or in haemophilia A patients with inhibitors
- Distribution arrangements will support local delivery for patients who can appropriately self-administer Hemlibra at home, with ongoing clinical oversight from a Haemophilia Treatment Centre. This will include distribution through a community pharmacy, or home delivery on an exception basis within a defined set of eligibility criteria.
- Transition arrangements for Hemlibra will take account of the need for appropriate clinical oversight of transitioning patients, and the efficient use of stock of current products already held by Haemophilia Treatment Centres and patients, and stock required to be held in Australia under NBA contracts.

Clinical guidance on the appropriate use of Hemlibra is available here.

Specific additional clinical governance and management arrangements for the provision of Hemlibra may also apply in each State and Territory, or at a local health district or hospital level.

This document provides information on implementation, distribution and transition arrangements for Hemlibra under the NBA's contract with the product supplier Roche (including through appropriate supply chain providers subcontracted by Roche). It will be useful for patients and their carers, specialist clinical staff at Haemophilia Treatment Centres (HTCs), other relevant clinical personnel, and health service managers.

Hemlibra is a Schedule 4 medication which means that a doctor or other eligible prescriber will be required to write a prescription for Hemlibra, and Hemlibra will need to be dispensed by a pharmacy or health service from a suitable location in a manner which meets the requirements for prescription and dispensing of S4 medications under applicable State and Territory laws. The arrangements described in this document have been designed in a manner which will enable these requirements for prescription and dispensing to be met.

OVERVIEW OF HEMLIBRA ORDERING AND DELIVERY

There will be two primary pathways for distribution of Hemlibra under NBA arrangements:

- Delivery to an Approved Health Provider (AHP), which will be a HTC (or an alternative AHP by coordination with an HTC), and
- Delivery by arrangement to an approved Community Pharmacy close to a patient, through contracted arrangements established by Roche, and supervised by an HTC.

A third pathway, home delivery, can be requested by an HTC for patients on an exception basis, within a defined set of eligibility criteria specified below.

These three pathways are summarised as follows, and further detail is provided at **Appendix 1**:

	1) Approved Health Provider (AHP)	**2) Community Pharmacy**	**3) Home delivery**
Description	Patients to start treatment with Hemlibra at an AHP which is a Haemophilia Treatment Centre (HTC), or at a non-HTC AHP in coordination with a supervising HTC, to ensure adequate education and training on subcutaneous injection technique	When the supervising HTC is confident the patient can self-inject, or that the patient's caregiver is appropriate to administer Hemlibra, a patient or carer can nominate a suitable community pharmacy for collection of Hemlibra	Requested by an HTC, by exception and within the conditions approved by the National Blood Authority for patients that live too far from a community pharmacy set out below. Hemlibra will be shipped to an AHP pharmacy or a suitable community pharmacy for dispensing and then collected by courier contracted by Roche for delivery to the specific patient
Order placement	Order to be sent directly to Roche Customer Service	HTC to send order and prescription (copy) to Roche contracted representative to organise supply via Roche (in coordination with the supervising HTC)	HTC to send order and prescription (copy) to Roche contracted representative to organise delivery with AHP pharmacy or community pharmacy
Order process	Order form (prescription retained in AHP)	Order form and prescription	Order form and prescription

Eligibility for Community Pharmacy or Home Delivery

An HTC may initiate Community Pharmacy or Home Delivery for a patient under its clinical supervision, where the HTC considers the patient or carer to be adequately trained in subcutaneous injection techniques and to be otherwise suitable for Community Pharmacy or Home Delivery.

Home Delivery is available on an exceptional basis only, if the following additional requirements are met:

a. The patient is registered on the Australian Bleeding Disorders Registry (ABDR), and

b. The patient meets one or more of the following criteria:

    i. the patient lives in an urban area, but further than 10 km away from a suitable community pharmacy,

ii. the patient lives in a rural or remote area with no access to a suitable community pharmacy within 30 km, or

iii. the patient or their primary carer is unable to travel to their community pharmacy due to a lack of transport options.

PATIENT COMMENCEMENT AND TRANSITION

Once the clinical decision has been made by a specialist clinician at an HTC in conjunction with the patient that a patient should commence on Hemlibra, planning for the patient's commencement should take into account:

- appropriate training and support for the patient and any relevant carer in relation to subcutaneous injection of Hemlibra
- utilisation of existing stock of clotting factor product that may be held by the patient, to avoid expiry of unused product.

In addition to consideration of stock of clotting factor products held by relevant patients, the NBA will liaise with HTCs and current suppliers of clotting factor products in relation to forward planning of supply requirements and HTC intentions to commence patients on Hemlibra, in the interest of avoiding expiry of clotting factor products held in HTC inventory, or held by current suppliers as in-country reserves required under contracts with the NBA.

A patient commencing Hemlibra will progress through three different dosing stages, as follows:

Loading dose (up to 4-weeks supply):

- In this stage, the patient attends an initial consultation with a specialist HTC clinician, and if appropriate, Hemlibra is prescribed and dispensed from the HTC (or another AHP under the supervision of an HTC).
- The patient is provided with appropriate education, and the first loading dose, by HTC staff. The HTC will consider patient eligibility to move to Community Pharmacy distribution in the future - if so, the patient nominates a preferred community pharmacy for collection of future prescriptions (week 9 maintenance onward) and provides consent to be contacted by a Roche representative to advise of set up and supply.
- A patient not choosing Community Pharmacy distribution can continue to have Hemlibra dispensed at the HTC pharmacy (or at another AHP by arrangement with the HTC).
- The patient will be provided with appropriate Hemlibra ancillaries

Initial maintenance dose (4-weeks supply):

- In this stage the patient returns to the HTC or alternative AHP for prescription and administration of the first maintenance dose.
- For patients moving to community pharmacy, the patient/carer will need to complete a patient consent form with their haemophilia doctor or nurse, to be able to be contacted by a Riche representative.
- The HTC sends the Roche representative a copy of the completed patient consent form, prescription, and the completed order form provided by Roche specifying the schedule of dispensing.
- The patient will be contacted by the Roche representative who will initiate a welcome call and confirm details on the patient consent form.

- The patient's nominated community pharmacy is set up by the Roche representative to receive and dispense Hemlibra for the patient.
- The patient will be notified when their nominated community pharmacy is set up and is ready to dispense Hemlibra to the patient.
- The patient is provided with an appropriate number of Hemlibra ancillaries, and information on ordering provided by Roche.

Subsequent maintenance doses (from week 9 onwards):

- After a patient (or carer) has received proper training in subcutaneous injection technique and is confirmed by the HTC as suitable, subsequent maintenance doses of Hemlibra can be dispensed at a community pharmacy.
- The patient will be contacted by the Roche representative when supply has been delivered to the community pharmacy.
- The patient takes the original copy of the prescription to the community pharmacy and Hemlibra is dispensed.
- There is no co-payment passed on to the patient.
- The HTC will need to continue to send orders to the Roche representative every 4 weeks in order for the patient to continue to collect supply from the community pharmacy.
- Roche will provide HTCs with reports detailing their patients' supply location and dates of dispensing. Roche will highlight to HTCs when a patient may be due for a new script.

Product warning

The following warning appears in the Australian Product Information for Hemlibra approved by the Therapeutic Goods Administration, and must be taken into account at all times in relation to the prescription and use of Hemlibra:

WARNING: THROMBOTIC MICROANGIOPATHY AND THROMBOEMBOLISM

Cases of thrombotic microangiopathy and thrombotic events were reported when on average a cumulative amount of > 100 U/kg/24 hours of activated prothrombin complex concentrate (aPCC) was administered for 24 hours or more to patients receiving Hemlibra prophylaxis. Monitor for the development of thrombotic microangiopathy and thrombotic events if aPCC is administered. Discontinue aPCC and suspend dosing of Hemlibra if symptoms occur.

Appendix 1: Detailed requirements for Community Pharmacy and Home Delivery

Privacy consent

1. In order to provide Community Pharmacy or Home Delivery services, supply chain providers engaged by Roche will collect certain necessary information about the relevant patient, with the consent of the patient. All personal information collection in relation to Community Pharmacy or Home Delivery Orders must be retained and maintained in accordance with APP 11 of the *Privacy Act 1988 (Cth).*

Community Pharmacy distribution

2. Orders of Product for Community Pharmacy distribution must be initiated with Roche by a HTC and include the provision of a prescription and order form to the nominated party for managing the dispensing and delivery arrangements for the patient.

3. Roche must manage the following Community Pharmacy process with each individual HTC for patients who meet the eligibility requirements and who are nominated to access Community Pharmacy distribution:

    a. The patient will need to complete a patient consent form at their HTC which will need to be provided to Roche's nominated party together with the completed order form and copy of the prescription. The original copy of the prescription will be provided by the HTC to the patient.

    b. The patient will be contacted by the nominated party who will initiate a welcome call and confirm details on the patient consent form.

    c. The patient will be notified by the nominated party when their nominated community pharmacy is set up to receive Hemlibra and advised of the estimated time of the next Hemlibra (and if required, ancillaries) delivery at the pharmacy (approximately three weeks after first maintenance dose).

    d. The patient will be notified by the nominated party when supply has been delivered to nominated community pharmacy and is ready to be dispensed (from week nine maintenance onward)

    e. The patient will take the original copy of the prescription to the Community Pharmacy and Hemlibra will be dispensed.

    f. There will be no co-payment charged to the patient.

    g. The HTC will need to continue to send orders to the Roche representative every 4 weeks in order for the patient to continue to collect supply from the community pharmacy

    h. Roche will provide monthly reports to HTCs detailing their patients' supply location and dates of dispensing, and will highlight to HTCs when a patient requires a new prescription.

4. Roche's nominated provider must ensure that the patient signs for or otherwise gives written acknowledgement of the receipt of products at the time of delivery.

Home Delivery

5. Orders for Home Delivery must be initiated with Roche by a HTC and include the provision of a prescription and order form to Roche's nominated party for managing the dispensing and delivery arrangements for the Home Delivery patient.

6. The Supplier must manage the following Home Delivery process with each individual HTC for patients who meet the eligibility requirements and who are nominated to access Home Delivery:

a. The patient will need to complete a patient consent form at their HTC which will need to be provided to Roche's nominated party together with the completed order form and copy of the prescription. The original copy of the prescription will be provided by the HTC to the dispensing pharmacy.

b. The nominated party will arrange for the Product to be dispensed by the AHP pharmacy or a community pharmacy.

c. The nominated party will arrange for the third party logistic provider to collect the dispensed Product from the dispensing pharmacy and deliver it to the nominated address of the Home Delivery recipient in accordance with this Protocol.

7. The product will be delivered to the Home Delivery recipient's nominated address during business hours between Monday and Friday, within a minimum of two, four hour (2 x 4 hr) delivery windows per day. The delivery window must be confirmed at a minimum 48 hours in advance where practicable.

8. Should the delivery date fall on a public holiday, Roche must arrange delivery in consultation with the patient and HTC and in accordance with its contractual obligations to the NBA.

9. Roche's nominated provider must inform the Home Delivery recipient of the collection process if the recipient is not available to receive the product. These arrangements are to be confirmed with each individual HTC.

10. Roche's nominated provider must ensure that an approved Home Delivery recipient signs for or otherwise gives written acknowledgement of the receipt of products at the time of delivery. Deliveries must not be left without this acknowledgement of receipt. Recipients should be made aware of this requirement as part of the education process.

General requirements

11. Roche representatives must inform the recipient as soon as possible of any reason delivery cannot be made, and arrange a delivery time which is convenient to the recipient.

12. Roche representatives must ensure that they receives instruction from each HTC on where to redirect the Order in the event the Community Pharmacy or Home Delivery recipient is not available to accept the delivery.

13. All components required for reconstitution and administration of Product delivered to Community Pharmacy or Home Delivery recipients must be provided at the time of supply.

14. Alternate or additional components must be supplied free of charge with the Product.

15. Roche must make available an accessible feedback mechanism for patients, HTCs and clinicians to provide their feedback to the Supplier.

16. In the event of a product recall, Roche must arrange for the recovery of recalled product from the Community Pharmacy or Home Delivery recipient.