**Schedule C1**

# Community Pharmacy Anti-Coagulation Management Services

## 1. Definition

This service specification relates to the anticoagulation management of Service Users on warfarin by an accredited community pharmacy service provider.

## 2. Service Objectives

The overall objective of this Community Pharmacy Anti-coagulation Management Service is the provision of INR[1] point-of-care testing by community pharmacy, and the adjustment of warfarin doses within a defined range with the aid of an approved decision-support system.

The service aims to:

(a) support Service Users and their families/whanau to better understand and manage their warfarin medication;

(b) reduce warfarin-related adverse medication events;

(c) improve accessibility and convenience for Service Users;

(d) improve multidisciplinary management of Service Users prescribed warfarin in the community;

(e) reduce the burden on Medical Practitioners; and

(f) prioritise services to the following patient groups, where possible

- People with venous access issues
- People with poor attendance at the practice, or those the practice has difficulty contacting with the results of the INR test
- People with reduced compliance and/or with reduced warfarin control
- High needs patients / people with poor health literacy
- People with mobility issues

## 3. Service Users

To be eligible to receive Community Pharmacy Anti-coagulation Management Services Service Users must:

(a) be referred by a Medical Practitioner who delegates point-of-care warfarin testing, dose adjustment and associated patient counselling to a community pharmacy service;

(b) either:

  (i) be taking warfarin medication; or

  (ii) be requiring warfarin loading and initial stabilisation; or

  (iii) be overlapping warfarin medication with low molecular weight heparin (LMWH);

(c) be mobile and able to access Community Pharmacy Anti-coagulation Management Services; and

(d) not be excluded from receiving Community Pharmacy Anti-coagulation Management Services under clause 7 of this service specification.

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[1] International Nomalised Ratio

# 4. Access criteria

## 4.1 Service User Access / Exit criteria

(a) The Service User access criteria is as follows:

(i) The Service User is referred by a Medical Practitioner; and

(ii) The Service User consents to registration in the Community Pharmacy Anti-coagulation Management Service.

(b) The Service User exit criteria are as follows:

(i) The Service User chooses to exit the Community Pharmacy Anti-coagulation Management Service, or leaves the district, or is managed by another Provider (e.g. another Pharmacy or in ARRC);

(ii) The Service User dies; or

(iii) The Service User is non-compliant and/or has not attended the Community Pharmacy Anti-coagulation Management Service.

The Provider must dis-enrol the Service User when any of these factors apply, or in the case of 4.1 (b)(ii) when the Provider is informed that the Service User has died, or is informed of this by our Payment Agent.

(c) Unless otherwise agreed by the DHB the maximum number of Service Users registered per Pharmacy is 50. The provider will be formally notified of any change without the need for a formal variation.

## 4.2 Minimising barriers to access

You agree to minimise any barriers to Service Users accessing the Community Pharmacy Anti-coagulation Management Services to the greatest extent possible.

## 4.3 Opening hours

Community Pharmacy Anti-coagulation Management Services must be available to Service Users at all times when your Pharmacy is open for normal business, subject to the conditions set out in clause 5.2 in the service specification for Core Pharmacy Services and the availability of an accredited Pharmacist.

# 5. Service Components

## 5.1 Processes

(a) This service specification for Community Pharmacy Anti-coagulation Management Services should be read in conjunction with the relevant clauses in the service specification for Core Pharmacy Services and, in particular, you must comply with clauses 6.1(a) to (e) of that service specification, where applicable.

(b) This Community Pharmacy Anti-coagulation Management Service involves:

(i) obtaining the consent of the Service User to be registered with the Pharmacy for this Community Pharmacy Anti-coagulation Management Service;

(ii) documenting Medical Practitioner consent to be involved in this Community Pharmacy Anti-coagulation Management Service and acceptance of the Community Pharmacy Anti-coagulation Management Service standing order;

(iii) undertaking Service User assessment each time the test is undertaken in order to establish the Service User's history and any symptoms, and if any Service User factors may influence the results (e.g. a missed dose of warfarin);

(iv) performing the INR test using a drop of blood on the test strip of an approved testing device using an approved decision support tool;

(v) dose adjustment made by the supervising Pharmacist supported by an approved decision support tool with a validated dosing algorithm supported by published data;

(vi) giving the Service User the results of the test and providing advice on the dose of warfarin to take each day until the next test as a hard copy dosing calendar;

(vii) giving the Service User counselling and education about warfarin medication, when required, using an approved Warfarin Education Programme;

(viii) electronically providing the Medical Practitioner with information on the results of the monitoring and changes to the warfarin regime;

(ix) requesting medical review by the Service User's Medical Practitioner if any INR is <1.5 and >4.0;

(x) contacting the Service User's Medical Practitioner directly if the Pharmacist is concerned about the Service User's symptoms, results, or the dose recommendation;

(xi) keeping a full record of the Service User's care management plan as provided by the approved on-line decision support tool;

(xii) undertaking quality assurance activities (refer to clause 8);

(xiii) auditing anticoagulant management by regularly monitoring anticoagulant control of individual patients and cumulative results using approved decision support software;

(xiv) auditing compliance for timeliness of testing in order to identify Service Users with compliance issues using the approved decision support software; and

(xv) recording the incidence of adverse events (in particular the incidence of bleeding) including hospital admissions using the approved decision support software.

(xvi) sending the results to a Laboratory Test Repository, if available, via Healthlink.

### 5.2 Facilities and Settings

The Pharmacy from which you provide Community Pharmacy Anti-coagulation Management Services must be licensed by the licensing authority under the Medicines Act 1981 and registered with the Ministry of Health.

### 5.3 Support Services

You agree to facilitate Service Users' access to support and advocacy services in accordance with clause G6.6.

# 6. Service Linkages

a) A strong professional relationship must be in place between the Medical Practitioner and Pharmacy/Pharmacist providing this Service.
b) You will work within the framework of local anti-coagulation policies, procedures and referral processes.
c) The Pharmacy must have the appropriate secure IT connection to allow electronic linkage with general practice.
d) The Pharmacy must be involved in an organised system of external quality assurance (refer to Clause 8 – Additional Quality Requirements).

# 7. Exclusions

a) Service users without a general practitioner.

b) Service users in an Aged Residential Care Facility (unless otherwise agreed by the DHB that Community Pharmacy Anti-coagulation Management Services may be provided in this setting).

c) Service Users who have anti-phospholipid syndrome, anti-cardiolipid syndrome, lupus anticoagulant syndrome and/or receiving active anti-neoplastic treatment are excluded from receiving Community Pharmacy Anti-coagulation Management Services.

# 8. Additional Quality Requirements

## **8.1** Additional requirements

The quality requirements set out in clauses 8.2, 8.3 and 8.4 of this service specification are additional to your quality obligations under the Quality Specifications in Part G.

## 8.2 Internal quality control

Each Community Pharmacy Anti-coagulation Management Service provider is required to undertake the following internal quality control activities:

- Deliver the Service as per the Standing Order, and undertake annual review to ensure pharmacists accredited to undertake the Service are operating according to the Standing Order
- Perform testing in line with the standard operating procedure
- Report on adverse events, anticoagulant control and patient compliance in each quarterly monitoring report
- Ensure internal quality control testing on the INR Monitoring device is performed in line with the recommended procedure (a code chip is supplied by the manufacturer to regularly calibrate the machine)

## 8.3 External quality assurance

The provider must be involved with an organised system of external quality assurance e.g. NEQAS[2], RCPA[3] or other external quality assurance programme, for example with the local laboratory. As an additional quality check the provider may compare test results on selected Service Users.

## 8.4 Acceptability

(a) Community Pharmacy Anti-coagulation Management Services must be provided from premises that conform to relevant standards issued by the Ministry of Health or the Pharmaceutical Society.

(b) A particular requirement for delivery of this Community Pharmacy Anti-coagulation Management Service is access to a private area within the Pharmacy for testing and counselling.

(c) Quarterly Community Pharmacy Anti-coagulation Management Service evaluation will be undertaken to determine quality outcomes and measures as measured against goals predetermined by the Ministry of Health or the Pharmaceutical Society.

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[2] ***National External Quality Assessment Service (United Kingdom)***
[3] ***The Royal College of Pathologists of Australasia (Australia)***

# 9. Qualified Provider

In order to be a qualified provider for Community Pharmacy Anti-coagulation Management Services:

(a) the Pharmacists undertaking this Community Pharmacy Anti-coagulation Management Service have a current Annual Practicing Certificate without restrictions; and

(b) at least two pharmacists per site have attended an accredited Community Pharmacy Anti-coagulation Management Services training course, and are accredited to undertake Community Pharmacy Anti-coagulation Management Services. NB One of the two pharmacists can be part-time, or a locum. If there is a particular reason this is not able to be achieved, for example the pharmacist is a sole operator, the DHB must be satisfied the Provider can guarantee safety and quality of the service in the event of unexpected absence or leave; and

(c) accredited Pharmacists must be re-certified biennially**.**

# 10. Safety

a) The Medical Practitioner retains overall responsibility for the Service User's management, but delegates that care to the Pharmacist through a standing order.
b) You will work within the framework of local anti-coagulation policies, procedures and referral processes.
c) Only accredited Pharmacists trained by an approved Community Pharmacy Anti-coagulation Management Services training course are able to provide this Community Pharmacy Anti-coagulation Management Service.
d) The Pharmacist is responsible for the quality assurance programme that ensures the test device is providing reliable results (refer to the Quality Requirements in Clause 8).

# 11. Purchase Units and Reporting Requirements

## 11.1 Purchase Units

The following Purchase Unit applies to Community Pharmacy Anti-coagulation Management Services. Purchase Units are defined in the Ministry of Health's data dictionary and correspond with the relevant services and payment terms specified in Schedule H1.

| PU ID | PU Short Name |
|---|---|
| PH1031 | Community Pharmacy Anti-coagulation Management Service |

## 11.2 Reporting Requirements

(a) Each Service User needs to have an accurate NHI number recorded.

(b) You agree to report information in accordance with the Pharmaceutical Transactions Data Specification, the Procedures Manual, and the terms and conditions set out in this Agreement including Part H.

(c) You will be advised of any additional reporting requirements. From time to time NHI level data will be requested for more detailed analysis.

## 11.3 Quarterly Reporting

Quarterly reporting will be provided to us as follows using an agreed reporting template:

| Reporting Period | Report Due |
|---|---|
| 1 July – 30 September | 20 October |
| 1 October – 31 December | 20 January |
| 1 January – 31 March | 20 April |
| 1 April – 30 June | 20 July |

| Quarterly Report | |
|---|---|
| Quarterly Summary | Number of Service Users registered by NHI with the Community Pharmacy Anti-coagulation Management Service in the quarter (i.e. active patients plus new patients minus patients who have exited the Community Pharmacy Anti-coagulation Management Service) |
| | Average number of INR tests per quarter |
| | Documentation of Key Performance Indicators<br>– Compliance (Tests on time, 1-3 days, 4-7 days, 7+ days)<br>– Control (Tests in range, tests above, tests below)<br>– Adverse events (Total recorded bleeds, Total recorded hospital admissions) |
| | A brief narrative report outlining progress implementing the service in this quarter, and any issues experienced. |

Send reporting to: performance_reporting@moh.govt.nz

Performance Reporting Team
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Private Bag 1942
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