Schedule 2 Part A Service Specification

Service Specification No.	02
Service	Anti-coagulation Monitoring Levels 3, 4 & 5
Commissioner Lead	NHS Sheffield Clinical Commissioning Group Linda Cutter (Head of Commissioning – Elective Care)
Provider Lead	GP practice/community pharmacy as identified as Provider in the Contract under which this Service Specification sits
Period	1st April 2019 – 31st March 2020
Date of Review	Annually in March

1. Population Needs

1.1 National/local context and evidence base

Warfarin is used in the management of a number of patients and conditions including patients with atrial fibrillation, DVTs and other disorders.

While it is a very effective drug in these conditions, it can also have serious side effects, e.g. severe haemorrhage. These side effects are related to the International Normalised Ratio (**INR**) level, which measures the delay in the clotting of the blood caused by the warfarin.

While the 'normal' INR is 1, the specific range of INR values depends on the disease and the clinical conditions.

This Service Specification has been designed to commission the monitoring of warfarin in primary care/community pharmacy with the aim of stabilising the INR within set limits to help prevent serious side-effects while maximising effective treatment.

Please note this document works alongside the Standard Operating Procedure for the Provision of a Level 3,4 and 5 Anticoagulation Service.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	**Preventing people from dying prematurely**	**X**
Domain 2	**Enhancing quality of life for people with long-term conditions**	
Domain 3	**Helping people to recover from episodes of ill-health or following injury**	**x**
Domain 4	**Ensuring people have a positive experience of care**	
Domain 5	**Treating and caring for people in safe environment and protecting them from avoidable harm**	**X**

2.2 Local defined outcomes

- Patients receiving care closer to home, by treatment being administered at a local GP practice or community pharmacy;
- increased patient choice, through giving an option to be seen locally;
- efficient use of National Health Service resources; and
- reduction in secondary care activity through primary care/community pharmacy treatment in the community.

3. Scope

3.1 Aims and objectives of service

The aim of this Service is to maximise effective treatment and to prevent serious side effects of warfarin through regular monitoring of Service Users.

This aim will be met through the delivery of a Service which meets the following outcomes:

- controlled INR within the agreed range;
- the regular review of warfarin and discontinuation where appropriate;
- a recognised safe transfer mechanism for Service Users from secondary to primary care;
- a convenient Service for Service Users;
- educating service users on their anticoagulation therapy

3.2 Service description/care pathway

a) Pathway

Service Users will usually be initiated on warfarin in a secondary care setting though some general practitioners may determine it is appropriate to initiate therapy for patients identified as having atrial fibrillation.

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Where warfarin treatment is initiated in secondary care for specified indications for specified lengths of time, the Provider will work with secondary care to ensure there is a recognised mechanism for safe transfer of the Service User utilising the recognised transfer of care.

Service Users with atrial fibrillation who have any one of the sub-optimal INR control as follows:

- 2 INRs >5 in the last 6 months;
- 1 INR >8 in the last 6 months;
- 2 INRs <1.5 in the last 6 months (without planned interruptions); and
- Time in therapeutic range <65%,

are to be considered by the provider for changing to one of the newer direct acting oral anticoagulants (Non vitamin K Oral Anticoagulants (**NOAC**) s or Direct Oral Anticoagulants (**DOAC**))[1].

Where the Service is provided by a general practitioner, they may initiate warfarin for thromboprophylaxis in atrial fibrillation (level 5 provision). This is an optional element of the Service for which a separate one-off payment is made, to cover the costs of the additional consultations required to stabilise the Service User. The dosing guidelines to be followed for initiation are included in the *Standard operating procedure for the provision of level 3, 4 and 5 anticoagulation service*; NHS Sheffield Clinical Commissioning Group (April 2017), (as updated from time to time) (hereafter referred to as the '**SOP**').

Where treatment is initiated in primary care The Provider will prepare, with the Service User an individual management plan which gives the diagnosis, planned duration and therapeutic range to be obtained (e.g. the yellow book).

The Provider is required to ensure that at initial diagnosis, and at least annually, an appropriate review of the Service User's health is carried out. This includes checking for potential complications and a review of the Service User's monitoring records.

Referrals for initiation or monitoring of warfarin will usually be made to the Provider from secondary care. Referrals will be made via the agreed transfer process via shared care protocols.

[1] https://www.nice.org.uk/guidance/cg180

The provider is required to have an effective system in place that identifies all patients under the Local Commissioned Service (LCS) to be called, recalled and assessed at the intervals as determined by the SOP and for this to be evidenced and documented within the patient electronic record.

b) Records

The Provider is required to maintain a register of all Service Users they are responsible for monitoring on warfarin and as a minimum this register will include:

- the clinical reason for warfarinisation;
- the Service User's name and date of birth;
- the indication for and duration of treatment;
- computerised linkage of medication to indication for treatment;
- dosing decisions;
- target INR; and
- relevant clinical history, examination findings and test results.

The above entries must be recorded in both the Service Users' electronic clinical record (for GP practices) as well as in the Clinical Decision Support Software (**CDSS**).

The Provider should also keep a record of the number of 'bleeding episodes' requiring hospital admission and deaths caused by anti-coagulants and report these as incidents through INR Star and the commissioner will monitor this through the audit process.

The following read codes must be used:

- Anticoagulation monitoring in primary care:
  - SystmOne; XaMh8
  - EMIS Web; 66QD
- Home visit for anticoagulation monitoring:
  - SystmOne; XaQyK
  - EMIS Web; 9K27
- Self-monitoring of INR:
  - SystmOne; XaNbr
  - EMIS Web; 66QE

c) Clinical Decision Support System (**CDSS**)

Based on level 1A evidence from the *Guidelines on oral anticoagulation with warfarin – fourth edition*; D. Keeling et al. (June 2011) which states that computer-assisted dosing is superior to manual dosing for patients on warfarin; Providers must use an appropriate CDSS and are advised to use the web based INRstar, as approved by NHS Sheffield Clinical Commissioning Group. The costs for the CDSS are built into the price the Provider receives per patient, for this Service. Providers may opt to use other approved CDSS but where this is more expensive only the equivalent costs of INRstar are incorporated into the payment fee.

Providers are responsible for ensuring all appropriate licences are in place, dependant on the level of service being provided and licences are kept up to date.

d) Meters

For those Providers undertaking INR testing at level 4, the meters used should meet the agreed standards for medical devices. Most providers are using Roche meters and are encouraged to use the CoaguChek XS Plus meter. Testing strips must not be prescribed on FP10, except for Service Users who are self-monitoring.

Where Service Users have bought their own meters and the Provider is giving dosing advice and guidance, the Provider is required to:

- ensure that the patient is using the meter correctly;

- check against a venous sample or quality control test on at least an annual basis; and
- class these patients as Level 3.

e) Education

The Provider is required to ensure Service Users can use any self-monitoring equipment effectively and safely (and/or their carers and support staff where appropriate) regarding their warfarin therapy, including the provision of the National patient-held information booklet.

f) Performance and monitoring

By signing the Contract under which this Service Specification sits, the Provider is consenting to Sheffield CCG accessing non-patient identifiable data through INRstar Analytics. This information will be used to analyse performance and delivery of the Service and contribute to any audits.

Providers who use near patient testing equipment are to participate in the web based National External Quality Assurance Scheme (**NEQAS**). The cost for this is built into the price the Provider receives per patient. Providers are responsible for ensuring subscriptions to NEQAS are in place and are kept up to date. As agreed through Schedule A- Conditions Precedent in the Particulars of this contract.

3.3 Population covered

This Service will be available to every patient registered with a Sheffield General Practice, or ordinarily resident in Sheffield where not registered with a General Practice at all. Where a practice cannot provide the service the patient should be signposted to where the service is available through the shared care protocols.

Where the Service is provided by someone other than the Service user's own GP the procedures as detailed in the SOP must be followed.

3.4 Any acceptance and exclusion criteria and thresholds

Acceptance and exclusion criteria are as detailed in the SOP.

3.5 Interdependence with other services/providers

The Provider will be required to work together with other professionals where appropriate.

Therapy is normally initiated in secondary care, for recognised indications for specified lengths of time. There is a recognised mechanism for safe transfer of care between secondary and primary care providers (see SOP). Therefore, strong interdependence with secondary care is required for delivery of this Service.

When appropriate, the Service should refer Service Users promptly to other necessary services and to the relevant support agencies, using locally agreed guidelines where these exist.

4. Applicable Service Standards

The Provider is required to comply with the following:

4.1 Applicable national standards (e.g. NICE)

- *Atrial fibrillation management CG180*; National Institute for Clinical Excellence (June 2014)

4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal

Colleges)

The National Patient Safety Agency has issued guidance that must be used in conjunction with this specification.
http://www.nrls.npsa.nhs.uk/resources/?entryid45=59814&q=0%c2%acwarfarin%c2%ac

- *Guidelines on oral anticoagulation with warfarin – fourth edition*; D. Keeling et al. (June 2011)
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4.3 Applicable local standards

- *Standard operating procedure for the provision of level 3, 4 and 5 anticoagulation service*; NHS Sheffield Clinical Commissioning Group (April 2017)

5. Location of Provider Premises

The Provider's premises are located at individual general practices and community pharmacies at the Provider's locations under which they deliver this Contract