Primary Care Commissioning Committee (PCCC)

Date: Tuesday 25th September
Time: 9-11.15am
Location: Vassall Centre, Gill Avenue, Bristol, BS16 2QQ

Agenda number: 7

Report title: LES Review Update

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Report Sponsor: Martin Jones, Medical Director Commissioning and Primary Care

1. Purpose

The purpose of the paper is to update the Committee on progress with the LES review and seek approval for the next steps and approaches identified.

2. Recommendations

The Primary Care Commissioning Committee is asked to:

- Discuss and approve that the draft BNSSG service specifications for Anticoagulation, Near Patient Testing and Supplementary Services (Appendix A) move to engagement with practices and more widely with the Local Medical Committee (LMC) before being considered by the Committee for final approval
- Note and approve the approach to finance proposed in Appendix B
- Note the Highlight Report in Appendix C

3. Executive Summary

The attached suite of papers set out the progress of the LES Review. It should be noted that further information is required before a recommendation on the future of the Minor Injury Service be presented to the Committee. The specifications presented in Appendix A have been developed as a single BNSSG specification building on the specifications in each former CCG area. There are a number of key points to note:

- The proposed inclusion of ear wax removal subject to NICE guidance and following self care (currently within 2 of 3 specifications) within the Supplementary Services specification and an area where a small number of practices are developing a private practice

- Anticoagulation has been developed as a single BNSSG specification, however, it continues to be supported by different pathways (acute trust pathway in Bristol and South Gloucestershire for warfarin dosing and monitoring) and further work is needed to identify whether this should continue. There are financial risks associated with changing pathways and offering an enhanced level 4 service in Bristol and South Gloucestershire which may not be offset in the current arrangements with the acute trusts (see Appendix B). An assessment of risk in relation to the viability of existing services would also need to be made.
- The specification for Near Patient Testing has been aligned for current content only and a final review is needed to ascertain whether other areas should be included and what the criteria for inclusion of new drugs should be.
- Work will be undertaken to identify a recommended set of EMIS codes and EMIS templates to support automated extraction to monitor delivery of the specifications including Supplementary Services.

4. Financial resource implications

These are set out in Appendix B. Work to develop an indicative common tariff for Near Patient Testing and Anticoagulation is modelled in Appendix B. It is recommended that no decisions are made on the tariffs for each enhanced service until the full suite of specifications for 2019/2020 have been finalised in December to allow for a complete and concurrent appraisal of the combined implications for the CCG and for practices.

5. Legal implications

The LMC has advised that ear wax removal is an area which has seen increased litigation at a national level. This needs to be further understood. Its inclusion is currently supported by NICE guidance which recommends that this is available in primary care.

6. Risk implications

The key risks are set out in the Highlight Report in Appendix C.

7. Implications for health inequalities

The draft specifications seek to develop a common offer for people across BNSSG and reduce inequalities for our population.

8. Implications for equalities (Black and Other Minority Ethnic/Disability/Age Issues)

The draft specifications align existing specifications and do not therefore represent significant change. Equality Impact and quality impact screening will be undertaken to support the specifications prior to presentation to PCCC for final approval in December.

9. Implications for Public Involvement

The draft specifications presented develop a consistent offer across BNSSG and seek to support the delivery of care closer to home which is consistent with what patients and people tell us they want to see. No formal public involvement has been undertaken to support the alignment of the specifications. This is planned to support the development of phase 3 of the Locality Transformation Scheme.

BNSSG Primary Care Supplementary to Essential and Additional Services Scheme

NHS Standard Contract Information Pack (2019 - 2021)

This Pack contains:

1. **Service Specification:** (to be inserted Schedule 2 Part A: Contract Particulars)
2. **Schedule of Invoicing:** (to be inserted Schedule 3 Part H: Contract Particulars)
3. **Monitoring/Audit Form:** (to be inserted Schedule 3 Part A: Contract Particulars)

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1. **Service Specification:**

SCHEDULE 2 – THE SERVICES

A. Service Specifications

Mandatory headings 1 – 4: mandatory but detail for local determination and agreement
Optional headings 5-7: optional to use, detail for local determination and agreement.

All subheadings for local determination and agreement

Service Specification No.	
Service	**BNSSG Primary Care Supplementary to essential and additional services scheme**
Commissioner Lead	**BNSSG CCG**
Provider Lead	**GP practices**
Period	**1 April 2019 - 31 March 2021**
Date of Review	

1. Population Needs

1.0 National/local context and evidence base

1.1 In January 2014, NHS England area teams were asked to review local PMS agreements over a two-year period ending in March 2016. While the responsibility for the review lay with NHS England the CCG had a role in developing plans for the reinvestment of the PMS premium. In September 2014 NHS England published a "Framework for Personal Medical Services (PMS) agreements review" which outlined a number of principles to be adopted as part of the process. These are that when considering reinvestment in primary care services it:

- reflects joint strategic plans for primary care that have been agreed with the relevant CCG(s);
- secures services or outcomes that go beyond what is expected of core general practice;
- helps reduce health inequalities;
- offers equality of opportunity for GP practices in each locality (i.e. if one or more practices in a given locality are offered the opportunity to earn extra funding for providing an extended range of services or meeting enhanced quality requirements, other practices in that locality capable of providing those services or meeting those requirements should have the same opportunity);
- supports fairer distribution of funding at a locality level.

The framework also emphasises that the PMS premium funding must all be reinvested in GP practices within a CCG area. NHS England South has developed a set of principles and guidance "The PMS Review: principles, process and timeline" which sets out the expectations of local CCGs when considering reinvestment of the premium to be consistent across the South region.

This process also includes all PCT legacy payments to practices which were passed to the CCG.

1.2 The 3 former CCGs have worked hard with NHS England, the LMC, and member practices to agree an approach which meets the local and national principles and objectives. We have discussed and agreed a number of local principles which set out in section 1.3 below. We expect this decision to result in the reduction of unwarranted variation between practices and that, over time, patients will be able to expect the same level of high quality care and access to services at any practice in BNSSG.

1.3 The key local principles are:

- All premium funding will be re- invested into GP provided primary care in BNSSG.
- All practices will be eligible for reinvestment if they are capable of delivery of appropriate services
- Reinvested funding will **not** be linked to a requirement for new primary care activity, as we recognise that practices are already under intense workload pressures
- We recognise that some services provided by practices are considered not to be part of the core contract, and we will give serious consideration to re-investing the premium to commissioning these services
- We understand that many practice staff are employed using existing funding, and we may need to consider commissioning population based services to be able to continue benefiting from the expertise of these staff, if individual practices are unable to continue the employment of these staff.
- We need to continue to work with the secondary care trusts locally to ensure that money is actually moved out of secondary care when services are provided in primary care
- We have met with the LMC to discuss these principles, they approved of our approach and in particular were reassured that we will not be seeking more for the same from practices. We are committed to working closely with the LMC through this process and in developing the reinvestment plan
- This is an opportunity to consolidate what we do, to focus on the important aspects of Primary Care and to begin to support each other to set outcomes and standards that we feel will improve the health of our patients

1.4 The approach agreed by the CCGs was to reinvest the premium funding across all practices to deliver supplementary activities, using the Carr Hill weighted formula, as this is the only nationally negotiated and widely used formula to fund practices according to patient need.

1.5 The premium and legacy funding will be removed from 1 April, 2016 over a five year period at the rate of 20% per annum to give practices time to adjust. This will be net of the CCG reinvestment.

1.6 This specification has been developed to provide a funding contribution to each practice in BNSSG on a weighted patient basis for services not funded for in the core contract (ie essential or additional services) but that are recognised as activity best

provided by a GP. It is hoped that this will remove any unwarranted variation in general practice so that patients can expect the same level of high quality care and access to services at any practice, or group of practices, in BNSSG.

2. Outcomes

2 NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	✓
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	✓
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	✓

3. Scope

Aims and objectives of service

3.2 The aims of the specification are as follows:

- Continuing provision of general practice services
- Reduction in unwarranted variation in general practice
- Developing and sharing best practice
- Continuing to provide improved and enhanced access for routine and urgent appointments to meet patient needs
- Developing approaches to clinical skill mix in primary care teams to best meet the needs of the practice patient population and with best use of resources available
- Working with other practices and the CCG towards appropriate scaling of services, recognising not all services are appropriate to be provided by each practice
- Consistent or reduced activity in A&E admissions and urgent care services
- Development of a consolidated primary care base upon which new pathways, standards and outcomes can be set to improve the health of BNSSG patients
- Engagement in work programmes to support CCG strategic outcomes e.g. reduction in emergency admissions, mental health agenda, data sharing

3.3 Practices are required, where it is appropriate for the needs of their patients, to undertake the following:

A. Specified Non-Core Contract Work

It is recognised both nationally and locally, that since the introduction of the GMS contract in 2004, there has been an increase in the quantity and range of activity that primary care is requested to undertake, sometimes on behalf of other organisations. Examples of areas of additional workload that is included within this activity includes:

- Phlebotomy initiated by primary care only, and not where it is part of an acute contract (to be subject to review, including for under 16s))
- Removal of post op stitches, dressings and wound checks (if staples removal equipment is provided by the hospitals)
- Dressings (including 3 and 4 layer bandaging where appropriate) and wound care for non housebound patients
- Follow-up of patients and ongoing monitoring where patients have been stabilised
- Primary Care requested ECGs, spirometry, nebulising, pulse oximetry
- Glucose tolerance testing (antenatal) – however interpretation and follow up remain the responsibility of the requesting clinician
- Doppler scanning for compression bandaging
- Delivery of Gonadotrophin-releasing hormone antagonist (GnRH analogues/ LHRH) treatment (e;g Triptorelin, Goserelin once stabilised with a practice agreed protocol)
- 24 hour BPs or offer home BP monitoring
- Depo injections related to stable mental health patients
- Prescribing to midwifery services where not initiated by the consultant and where clinical responsibility remains appropriate for community management.
- Tests and procedures required under agreed referral pathways, this includes ear irrigation when the following criterion has been met:
    - The patient has applied ear wax softening drops for up to 5 days and this has not been effective (as set out in NICE guidance).
- Managing post natal checks (excludes immediate baby checks from rapid discharge patients)

B. Best practice Primary Care

These reflect best practice for activities in the core contract and should be applied as appropriate

- The management of chronic diseases in primary care
- Involvement and communication towards the management of complex patients using wider community service providers to ensure the provision of holistic care

- Child and adult safeguarding work towards the safe management and co-ordination of vulnerable patients in accordance of national requirements
- Use of BNSSG CCG Referral Service and/or e-referrals where appropriate
- Responding to requests from agreed 3rd party service providers for verifying up to date patient call up lists e.g. screening service such as breast, bowel and retinopathy
- Processing referrals for Interventions not normally funded (INNF) where initiated by General Practice
- Identification and support for carers to include active signposting to voluntary sector services
- Adherence to local clinical pathways that have been agreed and made available to GP practices for implementation, for example on the BNSSG formulary and the CCG Remedy site
- Patient education regarding primary care services in and out of hours, and other NHS services using website, electronic message boards e.g. JX boards, patient notice boards
- Utilising the standard NHS 111 phone message for out of hours
- A well maintained practice website in addition to NHS choices
- Timely medical records summarising
- Signing data sharing agreements where this supports CCG and practice objectives as appropriate
- Supporting the development of demand and capacity metrics for primary care

3.4 Most practices will already be undertaking this work and should now continue to deliver this work at current or reasonable levels for the practice as part of this enhanced service. Where individual practices are not providing a particular element of this work already it is expected they will develop a plan if necessary with other nearby practices to either provide this activity themselves for their patients or to subcontract this work to a nearby provider for the benefit of their patients. Where specialised skill sets are required, practices will be expected to work together to provide this service at a reasonable location for their patient if not at their own practice over the next 2 years.

3.5 As and when there are pathway developments to do more work in primary care towards the care closer to home/out of hospital care agenda then it is expected these will need to be commissioned appropriately with funding apportioned accordingly. The CCG is working towards outcome based commissioning where payment will in future be linked to measurable patient outcomes.

4. Applicable Service Standards

4.1 Applicable national standards (eg NICE)

See section 3.3A

4.2 Applicable standards set out in Guidance and/or issued by a competent body (eg Royal Colleges)

Not applicable

4.3 Applicable local standards

Not applicable

5. Applicable quality requirements and CQUIN goals

SUPPLEMENTARY SERVICES RETURN

Please complete the form and return it attached to a covering email from a practice partner or practice manager stating that they have completed it on behalf of the practice. This will save the need for it to be printed, signed and then scanned. Please return to the following email address xxxxxxxxxxxxxxxxxxby the 15th April of each year. :
(name of practice) confirms that it has delivered the following supplementary services during the financial year ( ) Please state the year this report relates to.

	Yes - Fully delivered	*Partially delivered*	*Not delivered yet*
Phlebotomy – this does not include requests from secondary care where there is on-going hospital follow-up apart from shared care agreements.	☐	☐	☐
Removal of stitches, dressings and wound checks.	☐	☐	☐
Wound care including 3 and 4 layer bandaging.	☐	☐	☐
Follow-up of patients and ongoing monitoring (excluding QOF) as per agreed pathway or where there is on-going hospital follow-up apart from shared care agreements.	☐	☐	☐
Routine ECGs, spirometry, nebulising, pulse oximetry.	☐	☐	☐
Glucose tolerance testing (antenatal) – interpretation and follow-up of results remains the responsibility of the requesting clinician.	☐	☐	☐
Doppler scanning for vascular assessment in lower limbs.	☐	☐	☐
Delivery of Gonadotrophin-releasing hormone antagonist (GnRH analogues/.LHRH) treatment (e.g. Triptorelin, Goserelin).	☐	☐	☐
24 hour BPs including home BP monitoring.	☐	☐	☐

Depo injections for mental health patients who are stable.	☐	☐	☐
Tests and procedures required under agreed referral pathways, this includes ear irrigation	☐	☐	☐
Managing routine post-natal checks (excludes immediate baby checks from rapid discharge patients).	☐	☐	☐
Support to midwifery teams including prescribing. Prescribing choice and responsibility should be in line with BNSSG formulary requirements.	☐	☐	☐

* If you have marked any services as only partially provided, or not provided at all, please complete and return an action plan detailing what will be done to remedy the situation.

SCHEDULE 2 – SERVICE SPECIFICATION - APPENDIX 2

SUPPLEMENTARY SERVICES ACTION PLAN

For practices that need to complete this form, please return it attached to a covering email from a practice partner or practice manager stating that they have completed it on behalf of the practice. This will save the need for it to be printed, signed and then scanned. Please return to the following email address xxxxxxxxxxxby the 15th April of each year. :

Practice: name of practice **Year this Action Plan covers:**

Please note that this only needs to be submitted if services are not being delivered or are only partially delivered.

Which service(s) does this apply to:

1.

2.

3.

Reasons for not supplying this service in full.

1.

2.

3.

Proposed action plan for the delivery of this service. **Date**

1.

2.

3.

SCHEDULE 2 – THE SERVICES

B. Service Specification

Service Specification No.	
Service	Medicines Monitoring LES
Commissioner Lead	
Provider Lead	
Period	
Date of Review	

1. Population Needs

3.6 National/local context and evidence base

This enhanced service specification outlines a specialised monitoring service for certain immunosuppressants and anti-inflammatory treatments. Immunosuppressants and anti-inflammatory treatments occupy an important place in the management of many autoimmune and inflammatory diseases. All treatments used have the potential for harm as well as benefit. Appropriate and vigilant monitoring during therapy is required to minimise the risk of adverse effects and maintain patient safety.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	**Preventing people from dying prematurely**	
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**	
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**	✓

2.2 Local defined outcomes

All of the drugs covered by this service are appropriate for shared care between a specialist and a GP practice. The BNSSG Joint Formulary contains Shared Care Protocols (SCPs) which offer guidance in this respect. Experience demonstrates that patients are more likely to engage with a regular monitoring service for their long-term condition that is provided in an organised manner in a convenient location such as closer to home in primary care. Appropriate and vigilant monitoring during therapy is required to minimise the risk of adverse effects.

3. Scope

3.1 Aims and objectives of service

Aims:

To ensure patients treated with certain drugs with specific monitoring requirements are monitored by a service that is safe, effective, sustainable and closer to home.

Objectives:

To provide patients with the information they need to safely manage their treatment

To monitor the safety and effectiveness of treatment by performing defined investigations monitoring at defined regular intervals

To ensure that patients are managed appropriately, in collaboration with specialists where necessary, according to the results of the defined investigations

To provide these patients with optimised treatment

To provide a therapy monitoring service close to the patient

To evaluate the quality of care delivered through an annual audit process and to effect change when required to improve the service provided

3.2 Service description/care pathway

All of the drugs covered by this service are included in the BNSSG Joint Formulary and are appropriate for shared care between a specialist and a GP practice. The BNSSG Joint Formulary contains Shared Care Protocols (SCPs) which offer guidance in this respect. Regular monitoring and/or administration is required as part of the BNSSG Shared Care Protocol (SCP).

GP practices are required to ensure that the correct monitoring and investigations are done, at the correct frequency according to the SCP and/or specialist advice, and the results of the investigations are reviewed and appropriate action is taken as required, including amendment of the current prescription. Monitoring is predominantly undertaken using blood tests, however other monitoring is also required for some of the included medications as set out in the Shared Care Protocols (SCPs).

The latest versions of the Shared Care Protocols (SCPs) are available from: http://www.bnssgformulary.nhs.uk/Shared-Care-Protocols/

The medications subject to this LES will be subject to change. As new drugs are deemed suitable for shared care according to the BNSSG Formulary and a shared care protocol (SCP) is put in place amendments may be effected.

The medicines currently requiring monitoring as part of this LES are:

- Azathioprine
- Denosumab (Prolia) 60mg/ml
- Leflunomide
- Mercaptopurine
- Methotrexate
- Penicillamine
- Sodium aurothiomalate
- Sulfasalazine

To ensure accurate payment patients recieveing Penicillamine must be Read-Coded for the relevant disease covered by the Shared Care Protocol (SCP); 'Cystinuria' (Read Code C3001) or 'Rheumatoid arthritis and other inflammatory polyarthropathy' (Read Code N04) or their sub-codes.

By agreeing to participate in this LES the practice will also be required to provide the following information:

- Assurance that a robust re-call system is in place to ensure recall of patients for the necessary monitoring
- Assurance that there is a process to identify and manage patients not engaging with the necessary monitoring including cessation of prescriptions.
- During quarter two submit a review of practice monitoring activity as per the provided template
- The practices current standard operating procedure for the above activities as part of the review of practice monitoring activity
- Share information with BNSSG CCG about significant events,

including root cause analyses, involving the medications included in this LES. Information should be reported within 48 hours of the clinician being made aware of the incident and should be shared using the BNSSG CCG online clinical reporting tool Datix https://bnssg-datix.scwcsu.nhs.uk/

- Number of patients monitored each quarter as part of this LES if Emis Search and Report becomes unavailable.

3.3 Population covered

This service is for all patients registered with a participating practice, for whom it is clinically appropriate and beneficial.

3.4 Any acceptance and exclusion criteria and thresholds

Any patients having all of the necessary monitoring for these medications provided by another care provider are excluded from this LES.

3.5 Interdependence with other services/providers

N/A

4. Applicable Service Standards

4.1 Applicable national standards (eg NICE)

The following guidance from NICE:

- Psoriasis: assessment and management (CG153)
- Spondyloarthritis in over 16s: diagnosis and management (NG65)
- Denosumab for the prevention of osteoporotic fractures in postmenopausal women (TA204)
- Rheumatoid arthritis in adults: management (NG100)
- Crohn's disease: management (CG152)
- Ulcerative colitis: management (CG166)

4.2 Applicable standards set out in Guidance and/or issued by a competent body (eg Royal Colleges)

- British Association of Dermatologists' guidelines for the safe and effective prescribing of azathioprine 2011. Meggitt SJ, Anstey AV, Mohd Mustapa MF, Reynolds NJ, Wakelin S. Br J Dermatol 2011; 165; 711-734.

- British Association of Dermatologists' guidelines for the safe and

effective prescribing of methotrexate for skin disease 2016. Warren R.B., Weatherhead S.C., Smith C.H., Exton L.S., Mohd Mustapa M.F., Kirby B., Yesudian P.D. Br J Dermatol 2016; 175: 23-44.

- BSR and BHPR guideline for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs. BSR and BHPR guideline for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs. Jo Ledingham, Nicola Gullick, Katherine Irving, Rachel Gorodkin, Melissa Aris, Jean Burke, Patrick Gordon, Dimitrios Christidis, Sarah Galloway, Eranga Hayes, Andrew Jeffries, Scott Mercer, Janice Mooney, Sander van Leuven, James Galloway, on behalf of the BSR and BHPR Standards, Guidelines and Audit Working Group. Rheumatology, Volume 56, Issue 6, 1 June 2017, Pages 865–868,

4.3 Applicable local standards

BNSSG Shared Care Protocols (SCPs)
http://www.bnssgformulary.nhs.uk/Shared-Care-Protocols/

5. Applicable quality requirements and CQUIN goals

5.1 Applicable Quality Requirements (See Schedule 4 Parts [A-D])

During quarter two submit a review of practice monitoring activity as per the provided template.

5.2 Applicable CQUIN goals (See Schedule 4 Part [E])

N/A

6. Location of Provider Premises

The Provider's Premises are located at:

Principal:

Branch:

SCHEDULE 3 – PAYMENT

A. Local Prices

What will be Paid For?

Monitoring will be paid for on a "per drug" basis.

Practices will be remunerated using the following scale to which reflects the increased workload of more frequent monitoring. New medicines will be added into this schedule when deemed suitable for shared care according to the BNSSG Formulary and a shared care protocol (SCP) is in place.

Practices will be paid an annual sum of £XX per 10,000 patients when sigining upto the LES to reflect that there will be a number of patients newly initiated onto the medications covered by the LES each year and some of these patients have slightly increased monitoring requirements during year one of therapy.

Amount of annual monitoring	Drugs currently included	Practice Payment (£) per year
2 - 3	Denosumab (Prolia)	50
4 -5	Azathioprine Leflunomide Sodium aurothiomalate Methotrexate Penicillamine (Nephrology)	
6 – 8	Mercaptopurine Sulfasalazine (one year only)	
9 - 12	Penicillamine (Rhuematology)	

From 1st April 2019 payment will be transferred to practices on a quarterly basis.

How will Payments be Made and Calculated

The total number of patients issued with the relevant medication in each quarter will be multiplied by the appropriate level of payment and divided by 4 to provide a quarterly payment value.

How Will Activity Data be Obtained?

BNSSG CCG will obtain information on the number of patients being treated with the relevant medication and being monitored under this LES using Emis Search and Report.

A. Expected Annual Contract Values

This will vary as per payment schedule set out in schedule 3A

B. Notices to Aggregate / Disaggregate Payments

As detailed in Schedule 3A

C. Timing and Amounts of Payments in First and/or Final Contract Year

As detailed in Schedule 3A

SCHEDULE 4 – QUALITY REQUIREMENTS

A. Operational Standards

There are no specific requirements relating to this contract beyond those already in place for providers delivering general or personal medical services and those detailed in Section 2 - The Service Specification.

B. National Quality Requirements

There are no specific requirements relating to this contract beyond those already in place for providers delivering general or personal medical services and those detailed in Section 2 - The Service Specification.

C. Local Quality Requirements

There are no specific requirements relating to this contract beyond those already in place for providers delivering general or personal medical services and those detailed in Section 2 - The Service Specification.

D. Never Events

There are no specific requirements relating to this contract beyond those already in place for providers delivering general or personal medical services and those detailed in Section 2 - The Service Specification.

E. Commissioning for Quality and Innovation (CQUIN)

There are no specific requirements relating to this contract beyond those already in place for providers delivering general or personal medical services and those detailed in Section 2 - The Service Specification.

F. Local Incentive Scheme

There are no specific requirements relating to this contract beyond those already in place for providers delivering general or personal medical services and those detailed in Section 2 - The Service Specification.

G. Clostridium difficile

There are no specific requirements relating to this contract beyond those already in place for providers delivering general or personal medical services and those detailed in Section 2 - The Service Specification.

H. CQUIN Variations

There are no specific requirements relating to this contract beyond those already in place for providers delivering general or personal medical services and those detailed in Section 2 - The Service Specification.

SCHEDULE 2 – THE SERVICES

C. Service Specification

Service Specification No.	
Service	Anticoagulation LES: INR monitoring and vitamin K anticoagulant dosing
Commissioner Lead	
Provider Lead	
Period	
Date of Review	

1. Population Needs

3.7 National/local context and evidence base

This enhanced service specification outlines both an INR monitoring and Vitamin K antagonist dosing service for patients receiving vitamin K antagonists medications. Vitamin K antagonists have a valuable role in blood clot and stroke prevention, with regular monitoring required to prevent adverse effects.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	**Preventing people from dying prematurely**	✓
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**	✓
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**	✓

2.2 Local defined outcomes

Anticoagulants: Warfarin and Phenindione are included in the BNSSG Joint Formulary and are therefore appropriate for prescribing in primary care. Acenocoumarol is non-formulary but included in this LES to cover the small number of patients who are unable to take warfarin or Phenindione.

Experience demonstrates that patients are more likely to engage with a regular monitoring service for their long-term that is provided in an organised manner in a convenient location such as closer to home in primary care. Appropriate and vigilant monitoring during therapy is required to minimise the risk of adverse effects.

3. Scope

3.1 Aims and objectives of service

Aims:

To ensure patients who need initiation on a Vitamin K antagonist or are receiving maintenance treatment with a vitamin K antagonist get care that is safe, effective and sustainable.

Objectives:

To safely initiate and maintain suitable patients on vitamin K antagonist therapy.

To provide patients receiving a vitamin K antagonist with the information they need to safely manage their treatment.

To improve patient education in relation to their condition, understanding of their treatment, target INR range, the effects of over or under anticoagulation, the effect of diet changes, affects on lifestyle and the importance of interactions with other medications.

To monitor the safety and effectiveness of vitamin K antagonist treatment by ensuring the INR is measured at appropriate regular intervals.

To ensure the dose of vitamin K antagonist is amended as required in response to INR test results

To ensure that patients with very high or very low INR results are managed appropriately, in collaboration with specialists where necessary

To ensure that patients who do not regularly achieve therapeutic INRs are reviewed and appropriate action is taken to improve the patients ‘time in therapeutic range’

To provide the service to a high standard in a way that is convenient for patients.

To ensure that providers of care work together and share data relating to anticoagulation to support safe and effective care for the patient .

To evaluate the quality of care through a regular audit process, effecting change when required to improve the service provided.

3.2 Service description/care pathway

Across BNSSG different care pathway models have been in operation for vitamin K anticoagulation monitoring and dosing. This LES is intended to formalise the offer from BNSSG CCG to practices for the continuation of the vitamin K antiocoagulant monitoring service and, where appropriate, the vitamin K anticoagulant dosing service.

Two levels of services are offered to GP practices:

Advanced level
Basic Level.

It is intended that GP practices continue to deliver the level of service they were providing in September 2018. Practices should discuss with BNSSG CCG if they are considering changing their level of service.

Description of the basic service:
The GP practice provides a phlebotomy service obtaining venous blood samples from patients prescribed a vitamin K antagonist.

The venous blood sample is supplied to a secondary care organistation to establish the patients INR and for the secondary care organistation to make decisions on the appropriate dosage of vitamin K antagonists and communicate the required dosage to the patient.

GP practices must ensure the INR is being monitored as per the clinicians recommendation and that the INR level is safe before issuing repeat prescriptions for vitamin K anticoagulants

GP practices will liaise as necessary with the patient's vitamin K antagonist dosing clinic to discuss patient care issues such as regular elevated INRs or poor time in therapeutic range.

Ensure patients receiving vitamin K anticoagulants receive an annual medication review to consider whether anticoagulation therapy is still indicated and appropriately managed, including a review of time in therapeutic range.

GP practices are required to maintain records for those patients prescribed vitamin K antagonist therapy that details (for each patient):

- The target INR range
- The intended duration of therapy

GP practices are required to ensure that patients prescribed vitamin K antagonist therapy hold an Oral Anticoagulant Therapy booklet and anticoagulant alert card (provided to practices free of charge by NHS England), and also ensure that patients and where appropriate their carers understand:

- Why they require anticoagulation treatment
- The importance of adherence to treatment and monitoring
- The consequences of sub-therapeutic treatment, and overdose
- Restrictions on diet, and lifestyle
- The possibility, and consequences of drug interactions

A checklist for patient information is provided in appendix 1.

Share information with BNSSG CCG about significant events, including root cause analyses, involving the medications included in this LES. Information should be reported within 48 hours of the clinician being made aware of the incident and should be shared using the BNSSG CCG online clinical reporting tool Datix https://bnssg-datix.scwcsu.nhs.uk/

Description of the advanced service:
The GP practice provides a service obtaining finger-prick blood samples from patients using point-of-care INR testing technology to determine the patients INR test result.

The GP practice uses appropriately governed anticoagulant management software, to help make decisions on the appropriate dosage of vitamin K antagonist and communicate the required dosage to the patient.

GP practice to provide a robust recall sytem for patients prescribed vitamin K antagonist therapy to ensure INR is monitored at the frequency recommended by the dosing clinician and patients not engaging with INR monitoring are identified and managed, including temporary cessation of prescription supply.

GP practice to have clinical treatment pathways inplace to appropriately manage patients who are have very high, or very low INR results

GP practices must ensure the INR is being monitored as per the clinicians recommendation and that the INR level is safe before issuing repeat prescriptions for vitamin K anticoagulants.

Ensure patients receiving vitamin K anticoagulants receive an annual medication review to consider whether anticoagulation therapy is still indicated and appropriately managed, including a review of time in therapeutic range.

GP practices are required to maintain records for those patients prescribed vitamin K antagonist therapy that details (for each patient):

- The target INR range
- The intended duration of therapy

GP practices are required to ensure that patients prescribed vitamin K antagonist therapy hold an Oral Anticoagulant Therapy booklet and anticoagulant alert card (provided to practices free of charge by NHS England), and also ensure that patients and where appropriate their carers understand. A checklist for patient information is provided in appendix 1:

- Why they require anticoagulation treatment
- The importance of adherence to treatment and monitoring
- The consequences of sub-therapeutic treatment, and overdose
- Restrictions on diet, and lifestyle
- The possibility, and consequences of drug interactions

GP practices are required to submit during quarter two a review of their monitoring and dosing service as per the provided template.

Share information with BNSSG CCG about significant events, including root cause analyses, involving the medications included in this LES. Information should be reported within 48 hours of the clinician being made aware of the incident and should be shared using the BNSSG CCG online clinical reporting tool Datix https://bnssg-datix.scwcsu.nhs.uk/

3.3 Population covered

This service is for all patients registered with a participating practice, for whom it is clinically appropriate and beneficial.

3.4 Any acceptance and exclusion criteria and thresholds

Only patients currently being prescribed warfarin, acenocoumarol or phenindione by a clinican at the practice with which they are registered will be included in this service.

3.5 Interdependence with other services/providers

Providers will need to:

- Share data via EMIS (Enterprise/Search and Report) for the purposes of audit and payment
- Share data via Connecting Care for the purposes of patient safety
- Liaise with colleagues working for providers of clinical laboratory services where appropriate
- Liaise with colleagues working for providers of anticoagulation dosing services where appropriate

4. Applicable Service Standards

4.1 Applicable national standards (eg NICE)

NPSA: anticoagulant actions that can make anticoagulant therapy safer:

https://www.sps.nhs.uk/articles/npsa-alert-actions-that-can-make-oral-anticoagulant-therapy-safer-2007/

NICE guidance: Atrial fibrillation: management

https://www.nice.org.uk/guidance/cg180

NICE guidance: Venous thromboembolism in adults: diagnosis and

management

https://www.nice.org.uk/guidance/qs29

NICE guidance: Atrial fibrillation and heart valve disease: self-monitoring coagulation status using point-of-care coagulometers

https://www.nice.org.uk/guidance/dg14

4.2 Applicable standards set out in Guidance and/or issued by a competent body (eg Royal Colleges)

Oral Anticoagulation with Warfarin - 4th Edition. Keeling , Baglin T, Tait C,

Watson H, Perry D, Baglin C, Kitchen S, Makris M; British Committee for Standards in Haematology. Br J Haematol. 2011 Aug;154(3):311-24

4.3 Applicable local standards

N/A

5. Applicable quality requirements and CQUIN goals

5.3 Applicable Quality Requirements (See Schedule 4 Parts [A-D])

GP practices are required to submit during quarter two submit a review of the practices vitamin K antagonist anticoagulation monitoring as per the provided template.

5.4 Applicable CQUIN goals (See Schedule 4 Part [E])

N/A

6. Location of Provider Premises

The Provider's Premises are located at:

Principal:

Branch:

SCHEDULE 3 – PAYMENT

B. Local Prices

What will be Paid For?

Two levels of service Advanced Level and Basic Level are commissioned. Payment will be based on the service level provided by the practice.

Practices need to inform the CCG of the level of service they intend to provide.

It is intended that GP practices continue to deliver the level of service they were providing in September 2018. Practices should discuss with BNSSG CCG if they are considering changing their level of service.

Payment will be calculated by EMIS (Search and report) as follows:
the number of patients with a current medication course for warfarin, warfarin sodium, phenindione or acenocoumarol that have had at least 1 documented INR measurement (42QE) in the last 100 days.

5.3 Tariff

The commissioner will allocate payment as follows:

- Basic - £x per patient per year
- Advanced - £x per patient per year

The sum for the advanced service includes an amount for the practice to purchase Coaguchek test strips (at approximately 16 strips per patient per year). For patients being monitored and dosed under this LES, additional strips must not be put on prescription, they must be ordered by the GP practice directly from Roche, where a pre-negotiated discount will be applied for all providers of BNSSG CCG.

How will Payments be Made and Calculated

The total number of patients receiving vitamin k antagonist therapy in each quarter will be multiplied by the appropriate level of payment and divided by four to provide a quarterly payment value.

How Will Activity Data be Obtained?

EMIS Web Search and Report will be used to export data from practice systems relating to numbers of patients the service has been provided for in each quarter.

D. Expected Annual Contract Values

As detailed in Schedule 3A

E. Notices to Aggregate / Disaggregate Payments

As detailed in Schedule 3A

F. Timing and Amounts of Payments in First and/or Final Contract Year

As detailed in Schedule 3A

SCHEDULE 4 – QUALITY REQUIREMENTS

E. Operational Standards

There are no specific requirements relating to this contract beyond those already in place for providers delivering general or personal medical services and those detailed in Section 2 - The Service Specification.

F. National Quality Requirements

There are no specific requirements relating to this contract beyond those already in place for providers delivering general or personal medical services and those detailed in Section 2 - The Service Specification.

G. Local Quality Requirements

There are no specific requirements relating to this contract beyond those already in place for providers delivering general or personal medical services and those detailed in Section 2 - The Service Specification.

H. Never Events

There are no specific requirements relating to this contract beyond those already in place for providers delivering general or personal medical services and those detailed in Section 2 - The Service Specification.

E. Commissioning for Quality and Innovation (CQUIN)

There are no specific requirements relating to this contract beyond those already in place for providers delivering general or personal medical services and those detailed in Section 2 - The Service Specification.

I. Local Incentive Scheme

There are no specific requirements relating to this contract beyond those already in place for providers delivering general or personal medical services and those detailed in Section 2 - The Service Specification.

J. Clostridium difficile

There are no specific requirements relating to this contract beyond those already in place for providers delivering general or personal medical services and those detailed in Section 2 - The Service Specification.

K. CQUIN Variations

There are no specific requirements relating to this contract beyond those already in place for providers delivering general or personal medical services and those detailed in Section 2 - The Service Specification.

Appendix 1

Warfarin Initiation - Patient Education Checklist

It is essential patients are given sufficient education and counselling when they are initiated onto warfarin (at their **first** appointment). The GP/nurse should give particular consideration to the need to include **carers** in the education of the patient.

Information	Key points covered	Tick ✓
What is warfarin?	Name of drug, tablet colours and strengths	
What does this drug do?	'thins' the blood, concept of INR	
Why do I need to take it?	Prevents clots from forming/getting bigger. Individual patient's need for this	
How long will I need to take it?	Explain individual treatment plan	
How much is needed?	Varies from person to person and over time. Blood tests needed to tell	
When should Warfarin be taken?	About the same time every day	
Action to be taken if a dose is missed	Do not take double dose next time. Make note of missed dose. If a few hours late – still take dose	
What happens in the INR clinic	Local surgery arrangements	
Common side effects of warfarin	Bruising easily, cuts take longer to stop bleeding – care needed with shaving, knives etc. Periods may be heavier/longer	
Signs of having taken too much warfarin	Unexplained bruising, blood in urine or motions, small nosebleeds – **contact GP** Any bleeding that will not stop e.g. Large nosebleed, large amount of blood in urine, vomiting blood – refer immediately to casualty (be aware of Vitamin K protocol)	
Do **NOT** get pregnant	Contact GP immediately if you think you may be	
Taking other medication	**Avoid aspirin** as a painkiller – paracetamol is safer for headaches etc. Always check with your chemist or GP	
What about existing treatment with other drugs?	Your doctor will allow for them in warfarin dosing	
Dietary advice	Normal balanced diet. Keep alcohol intake to recommended 2 units a day	
Action to take if feeling ill	See GP as normal if not related to warfarin. If warfarin related, speak to surgery anticoagulation staff	
Lifestyle factors	An increase in dietary vitamin K (e.g. becoming vegetarian) may affect your INR results. Advice regarding alcohol/ smoking/ holidays	
Information leaflets	Information leaflets and fact sheets are available (see overleaf), provide patient with something to go away and read	
What to do if dental treatment required / having surgery	Patient must seek advice from the GP or INR clinic as they may need to stop their warfarin before the procedure.	

Date the above explained

……

Signature of nurse or GP

……

Signature of Patient

……..

An information booklet **must be given** to the patient to reinforce the verbal counselling.
For domiciliary patients, the community healthcare professional should provide a copy of this signed form to the GP surgery to be included in the patients' medical records.

Appendix 2

Management of patients with INR results that are very high

- **Provided for information only to practices providing a basic level service.**
- **Provided as guidance for practices providing an advanced level service.**

Patients prescribed vitamin K antagonists who are over-anticoagulated, but do not have significant bleeding, can be managed appropriately in the community.

Treatment of over-anticoagulation (INR results >6.0)

For severe asymptomatic over-anticoagulation or over-anticoagulation with mild bleeding, oral vitamin K is effective in most primary care settings. Small doses effectively reduce INR without fully reversing anticoagulation and reduce the risk subsequent resistance to re-anticoagulation.

The recommended treatment for this group of patients is vitamin K. The medicine used is phytomenadione (Konakion® MM Paediatric) 2mg/0.2ml. This is an intravenous preparation that is also licensed for oral administration. The recommended dose corresponds to a very small volume and therefore appropriate oral syringes, provided by the manufacturer, need to be used, and some patients may need assistance.
http://www.medicines.org.uk/emc/medicine/1699

Vitamin K (phytomenadione) should not be given intramuscularly because of the risk of muscle haematoma.

Always assess the patient and the causes of high INR.

INR	Suggested Action
INR greater than 6.0 but less than 8.0 No bleeding or minor bleeding (e.g. nosebleed that is controlled) or minor bruising Carefully assess the patient for additional risk factors - e.g. aged over 70, epistaxis, previous bleeding complications, patient has already taken warfarin since INR taken.	1. Reduce warfarin dose or stop 2. Consider restarting when INR is less than 5.0 3. Consider prescribe/administer between 500micrograms and 1mg of phytomenadione orally *if the patient has other risk factors for bleeding.*

INR greater than 8.0 No bleeding or minor bleeding Carefully assess the patient for additional risk factors/concurrent illness or medication causing high INR - e.g. aged over 70, epistaxis, previous bleeding complications	1. Advise patient to stop taking warfarin 2. Prescribe/administer 1mg of phytomenadione orally • A lower dose (500micrograms) should be considered if the patient has a high thrombotic risk (mechanical heart valves/ previous CVE/ DVT whilst anticoagulated/ target INR >2.0-3.0) • A higher dose should be considered if the patient has a high bleeding risk 3. Consider restarting when INR < 5.0
INR	**Suggested Action**
INR greater than 10.0 No bleeding or minor bleeding Carefully assess the patient for additional risk factors/concurrent illness or medication causing high INR - e.g. aged over 70, epistaxis, previous bleeding complications	1. Advise patient to stop taking warfarin 2. Prescribe/administer 2.5mg of phytomenadione orally • A lower dose should be considered if the patient has a high thrombotic risk (mechanical heart valves/ previous CVE/ DVT whilst anticoagulated/ target INR >2.0-3.0) • A higher dose should be considered if the patient has a high bleeding risk 3. Consider restarting when INR < 5.0
INR greater than 12.0 No bleeding or minor bleeding Carefully assess the patient for additional risk factors/concurrent illness or medication causing high INR - e.g. aged over 70, epistaxis, previous bleeding complications	1. Advise patient to stop taking warfarin 2. Prescribe/administer 5mg of phytomenadione orally • A lower dose should be considered if the patient has a high thrombotic risk (mechanical heart valves/ previous CVE/

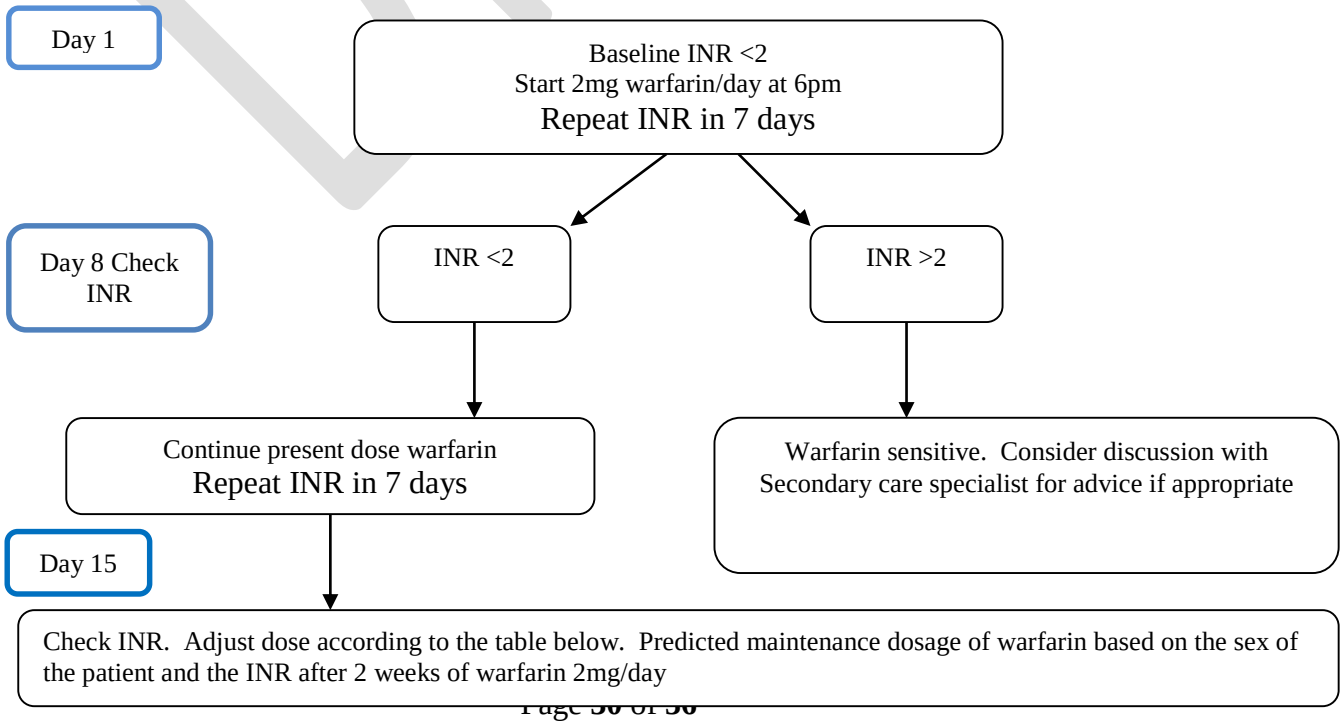
	DVT whilst anticoagulated/ target INR >2.0-3.0) • A higher dose should be considered if the patient has a high bleeding risk 3. Consider restarting when INR < 5.0
Major Bleeding	Arrange urgent admission to hospital: The patient will need intravenous prothrombin complex concentrate (PCC) and intravenous phytomenadione

Obtaining stock of phytomenadione (vitamin K)

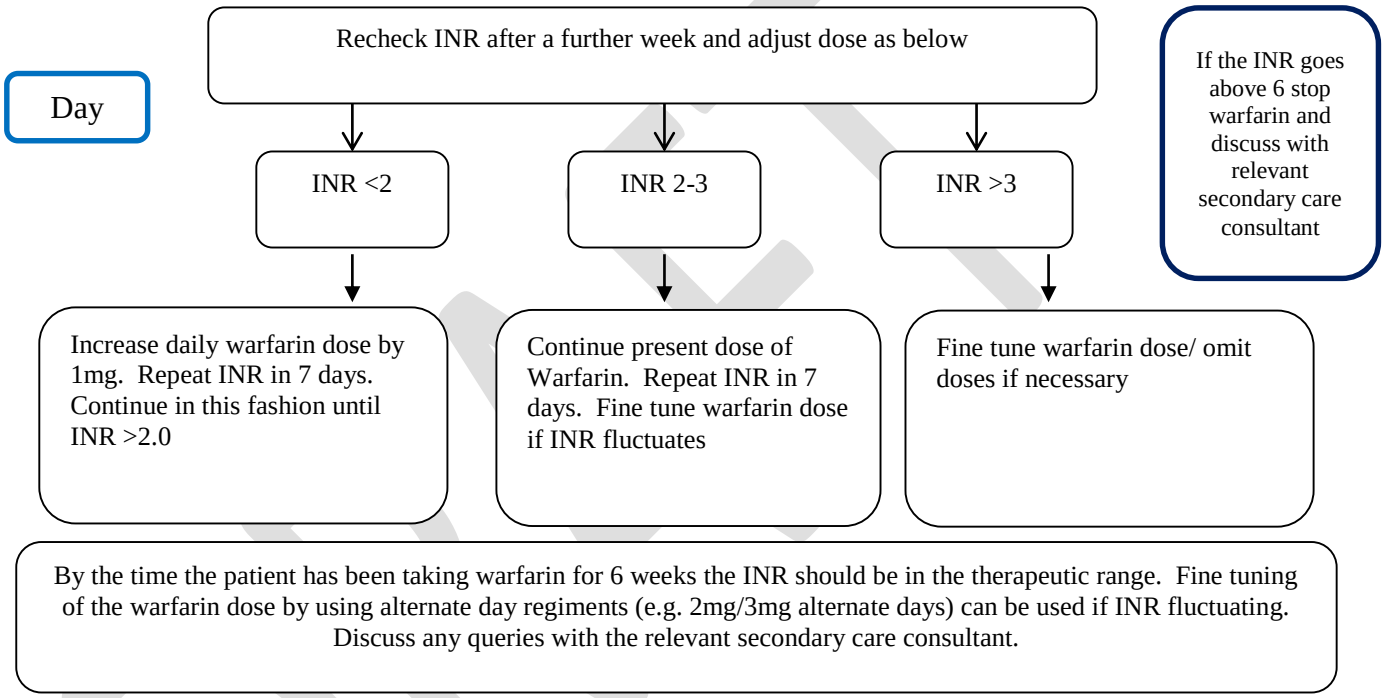
- Phytomenadione (Konakion® MM Paediatric) 2mg/0.2ml is inexpensive and general practices should hold stock.
- NHS England commissions a number of community pharmacies to hold stock. This list can be accessed here: https://www.bnssgformulary.nhs.uk/includes/documents/2017-18%20Specialist%20Meds%20Enhanced%20Service%20info.pdf
- The local GP OOH provider holds stock.
  Brisdoc Healthcare Services Ltd. can be contacted out-of-hours. This telephone number is for clinicians and should not be given to patients: 0117 2449283

Appendix 3

Slow Warfarin Initiation Regime for GP practices



MALE		FEMALE	
INR AT Week 2	**Maintenance Dose**	**INR at Week 2**	**Maintenance Dose**
1.0	6mg/day	1.0-1.1	5mg/day
1.1-1.2	5mg/day	1.2-1.3	4mg/day
1.3-1.5	4mg/day	1.4-1.9	3mg/day
1.6-2.1	3mg/day	2.0-3.0	2mg/day
2.2-3.0	2mg/day	>3.0	1mg/day
>3.0	1mg/day		



Based on: A. Oates et al. A new regimen for starting warfarin therapy in out-patients.

Useful contacts

NBT	**UHB**	**Weston**
Anticoagulation Monitoring Service Department of Haematology Pathology Sciences Laboratory Southmead Hospital Westbury-on-Trym Bristol BS10 5NB Anticoagulation Monitoring Service: Tel: 0117 323 8363 Fax: 0117 323 5638 e-mail AMS@nbt.nhs.uk	Anticoagulation Monitoring Service Pharmacy Department Bristol Royal Infirmary Upper Maudlin Street Bristol BS2 8HW Anticoagulation Monitoring Service Tel: 0117 342 3874 Fax: 0117 342 3568 e-mail warfarin.helpline@uhbristol.nhs.uk (not suitable for patient identifiable data)	

(not suitable for patient identifiable data) Secure e-mail: nbn-tr.ams@nhs.net Haematology SpR: via switchboard 0117 950 5050 Blood Sciences Laboratory Manager 0117 323 6306 On-call pharmacist: via switchboard 0117 950 5050	Haematology SpR: via switchboard 0117 923 0000 Haematology laboratory 0117 342 2598 On-call pharmacist: via switchboard 0117 923 0000	

Acknowledgements

We are grateful to staff at University Hospitals Bristol NHS Foundation Trust and North Bristol NHS Trust for their help in producing this document.

Anticoagulant Monitoring Primary Care Service Audit 2019/20 (for services undertaken in 2018/19)

Please complete the audit below with details of patients receiving care under the Near Patient Testing Primary Care Service during the period 1st April 2018 to 31st March 2019.

Practice name:	
Practice code:	

Declaration
I confirm that the below activity is a true record of that undertaken by the practice for the period 1st April 2018 to 31st March 2019 with respect to the Anticoagulant Monitoring Primary Care Service agreement.

Name:	
Position:	
Date:	

Contact at practice for audit (if different from above)	
Contact details:	
Telephone	
E-mail:	

Any enquiries regarding this audit should be directed to:
Medicines Optimisation Team
NHS BNSSG CCG
Tel: 0117 900 3432

Please complete and return this audit electronically by
1st October 2020 to:
Xxxxcxxx

Audit Standards

Audit Standards	
Patients prescribed warfarin (or acenocoumarol /phenindione) have a documented indication	100%
Patients prescribed warfarin (or acenocoumarol /phenindione) have a documented INR target or INR range	100%
Patients prescribed warfarin (or acenocoumarol /phenindione) have a documented stop date / duration of treatment	100%
Number of audited patients with INRs > 5 but ≤ 8 on one or more occasion	10% or less
Number of audited patients with INRs > 8 on one or more occasion	5% or less
Time in therapeutic range for the practice calculated on computer aided dosing software	65% or more
There is a mechanism in place in the practice to deal with DNA's (for warfarin (or acenocoumarol /phenindione) monitoring)	100%
There a mechanism in place to assure that the most recent INR result is viewed prior to signing warfarin(or acenocoumarol /phenindione) prescriptions	100%

Audit

Practice Name	

Please detail the following:

A	Number of patients managed under a basic service (Practice takes the blood sample, testing is undertaken by the hospital trust, and dosing is undertaken by the hospital trust)	
B	Number of patients managed under an advanced service (Practice takes the blood sample, tests sample and dosing is undertaken by the practice.)	

If the number of patients managed under a basic service (Answer A) is 30 or less, please audit the total number of patients.

If the number of patients managed under a basic service is greater than 30, please randomly select 30 patients or a sample of 20% of those patients (whichever is the **greater**) and complete the audit for this number of patients.

For those patients managed under an advanced service please complete the audit for all patients.

			Number of patients	Percentage
C	i	Number of basic service patients included in this audit		
	ii	Are you using a sample of your basic service patients (as described above)	Yes / No	
	ii	Number of advanced service patients included in this audit (this should be the same as detailed in		
D	Number of audited patients with a documented indication for warfarin			
E	Number of audited patients with documented INR target or INR target range.			
F	Number of audited patients with documented stop date or duration of warfarin treatment (life - long, 1 year etc.)			
G	Is there a mechanism in place to ensure that the most recent INR result is viewed prior signing warfarin (acenocoumarol or phenindione)		Yes / No	
H	If **NO** to the above question (J), are you reviewing your process for the prescribing of warfarin (acenocoumarol or phenindione)?		Yes / No	

Complete the following questions if offering the advanced service:

I	Number of audited patients with INRs > 5 but ≤8 on one or more occasion.		
J1	Number of audited patients with INRs > 8 on one or more occasion.		

J2	For the patients highlighted in H1 (i.e. those with an INR of >8 on one or more occasion) please state what action was taken for each patient. (add additional rows as necessary)			
	EMIS number	Action taken		
K	For advance level service proportion of patient time in therapeutic range (average for practice over the 12 months)			
L	Is there a mechanism in place to deal with DNA's?		Yes / No	

Key Outcomes of audit including any actions taken / planned:

Appendix B – Financial Implications of revised service specifications for Near Patient Testing (NPT) and Anti-Coagulation Local Enhanced Services

1. Background

As part of the CCG recovery programme, and in line with the financial plan agreed with NHSE, the CCG has a requirement to deliver £37m of savings in 2018/19 (approximately 3% of the total CCG allocation).

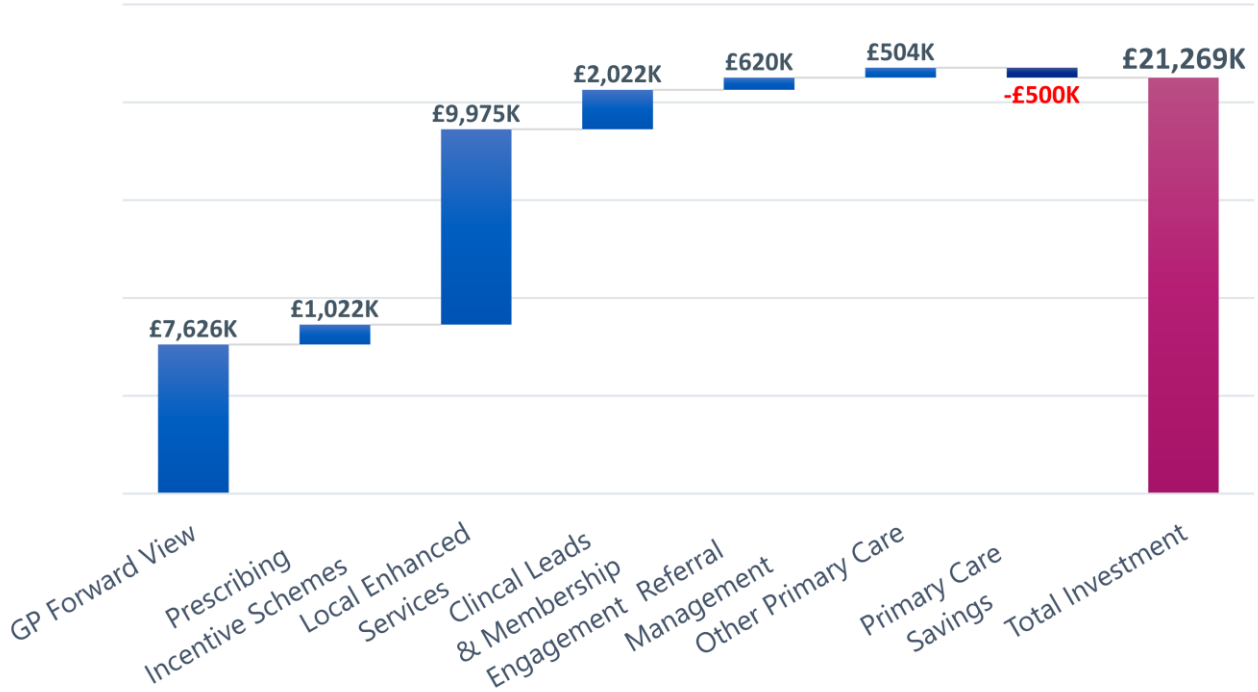
As part of this plan, there is a savings target of £500k to be delivered from the entire Primary Care budget (with a £1million full-year effect to be achieved in 2019/20). This equates to less than 0.4% of the total primary care budget this year, and 0.7% recurrently.

The LES review is one of the initiatives which we anticipate may contribute to this target.

2. Investment in Primary Care 2018/19

CCG investment in enhanced services (including prescribing incentive schemes), commitment to investing in the GPFV, and transformation funding totals £18.6 million in 2018/19, which represents a 3.5% increase in planned spend compared to 2017/18.

In addition to this, there is a further £2 million investment in Clinical Leadership and Membership engagement, and £0.6m investment into referral management.



In total, the CCG commits £21.8 million of it's total allocation to Primary Care Services, which in addition to the delegated budget for core primary care services of £122.1m, totals £143.4m. The primary care savings target represents of £0.5m represents 0.4% of the total funding.

3. Financial Appraisal of Revised Service Specifications

As service specifications have been developed, detailed financial and activity modelling has been done to capture the impact of the revised specification on future CCG funding requirements, on Practice level income, and where possible, value for money comparisons (against provision in other settings) to ensure best use of resources.

3.1 Near Patient Testing (NPT)

3.1.1 Current Financial Arrangements

Whilst there were some small differences in the medications covered by the legacy specifications, the financial mechanisms for reimbursement to practices were broadly similar, with practices being paid between £75 and £85.24 per patient (paid to practices on a quarterly basis). Total spend in 2017/18 was approximately £640K (See table 1 below), with 99% of practices signed up.

Table 1: 2017/18 NPT LES Reimbursement

Locality	Patient Numbers (2017/18)	Annual Payment	Practice Payments (£)
Bristol			
Inner City & East Bristol	822	£85.24	£70,067
North & West Bristol	1,134	£85.24	£96,662
South Bristol	1,282	£85.24	£109,278
Bristol Total	**3,238**	**£85.24**	**£276,007**
North Somerset			
Woodspring	1,159	£85.00	£98,515
Worle Weston Villages	1,197	£85.00	£101,745
North Somerset Total	**2,356**	**£85.00**	**£200,260**
South Gloucestershire			
SG Locality	2,221	£75.00	£166,575
South Gloucestershire Total	**2,221**	**£75.00**	**£166,575**
Grand Total	**7,815**		**£642,842**

3.1.2 NPT proposed Financial Model

In addition to harmonising the level of payment received by practices, the revised service specification and financial reimbursement seeks to reflect the varying workload carried out in primary care depending on number of interventions, and the frequency of monitoring required for specific medications.

It is proposed that new medicines will be added into the schedule moving forward as medicines on the BNSSG Joint Formulary move from Red (specialist only), to Amber (suitable for shared care with GP) and shared care protocols are approved.

The BNSSG Joint Formulary group will continue to confirm the clinical appropriateness of medicines for shared care between primary and secondary care including information on usage figures.

Payment Level	Amount of annual monitoring	Drugs currently included	Practice Payment (annual)	Practice Payment (quarterly)
0	1		None as considered part of annual patient disease monitoring and management	None as considered part of annual patient disease monitoring and management
1	2-3	Denosumab (Prolia)	£50.00	£12.50
2	4-5	Azathioprin	£70.00	£17.50
		Leflunomide		
		Sodium aurothiomalate		
		Methotrexate		
		Penicillamine (Nephrology)		
3	6-8	Mercaptopurine (oral)	£100.00	£25.00
		Sulfasalazine (oral)		
4	9-12	Penicillamine(Rhuematology)	£120.00	£30.00

In addition to this, practices will be paid an annual sum of £350 per 10,000 patients when signing up to the LES to reflect that there will be a number of patients newly initiated onto the medications covered by the LES each year, and some of these patients have slightly increased monitoring requirements during year one of therapy.

Based on this revised specification, and the standardisation of medication included within the LES, the financial implication of the revised specification has been modelled as follows:

Table 2: Proposed 2019/20 reimbursement (based on prior year patient numbers)

Locality	Level 1	Level 2	Level 3	Level 4	TOTAL	Activity Based Payments (£)	Sign Up Payment	Total Practice Payments (£)
Bristol								
Inner City & East Bristol	49	650	169	3	871	£65,210	£5,307	£70,517
North & West Bristol	80	891	243	0	1,214	£90,670	£6,097	£96,767
South Bristol	94	993	289	0	1,376	£103,110	£5,596	£108,706
Bristol Total	**223**	**2,534**	**701**	**3**	**3,461**	**£258,990**	**£16,999**	**£275,989**
North Somerset								
Woodspring	57	855	247	0	1,159	£87,400	£3,966	£91,366
Worle Weston Villages	36	904	257	0	1,197	£90,780	£3,862	£94,642
North Somerset Total	**93**	**1,759**	**504**	**0**	**2,356**	**£178,180**	**£7,828**	**£186,008**
South Gloucestershire								
SG Locality	122	1,798	423	0	2,343	£174,260	£8,584	£182,844
South Gloucestershire Total	**122**	**1,798**	**423**	**0**	**2,343**	**£174,260**	**£8,584**	**£182,844**
Grand Total	**438**	**6,091**	**1,628**	**3**	**8,160**	**£611,430**	**£33,411**	**£644,841**

This proposal represents an increase of £2K in total cost to the CCG, the impact of which at locality level is set out in the following table:

Table 3: Financial Impact of revised specification at locality level

Locality	2017/18 Practice Payment	Proposed Practice Payment	Difference
Bristol			
Inner City & East Bristol	£70,067	£70,517	£450
North & West Bristol	£96,662	£96,767	£105
South Bristol	£109,278	£108,706	-£572
Bristol Total	**£276,007**	**£275,989**	**-£18**
North Somerset			
Woodspring	£98,515	£91,366	-£7,149
Worle Weston Villages	£101,745	£94,642	-£7,103
North Somerset Total	**£200,260**	**£186,008**	**-£14,252**
South Gloucestershire			
SG Locality	£166,575	£182,844	£16,269
South Gloucestershire Total	**£166,575**	**£182,844**	**£16,269**
Grand Total	**£642,842**	**£644,841**	**£1,999**

3.1.3 NPT Further Considerations

- As new medicines are proposed to be added to the NPT LES, there needs to be a clear understanding of current pathway costs, and assurance that any additional cost in primary care is off-set by a reduction in secondary care activity.

- Whilst presented in summary for the purposes of this paper, there is a full practice level impact that supports this paper.

As service specifications have been developed, detailed financial and activity modelling has been done to capture the impact of the revised specification on future CCG funding requirements, on Practice level income, and where possible, value for money comparisons (against provision in other settings) to ensure best use of resources.

3.2 Anti-Coagulation

3.2.1 Current Financial Arrangements

There is significant variation in the current delivery model and financial arrangements for the existing Anti-coagulation LES. This is outlined in the schedule below:

Point of Delivery	Bristol	North Somerset	South Gloucestershire
Primary Care	£57 per patient annually for Level 1 service £120 per patient annually for advanced service	Initiation: £125 per ambulatory patient £115 per domiciliary patient On-going **monitoring:** £170 per ambulatory patient £111 per domiciliary patient	£60 per patient annually for testing & monitoring of bloods only. No payment for first ten patients
Acute Care	Warfarin Monitoring Service at UHB (block contract). Approx. £150K annual value INR Direct Access Pathology	Minimal Acute Activity	NBT currently also provides a warfarin monitoring service. Activity Is paid for under PbR tariff.

Table 4: 2017/18 Anti-Coagulation LES Reimbursement

Level / Locality	2017/18 Patient Numbers (Based on EMIS Search & Report)	2017/18 Practice Payment	Average Payment per Patient
Basic			
Inner City & East Bristol	608	£34,656	£57
North & West Bristol	827	£47,139	£57
South Bristol	943	£53,751	£57
SG Locality	1,933	£115,980	£60
Basic Total	**4,311**	**£251,526**	
Advanced			
North & West Bristol	45	£5,400	£120
South Bristol	199	£23,880	£120
Woodspring	1,479	£235,742	£159
Worle Weston Villages	1,174	£183,897	£157
Advanced Total	**2,897**	**£448,919**	
Grand Total	**7,208**	**£700,445**	

3.2.2 Anti-Coagulation proposed financial model

Two levels of service (Advanced Level and Basic Level) are offered in the specification. Payment will be based on the service level provided by the practice.

Payment will be calculated by EMIS (Search and report) as follows: the number of patients with a current medication course for warfarin, warfarin sodium, phenindione or acenocoumarol that have had at least 1 documented INR measurement (42QE) in the last 100 days.

Proposed Tariff

- Basic - £57 per patient per year
- Advanced - £155 per patient per year

The sum for the advanced service includes an amount for the practice to purchase Coaguchek test strips (at approximately 16 strips per patient per year). For patients being monitored and dosed under this LES, additional strips must not be put on prescription, they must be ordered by the GP practice directly from Roche, where a pre-negotiated discount will be applied for all providers of BNSSG CCG.

Table 5: Financial Impact of revised specification at locality level

Level / Locality	Practice Numbers	2017/18 Practice Payment	Proposed Practice Payment	Difference
Basic				
Inner City & East Bristol	13	£34,656	£34,656	£0
North & West Bristol	15	£47,139	£47,139	£0
South Bristol	13	£53,751	£53,751	£0
SG Locality	24	£115,980	£110,181	-£5,799
Basic Total	**65**	**£251,526**	**£245,727**	**-£5,799**
Advanced				
North & West Bristol	1	£5,400	£6,975	£1,575
South Bristol	1	£23,880	£30,845	£6,965
Woodspring	7	£235,742	£229,245	-£6,497
Worle Weston Villages	11	£183,897	£181,970	-£1,927
Advanced Total	**20**	**£448,919**	**£449,035**	**£116**
Grand Total	**85**	**£700,445**	**£694,762**	**-£5,683**

The above analysis assumes no change to the current number of practices offering the advanced level service (as at September 2018). The current service model means that all North Somerset practices provide an advanced level service (plus a further 2 in Bristol localities), covering approximately 29% of weighted practice populations.

3.2.3 Anti-Coagulation Further Considerations

- Depending on practice sign up, there is a risk that a number of practices may wish to sign up to providing the advanced level service. Whilst the current financial proposal falls within the existing budget, any shift of practices from the Basic to the Advanced Level would represent an additional financial risk to the organisation:

Table 6: Financial Impact of new practices offering advanced Anti-coagulation LES

Percentage of Population Covered by Advanced Level Practices	Modelled Full Year Cost	Additional Cost
Current (29%)	**£694,762**	**£0**
35%	£713,578	£18,816
50%	£778,454	£83,692
75%	£928,688	£233,926
100%	£1,117,240	£422,478

- The current block contract arrangements with UHB for Warfarin monitoring is becoming increasingly more expensive due to reducing patient numbers being seen by the service, effectively increasing the cost per patient to the CCG.

  In order to ensure value for money, the CCG should be looking to re-negotiate the terms of the current block arrangement to a variable basis.

- Whilst presented in summary for the purposes of this paper, there is a full practice level impact that supports this paper.

Recommendations

The Committee is asked to note and discuss the financial modelling and further considerations identified. It is recommended that no decisions are made on the tariffs for each enhanced service until the full suite of specifications for 2019/2020 have been finalised in December to allow for a complete and concurrent appraisal of the combined implications for the CCG and for practices.

Project Highlight Report

Bristol, North Somerset and South Gloucestershire Clinical Commissioning Group

Primary Care

Approach to commissioning Local Enhanced Services (LES) across BNSSG

Overall Summary			
Report Date	18.09.18		
Project Name	Approach to commissioning Local Enhanced Services (LES) across BNSSG		
Report Author	Jenny Bowker – Head of Primary Care Development Heather Allward – Programme Officer		
Start Date	April 2018	End Date	April 2019
Overall Project Status	On target	Previous Project Status	On target
Explanation of Project Status	Work is underway to prepare for new specifications and we are currently projected to be on target for 1st April 2019 completion date.		
Achievements for Current Period	• The in-year position for Local Enhanced Services (LES') has been confirmed to practices. • Presentation shared with all practices in BNSSG in August to answer key questions. • Draft service specifications for NPT, Anticoagulation and Supplementary Services presented to PCCC for further engagement. • Work is in progress to complete financial modelling of recommendations for the CCG and for the impact at practice level.		

Tasks and Milestones

- Contracts for 2018/19 to be issued to practices by 28.09.18 including in year reporting requirements for revised offer for Bristol Primary Care Agreement (BPCAg) and South Gloucestershire Compact.
- Develop FAQ for practices to answer common queries across BNSSG and to support October membership meetings.
- Contracting model to support locality delivery of enhanced services for April 2019 to be developed and recommended to Primary Care Operational Group (PCOG) then PCCC in December.
- Final specifications for 19/20 for all services to be approved at December PCCC following review at PCOG.

Contracting timeframes for 19/20 LES':

- Final service specifications to be sent to practices by the end of January 2019
- EOIs sent out 1st February, due 28th February
- Contracts built between 1st-22nd March
- Practices to sign and return contracts week commencing 25 March ready for 1st April 2019.

Near Patient Testing (NPT), Anticoagulation, Supplementary Services

- Engagement on draft NPT service specification took place at the Drugs and Therapeutic committee in July.
- Draft aligned specifications and tariff shared at PCOG in September to be recommended for membership engagement by PCCC on 25.09.18.
- Serve notice on existing contracts by 30.09.18 to give 6 months' notice in preparation for new specification 1st April 2019.
- Membership engagement on draft service specifications for NPT, Anticoagulation and Supplementary Services in October.
- EIA/QIA screening to be completed in October.

Dementia

- Draft BNSSG dementia service specification to be recommended for membership engagement at October PCCC.
- Membership engagement on draft service specification in November.
- EIA/QIA screening to be completed in November.

DVT

- Service specification and procurement approach approved on 04.09, contract anticipated to be awarded in December 2018.
- DVT service specification for the LES element of the pathway to be recommended for approval at November PCCC. There has already been significant membership engagement for DVT LES.

Diabetes

- Draft service specification for diabetes to be recommended for membership engagement at October PCCC.
- Membership engagement on draft service specification in November.
- EIA/QIA screening to be completed in November.

Minor Injuries

- We have most of the information however we need to get more information for the period September 2017 - September 2018 to inform the evaluation and final recommendation. Timeline for completion to be confirmed by 28.09.18.

Care Homes with and without nursing

- First draft service specification for care homes to be reviewed at LES Review Steering Group 18.09.18.
- Draft service specification to be discussed at STP integrated care steering group on 23.10.18.
- Draft service specification for care homes to be recommended for membership engagement at October PCCC.
- Membership engagement on draft service specification in November.
- EIA/QIA screening to be completed in November.

Locality Transformation Scheme (LTS) Phase 3

The LTS Phase 3 paper to PCCC sets out next steps for developing and strengthening integrated community localities and this will be overseen by the STP integrated care steering group.

Risks

	Mitigation
Practice uncertainty about the future of their income streams and engagement in the review	• Finance impact assessment to be undertaken at practice level. • Ongoing communication to membership meetings about outcome of the review and development of new offer for 1st April 2019. • Write to practices to confirm the position for local enhanced services for this financial year by 03.08.18.
Locality model not ready to take on at scale provision	• Agree framework and steps with Locality Providers to be ready to provide locality solutions • Paper on LTS phase 3 sets out next steps for developing and strengthening integrated community localities to be overseen by the STP integrated care steering group. • LMC is able to provide advice to locality provider vehicles on developing indemnity agreements to support staff working across practices.

LES review proposals pose a financial risk either to the CCG or to individual practices	• Financial modelling to support individual enhanced service specifications will be undertaken, however, no final decisions will be made until we can cost the combined implications for the suite of new specifications – both for the CCG and for individual practices

Issues

- Financial modelling of new services is dependent on the development of service specifications for 2019/20 and these are being developed between September and December. Financial modelling data to be presented at PCCC in September will need to be updated once the work on all LES specifications has concluded.