Service Specification No.	
Service	**General Practice Specialised Medicines Service**
Commissioner Lead	
Provider Lead	
Period	1st July 2017 – 30th June 2018
Date of Review	December 2017

1. Population Needs

1.1 National/local context and evidence base

The changes brought about by the Health and Social Care Act 2012 necessitated the re-specification of the payment schemes previously undertaken under enhanced services to the primary care medical contract.

Previous discussions between the CCGs and the LMC indicated that a unified framework across Devon for schemes involving drugs would be desirable. Building on these discussions, the enhanced services framework which had been previously agreed in principle was further developed and validated against a wider range of medication-related enhanced services. This framework was found to have a high degree of face validity. That is, drugs for which more practice level input is required or where the impact on a GP"s workload is greater produce higher scores.

The enhanced services framework was developed to provide a means of assessing the impact of a drug on primary care activity and determine the value of this work in a transparent and consistent manner. It was envisaged that the framework would be used to fund the INR monitoring service, shared care guidelines, the prescribing and administration of GnRH analogues (eg Zoladex®) and additional work associated with some specialised drugs prescribed in primary care following secondary care initiation which may be considered to be beyond the scope of essential services outlined in the GMS contract. The framework has been accepted by the LMC for the general practice specialised medicines service since 2014-2015.

2. Outcomes

2.1 NHS Outcomes Framework Domains and 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 Outcome

The agreement of this General Practice Specialist Medicines Service would permit the equitable funding of specialised medication activity across all areas of Devon, on the basis that where the CCG agrees funding for primary care in one geographical location in Devon the fee will be commensurate with similar activity elsewhere in Devon. The scheme will permit local implementation of initiatives to meet local needs where funding is made available, without prejudice to other areas with different needs or where funding is not available.

It is proposed that the current amount of funding for this Service is distributed over the funded schemes by means of a five tiered payment structure using this framework.

3. Scope

3.1 Aims and objectives of service

The aim of the proposed Specialist Medicines Service is to permit equitable funding of specialised medication activity across all areas of Devon through use of a tiered framework which incorporates staff activity, impact of lack of familiarity with a drug on a GP"s workload and clinical responsibility.

GPs taking on responsibilities through this service framework do so on a case by case basis as has always been the case with "shared care".

3.2 Service description/care pathway

This section presents a detailed work up of a framework for primary care services that had previously been under discussion with the LMC during 2012 involving a variety of individuals whose roles have subsequently changed. Discussions at that time indicated support for the principle of a framework which had been developed with domains of activity identified and weightings attached. This had been „road tested" on a small number of activities including three shared care guidelines. After modifications, a revised framework weighting emerged that appeared more appropriate to shared care drugs and INR testing/warfarin prescribing. During the subsequent transition of the NHS commissioning organisations no

new work was conducted on this proposal.

The original framework for enhanced services was previously discussed at the commissioner/LMC meetings and agreed in principle. Since then, the "impact domain" of the framework has been more clearly articulated to capture more fully the impact on a GP's workload of prescribing new drugs or established drugs which are not frequently used in primary care. In addition, the allocation of points for governance now recognises the difference between sole management responsibility and shared care responsibility. Full management responsibility for treatment requiring an unfamiliar drug to primary care has a greater score than either shared care or the full management responsibility for established primary care drugs.

The proposed framework incorporates staff activity including administration and visits to a healthcare assistant, nurse or GP, interpretation of diagnostic tests and impact of lack of familiarity of a drug on a GP's workload and clinical responsibilities. The framework covers the cost of patient care. The costs of using practice owned equipment, as is the case with near patient INR testing, is not included in the framework and would be an additional payment to be overall commensurate with the former anticoagulation NES.

The framework is shown below and accompanied by assumptions used in assigning weights to the various medicines services currently funded.

Specialised medicines payments framework

		Score					
		0	1	2	3	4+	Weighting
Staff Costs	Admin Input	Not required	Single process	on-going recall system or single process with follow up	on-going recall system with follow up	Exceptional	7.5
	Routine HCA Input	Not required	4 or less contacts pa.	5-7 contacts pa	8 - 12 contacts pa	Exceptional	7.5
	Routine nurse Input	Not required	4 or less contacts pa.	5-7 contacts pa	8 - 12 contacts pa	Exceptional	15
	Routine GP Input	Not required	4 or less contacts pa.	5-7 contacts pa	8 - 12 contacts pa	Exceptional	50
	Diagnostic Tests	Not required	HCA interpretation	Nurse interpretation	routine GP interpretation	Exceptional	5
Impact assessment	Impact of unfamiliarity with drug	Established drug used in > 1 in 500 pts	New drug used in > 1 in 500 pts	use in between 1 in 500 and 1 in 2000 pts	use in fewer than 1 in 2000 pts		5
	Governance/Clinical responsibility	Not applicable	Full for established drug (use in conjunction with impact score 0)	Shared	Full for less familiar drug (use in conjunction with impact score of 1,2 or 3)		10

The assumptions used in testing the framework are listed below.

Administrative input: it is assumed that an on-going recall system with follow-up would be used for existing guidance.

Routine HCA (health care assistant) input: used when blood samples taken or anthropometric measurements required.

Routine nurse input: used when clinical measurements required (e.g. blood pressure or pulse). If blood sample also required, it is assumed that the nurse would take this at the same visit. Also, used for administration of injections.

Routine GP visit: requires patient consultation for a specified reason documented in guidance above normal level of care for patient with this diagnosis.

Diagnostic tests: it is assumed that all results of blood tests, clinical and anthropometric measurements are interpreted by GP. There is no interpretation of tests or measurements leading to a clinical decision by a health care assistant or nurse.

Impact of unfamiliarity of drug: this category allows for the additional impact on a GP"s workload of care for a patient receiving a drug which is not routinely used in primary care. This allows for new drugs and for established drugs which are not frequently prescribed.

Governance / clinical responsibility: the score for this category is conditional on the familiarity of the GP with the drug. Clinical responsibility is always assigned a weighting, whether it is shared responsibility or full clinical responsibility. Shared care and taking full clinical responsibility for drugs which are new or not frequently prescribed in primary care is given a higher score than full clinical responsibility for drugs routinely prescribed in primary care.

Testing of the framework

The framework has been tested using existing shared care guidelines from North and East Devon, Plymouth and Torbay and the LES for monitoring of INRs. This gave 32 clinical scenarios with differing levels of activity. The scores produced across the range of activities are shown in Appendix One. A practising GP member of the Devon LMC with a particular interest in prescribing, formulary and shared care has been asked to sense check the scores produced for each medication.

Outcomes of testing framework

- The scores achieved demonstrate that the framework differentiates between level of activity, both in terms of frequency of visits to the practice and the type of staff involved, and also in terms of the impact on a GP"s workload of prescribing new drugs and drugs which are not frequently used in primary care.
- The scores increase with an increase in level of activity. The lowest scores are achieved for guidelines where the drug is prescribed by the GP and all other care is undertaken by secondary care.
- The highest scores are achieved for guidelines where frequent visits to a nurse are required for drug administration or clinical measurements (e.g. regular monitoring of blood pressure and/or pulse) together with the taking of blood samples and the interpretation of test results by a GP.
- The impact of prescribing new drugs or established drugs which are not frequently prescribed in primary care is reflected by the scores at every level of activity. Higher scores are achieved for drugs which are not frequently prescribed in primary care, for shared care and for taking on full responsibility for less familiar drugs.

Developing the tiers to determine funding

To determine the number of tiers and point threshold of each tier, all possible levels of activity were replicated for each combination of the two variables, impact of unfamiliarity with a drug and level of clinical responsibility. Using the framework, 29 levels of activity were identified which might feasibly occur in clinical practice. This included levels of activity outside the scope of the current shared care guidelines and LES for INR to future proof the framework. Eight combinations of familiarity with the drug and level of clinical responsibility were identified which when combined with levels of activity gave a total of 232

clinical scenarios. Similar levels of activity were grouped together resulting in five groups, with the highest group representing exceptional circumstances. Thus, five funding tiers were adopted. The point threshold for each tier was calculated from the range of points from the lowest point of the first tier to the lowest point of the fifth tier. Figure 1 (Appendix 1) shows the allocation of tiers across the clinical scenarios. The level of funding increases as the level of activity increases and as the impact of unfamiliarity of a drug and level of clinical responsibility increases. Shared care guidelines funded by NHS Devon and NHS Plymouth and currently funded by NEW Devon CCG are included in Figure 1 (Appendix 1) as are levels 1 and 2 of the INR service.

Payment for each tier

For planning the new framework the amount of money available was based on historical spend (ie the total amount paid out next year would be the same if activity remained the same but there is a redistribution of how this is paid out).

Tier 1: Fee per patient is £47.94

- Equivalent to highest locally agreed cost for drugs which fall into tier 1, that is GnRH analogues.
- Western locality practices receive funding at same level as currently.
- Payments for Eastern and Northern locality practices will increase to bring them in line with Western locality practices.

Tier 2: Fee per patient is £81.61

The cost for tiers 2 and 3 has been determined by calculating the mean payment per point based on the current funding of drugs within a specific tier and multiplying this figure by the mean point score for the same drugs.

- Pays higher for some currently funded drugs and lower for other drugs.
- This tier includes drugs which are funded in some areas and not others. Therefore practices in some areas will be funded for work which they were not previously funded for.
- Money from this tier will also be used to fund the highest paid tier.

Tier 3: Fee per patient is £102.01

- Payment for tier 3 is equivalent or higher than currently funded cost of shared care for drugs which fall into this tier.

Tier 4: Fee per patient is £122.41

- Tier 4 payment is approximately 30% higher than the current shared care payment for drugs within this tier in recognition of the complexity of work associated with these drugs.
- This tier includes drugs which are funded in some areas of the CCG but not others. Therefore practices in some areas will be funded for work which they were not previously funded for.

The fifth tier is for drugs judged to represent an exceptional workload. None of the current shared care guidelines or LES for medicines falls into this tier.

What these changes mean for different localities

Practices in the Western locality will be funded for shared care for ciclosporin which they did not receive funding for previously. Practices in Eastern and Northern locality will be funded for shared care for atomoxetine and methylphenidate which was not previously funded.

INR level 1 and 2 services

- INR level 1 service will receive a tier 2 fee plus an additional enhanced payment to reflect the resource required for warfarin services within general practice. The level 1 service includes practice-funded phlebotomist or pharmacist etc, practice sample, laboratory test, practice dosing

- INR level 2 service will receive the tier 2 fee and an additional cost to cover equipment plus an additional enhanced payment to reflect the resource required for warfarin services within general practice. The level 2 service includes practice-funded phlebotomist or pharmacist etc, practice sample, practice test, practice dosing

Medicine	Service specification	Funding tier	Fee per patient
Atomoxetine	Shared care guideline	2	£81.61
Azathioprine	Shared care guideline	2	£81.61
Ciclosporin	Shared care guideline	4	£122.41
Denosumab for osteoporosis	Specialised medicines service guideline	2(Year 1)*	£81.61
Denosumab for osteoporosis	Specialised medicines service guideline	3 (Year 2 onwards)*	£102.01
Gonadorelin analogues	Gonadorelin analogues shared care (prostate cancer)	1	£47.94
Hydroxycarbamide for myeloproliferative disorders	Specialised medicines service guideline	2	£81.61 **North and East only**. In the West this drug remains secondary care only.
Leflunomide	Shared care guideline	3	£102.01
Lithium	Specialised medicines service guideline	1	£47.94
Lisdexamfetamine	Shared care guideline	2	£81.61
Mercaptopurine	Shared care guideline	3	£102.01
Methotrexate	Shared care guideline	2	£81.61
Methylphenidate	Shared care guideline	2	£81.61
Modafinil	Specialised medicines service guideline	2	£81.61
Mycophenolate for eczema	Specialised medicines service guideline	3	£102.01
Mycophenolate for autoimmune conditions	Specialised medicines service guideline	3	£102.01
Penicillamine	Shared care guideline	3	£102.01
Riluzole	Shared care guideline	2	£81.61
Sodium aurothiomalate (gold)	Shared care guideline	4	£122.41
Sodium oxybate	Specialised medicines service	2	£81.61
Sulfasalazine	Shared care guideline	1	£47.94
Warfarin	INR level 1 service specification**	2	£81.61 (tier 2 fee) plus £2.52 (additional payment to support practice resource)
Warfarin	INR level 2 service specification**	2	£81.61 (tier 2 fee) plus £32.79 & £2.52 (additional payments for equipment & resource)

*Denosumab: the fee is lower for the first year of treatment to reflect specialist initiation of treatment. From the second year of treatment onwards, primary care is expected to take full responsibility for patients receiving denosumab.

**Warfarin services level 1 and 2:

- Level 1: practice-based phlebotomist or pharmacist etc., practice sample, laboratory test, practice dosing
- Level 2: practice-based phlebotomist or pharmacist etc., practice sample, practice test, practice dosing

The level 1 service will receive a tier 2 fee, plus an additional enhanced payment of £2.52 to reflect the resource required for warfarin services within general practice.
The fee for the specialised medicines enhanced service does not cover equipment. Therefore the total fee for the level 2 service includes the tier 2 fee and an additional fee to cover the costs of

equipment (£32.79) plus an additional enhanced payment of £2.52 to reflect the resource required for warfarin services within general practice.

Periodic review
The LMC will be consulted about the drugs to be funded under this scheme on a periodic basis. These discussions will allow for recognition of the impact of new specialised medicines and also that some specialised medicines will have become established in practice and familiar to GPs.

3.3 Population covered
The registered population of the practice.

3.4 Any acceptance and exclusion criteria and

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thresholds

It is envisaged that the framework will be used to fund the INR monitoring service, shared care guidelines, the prescribing and administration of GnRH analogues (eg Zoladex®) and additional work associated with some specialised drugs prescribed in primary care following secondary care initiation which may be considered to be beyond the scope of essential services outlined in the GMS contract.

3.5 Interdependence with other services/providers

Where a future shared care guideline or service redesign is proposed the framework will be used to show the proponents what the primary care commissioning service cost will be. This allows identification of the funding that is needed for the service design to be explicitly known early in the process.

4. Applicable Service Standards

Providers and practitioners will adhere to the local and national guidelines or any updated versions thereof.

4.1 Applicable national standards (eg NICE)

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

4.3 Applicable local standards

This document presents an overarching proposal for primary care payment for specialised medicines. The services and shared care guidelines covered by this payment scheme have each been developed taking into account applicable national standards (e.g. NICE guidance), guidance from professional bodies and applicable local standards.

5. Applicable quality requirements and CQUIN goals

5.1 Applicable Quality requirements (See schedule 4 Parts A – D)

Not applicable

5.2 Applicable CQUIN goals (See schedule 4 Part E)

Not applicable

6. Location of Provider Premises

Main surgery and any branch sites as per GMS, PMS or APMS agreement.

7. Individual Service User Placement

Not applicable

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Appendix 1

Table 1:Results of testing specialised medicines payment framework on existing shared care guidelines for North and East Devon, Torbay and Plymouth and LES for INR monitoring

Level of activity for GP practice	Weighted Score	Comment
All care undertaken by secondary care		
	0	Level 1 of former anticoagulation NES
Prescribing		
	25-35	Range of scores reflects familiarity with drug. Highest scores given to drugs estimated to be prescribed in fewer than 1 in 2000 patients
Prescribing and administration		
Monthly administration	102.5	Injection – scores reflect administration by nurse and high score for lack of familiarity
Three monthly administration	67.5	Injection – administered by nurse. More frequently prescribed drug than previous example
Prescribing and taking bloods		
Three monthly monitoring	65	High score for lack of familiarity
Taking bloods and interpreting results		
Monthly monitoring	80	Established drug
Taking bloods, BP and interpreting results		
Two monthly monitoring	102.5	High score for lack of familiarity
Prescribing, taking bloods and interpreting results		
Monthly monitoring	70-95	Lowest score for frequently used established drugs. Higher scores reflect shared care and lack of familiarity with drug.
Two monthly monitoring	87.5	Higher score for lack of familiarity
Three monthly monitoring	65-85	Higher scores reflect lack of familiarity with drug and level of responsibility ranging from shared care to full responsibility for a less frequently prescribed drug
Six monthly monitoring	80	Higher score for lack of familiarity
Prescribing, taking bloods, BP, interpreting results		
Monthly monitoring	102.5 – 117.5	Higher score reflects difference between established drug and drug estimated to be prescribed in less than 1 in 2000 patients
Three monthly monitoring	87.5	High score for lack of familiarity
Six monthly monitoring	77.5	New drugs estimated to be used in more than 1 in 500 patients
Prescribing, administration of drug, taking bloods and interpreting results		
Monthly administration and monitoring	117.5	High score for lack of familiarity

Figure 1: Level of activity and tier for determining funding

	Impact of unfamiliarity with drug and degree of clinical responsibility*							
	Established, full, >1 in 500	**Established, shared care, >1 in 500**	**New drug, shared care, >1 in 500**	**Between 1 in 500 &1 in 2000, shared**	**<1 in 2000, shared**	**New drug, full, > 1 in 500**	**Between 1 in 500 &1 in 2000, full**	**< 1 in 2000, full**
Activity level								
Prescribing only of agreed drugs								
HCA taking bloods or measuring weight ≤ 3 monthly.	N/A					N/A	N/A	N/A
HCA taking bloods or measuring weight approx 2 monthly.	N/A					N/A	N/A	N/A
Administration and/or clinical measurements by nurse ≤ 3 monthly				GnRH				
HCA taking bloods or weighing every 4 to 6 weeks.	N/A					N/A	N/A	N/A
HCA taking bloods or measuring weight ≤ 3 monthly. GP interpretation of test results	Lithium	Sulfa			Riluzole			
HCA taking bloods or measuring weight approx 2 monthly. GP interpretation of test results								
Administration and/or clinical measurements by nurse approx two monthly								
Administration and/or clinical measurements by nurse ≤ 3 monthly. GP interpretation			Atomox, Lisdex, Methlyphen,		Modafinil, sodium oxybate			
HCA taking bloods and nurse administration <=3 monthly. GP interpretation of tests	N/A			Denosumab osteopososis (Year 1)		N/A	N/A	N/A
HCA taking bloods or weighing every 4 to 6 weeks. GP interpretation of test results.	INR level 1 and 2	AZA, MTX			MTP, Mycoph, Penicilla			
Administration and/or clinical measurements by nurse every 4 to 6 weeks								
HCA taking bloods and nurse administration <= 3 monthly. GP interpretation of results.							Denosumab for osteoporosis (Year 2 onwards)	
HCA taking bloods > monthly. GP interpretation of test results								
GP consultation ≤ 3 monthly								
GP consultation and HCA visit (eg. taking bloods) ≤ 3 monthly								
Administration and/or clinical measurements by nurse every 4 to 6 weeks. GP interpretation of results		Leflunomide			**Ciclo, Gold**			
Administration and/or clinical measurements by nurse > monthly								
GP consultation and nurse visit ≤ 3 monthly								

Administration and/or clinical measurements by nurse > monthly. GP interpretation of test results								

Notes:

Tier 5 represents exceptional levels of activity and includes activities where frequent consultation with a GP is required in addition to the usual level of care for a patient with a specific diagnosis.

Shared care guidelines currently funded by NEW Devon CCG and level 1 and 2 INR services are included in Figure One.

Key:

Atomox: Atomoxetine
AZA: Azathioprine
Ciclo: Ciclosporin
GnRH: Gonadorelin analogues
Gold: Sodium aurothalamate
Lisdex: Lisdexamfetamine
Methylphen: Methylphenidate
MTP: Mercaptopurine for inflammatory bowel disease
MTX: Methotrexate
Mycoph: Mycophenolate
Penicilla: Penicillamine
Sulfa: Sulfasalazine

N/A: clinical scenario not applicable to drugs where the GP takes on full clinical responsibility. Under full clinical responsibility, the results of blood samples or anthropometric measurements taken by a HCA would be interpreted by the GP.

*Impact of unfamiliarity with drug and degree of clinical responsibility

Unfamiliarity with drug:

- Established drug used in >1 in 500 patients
- New drug used in >1 in 500 patients
- Use in between 1 in 500 patients and 1 in 2000 patients
- Use in fewer than 1 in 2000 patients

Clinical responsibility:

- “full” responsibility or “shared care”

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