Service Specification No.	5
Service	General Practice Specialised Medicines Service (South Devon and Torbay CCG)
Commissioner Lead	Reviewed by Lucy Morris, Primary Care Project Officer
Provider Lead	
Period	1st July 2017 – 30th June 2020 (3 months' notice will be required to terminate this contract by either party)
Date of Review	1st April 2019

1. Population needs

1.1 National/local context and evidence base

Across Devon there are financial agreements in place for a wide variety of CCG commissioned services which practices may undertake, many relating to medicines use, including activity associated with the prescribing, monitoring or administration of drugs.

There is commonality in intent between these schemes, which is to recompense the practices for the work and/or responsibility undertaken. There is divergence in the drugs included in various schemes and the level of payments made. The differences largely reflect the historical position of commissioning organisations that have existed across Devon and the agreements made on individual services between contractor representatives and the commissioning organisations.

Previous discussions between the CCGs and the LMC have 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, has been further developed and validated against a wider range of medication-related enhanced services. This framework has been 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 to produce high scores.

The enhanced services framework has been 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 is envisaged that the framework will be used to fund shared care guidelines 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.

2. Outcomes

2.1 NHS outcome framework domains and indicators

Domain 1	**Preventing people 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 a safe environment and protecting them from avoidable harm**	✓

2.2 Locally defined outcome

This framework will be used to fund acknowledged 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 agreement of this General Practice Specialist Medicines Service would permit the equitable funding of specialised medication activity across all areas within the South Devon and Torbay CCG footprint. 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 the service

The aim of the proposed Specialist Medicines Service is to support specialised medication activity across SDT CCG footprint 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 framework for primary care provision based on a historical arrangement.

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 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
Impact assessment	Diagnostic Tests	Not required	HCA interpretation	Nurse interpretation	routine GP interpretation	Exceptional	5
	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 ongoing 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.

Medicine	**Service specification**	**Funding tier**	**Fee per patient**
Atomoxetine	Shared care guidance	2	£81.61
Azathioprine	Shared care guidance	2	£81.61
Ciclosporin	Shared care guidance	4	£122.41
Dexamfetamine	Shared care guidance	2	£81.61
Lisdexamfetamine	Shared care guidance	2	£81.61
Leflunomide	Shared care guidance	3	£102.02
Mercaptopurine	Shared care guidance	3	£102.02
Methotrexate (oral formulation only)	Shared care guidance	2	£81.61
Methylphenidate	Shared care guidance	2	£81.61
Penicillamine	Shared care guidance	3	£102.02
Riluzole	Shared care guidance	2	£81.61
Sodium aurothiomalate (gold)	Shared care guidance	4	£122.41
Sulfasalazine	Shared care guidance	1	£47.94

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 provider.

3.4 Any acceptance and exclusion criteria and thresholds

It is envisaged that the framework will be used to fund the shared care guidelines and additional work associated with some specialised drugs prescribed in primary care following secondary care information, 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 that 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.

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

Formal incidents should continue to be reported to NHS England using the SEA form.
https://www.england.nhs.uk/south/wp-content/uploads/sites/6/2015/08/sea-incident-report-form.doc
For any other issues of poor quality or service, parts of the system not working well or negative patient experience. Please continue to complete a Yellow Card form which can be found on the CCG's website:
http://www.southdevonandtorbayccg.nhs.uk/contact-us/yellow_card/Pages/default.aspx

6. Location of Provider Premises

The provider premises.

Appendix 1

Table 1:Historic specialist meds payment framework

Level of activity for GP practice	Weighted Score	Comment
All care undertaken by secondary care		
	0	Example used: level 1 of INR service
Prescribing		
	25-35	Range of scores reflects familiarity with drug. Highest scores given to drugs estimated to be
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
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
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: Historic representation by drug activity and associated tiering

	Impact of unfamiliarity with drug and degree of clinical responsibility*							
Activity level	**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**
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								
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.		Sulfa		Riluzole				
HCA taking bloods or measuring weight approx. 2 monthly. GP interpretation of test results.								
Administration and/or clinical measurements by nurse approx. 2 monthly.								
Administration and/or clinical measurements by nurse ≤ 3 monthly. GP interpretation of test results.								
HCA taking bloods > monthly	N/A					N/A	N/A	N/A
HCA taking bloods or weighing every 4 to 6 weeks. GP interpretation of test results.		AZA, MTX			MTP, Penicilla			
Administration and/or clinical measurements by nurse every 4 to 6 weeks.								
Administration and/or clinical measurements by nurse approx. 2 monthly. GP interpretation of results.					EPO			
HCA taking bloods > monthly. GP interpretation of test results.								
GP consultation ≤ 3 monthly.								
GP consultation and HCA visit (e.g., 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.

Key:
Atomox: Atomoxetine
AZA: Azathioprine
Ciclo: Ciclosporin for dermatological conditions
EPO: Erythropoietin for renal anaemia
Gold: Sodium aurothalamate
Methylphen: Methylphenidate
MTP: Mercaptopurine for inflammatory bowel disease
MTX: Methotrexate for rheumatological conditions
Penicilla: Penicillamine

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"