NHS Standard Contract - SCHEDULE 2 – THE SERVICES

Shared Care Drugs Requiring Monitoring

Service Specification No.	
Service	Shared Care Drugs Requiring Monitoring Local Enhanced Service
Commissioner Lead	Dr Avanthi Gunasekera, Strategic Clinical Executive
Provider Lead	As signed
Period	1 April 2022 to 31 March 2023 ~~1 April 2021 to 31 March 2022~~
Date of Review	Annual review

1. Population Needs

This document outlines the specialised services to be delivered by the provider. The specification of this service is designed to cover the enhanced aspects of clinical care of the patient, all of which are beyond the scope of essential services. No part of the specification by commission, omission or implication defines or redefines essential or additional services.

The service should be provided using the following shared care protocols:
http://www.rotherhamccg.nhs.uk/shared-care-protocols-and-patient-group-directions.htm

1.1 Background
The treatment of several diseases within the fields of medicine, particularly including rheumatology, dermatology and gastroenterology, are increasingly reliant on drugs that, while clinically effective, need regular blood monitoring. This is due to the potentially serious side-effects that these drugs can occasionally cause. It has been shown that the incidence of side-effects can be reduced significantly if this monitoring is carried out in a well organised way, close to the patient's home.

1.2 Aims
The drug monitoring service is designed to be one in which:

- therapy should only be started for recognised indications for specified lengths of time;
- maintenance of patients first stabilised in the secondary care setting should be properly controlled;
- the service to the patient is convenient;
- the need for continuation of therapy is reviewed regularly;
- the therapy is discontinued when appropriate;
- the use of resources by the National Health Service is efficient.

As per the NHS Rotherham CCG Quality Contract, if practices do not wish to deliver this service it must be sub-contracted to another practice following discussions with the CCG. All patients must have access to this service.

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	N/A
Domain 2	Enhancing quality of life for people with long-term conditions	Yes
Domain 3	Helping people to recover from episodes of ill-health or following injury	N/A
Domain 4	Ensuring people have a positive experience of care	Yes
Domain 5	Treating and caring for people in safe environment and	Yes

	protecting them from avoidable harm	

3. Scope

3.1 Service Outline
This Local Enhanced Service will fund:

- **A shared care drug monitoring service** in respect of the following specified drugs:
  - LEFLUNOMIDE
  - METHOTREXATE
  - INTRAMUSCULAR GOLD INJECTIONS
  - SULPHASALAZINE
  - AZATHIOPRINE
  - MYCOPHENOLATE
  - 6-MERCAPTOPURINE
  - DENOSUMAB
  - TESTOSTERONE
  - IBANDRONIC ACID

- Practices will have and maintain an up to date register of all the patients who are being treated under this agreement. As a minimum the register will contain the patient name, date of birth, diagnosis and treatment.
- Practices will have in place a systematic call and recall system for the patients on the register.
- Patients will normally have their medication commenced and stabilized in secondary care prior to being monitored in the primary care setting. Secondary care clinicians will, where appropriate, provide patients and their carers with information in regard to the management of their condition and ensure they know how to access additional information if required.
- Practices will have in place for each patient an individual management plan which gives the reason for treatment, the planned duration, the monitoring timetable and if appropriate, the therapeutic range to be obtained.
- Practitioners providing this service will maintain professional links with the local consultant in the specialties this agreement covers.
- Practices will be expected to accept patients on to the scheme and will facilitate the discharge of patients from secondary care. Practices will be requested by the consultant to take over the patients drug monitoring in writing. ~~, and practices will confirm they have taken on the responsibility for individual patient care in writing.~~
- The practice should always refer to the most up to date version of the shared care protocol via the CCG website, and paper copies need not be sent.
- Practices will ensure that all staff involved with provision of care under this scheme have the necessary training and skills to do so.

3.2 Serious Adverse Events
- Practices will be familiar with and act in accordance with the policy on "Reporting Serious Adverse Events" via the National Reporting Learning System (NRLS) or its successor.
- All emergency admissions or deaths of any patient covered under this service, where such admission or death is or may be due to usage of the drug(s) in question or attributable to the relevant underlying medical condition. This must be reported to the CCG within 72 hours of the information becoming known to the practitioner. This is in addition to the practitioner's statutory obligations.

3.3 Accreditation
Those doctors who have previously provided services similar to the proposed enhanced service and who satisfy at appraisal and revalidation that they have such continuing medical experience, training and competence as is necessary to enable them to contract for the enhanced service shall be deemed professionally qualified to do so.

3.4 Annual Review
Practices will undertake an annual review that will as a minimum include the following information.

- The numbers and diagnosis of each patient group.
- The numbers of new and discharged patients.
- Details of any computer assisted decision making equipment or near patient testing equipment used and arrangements in place for internal and external quality assurance.
- Details of on-going education and training in relation to the provision of this service.
- Assurance that all staff responsible for prescribing have the necessary skills to prescribing safely.

3.5 Activity Reporting
Practices will submit a quarterly data report to the CCG via the LES data worksheet when requested by the Primary Care Team. As a minimum the dataset will include the numbers of total patients, total number of patients monitored by the practice, total new patients this quarter (to clarify this means number of new patients monitored by practice), total follow up appointments and total consultations provided under this scheme.

3.6 Patient Satisfaction
In order to ensure patients are satisfied with the Shared Care Drug Monitoring service, the CCG will undertake a rolling SMART survey to monitor patient satisfaction. GP practices will provide the patient with the appropriate link for completion.

3.7 Remuneration
Remuneration is based on the level of service provision and the numbers of patients in the scheme at the end of each quarter.

Payment will be £110.71 per patient per annum for the following drugs:

- Leflunomide, Methotrexate, Intramuscular gold injections, Sulphasalazine, Azathioprine, Mycophenolate, 6-mercaptopurine

Payment will be £55.36 per patient per annum for the following drugs:

- Denosumab
- Testosterone

Payment will be £27.69 per patient per annum for the following drugs:

- Ibandronic acid

Remuneration will be adjusted on a quarterly basis to reflect the increase or decrease in patients being monitored.

<u>Consequences for late submission of activity data:</u>

- 1 – 7 days: 5% of payment
- 8 – 14 days: 10% of payment and payment won't be released until the next payment run
- 15 – 21 days: 50% of payment and payment won't be released until the next payment run
- Submissions received after 21 days (3 weeks) will receive no payment.

A reminder by email will be sent out at least one week prior to submission date. It is the responsibility of the practice to ensure that any changes to contact details for the Practice lead/ practice manager are notified to the GP Commissioning team.

In the event of unforeseen exceptional circumstances e.g. unplanned admission to hospital, there is scope for the CCG to process a payment without precedent. It is however a practice responsibility to put in place sufficient contingency arrangements to ensure activity is submitted by the date specified.

If the CCG makes a payment to a practice under the LES and :

a) The practice was not entitled to receive all or part thereof, whether because it did not meet the entitlement conditions for the payment **<u>or because the payment was calculated incorrectly</u>** (including where a payment on account overestimates the amount that is to fall

due);or

b) the CCG was entitled to withhold all or part of the payment because of a breach of a condition attached to the payment, but is unable to do so because the money is already been paid,

then the CCG is entitled to repayment of all or part of the money paid.

Any suspicions of fraud will be referred to the CCG's Counter Fraud Specialist for further investigation. It is important to recognise that claiming for procedures that do not fall within the service specification may constitute fraud and will be referred to the CCGs Counter Fraud Specialist for further investigation.

3.8 Audit – Compliance with the Scheme

Practices will be selected at random for audit (and also if the GP for Primary Care identifies any potential irregularities). Practices selected for audit are required to work with the auditors to demonstrate to them that all parts of the scheme have been complied with.

3.9 Termination of Agreement

This service forms part of the basket of enhanced services of the Rotherham Quality Contract, and is therefore subject to the terms outlined in the Quality Contract.

Following the recent publication of the 'Investment and Evolution: A five-year framework for GP contract reform to implement The NHS Long Term Plan' the CCG acknowledges that further guidance may influence the future delivery of Local Enhanced Services.

All Local Enhanced Services will be subject to regular review in line with the development of Primary Care Networks (PCNs). Three months' notice will be given to Providers if services are to transfer to PCN delivery and/or payment.

NHS
Rotherham
Clinical Commissioning Group

Rotherham Shared Care Protocols – Monitoring

ALL prescribing can be passed to the GP after 3 months if patient is stable (or otherwise stated)

	Shared Care Protocols	Monitoring	Initial	Maintenance	On dose increase	Action to take
Methotrexate (Oral[1] & IM[2])	Rheumatology, Dermatology (Oral only)	FBC, U&Es, LFTs & CRP	2 weekly until a stable dose for 6 weeks, Then monthly for 3 months	3 monthly	Additional FBC, U&Es & LFTs after 2, 4 & 6 weeks	IF: WCC <3.5 x10^9/l AST or ALT >100 Neutrophils <1.8 x10^9/l Platelets <150 x10^9/l **OR:** Severe sore throat / Oral Ulceration / Fever / Rash **Stop medication** and contact consultant
Mycophenolate	Rheumatology	FBC, U&Es, LFTs & CRP	2 weekly until a stable dose for 6 weeks, Then monthly for 3 months	3 monthly	Additional FBC, U&Es & LFTs after 2, 4 & 6 weeks	
Azathioprine	Rheumatology & Gastroenterology	FBC, U&Es, LFTs & CRP	2 weekly until a stable dose for 6 weeks, Then monthly for 3 months	3 monthly	Additional FBC, U&Es & LFTs after 2, 4 & 6 weeks	
Sulphasalazine	Rheumatology & Gastroenterology	FBC, U&Es, LFTs & CRP	2 weekly until a stable dose for 6 weeks, Then monthly for 3 months	3 monthly up to 12 months Then 6 monthly	NONE	
6-mercaptopurine	Gastroenterology	FBC, U&Es, LFTs & CRP	2 weekly for a month & monthly for 2 months	3 monthly	Additional FBC, U&Es & LFTs after 2, 4 & 6 weeks	
IM Gold	Rheumatology	FBC, U&Es, LFTs, CRP & urine dipstick	Monthly for 2–4 months	FBC & urine dipstick prior to EACH injection[3]	Additional FBC, U&Es & LFTs after 2 & 4 weeks	**As above** and if 1+ protein on 2 consecutive occasions with negative MSU
Leflunomide	Rheumatology	FBC, U&Es, LFTs, CRP & BP	2 weekly until a stable dose for 6 weeks, Then monthly for 3 months	3 monthly	Additional FBC, U&Es & LFTs after 2, 4 & 6 weeks	**As above** and STOP If blood pressure increases and cannot be controlled with medication
Hydroxychloroquine	**NO** Shared Care Protocol or LES payment prescribing can transfer at 4 weeks. Rheumatology	Baseline FBC, U&Es, LFTs U&Es 6 monthly in those over 60 or at risk of renal impairment If pre-existing eye disease annual assessment with optometrist or earlier if significant changes				
Denosumab	Metabolic Bone Clinic at Northern General Hospital	Prior to injection at 6 months: Check PINP (reduced by 10ng/ml from baseline and/or the level is <35ng/ml) Serum Calcium (range 2.2-2.6mmol/l)		6 monthly thereafter	Serum Calcium prior to each injection (range 2.2-2.6mmol/l)	If hypocalcaemia do not administer and contact MBC
Testosterone[4] (Topical & IM)	Urology have SCP	Before 10am: PSA & serum testosterone and FBC includ. haematocrit		6 monthly	NONE	Phone Urology for advice (Or initiating department)
Ibandronic acid in women with breast Cancer	Oncology	Renal function & Serum Calcium		Annual	If Calcium out of range or renal function becomes severe (eGFR < 30 ml/min) – discontinue and contact consultant. Reduce dose if eGFR < 50 ml/min (see SCP)	

ALL prescribing can be passed to the GP after 3 months if patient is stable (or otherwise stated)

[1] Oral Methotrexate can be prescribed & Monitored by GPs under the SCP and LES

[2] IM methotrexate is RED and prescribing **cannot** be passed to the GP. Monitoring can be done via the LES and payment received.

[3] IM Gold - after 3 months it is permissible to work one FBC in arrears

[4] LES can also be claimed for other departments such as Endocrinology, Andrology & Transgender

Eloise Summerfield, Medicines Management Team, Rotherham CCG, October 2019

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