HIGH RISK DRUG MONITORING SERVICE SPECIFICATION

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Contracts for Enhanced Services
1 October 2024- 31 March 2030

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1 INTRODUCTION

This Service Specification forms the Local Enhanced Service (LES) for High-Risk Drug Monitoring in primary care.

This Service Specification works towards meeting the Scottish Government priorities and NHSH Local Delivery Plan (LDP): Outcome 3, Stay well and Outcome 4, Anchor well.

2 CLINICAL SPECIFICATION

Purpose

The purpose of this LES is to provide a safe and effective care for patients taking specified high-risk medication; to include Disease Modifying Anti-Rheumatic Drugs (DMARDs).

Service Aims

This LES service provides **a drug monitoring service** in respect of the following specified drugs under a shared care agreement:

- Apremilast
- Azathioprine
- Ciclosporin (Also Spelt Cyclosporin)
- Hydroxychloroquine
- Leflunomide
- Mercaptopurine
- Mesalazine
- Methotrexate
- Mycophenolate
- Penicillamine
- Sulphasalazine
- Tacrolimus

** Sulphasalazine and Mesalazine (monitoring is **NOT** claimable after 1 year from stabilisation of dose).

No other drugs are claimable. NHS Highland will continually review this list of specified drugs.

Prescribers must ensure that they have a failsafe system for checking that it is safe to continue prescribing these drugs, which can be verified at any subsequent payment verification visit, and we therefore strongly recommend that the results from the relevant blood monitoring tests i.e. from within the required time period, are <u>available and support continuing use of the drug before</u> signing prescriptions and that this check has been recorded in patients' contemporaneous medical records.

Service Criteria

Enhanced service requirement
From 1 October 2024 the practice must: Confirm that all patients being monitored in primary care are coded in accordance with the LES. High risk drug monitoring - primary care (**READ code 66P7**)
Ensure the correct clinical coding and template is used to ensure compliance with the

recording and monitoring requirements of the LES.
Accept clinical responsibility for the patient provided the shared care criteria have been met. Repeat prescribing no sooner than specified in the shared care agreement after initiation.
Be able to produce and maintain an up-to-date register of all high-risk drug monitoring service patients, indicating patient name, date of birth, the indication and intended duration of treatment, date of last hospital appointment, as well as a schedule of monitoring results.
Ensure that systematic call and recall of patients on the register is taking place for blood monitoring in line with the shared care agreement.
Discuss any important test abnormality (out with shared care parameters) or suspected adverse reactions with the consultant before continuing treatment.
Ensure that the patient (and/or their carers when appropriate) has and is given a copy of an individual management plan, which gives the reason for treatment, the planned duration and a monitoring timetable.
Referral for pneumococcal and influenza vaccination if required.
Annual review and audit to ensure compliance with the monitoring schedules.

Training
The service shall have an appropriate staffing structure in terms of skill, experience and numbers and shall be delivered by appropriately qualified and trained individuals.

The provider will ensure that all clinical staff meet the CPD requirements of their professional and regulatory bodies, that they are competent to deliver the service and that their skills are regularly updated.

Useful links
DMARD monitoring in Primary Care (nhsh.scot)
The monitoring schedules are based on the British Society for Rheumatology (BSR) and British Health Professionals in Rheumatology (BHPR) guidelines for disease-modifying anti-rheumatic drug (DMARD) therapy, in consultation with the British Association of Dermatologists and accredited by NICE
Patient information - Disease-modifying anti-rheumatic drugs (DMARDs) | Side-effects (versusarthritis.org)

Recording Information
The following read codes will be used for monitoring and payment purposes:

2 codes required to claim under this LES – DMARD service code & DMARD monitoring in general practice. The others are to support audit and clinical care.

Please note apremilast, sulphasalazine and mesalazine where monitoring is either not required, or has ceased – add code ‘monitoring no longer required’.

Read codes	Screen description	Read code description	When to be used
9kD..	Commence DMARD service	NPT – enhanced service admin	When patient commences service - **claim**
66P7	DMARD monitored (in general practice)	High risk drug monitoring - primary care	All patients currently taking one of the listed drugs /

			New registered patients / existing patients starting any of the listed drugs with shared care request from secondary care - **claim**
66P9	High risk drug monitored elsewhere	High risk drug monitoring – secondary care	All patients currently taking one of the listed drugs / New registered patients / existing patients starting any of the listed drugs being monitored in secondary care - no claim
9NiL	DNA monitoring appointment	DNA GP DMARD Monitor clinic	If a patient fails to attend for monitoring
8CAG	Check / advise Pneumococcal immunisation up to date	Pneumococcal immunisation advised in surgery	GP has considered, advised +/- referred for immunisation - audit
68NN	Check / advise flu immunisation up to date	Influenza immunisation advised in surgery	GP has considered, advised +/- referred for immunisation - audit
8CT7	Monitoring no longer required	Stopped by healthcare professional	On high risk medication (from list) not, or no longer, requiring monitoring – no claim
9kD0.	Complete DMARD service	NPT – enhanced service completed	When medication is stopped or monitoring requirement completed – stop claim

3 QUALITY

Practices will be expected to participate in an audit as part of the overall quality assurance of the service. This should demonstrate compliance with the monitoring schedules. Details as specified in section 2.1 to 2.4

4 FINANCE & SERVICE PRICING

Contract value

Payment per patient registered under high-risk drug monitoring service in primary care per annum.

The payment for patients being monitored in general practice will be **£226.53** per annum.

No payment can be claimed for patients being monitored under secondary care.

5 DRUG MONITORING REQUIREMENTS

The following shared care drugs will be included in the service specification. Indications and monitoring details will be in line with national or local guidelines and this section updated by 1 February 2024.

Please also refer to:
DMARD monitoring in Primary Care (resources)
DMARD monitoring in Primary Care (Resources) | Right Decisions (scot.nhs.uk)
General Principles of Managing adults on Disease-modifying anti-rheumatic drugs (DMARDs).
Scenario: General principles of managing DMARDs | Management | DMARDs | CKS | NICE

Drug	Apremilast	
Dosage Regimes	As advised by specialist	
Monitoring	Laboratory monitoring	None required
TAM Link	https://cks.nice.org.uk/topics/dmards/management/monitoring-of-dmards/#apremilast	
Note	No associated payment due to nil monitoring requirements – to be included on register only.	

Drug	Azathioprine	
Dosage Regimes	As advised by specialist	
Monitoring	FBC, U&E, LFTs	• Prior to treatment, then • every 2 weeks until dose stable for 6 weeks, then • monthly for 3months, then • every 12 weeks
	Dose Increase	Every 2 weeks until dose stable for 6 weeks, then revert to previous schedule.
	High Risk of toxicity	Monitor more frequently
TAM Link	https://cks.nice.org.uk/topics/dmards/management/monitoring-of-dmards/#azathioprine	

Drug	Ciclosporin (Also Spelt Cyclosporin)	
Dosage Regimes	As advised by specialist	
Monitoring	FBC, U&E, LFTs, glucose & BP	• Prior to treatment, then • every 2 weeks until dose stable for 6 weeks, then • monthly
	Lipids	As above if prescribed by dermatology
	Long term	People who have been stable for 12months can be considered for reduced monitoring frequency (every 3 months) on an individual basis.
	Dose Increase	Every 2 weeks until dose stable for 6 weeks, then revert to previous schedule.
	High Risk of toxicity	Monitor more frequently

TAM Link	https://cks.nice.org.uk/topics/dmards/management/monitoring-of-dmards/#ciclosporin
Note	Specific dermatology monitoring above that required by rheumatology: Drugs affecting the immune response (Formulary) | Right Decisions (scot.nhs.uk)

Drug	Hydroxychloroquine	
Dosage Regimes	As advised by specialist	
Monitoring	U&E	Prior to treatment, then Annually in people aged over 70; and in those with pre-existing renal impairment, hypertension, and/or diabetes.
	Eye assessment (ideally including optical coherence tomography)	Annually for all people who have taken hydroxychloroquine for greater than 5years; or if on tamoxifen; or if eGFR <60; or if high-dose therapy (>5mg/kg/day)
TAM Link	https://cks.nice.org.uk/topics/dmards/management/monitoring-of-dmards/#hydroxychloroquine	

Drug	Leflunomide	
Dosage Regimes	As advised by specialist	
Monitoring	FBC, U&E, LFTs, BP & weight	• Prior to treatment, then • every 2 weeks until dose stable for 6 weeks, then • monthly for 3months*, then • every 12 weeks
	Dose Increase	Every 2 weeks until dose stable for 6 weeks, then revert to previous schedule.
	High Risk of toxicity	Monitor more frequently
* If leflunomide is **combined with methotrexate**, continue monthly monitoring until stable for 12 months, then consider reduced frequency on individual basis.		
TAM Link	https://cks.nice.org.uk/topics/dmards/management/monitoring-of-dmards/#leflunomide	

Drug	Mercaptopurine	
Dosage Regimes	As advised by specialist	
Monitoring	FBC, U&E, LFTs	• Prior to treatment, then • every 2 weeks until dose stable for 6 weeks, then • monthly for 3months, then • every 12 weeks
	Dose Increase	Every 2 weeks until dose stable for 6 weeks, then revert to previous schedule.
	High Risk of toxicity	Monitor more frequently
TAM Link	For mercaptopurine look at the requirements for azathioprine	

	https://cks.nice.org.uk/topics/dmards/management/monitoring-of-dmards/#azathioprine

Drug	Mesalazine	
Dosage Regimes	As advised by specialist	
Monitoring	FBC*, U&E, LFTs	• Prior to treatment, then • every 2 weeks until dose stable for 6 weeks, then • monthly for 3 months, then • at least every 12 weeks
	Long term	After 12 months, monitoring may be stopped
	Dose Increase	Every 2 weeks until dose stable for 6 weeks, then revert to previous schedule.
	High Risk of toxicity	Monitor more frequently
* Urgent FBC if patient complains of intercurrent illness during initiation of treatment.		
TAM Link	For mesalazine look at the requirements for sulphasalazine https://cks.nice.org.uk/topics/dmards/management/monitoring-of-dmards/#sulfasalazine	
Note	No associated payment once no further monitoring required – to be included on register only.	

Drug	Methotrexate	
Dosage Regimes	As advised by specialist	
Monitoring	Urinalysis	Prior to treatment
	FBC, U&E, LFTs	• Prior to treatment, then • every 2 weeks until dose stable for 6 weeks, then • monthly for 3 months*, then • at least every 12 weeks
	Procollagen III	Every 3 months if treatment is for psoriasis
	Dose Increase	Every 2 weeks until dose stable for 6 weeks, then revert to previous schedule.
	High Risk of toxicity	Monitor more frequently
* If methotrexate is **combined with leflunamide**, continue monthly monitoring until stable for 12 months, then consider reduced frequency on individual basis.		
TAM Link	https://cks.nice.org.uk/topics/dmards/management/monitoring-of-dmards/#methotrexate	
Note	Dermatology will perform clinical monitoring every 3 months Drugs affecting the immune response for eczema (Formulary) | Right Decisions (scot.nhs.uk)	

Drug	Mycophenolate	
Dosage Regimes	As advised by specialist	
Monitoring	FBC, U&E, LFTs	• Prior to treatment, then • every 2 weeks until dose

		stable for 6 weeks, then • monthly for 3 months, then • at least every 12 weeks
	Dose Increase	Every 2 weeks until dose stable for 6 weeks, then revert to previous schedule.
	High Risk of toxicity	Monitor more frequently
TAM Link	https://cks.nice.org.uk/topics/dmards/management/monitoring-of-dmards/#mycophenolate-mofetil	

Drug	Penicillamine	
Dosage Regimes	As advised by specialist	
Monitoring	FBC, U&E, LFTs & urinalysis (blood/protein)	• Prior to treatment, then • every 2 weeks until dose stable for 6 weeks, then • monthly
	Long term	After 12 months, consider reducing monitoring to 3 monthly
	Dose Increase	Every 2 weeks until dose stable for 6 weeks, then revert to previous schedule.
TAM Link	https://cks.nice.org.uk/topics/dmards/management/monitoring-of-dmards/#penicillamine	

Drug	Sulphasalazine	
Dosage Regimes	As advised by specialist	
Monitoring	FBC*, U&E, LFTs	• Prior to treatment, then • every 2 weeks until dose stable for 6 weeks, then • monthly for 3 months, then • at least every 12 weeks
	Long term	After 12 months, monitoring may be stopped
	Dose Increase	Every 2 weeks until dose stable for 6 weeks, then revert to previous schedule.
* Urgent FBC if patient complains of intercurrent illness during initiation of treatment.		
TAM Link	https://cks.nice.org.uk/topics/dmards/management/monitoring-of-dmards/#sulfasalazine	
Note	No associated payment once no further monitoring required – to be included on register only.	

Drug	Tacrolimus	
Dosage Regimes	As advised by specialist	
Monitoring	FBC, U&E, LFTs, glucose & BP	• Prior to treatment, then • every 2 weeks until dose stable for 6 weeks, then • monthly
	Long term	People who have been stable for 12months can be considered for

		reduced monitoring frequency (every 3 months) on an individual basis.
	Dose Increase	Every 2 weeks until dose stable for 6 weeks, then revert to previous schedule.
	High Risk of toxicity	Monitor more frequently
TAM Link	https://cks.nice.org.uk/topics/dmards/management/monitoring-of-dmards/#tacrolimus	

When to Refer:
https://cks.nice.org.uk/topics/dmards/management/general-principles-of-managing-dmards/#when-to-refer

- **For people on any High Risk Monitoring Drug, or other Disease-modifying anti-rheumatic drug (DMARD), consider stopping treatment and referring urgently to specialist if monitoring results show any of the following:**
  - White cell count lower than 3.5 x 10^9/L.
  - Mean cell volume higher than 105 fL.
    - Check B12, folate, and thyroid-stimulating hormone levels.
    - If abnormal, treat; if normal, discuss with specialist team.
  - Neutrophils lower than 1.6 x 10^9/L.
  - Creatinine has increased by more than 30% over 12 months and/or calculated glomerular filtration rate (GFR) is lower than 60 mL/min.
    - Repeat in 1 week.
    - If still more than 30% from baseline, withhold and discuss with specialist team.
  - Unexplained eosinophilia higher than 0.5 x 10^9/L.
  - Alanine aminotransferase (ALT) and/or aspartate transaminase (AST) higher than 100 U/L.
  - Platelet count lower than 140 x 10^9/L.
  - Unexplained reduction in albumin lower than 30 g/L.
  - Blood pressure higher than 140/90mmHg.
    - If on ciclosporin, stop treatment and discuss with specialist team.
    - If on other DMARDs, manage in accordance with hypertension guidelines.
  - Urinary protein 2+ or more.
    - Check mid-stream urine sample.
    - If evidence of an infection, treat appropriately; if sterile and 2+ proteinuria or more persists on two consecutive measurements, withhold until discussed with specialist team.
- **For people on any High Risk Monitoring Drug, or other Disease-modifying anti-rheumatic drug (DMARD), consider stopping treatment and referring urgently to rheumatology if the person develops any of the following signs or symptoms:**
  - Skin/mucosal reaction, for example rash, pruritus, mouth, or throat ulceration.
  - Sore throat.
  - Fever.
  - Unexplained bruising, or bleeding.
  - Nausea, vomiting, diarrhoea, or weight loss.
  - Diffuse alopecia.
  - Breathlessness, infection, or cough.
  - Peripheral neuropathy.

- **For a person on a biologic DMARD, consider stopping treatment and referring urgently to rheumatology if the person develops any of the following:**
    - Cough, haemoptysis, or weight loss (symptoms of tuberculosis).
    - Signs or symptoms of heart failure, or worsening heart failure. For more information.
    - Shortness of breath or dry cough (symptoms of interstitial lung disease).
    - Skin rashes (be aware of lupus-like syndrome and erythema nodosum for people taking azathioprine).
    - Abdominal pain or new abdominal symptoms.