South East London Integrated Care System

Blood monitoring recommendations for Primary Care during Synnovis Cyber Attack

SEL Medicines Optimisation Team

Version: 11th July 2024

Approved by: South East London Integrated Medicines Optimisation Committee (SEL IMOC) via the urgent Triage Panel process following a rapid consultation and review

Original approval Date: 19th June 2024 **Last updated: 11th** July 2024 **Review Date:** September 2024

Note: This document is subject to regular change due to the evolving nature of the situation.

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Drug monitoring context and introduction

- The following slides offer interim advice on how best to manage blood test monitoring for a **selected range of common high-risk drugs** prescribed in primary care during the Synnovis incident period. This list is not comprehensive, and we will continue to update as we develop recommendations.
- Recommendations are largely based on advice issued nationally during Covid (Specialist Pharmacy Services) and local specialist expertise. This advice aims to be pragmatic and recommendations sit outside of published licensed information, local shared care guidelines and local/national guidance. The advice contained here should nonetheless be used alongside any usual clinical guidelines in place.
- Special consideration should be given to children and young people, frail and vulnerable adults, those with multimorbidity and polypharmacy.
- These recommendations aim to support healthcare professionals in making individual clinical decisions to best address patient needs at this time.
- Practices should agree internal processes for decision making and involving patients when changes are made to any blood monitoring (including for prescribed medication).
- If in doubt: Seek senior support in your organisation, utilise Consultant Connect, Advice and Guidance, and/or refer to Medicines Information service (see slide 4).

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General principles for drug monitoring

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Factors to consider

- **Discuss with the patient**
- **When starting therapy:**
  - Is it essential to initiate this drug immediately?
  - Is there a safer alternative? If it is in the best interests of the patient to select a treatment strategy that is outside an established treatment pathway, please document the reasons for this clearly in the notes. Reasons might include selection of an intervention with lower frequency monitoring/better risk profile in the context of the Synnovis incident.
- **When established on therapy**
  - There will be many patients who have been on the same medication for significant periods of time with adequate disease control and blood monitoring that has remained satisfactory
  - Is this treatment still required?
  - Is testing essential?
  - Can the monitoring intervals be extended safely?
  - It may be possible to safely increase the time interval for blood monitoring on a case-by-case basis. Where this is assessed to be appropriate, **the prescriber should document in the patient notes** that the prescription can be continued (specify duration and a timeline plan for when it will be necessary for the patient to next have monitoring bloods taken).
- **Documenting actions:**
  - Ensure you clearly document in the patient record any actions regarding changes to drug treatment or delayed blood testing outside of routine practice as a result of reduced blood testing capacity.
  - Use the Ardens templates to flag patients who will need to be recalled for testing

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Contact details for specialist advice

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- The following medicines helplines can be contacted for **patient specific** advice:
- For GSTT patients: Medicines Information: 020 7188 8748 (Monday – Friday 9am-5pm)
- For KCH patients: Medicines helpline: 020 3299 0588 (Monday – Friday 9.30am-4.30pm)
- For LGT patients: Medicines helpline: 020 8836 4900 (Monday – Friday 9am-5pm)
- For mental health related medicines:
  - SLaM Medicines Information: 020 3228 2317 (Monday – Friday 9am-5pm)
  - Oxleas Medicines Information: 01322 625002 (Monday – Friday 9am-4:45pm)
    Email: oxl-tr.medicinesinfo@nhs.net
- Other medicines queries can be referred to Specialist Pharmacy Services via: https://www.sps.nhs.uk/home/about-sps/get-in-touch/medicines-information-services-contact-details/

- Please also refer to the relevant shared care guideline on the SEL Integrated Medicines Optimisation Committee's (IMOC) webpage. Secondary care specialist contact details are included within each shared care guideline:
https://www.selondonics.org/icb/healthcare-professionals/medicines/sel-imoc/sel-imoc-shared-care-agreements/

Drug Class	Usual blood monitoring recommendations	Blood monitoring recommendations during reduced pathology capacity (for adults)		Considerations
ACE inhibitor / ARB / ARNI (sacubitril valsartan)	Baseline: U&Es and eGFR. Repeat two weeks after initiation or dose change, then at least annually thereafter (more frequently if clinically indicated)	**Hypertension**		
		During stabilisation For new initiation: • prioritise patients with the highest blood pressure first • for uncomplicated hypertension – consider using amlodipine first line, to avoid need for renal monitoring. In patients requiring ACEI / ARB for blood pressure control, diabetes or renoprotection – consider initiation as blood testing capacity allows. If previous blood test results have been stable, consider using baseline blood results from up to 6 months previously and **undertake usual blood monitoring** post-initiation/ dose titration.	**Once stable** If stable renal function and normal potassium levels, consider delaying routine checks for up to 6 months‡ Extending the monitoring interval is not suitable if the patient has: • Poor or declining renal function with CKD stage 3-5 • Severe liver disturbance or abnormal liver results within previous 3 months Extending the monitoring interval may not be suitable for patients with multiple / complex co-morbidities, polypharmacy or who are elderly or frail.	Optimise lifestyle interventions – smoking cessation, weight loss, diet, physical activity and alcohol. See page 3 of the CESEL hypertension Resource Pack *Other drugs that do not require renal monitoring include: • Doxazosin: Doxazosin monotherapy for hypertension has been associated with increased risk of hospitalisation for heart failure • Beta-blockers: Beta-blockers provide less protection from stroke than other anti-hypertensive drug classes

ACEI = Angiotensin Converting Enzyme Inhibitor
ARB = Angiotensin II receptor blocker
‡More frequent monitoring may be recommended by specialist clinicians for individual patients, which will be communicated to the GP on a case-by-case basis

Drug Class	Usual blood monitoring recommendations	Blood monitoring recommendations during reduced pathology capacity (for adults)		Considerations
Aldosterone antagonists - Spironolactone / eplerenone	Baseline U&Es, and eGFR Repeat 1 week after initiation or dose change Then monthly for first 3 months and then 3 to 6 monthly thereafter	**Heart Failure**		
		During stabilisation Patients requiring ACEI / ARB, sacubitril valsartan or aldosterone antagonist initiation or up titration for heart failure with reduced ejection fraction – refer to the community heart failure team	**Once stable** Consider extending the monitoring interval up to every 6 months.‡ More frequent monitoring may be recommended by specialist clinicians for individual patients, which will be communicated to the GP on a case-by-case basis. Extending the monitoring interval is not suitable if the patient has: • Poor or declining renal function with CKD stage 3-5 • Severe liver disturbance or abnormal liver results within previous 3 months Extending the monitoring interval may not be suitable for patients with multiple / complex co-morbidities, polypharmacy or who are elderly or frail.	Concerns – seek advice from the community HF teams in the first instance: • Bexley: Email: oxl-tr.cardiac@nhs.net Tel: 020 7188 8952 or 0208 3197060 • Bromley: Email: kch-tr.PRUHheartfailurenurses@nhs.net Tel: 01689866097 and Bleep number is 739 Email: kch-tr.br-bromleyintegratedheartfailurenurses@nhs.net Tel: 0797 1484 508 • Greenwich: Email: oxl-tr.cardiac@nhs.netTel: 0208 3197060 • Lambeth & Southwark: Email: Gst-tr.KHPcommunityHF@nhs.net Tel: 020 3049 4652 • Lewisham: Email: LH.commuhfreferrals@nhs.net Tel: 0203 049 3473

ACEI = Angiotensin Converting Enzyme Inhibitor
ARB = Angiotensin II receptor blocker
‡More frequent monitoring may be recommended by specialist clinicians for individual patients, which will be communicated to the GP on a case-by-case basis

<table>
<tr><th>Drug Class</th><th>Usual blood monitoring recommendations</th><th>Blood monitoring recommendations during reduced pathology capacity (for adults)</th><th>Considerations</th></tr>
<tr><td>Anticoagulants
Warfarin</td><td>INR checked frequently (up to daily) during loading phase, and at least 12 weekly once stable</td><td>Patients bleeding while on warfarin require urgent bloods via the emergency pathway.
INR Point of Care Testing should be considered first line as available. Venous samples should be used for monitoring out of therapeutic range for all appropriate indications.

During stabilization

More frequent routine monitoring (for example every 1–2 weeks) of the INR is recommended for people:
• At an increased risk of over coagulation, for example people with severe hypertension, liver disease (including alcoholic liver disease), or end-stage renal failure/dialysis.
• At increased risk of bleeding, for example people on high-intensity anticoagulation
• Aged ≥ 65 years and older for whom adherence to treatment may be difficult
• With recent out of range result (target INR ≥3.5)

New initiation for atrial fibrillation – consider a DOAC first line
See: SEL IMOC - Cardiovascular disease guidance - NHS South East London (selondonics.org)

Once stable

Once a stable INR has been achieved, changes in dose are seldom required. These patients should have an INR check at least once every 12 weeks.

Use point of care testing devices wherever available.
If INR > 5 or < 1.5 recheck a venous sample

For atrial fibrillation: Consider if patient may be suitable to switch to DOAC.

Consider self-checking of INR if remaining on warfarin.</td><td>Seek advice from local anticoagulant clinics where necessary (email):
• UHL: LH.Anticoagulation@nhs.net
• QEH: LG.QEAnticoagulant@nhs.net
• PRUH: kch-tr.br-anticoag@nhs.net
• KCH: kch-tr.dh-anticoag@nhs.net
• GSTT: gst-tr.anticoag@nhs.net
• Bexley community service at Bellegrove surgery: anticoag.bellegrove@nhs.net and The Albion surgery: albion.anticoag@nhs.net
• Bromley GP Alliance (BGPA): selicb.bgpaanticoagulation@nhs.net</td></tr>
</table>

INR = International Normalised Ratio
DOAC = Direct Oral Anticoagulant

Drug Class	Usual blood monitoring recommendations	Blood monitoring recommendations during reduced pathology capacity (for adults)		Considerations
Anticoagulants DOACs	Use blood results from within the last month to calculate CrCl. Serum creatinine should be checked at regular intervals based on creatinine clearance: • CrCl >60ml/min – check annually • CrCl 30-60ml/min – check 6 monthly • CrCl < 30ml/min – check 3 monthly • Elderly aged >75years and/or frail- check CrCl every 4 to 6 months and Hb/FBC At Initiation check clotting screen, U&Es and FBC.	**During stabilization** New initiation of DOACs in patients with stable U&Es and eGFR (CrCl) , clotting screen, LFTs, FBC - use baseline blood results from the previous six months – check local care record. In people with deteriorating or fluctuating renal function – do not delay renal monitoring. Where patients are at a boundary of dose adjustment e.g. CrCl 30ml/min for apixaban, CrCl 50ml/min for rivaroxaban and edoxaban, a dose adjustment may be required and so a current renal function would be necessary or consider a change to an alternative DOAC agent with a different dose adjustment threshold.	**Once stable** Where the routine 3, 6 or 12 monthly renal function check is due, consider delaying for up to 6 months if renal function has previously been stable. Patients with complex co-morbidities, such as heart failure or CKD stage 3-5 may require more frequent monitoring Patients with unexplained bleeding should have renal function, LFTs and FBC checked as a matter of urgency. Major bleeding refer to Emergency Department.	For patients prescribed DOACs for VTE please contact your local Anticoagulant clinic for queries/concerns (contact details above)
Digoxin	Annual checks: Serum calcium; Serum creatinine (for creatinine clearance); Serum magnesium· increased frequency may be required if long-term PPI co-prescribed, other medicines pre-disposing to hypomagnesaemia, or low calcium level; Serum potassium; Urea and electrolytes	**During stabilisation** No new initiations where renal function and U&E blood tests cannot be undertaken. Dose adjustments- seek specialist cardiology advice.	**Once stable** If signs of toxicity such as confusion, nausea, anorexia, or disturbance of colour vision - patient must stop taking and be referred to Emergency Department for urgent assessment. If previously stable renal function, - consider delaying routine monitoring for up to 6 months.	Monitor heart rate (bradycardia <60bpm)

DOAC = Direct Oral Anticoagulant
CrCl = Creatinine Clearance
CKD = Chronic Kidney Disease

Drug Class	Usual blood monitoring recommendations	Blood monitoring recommendations during reduced pathology capacity (for adults)		Considerations
Thiazide-type and thiazide diuretics	Baseline U&Es and eGFR Repeated 2 weeks after initiation. Repeat at least annually or more frequently if clinically indicated.	**Hypertension (indapamide / bendroflumethiazide)**		
		During stabilisation Consider using amlodipine in preference to a thiazide type diuretic, to avoid need for renal monitoring. For new initiation- baseline U&Es and eGFR- repeat 2 weeks after initiation and if clinically indicated thereafter. In patients requiring initiation of a thiazide type diuretic at step 2 or beyond, do not delay initiation and undertake usual blood monitoring.	**Once stable ‡** If previously stable renal function and normal potassium levels consider delaying routine checks for up to 6 months .	Optimise lifestyle interventions – smoking cessation, weight loss, diet, physical activity and alcohol. See page 3 of the CESEL hypertension resource pack
		Heart Failure (metolazone/bendroflumethiazide)		
		During stabilisation As an adjunct to loop diuretics for resistant oedema - to be managed by the HF teams. Initiation and up titration for heart failure with reduced ejection fraction – refer to the community heart failure team concerns – seek advice (HF Specialist team contact details above).	**Once stable** Consider extending the monitoring interval up to every 6 months.‡ Extending the monitoring interval is not suitable if the patient has: • Poor or declining renal function with CKD stage 3-5 • Severe liver disturbance or abnormal liver results within previous 3 months	

‡More frequent monitoring may be recommended by specialist clinicians for individual patients, which will be communicated to the GP on a case-by-case basis

Drug Class	Usual blood monitoring recommendations	Blood monitoring recommendations during reduced pathology capacity (for adults)		Considerations
Loop diuretic eg furosemide	Baseline U&Es and eGFR Repeated 2 weeks after initiation or dose change, then at least annually. High risk patients on diuretics with more frequent monitoring recommended includes those: • With existing chronic kidney disease (stage 3 or higher) • Aged 60 years or over • With relevant comorbidities such as diabetes mellitus or peripheral arterial disease • Taking a combination of a diuretic plus an angiotensin-converting enzyme (ACE) inhibitor, an angiotensin-II receptor antagonist (AIIRA), or an aldosterone antagonist • Those taking digoxin or drugs that prolong the QT interval (such as amiodarone) • Those with paroxysmal arrhythmias, unstable angina, or chronic liver disease	**During stabilisation** Initiation and dose titration – baseline and recheck within 2 weeks Check clinical management plan and / or seek advice from the community heart failure team where necessary.	**Once stable ‡** Stable dose, no clinical concerns – delay monitoring (3 to 6 months) Be aware of signs and symptoms of • fluid overload (under diuresis) and dehydration (over diuresis) that may require diuretic dose adjustments. Seek advice/refer to HF team if: patient is fluid overloaded, symptomatic hypotension, increasingly shortness of breath, rapid weight gain • HF decompensation that may require hospitalisation eg reduced urine output, fatigue and confusion, and evidence of ventricular arrythmias HF patients should be encouraged to monitor their body weights daily and report changes of >1.5kg above dry weight OR rapid weight gain over 2 to 3 days	Refer to information in SEL IMOC Heart Failure Guidance and seek advice from HF specialist team (contact details are above)

‡More frequent monitoring may be recommended by specialist clinicians for individual patients, which will be communicated to the GP on a case-by-case basis

<table>
<tr><th>Drug Class</th><th>Usual blood monitoring recommendations</th><th colspan="2">Blood monitoring recommendations during reduced pathology capacity (for adults)</th><th>Considerations</th></tr>
<tr><td rowspan="3">Statins and other lipid lowering therapies (LLTs)</td><td rowspan="3">Baseline: Lipid Profile, U&Es, LFTs, TSH, HbA1c, Urate (History of gout or raised uric acid)

3 months: LFTs, Lipid profiles, HbA1c (if uncontrolled), CK (if experiences muscle-related symptoms)

Annual: Lipids, LFTs (if clinically indicated)</td><td colspan="2">Consider fasting blood tests to minimise risk of raised triglycerides and need for repeat tests.</td><td rowspan="3">Optimise lifestyle interventions
See SEL IMOC Lipid Modification Guidance</td></tr>
<tr><td>During stabilisation</td><td>Once stable</td></tr>
<tr><td>Decisions to initiate lipid lowering therapies can be based on blood results within the past 12 months. For initiation of statins - lipid levels and liver transaminases results will suffice .

Prioritise for LLT initiation secondary prevention patients with evidence of uncontrolled LDL-C ≥2.5mmol/L in the last 6 months. Consider lower dose statin (atorvastatin 20mg) for patients with borderline eGFR (< 30 ml/min/1.73 m2).

Delay optimisation of patients with a history of myopathy or history of raised CK unless considered high risk.

If a patient experiences unexplained muscle symptoms (pain, tenderness or weakness) – check creatine kinase urgently.

Patients who have recently started or up-titrated a LLT, requiring their 3-month check: delay routine monitoring unless clinically indicated or a suspected adverse drug reaction.</td><td>In stable patients – delay routine lipid and LFT monitoring for up to 6 months.

If a patient experiences unexplained muscle symptoms (pain, tenderness or weakness) – check creatine kinase urgently.

For queries about medications started or optimised between March and May 2024, advice is available from Lipid Specialist Pharmacists:
• Lewisham and Greenwich – julia.parascandolo@gstt.nhs.uk
• Bexley and Lambeth – christiana.osmond@gstt.nhs.uk
• Bromley and Southwark – wasim.miyanji@gstt.nhs.uk</td></tr>
</table>

LLT = Lipid Lowering Therapy

Drug	Usual blood monitoring recommendations	Blood monitoring recommendations during reduced pathology capacity		Considerations
		During stabilisation	Once stable	
Denosumab	Adjusted Calcium: Before each dose *Patients with renal dysfunction:* • *Cockcroft-Gault CrCl < 30ml/min, eGFR < 30ml/min/1.73m^2 : Repeat 2 weeks post dose* • *Haemodialysis: Repeat 2 weeks post dose OR weekly for 4 weeks (as per local policy)* 25 Hydroxy Vitamin D: Annual Renal function: Annual Parathyroid hormone (CKD 4/5 only): Annual	**Before 1st dose:** Check renal function, adjusted calcium* and vitamin D **Before 2nd dose:** Check adjusted calcium* *(*Repeat adjusted calcium post dose for patients with renal dysfunction as per usual monitoring requirements)*	**From 3rd dose onwards:** Renal function: Annual Vitamin D: Annually, but if previous level sufficient and patient on adequate supplementation (see considerations) then consider pausing monitoring during reduced pathology capacity. Adjusted calcium can be checked on an annual basis if: • Cockcroft-Gault CrCl > 30ml/min or eGFR > 30ml/min/1.73m^2 **and** • previous two pre-dose adjusted calcium results in normal range If these criteria are not met, check adjusted calcium before each dose. For patients with Cockcroft-Gault CrCl < 30ml/min or eGFR < 30ml/min/ 1.73m^2, repeat 2 weeks post dose	**Ensure patient taking calcium and vitamin D supplementation (if appropriate).** Vitamin D level > 50nmol/L considered sufficient (> 70nmol/L before going in to winter) – see SEL Osteoporosis Pathway Consider pausing routine parathyroid hormone testing during reduced pathology capacity– any concerns should be discussed with specialist team Abnormal results should be managed according to the SEL denosumab shared care guideline

Drug	Usual blood monitoring recommendations	Blood monitoring recommendations during reduced pathology capacity		Considerations
Agomelatine	Liver profile^	During stabilisation	Once stable*	If signs and symptoms of liver impairment occur, treatment should be discontinued. Refer to specialist for advice on monitoring.
		Liver testing as per initiation protocol (see left), otherwise monitoring not routinely required.	Where patients are clinically stable and no dose increases, monitoring not routinely required.	
Amisulpride & sulpride	Renal profile# on initiation / baseline	During stabilisation	Once stable*	
		Not applicable for patients established on treatment, unless signs and symptoms of renal impairment.	Not applicable for patients established on treatment, unless signs and symptoms of renal impairment.	
All antipsychotics	Annually: FBC, plasma lipids, plasma glucose, weight/BMI, renal profile#, liver profile, blood pressure, ECG, prolactin if indicated	During stabilisation	Once stable*	
		Not applicable – specialist initiation.	For patients becoming due for annual blood tests, delay testing for up to 3 months	
Lithium	For stable patients in primary care, measure lithium plasma concentration every 3 months for the first year of treatment, then every 6 months. More frequent monitoring every 3 months in patients at higher risk of toxicity (>65 years old, interacting medicines, risk of impaired renal or thyroid function, raised calcium levels, poor symptom control or adherence, or where last level was 0.8mmol/L or higher). Body weight/BMI, renal profile#, and thyroid function every 6 months.	During stabilisation	Once stable*	
		Under specialist care. If prescribing in general practice for patients not yet stabilised: contact specialist for advice on management and blood testing.	For patients due routine blood tests: continue prescribing. Contact specialist for advice regarding delayed monitoring on case by case basis. For patients with signs of toxicity: patient must stop taking lithium. Refer to emergency department for urgent assessment. Dose adjustments – seek specialist advice.	

#Renal profile to include eGFR and Cr ^Liver profile to include albumin, AST or ALT *Stable patients are defined as those who have been on current treatment for > 12 months and at a stable dose for > 6 weeks

Drug	Usual blood monitoring recommendations	Blood monitoring recommendations during reduced pathology capacity		Considerations
Azathioprine	FBC, renal profile#, liver profile^ & GGT within 1 month of accepting shared care, then three monthly‡ **After dose change**: FBC, renal profile#, liver profile^ & GGT fortnightly for 6 weeks, then three monthly More frequent monitoring may be appropriate in patients at higher risk of toxicity	During stabilisation	Once stable*	Therapeutic drug level monitoring, if indicated, will be undertaken in secondary care In instances of abnormal blood test monitoring or adverse effects, action is required in line with usual monitoring requirements as listed here: Immunmodulatory shared care (selondonics.org) Contact specialist via advice and guidance for course of action for patients where extending monitoring interval is not suitable
		No changes recommended to usual monitoring protocol	Consider extending the monitoring interval up to every 6 months. Extending the monitoring interval is **not suitable** if the patient has: • Poor renal function with CKD ≥ 3 • Severe liver impairment or abnormal liver results due to immunomodulator use within previous 3 months • Severe abnormal WBC results due to immunomodulator use within previous 3 months	
Ciclosporin	FBC, renal profile#, liver profile^ & GGT, serum magnesium and potassium within 1 month of accepting shared care agreement, then three monthly‡ **After dose change**: FBC, renal profile#, liver profile^ & GGT, serum magnesium and potassium fortnightly for 6 weeks, then three monthly *Secondary care will check non-fasting lipids 1 month after initiation and monitor HbA1c annually*	During stabilisation	Once stable*	Three monthly monitoring of blood pressure and urine dipstick to continue 3 monthly in line with usual monitoring recommendations
		For those on 4-weekly monitoring, consider extending the monitoring interval to between 6-8 weeks with specialist advice	The British Society of Rheumatology advises that patients who have been stable for 12 months can be considered for reduced frequency monitoring on an individual patient basis. Seek specialist advice. For those who receive monitoring more frequently due to higher risk of toxicity, seek specialist advice for extensions to monitoring during this period.	

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‡More frequent monitoring may be recommended by specialist clinicians for individual patients, which will be communicated to the GP on a case-by-case basis

Drug	Usual blood monitoring	Recommended actions/ blood monitoring during reduced pathology capacity		Considerations
Hydroxychloroquine	No routine laboratory monitoring is required post initiation unless *>70yo, CKD, HTN, DM then Renal profile annually (CQC)*	During stabilisation	Once stable*	Ophthalmological examination is required annually if increased risk; otherwise once after 5 years and then annually
		No routine laboratory monitoring is required post initiation	No routine laboratory monitoring is required post initiation unless *>70yo, CKD, HTN, DM then Renal profile annually (CQC)*	
Leflunomide	FBC, renal profile#, liver profile^ & GGT within 1 month of accepting shared care agreement, then three monthly‡ **For patients co-prescribed methotrexate**: FBC, renal profile#, liver profile^ & GGT monthly. After 1 year of monthly monitoring, specialist clinicians may recommend reducing frequency of monitoring. **After dose change**: FBC, renal profile#, liver profile^ & GGT fortnightly for 6 weeks, then three monthly (**monthly if co-prescribed methotrexate**) More frequent monitoring may be appropriate in patients at higher risk of toxicity	During stabilisation	Once stable*	Blood pressure and weight monitoring to continue 3 monthly in line with usual monitoring recommendations In instances of abnormal blood test monitoring or adverse effects, action is required in line with Immunmodulatory shared care (selondonics.org) Contact specialist via advice and guidance for course of action for patients where extending monitoring interval is not suitable
		No changes recommended to usual monitoring protocol	Consider extending the monitoring interval up to every 6 months. Extending the monitoring interval is **not suitable** if the patient has: • Poor renal function with CKD ≥ 3 • Severe liver impairment or abnormal liver results due to immunomodulator use within previous 3 months • Severe abnormal WBC results due to immunomodulator use within previous 3 months • Combination therapy with methotrexate	

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Drug	Usual blood monitoring recommendations	Blood monitoring recommendations during reduced pathology capacity		Considerations
6-Mercaptopurine	FBC, renal profile#, liver profile^ & GGT within 1 month of accepting shared care agreement, then three monthly‡ **After dose change**: FBC, renal profile#, liver profile^ & GGT fortnightly for 6 weeks, then three monthly More frequent monitoring may be appropriate in patients at higher risk of toxicity	During stabilisation	Once stable*	Therapeutic drug level monitoring, if indicated, will be undertaken in secondary care In instances of abnormal blood test monitoring or adverse effects, action is required in line with Immunmodulatory shared care (selondonics.org) Contact specialist via advice and guidance for course of action for patients where extending monitoring interval is not suitable
		No changes recommended to usual monitoring protocol	Consider extending the monitoring interval up to every 6 months. Extending the monitoring interval is **not suitable** if the patient has: • Poor renal function with CKD ≥ 3 • Severe liver impairment or abnormal liver results due to immunomodulator use within previous 3 months • Severe abnormal WBC results due to immunomodulator use within previous 3 months	
Methotrexate	FBC, renal profile#, liver profile^ & GGT every 3 months (**monthly if co-prescribed leflunomide**) ‡ **After dose change**: FBC, renal profile#, liver profile^ & GGT fortnightly for 6 weeks, then three monthly (**monthly if co-prescribed leflunomide**) More frequent monitoring may be appropriate in patients at higher risk of toxicity	During stabilisation	Once stable*	It remains mandatory for a patient held monitoring record to be in place and up to date; can be electronic or paper In instances of abnormal blood test monitoring or adverse effects, action is required in line with Immunmodulatory shared care (selondonics.org) Contact specialist via advice and guidance for course of action for patients where extending monitoring interval is not suitable
		No changes recommended to usual monitoring protocol	Consider extending the monitoring interval up to every 6 months. Extending the monitoring interval is **not suitable** if the patient has: • Poor renal function with CKD ≥ 3 • Severe liver impairment or abnormal liver results due to immunomodulator use within previous 3 months • Severe abnormal WBC results due to immunomodulator use within previous 3 months • Combination therapy with leflunomide	

#Renal profile to include eGFR and Cr ^Liver profile to include albumin, AST or ALT *Stable patients are defined as those who have been on current treatment for > 12 months and at a stable dose for > 6 weeks ‡More frequent monitoring may be recommended by specialist clinicians for individual patients, which will be communicated to the GP on a case-by-case basis

<table>
<tr><th>Drug</th><th>Usual blood monitoring recommendations</th><th colspan="2">Recommended actions/ blood monitoring during reduced pathology capacity</th><th>Considerations</th></tr>
<tr><td rowspan="3">Penicillamine</td><td rowspan="3">FBC, Renal profile#, Urinalysis and Protein: Creatinine Ratio (PCR), Liver Profile^ within 1 month of accepting shared care agreement, then 3 monthly‡

More frequent monitoring may be appropriate in patients at higher risk of toxicity</td><td>During stabilisation</td><td>Once stable*</td><td rowspan="3">In instances of abnormal blood test monitoring or adverse effects, action is required in line with Shared Care Document Penicillamine for Treatment of Wilson's Disease</td></tr>
<tr><td>For patients newly initiated not already being monitored on a 3 monthly basis, consider extending the monitoring interval to up to 3 monthly.</td><td>Every 6 months once stable</td></tr>
<tr><td colspan="2">Re-advise patient to report presence of rash or oral ulceration. If severe or oral ulceration present withhold and discuss with specialist. Report sore throat, fever, infection, non-specific illness, unexpected bleeding and bruising, purpura.

Caution in elderly since increased toxicity has been observed in this patient population regardless of renal function.

Patients at higher risk of toxicity include:
• Poor renal function with CKD ≥ 3
• Severe liver impairment or abnormal liver results due to immunomodulator use within previous 3 months
• Severe abnormal WBC results due to immunomodulator use within previous 3 months</td></tr>
<tr><td rowspan="3">Sulfasalazine</td><td rowspan="3">FBC, Renal Profile#, Liver Profile^ & GGT within 1 month of accepting shared care agreement, then three monthly‡

After dose change: Fortnightly for 6 weeks, then three monthly.

After 1 year, no routine monitoring required if patient on monotherapy</td><td>During stabilisation</td><td>Once stable*</td><td rowspan="3">In instances of abnormal blood test monitoring or adverse effects, action is required in line with Immunmodulatory shared care (selondonics.org)

Contact specialist via advice and guidance for course of action for patients where extending monitoring interval is not suitable</td></tr>
<tr><td>As per usual guidance</td><td>After 12 months, stable patients require no routine monitoring unless patient is at high risk</td></tr>
<tr><td colspan="2">Re-advise patient to report presence of rash or oral ulceration. If severe or oral ulceration present withhold and discuss with specialist. Report sore throat, fever, infection, non-specific illness, unexpected bleeding and bruising, purpura.

Patients at higher risk of toxicity include:
• Poor renal function with CKD ≥ 3
• Severe liver impairment or abnormal liver results due to immunomodulator use within previous 3 months
• Severe abnormal WBC results due to immunomodulator use within previous 3 months</td></tr>
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Document change history

Date	Change made
19th June 2024	N/a – original approval date
3rd July 2024	• Cardiovascular disease medicines and denosumab added to document. • Contents page added to document. • Reference page updated
10th July 2024	• Page 6 – Hypertension – wording on blood monitoring for ACEi/ARBs during stabilisation clarified (no clinical changes made). Change approved via IMOC Chair's action.

References

- Medicines Monitoring – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice
- SPS COVID-19 monitoring advice – advice on file (archived content)
- Immunmodulatory shared care (selondonics.org)
- FRAMEWORK - SHARED CARE (selondonics.org)
- BSR and BHPR guideline for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs | Rheumatology | Oxford Academic (oup.com)
- Home - electronic medicines compendium (emc)
- Agomelatine – SEL information for primary care document
- Amisulpride and sulpride SPCs – routine blood monitoring not stated as requirement via emc.medicines.org.uk
- Aripiprazole – SEL shared care guideline, SPC
- Paliperidone – SEL shared care guideline
- Advice from SLAM pharmacy – details on file
- Expert input and opinion from cardiovascular leads in SEL
- Expert input and opinion from specialist osteoporosis clinicians and specialist pharmacists in SEL for denosumab