South East London Integrated Care System

# Blood monitoring recommendations for Primary Care during Synnovis Cyber Attack

## SEL Medicines Optimisation Team

## Version: 19th June 2024

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

**Approval Date:** 19th June 2024 **Review Date:** September 2024

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

# 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).

# General principles for drug monitoring

## 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

# Contact details for specialist advice

- 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/

## Mental health prescribing

| 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.<br><br>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).<br><br>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.<br><br>For patients with signs of toxicity: patient must stop taking lithium. Refer to emergency department for urgent assessment.<br><br>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

## Non-biological immunomodulating drugs (including Disease-modifying anti-rheumatic drugs (DMARDs))

| 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‡<br><br>**After dose change**: FBC, renal profile#, liver profile^ & GGT fortnightly for 6 weeks, then three monthly<br><br>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<br><br>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)<br><br>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.<br><br>Extending the monitoring interval is **not suitable** if the patient has:<br>• Poor renal function with CKD ≥ 3<br>• Severe liver impairment or abnormal liver results due to immunomodulator use within previous 3 months<br>• 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‡<br><br>**After dose change**: FBC, renal profile#, liver profile^ & GGT, serum magnesium and potassium fortnightly for 6 weeks, then three monthly<br><br>*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.<br><br>For those who receive monitoring more frequently due to higher risk of toxicity, seek specialist advice for extensions to monitoring during this period. | |

#Renal profile to include eGFR and Cr ^Liver profile to include albumin, AST or ALT

| Non-biological immunomodulating drugs (including Disease-modifying anti-rheumatic drugs (DMARDs)) | | | | |
|---|---|---|---|---|
| **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‡<br><br>**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.<br><br>**After dose change**: FBC, renal profile#, liver profile^ & GGT fortnightly for 6 weeks, then three monthly (**monthly if co-prescribed methotrexate**)<br><br>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<br><br>In instances of abnormal blood test monitoring or adverse effects, action is required in line with Immunmodulatory shared care (selondonics.org)<br><br>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.<br><br>Extending the monitoring interval is **not suitable** if the patient has:<br>• Poor renal function with CKD ≥ 3<br>• Severe liver impairment or abnormal liver results due to immunomodulator use within previous 3 months<br>• Severe abnormal WBC results due to immunomodulator use within previous 3 months<br>• Combination therapy with methotrexate | |

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*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

## Non-biological immunomodulating drugs (including Disease-modifying anti-rheumatic drugs (DMARDs))

| 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‡<br><br>**After dose change**: FBC, renal profile#, liver profile^ & GGT fortnightly for 6 weeks, then three monthly<br><br>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<br><br>In instances of abnormal blood test monitoring or adverse effects, action is required in line with Immunmodulatory shared care (selondonics.org)<br><br>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.<br><br>Extending the monitoring interval is **not suitable** if the patient has:<br>• Poor renal function with CKD ≥ 3<br>• Severe liver impairment or abnormal liver results due to immunomodulator use within previous 3 months<br>• 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**) ‡<br><br>**After dose change**: FBC, renal profile#, liver profile^ & GGT fortnightly for 6 weeks, then three monthly (**monthly if co-prescribed leflunomide**)<br><br>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<br><br>In instances of abnormal blood test monitoring or adverse effects, action is required in line with Immunmodulatory shared care (selondonics.org)<br><br>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.<br><br>Extending the monitoring interval is **not suitable** if the patient has:<br>• Poor renal function with CKD ≥ 3<br>• Severe liver impairment or abnormal liver results due to immunomodulator use within previous 3 months<br>• Severe abnormal WBC results due to immunomodulator use within previous 3 months<br>• 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

## Non-biological immunomodulating drugs (including Disease-modifying anti-rheumatic drugs (DMARDs))

<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‡<br><br>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.<br><br>Caution in elderly since increased toxicity has been observed in this patient population regardless of renal function.<br><br>Patients at higher risk of toxicity include:<br>• Poor renal function with CKD ≥ 3<br>• Severe liver impairment or abnormal liver results due to immunomodulator use within previous 3 months<br>• 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‡<br><br>After dose change: Fortnightly for 6 weeks, then three monthly.<br><br>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)<br><br>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.<br><br>Patients at higher risk of toxicity include:<br>• Poor renal function with CKD ≥ 3<br>• Severe liver impairment or abnormal liver results due to immunomodulator use within previous 3 months<br>• Severe abnormal WBC results due to immunomodulator use within previous 3 months</td></tr>
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# 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