

Shared Care Guideline

Prescribing and Monitoring of oral METHOTREXATE in adults Licensed and off-label indications

Dear GP,

Progressing to a stable, optimal dose usually takes about three months. Once achieved, a Shared Care arrangement with you will be requested. It will clarify responsibilities between the specialist and general practitioner (GP) for managing the prescribing of methotrexate such as:

1. Who will prescribe;
2. Who will monitor;
3. How often blood tests will be conducted and in which location;
4. Which clinician will be responsible for receipt and review of the results;
5. Who will communicate any necessary changes in dose to the patient and the GP;
6. Who will record test results in the Patient-Held Monitoring and Dosage Record booklet.

GPs are asked to participate in this shared care arrangement. If the GP is not confident to undertake these roles, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. However, the GP is encouraged to contact the consultant to discuss their concerns and consider if further support can be provided to enable shared care.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care should be explained to the patient by the Consultant / specialist nurse when treatment is initiated. It is important that patients are consulted about treatment and are in agreement with it.

Shared Care Criteria

Patients who are stabilised on methotrexate and have been monitored appropriately at baseline and after initiation of treatment with no problems identified during this period.

RESPONSIBILITIES and ROLES

Specialist team

1. Perform baseline tests (FBC, LFTs, U&Es, creatinine, chest X-ray).
2. Initiate and stabilise treatment with methotrexate and continue to prescribe until the GP formally takes over shared care.
3. Discuss the benefits and side effects of treatment with the patient. Provide the patient with a Patient Information Leaflet, explain it and ensure that the patient understands that dosing is at weekly intervals.
4. **Issue a Methotrexate Monitoring Booklet to the patient and explain monitoring schedule.** Emphasise the importance of carrying the booklet and showing it to healthcare professionals at all times.
5. Write to the GP with a standard letter asking whether he or she is willing to participate in shared care. The consultant should ensure that contact details are included within the request to enable the GP to contact them for further support or advice if needed.
6. Discuss the shared care arrangement with the patient.
7. Provide results of baseline tests and recommend frequency of monitoring to GP. Record results in the patient's Methotrexate Monitoring Booklet as appropriate. Recommend dose and timing of concomitant folic acid.
8. Periodically review the patient's condition and communicate promptly with the GP when treatment is changed. Counsel the patient on any dose changes that are made during clinic appointments and update the methotrexate booklet.
9. Inform GP of blood test results, actions to take in case of abnormal results, and advise the GP on when to adjust the dose, stop treatment, or consult with specialist.
10. Evaluate adverse effects reported by GP or patient.
11. Report adverse events to the MHRA and GP.
12. Ensure that clear backup arrangements exist for GPs to obtain advice and support at all times and aim to respond to the GP within 24 hours of receiving a query. See consultant contact details in request letter. Hospital trust contact details are also available at the end of this document.

The following responsibilities apply when methotrexate is prescribed for an off-label indication:

13. Ensure patients (or their parents or carers) are provided with sufficient information to allow them to make an informed decision when methotrexate is used for an off-label indication.
14. Ensure a clear, accurate and legible record is made in the patient notes when prescribing methotrexate for an off-label indication.
15. Ensure the approved off-label indication is clearly specified in the standard letter when methotrexate is used for an off-label indication.

General Practitioner

1. Reply to the request for shared care as soon as practicable by completing standard letters to the Consultant. If shared care is declined please contact the consultant to explain the reason.
2. Monitor patient's overall health and wellbeing.
3. Prescribe methotrexate at the dose recommended by the specialist team and ensure patient understands the number of tablets and strength of tablets to take. **Only 2.5 mg tablets should be prescribed.** 10 mg tablets **SHOULD NOT** be prescribed. Prescriptions should specify "once a week" and the day of administration. The term "as directed" **SHOULD NOT** be used.
4. Ensure that the patient understands that dosing is at weekly intervals.
5. Ensure that the patient knows that he/she must report the warning symptoms as listed under "Adverse Effects".
6. Ensure compatibility with other concomitant medication.
7. Monitor blood counts, hepatic and renal function at recommended frequencies as described (see "Monitoring"), and inform consultant if abnormal. All test results to be recorded in the "Patient-Held Monitoring and Dosage Record" and communicated appropriately.
8. Advise the patient on the date that the next blood test is due and arrange it.
9. Adjust the dose as advised by the specialist and counsel patient on any dose changes. Record dose changes in the "Patient-Held Monitoring and Dosage Record".
10. Stop treatment on the advice of the specialist or immediately if an urgent need to stop treatment arises.

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11. Report adverse events to the specialist and MHRA via the [yellow card scheme](#).
12. **All requests for repeat prescriptions should be reviewed individually prior to issuing.**
13. Offer annual influenza vaccination to the patient.
14. Offer patients a dose of the 23-valent unconjugated pneumococcal polysaccharide vaccine (e.g. Pneumovax ® II) prior to commencing methotrexate and again once the patient reaches 65 years (if not given within the previous 5 years).
15. Register on the GP portal service to access blood results: CDR (UCLH); GP bloods (NMUH). For RFL, the GP will be advised by the specialist team how blood results will be communicated.
16. Ensure a clear, accurate and legible record is made in the patient notes, when prescribing methotrexate for an off-label indication.

Patient

1. Report to the specialist or GP if he or she does not have a clear understanding of the treatment.
2. Share any concerns in relation to treatment with methotrexate.
3. Inform specialist or GP of any other medication being taken, including over-the-counter products.
4. Report any adverse effects or warning symptoms (sore throat, bruising, mouth ulcers, nausea, vomiting, abdominal discomfort, dark urine, shortness of breath) to the specialist or GP whilst taking methotrexate.
5. Bring the Methotrexate Monitoring Booklet to all appointments and when collecting supply of tablets.

Clinical Commissioning Group

1. To support GPs to decide whether or not to accept clinical responsibility for prescribing.
2. To support Trusts in resolving issues that may arise as a result of shared care.

SUPPORTING INFORMATION

Approved indications

Licensed indications

Adults with severe, active, classical or definite rheumatoid arthritis who are unresponsive to or intolerant of conventional therapy

Adults with severe, uncontrolled psoriasis, which is not responsive to other therapy

Off-label indications

Juvenile idiopathic arthritis
 Crohn's disease
 Sarcoidosis
 Psoriatic arthritis
 Systemic lupus erythematosus (SLE)
 Scleroderma

Vasculitis
 Atopic eczema
 Dermatomyositis
 Inflammatory myopathy
 Pemphigoid

The General Medical Council (GMC) guidance on prescribing unlicensed medicines advises that:
'When deciding on the best treatment for a patient you should weigh up all of the options, taking into account the evidence available. You should be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy.'

The off-label indications for methotrexate shared care were approved by the North Central London Joint Formulary Committee (NCL JFC) in August 2016 based on a review of the available evidence base. The tables below summarizes the grades and strengths of evidence supporting the use of methotrexate for the individual off-label indications.

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Specialty	Indication	Grade of Evidence	Strength of Evidence
Rheumatology	Juvenile Idiopathic Arthritis	1c	A
Gastroenterology	Crohn's Disease	2a	B
Dermatology &	Sarcoidosis	2b	B
Rheumatology	Psoriatic arthritis	2b/5**	B/D**
Rheumatology	Systemic Lupus Erythematosus	2b	B
Rheumatology	Sclerodema	2b	B
Rheumatology	Vasculitis	2b	B
Dermatology	Atopic eczema	2b	B
Dermatology	Dermatomyositis	2b	B
Rheumatology	Inflammatory myopathy	2b	B
Dermatology	Pemphigoid, pemphigus	4	C

Based on review of abstract. Grade and Strength of evidence has been assessed by two individuals independently.

****Kingsley et al. (2012) showing no significant benefit in tender and swollen joints (2b); expert opinion and national guidelines supports its use (5).**

Level	Type of evidence	Grade of evidence
1a	Systematic review (with homogeneity) of RCTs	A
1b	Systematic review with narrow confidence intervals	A
1c	Individual robust randomised, double-blinded trial	A
2a	Systematic review (with homogeneity) of cohort studies	B
2b	Individual cohort study (including low quality RCT)	B
2c	Outcomes Research Ecological studies	B
3a	Systematic review (with homogeneity) of case control studies	B
3b	Individual case control studies	B
4	Case series (and poor quality cohort & case-control studies)	C
5	Expert opinion without explicit critical appraisal.	D

Centre of Evidence-based Medicine – Levels of Evidence (March 2009)

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Dosage and Administration

Patients are given a small test dose of methotrexate (usually 5 mg to 7.5 mg) orally **ONCE weekly**. If after 7 days the full blood count (FBC) is stable methotrexate is continued. The schedule may be adjusted gradually (usually in 2.5 – 5 mg steps) to achieve an optimal response.

The usual maintenance dose of methotrexate is from 5 mg to 25 mg **ONCE weekly**. The licensed maximum weekly dose for rheumatoid arthritis is 20 mg weekly and for psoriasis is 25 mg. Some patients and conditions may require higher doses (up to 30 mg) on advice of the specialist. The dose will be dependent on the condition being treated and will be stipulated by the specialist team on transfer of care.

The lowest possible effective dose should be used. Methotrexate should be used with extreme caution in elderly patients and a lower dose should be considered.

Regular folic acid supplements should be given to reduce the risk of toxicity. **Please follow the regime detailed in the handover summary. Folic acid should not be taken on the same day as methotrexate.**

Methotrexate will be issued as **2.5 mg tablets**. Patients should consistently receive the same strength of tablets to avoid confusion with the 10 mg strength and therefore the risk of overdose. All patients should be fully counselled regarding the strength and number of tablets to take as a single weekly dose.

Patients will be issued with a Methotrexate Monitoring Booklet from the hospital on commencing methotrexate. All blood results and dose or change in dose should be recorded in this booklet.

Patients should be offered annual influenza vaccination. Patients should be offered a pneumococcus vaccine consisting of a dose of the 23-valent unconjugated pneumococcal polysaccharide vaccine prior to commencing methotrexate. This should be repeated when the patient reaches 65 years (if not given within the previous 5 years).

Cautions and Contraindications

- Profound impairment of renal or hepatic function or haematological impairment
- Liver disease including fibrosis, cirrhosis, recent or active hepatitis; active infectious disease; and overt or laboratory evidence of immunodeficiency syndrome(s)
- Serious cases of anaemia, leucopenia, or thrombocytopenia
- Pregnancy or breast-feeding; Following administration to a man or woman conception should be avoided by using an effective contraceptive method for at least 3 months after stopping methotrexate. (See under **Pregnancy and Lactation** below.)
- Patients with a known allergic hypersensitivity to methotrexate
- Exposure to chicken pox – patients who have had significant exposure to chicken pox but do not know if they have had chicken pox in the past, will need to have their varicella zoster antibody titre checked. If it is low, the patient will need varicella zoster immunoglobulin within 10 days of the initial exposure. If this is necessary, please contact the appropriate specialist nurse or specialist registrar or consultant
- Localised or systemic infection – including hepatitis B or C
- Methotrexate can cause interstitial pneumonitis and fibrosis. Patients complaining of unexplained dyspnoea or unexplained dry cough should stop taking methotrexate and be referred immediately to the Specialist.

Immunisations - live vaccines should be avoided. Influenza and pneumococcal vaccines are safe.

For a full list of cautions and contraindications, refer to the Summary of Product Characteristics. The National Patient Safety Agency has published actions to reduce the risks associated with oral methotrexate (www.npsa.nhs.uk).

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Monitoring

Regular monitoring according to the BSR/BHPR guideline for disease-modifying anti-rheumatic drug (DMARD) therapy in consultation with the British Association of Dermatologists¹ during treatment is essential to detect adverse reactions at an early stage and patients should be counselled about the risk factors and to report all signs and symptoms of toxicity.

- FBC, U&Es, creatinine, LFTs and chest X-ray should be measured before starting treatment.
- FBC, U&Es and LFTs should then be monitored fortnightly until dose of methotrexate and monitoring is stable for 6 weeks, then monthly thereafter until the dose and disease is stable for 1 year.
- Thereafter, the monitoring may be reduced in frequency to every two to three months, based on clinical judgement with due consideration for risk factors including age, co-morbidity, renal impairment, etc.

(NB. The frequency of monitoring advised by the specialist to the GP may vary from the above recommendations depending on patient factors. Check with specialist if required)

The following threshold laboratory values and symptoms require action as detailed in the table below.

Monitoring parameter	Action to be taken if changed
WBC <3.5x10 ⁹ /L	Withhold methotrexate <i>until discussed</i> with specialist
Neutrophils <2.0x10 ⁹ /L	Withhold methotrexate <i>until discussed</i> with specialist
Platelets <150x10 ⁹ /L	Withhold methotrexate <i>until discussed</i> with specialist
AST, ALT > twice upper limit of reference range	Withhold methotrexate <i>until discussed</i> with specialist
Unexplained fall in albumin (in absence of active disease)	Withhold methotrexate <i>until discussed</i> with specialist
Rash or oral ulceration, nausea and vomiting, diarrhoea	Withhold methotrexate <i>until discussed</i> with specialist
New or increasing dyspnoea or dry cough	Withhold methotrexate and discuss urgently with specialist
MCV >105fl	Withhold and check serum B12, folate and TFT and discuss with specialist team if necessary
Significant deterioration in renal function	Withhold methotrexate <i>until discussed</i> with specialist
Abnormal bruising or severe sore throat	Immediate FBC and withhold methotrexate until FBC result available

The specialist may conduct additional investigations as required e.g. CRP, ESR, (and PIIINP and liver biopsy for psoriatic patients). The results will be sent to the GP.

Adverse Effects

Possible adverse effects and what to do if they occur:

1. **Nausea and diarrhoea** – these will be minimised by the folic acid therapy. Some patients benefit by taking their NSAID (if they are on one) a few hours before or after, rather than at the same time as their methotrexate dose. If severe despite these measures, the methotrexate must be stopped, and the specialist nurse or specialist registrar or Consultant, contacted.
2. **Mouth ulcers, hair loss, and skin rash** – these usually respond to omitting a dose and resuming at a

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dose reduced by 2.5mg. Topical hydrocortisone may be used for skin rash. If any are severe (particularly stomatitis), the methotrexate must be stopped, and the specialist nurse or specialist registrar or Consultant, contacted.

- 3. Recurrent sore throat, infections and fevers** – these may indicate neutropenia, so the methotrexate must be stopped, the FBC checked, and the specialist nurse or specialist registrar or Consultant to be contacted.
- 4. Unexplained bruising or bleeding** – if severe, the APTT and FBC should be checked. If they are normal (see “Monitoring”), methotrexate may be continued and the specialist nurse or specialist registrar or Consultant, contacted. If they are abnormal, the methotrexate should be stopped, and the specialist nurse or specialist registrar or Consultant, contacted.
- 5. Unexplained cough or shortness of breath** – these may indicate pneumonitis or pulmonary fibrosis, so the methotrexate should be stopped and the specialist nurse or specialist registrar or Consultant, contacted.
- 6. Jaundice, abdominal discomfort, or dark urine** – these may indicate liver damage, so the methotrexate should be stopped and the specialist nurse or specialist registrar or Consultant, contacted.

Methotrexate was launched in 1989 and no longer has black triangle status. Serious suspected reactions (even if well recognised or causal link uncertain) should be reported to the MHRA via the [yellow card scheme](#).

Drug Interactions

Methotrexate is immunosuppressive and may therefore reduce immunological response to concurrent vaccination. Severe antigenic reactions may occur if a live vaccine is given concurrently.

Methotrexate is extensively protein-bound and may be displaced by other protein-bound drugs (e.g. diuretics, salicylates, hypoglycaemics), with a potential for increased toxicity.

NSAIDs can be continued whilst on methotrexate. The NSAID or its dose should not be changed without discussion with the Consultant. All patients should be regularly advised to avoid over-the-counter medications including aspirin and ibuprofen without the knowledge of the specialist team.

Concomitant use of other drugs with nephrotoxic or hepatotoxic potential should be avoided. Folate antagonists such as trimethoprim and co-trimoxazole should not be given concomitantly.

For a full list of drug interactions, refer to the Summary of Product Characteristics via www.medicines.org.uk.

Pregnancy and Lactation

- All patients, male and female, should be advised to avoid conception and pregnancy during treatment with methotrexate as it is an abortifacient as well as a teratogenic drug.
- Patients and their partners should be advised to continue contraception for at least 3 months after cessation of methotrexate therapy.
- In the case of accidental pregnancy, stop methotrexate immediately, continue folic acid supplementation (5 mg daily) and refer the patient to the specialist for evaluation of foetal risk and advice on further management.
- Patients should not breastfeed whilst taking methotrexate.

References

- BSR/BHPR guideline for disease-modifying anti-rheumatic drug (DMARD) therapy in consultation with the British Association of Dermatologists. Chakravarty et al., Rheumatology, 2008. Accessed via <http://rheumatology.oxfordjournals.org/cgi/data/kel216a/DC1/1>
- National Patient Safety Agency www.npsa.nhs.uk
- Summary of Product Characteristics Maxtrex tablets 2.5 mg. Pharmacia (last updated Oct 2014) - accessed (Mar 2015) via www.medicines.org.uk
- Clinical Knowledge Summaries (accessed July 2015); http://www.cks.nhs.uk/dmards/management/scenario_methotrexate/methotrexate_monitoring_requirements

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5. BNF Current Edition. Last accessed BNF68 (March 2015) <http://bnf.org/bnf/bnf/current/>
6. The green book – Department of health guidance on Immunisation against infectious disease, chapter 7, last updated Oct 2014 - accessed via www.gov.uk (March 2015)
7. Centre for disease and control, vaccine information sheet for pneumococcus – accessed via <http://www.cdc.gov/vaccines/hcp/vis/vis-statements/ppv.html> (accessed March 2015)
8. British Association of Dermatology recommendations
<http://www.bad.org.uk/shared/get-file.ashx?id=106&itemtype=document>
9. BSR/BHPR Guideline on prescribing drugs in pregnancy and breastfeeding – Part I: standard and biologic disease-modifying anti-rheumatic drugs and corticosteroids. Flint J *et al.* 2016 Accessed via: http://rheumatology.oxfordjournals.org/content/suppl/2016/01/09/kev404.DC1/kev404-Full_Guidelines.pdf
10. General Medical Council - Good practice in prescribing and managing medicines and devices – Prescribing Guidance: Prescribing unlicensed medicines (January 2013) - accessed via http://www.gmc-uk.org/guidance/ethical_guidance/14327.asp
11. North Central London Joint Formulary Committee (NCL JFC) Minutes August 2016 – accessed via <http://ncl-jfc.org.uk/minutes.html>

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Contact Details

Whittington Hospital	
Switchboard number:	0207 272 3070
Rheumatology CNS:	0207 288 5257
Rheumatology consultant:	0207 288 5740
Dermatology CNS:	0207 288 5062
Dermatology consultant:	0207 288 5266
Gastroenterology CNS:	Bleep 2893 or Extension 5692
Gastroenterology consultant:	Via switchboard
Gastroenterology Registrars:	Bleep 3036 or 3113
GI Helpline:	020 7288 5692
North Middlesex Hospital	
Switchboard number:	0208 887 2000
Rheumatology CNS:	0208 887 3662
Rheumatology consultant:	0208 887 2347
Dermatology CNS:	0208 887 2426
Gastroenterology CNS:	0208 887 2960
Gastroenterology consultant:	0208 887 2251
Royal Free Hospital	
Switchboard number:	0207 794 0500
Rheumatology CNS:	Extension 32494 / 34062 or rf-tr.rheumnurseshampstead@nhs.net
Rheumatology consultant:	Extension 32494
Dermatology CNS:	Extension 31623
Dermatology consultant:	Extension 31623
Gastroenterology CNS:	0207 830 2283 or rf.ibdnurses@nhs.net
Gastroenterology consultant:	0207 830 2283
Barnet Hospital	
Switchboard number:	0208 216 4600
Rheumatology CNS:	0208 216 4523
Rheumatology consultant:	0208 216 4028 / 5470
Dermatology CNS:	0208 216 5489
Dermatology consultant:	0208 216 5489
Gastroenterology CNS:	n/a
Gastroenterology consultant:	n/a
Chase Farm Hospital	
Switchboard number:	0208 375 2999
Rheumatology CNS:	0208 375 1628
Rheumatology consultant:	0208 375 1608
Dermatology CNS:	0208 375 1999
Dermatology consultant:	0208 375 1999
Gastroenterology CNS:	n/a
Gastroenterology consultant:	n/a
University College London hospitals	
Switchboard number:	0203 456 7890
Rheumatology CNS:	0203 447 9215 / 9035 / 9281 or uclh.rheumatology@nhs.net
Rheumatology consultant:	uclh.rheumatology@nhs.net
Dermatology CNS:	07507790466
Dermatology consultant:	uclh.dermatology@nhs.net
Gastroenterology CNS:	0203 447 5120 or IBD.Advice@uclh.nhs.uk
Gastroenterology consultant:	IBD.Advice@uclh.nhs.uk

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Shared care guideline written by Jay Pang – Royal Free Hospital and Balram Malhotra – University College London Hospitals, Rheumatology and Dermatology Pharmacists.
Agreed with NHS Camden May 2009.

Reviewed & Updated by Aoife Tynan - Rheumatology and Dermatology Pharmacist (RFL) & Kashyap Thakrar - Lead Formulary & Medicines Management Pharmacist (UCLH), July 2015.

Reviewed & Updated by Kashyap Thakrar - Lead Formulary & Medicines Management Pharmacist (UCLH) & Hanisha Amin – Camden CCG Prescribing Adviser, February 2017
Agreed with NHS Camden February 2017

Approved by North Central London Medicines Optimisation Committee March 2017

Ratified by NCL Joint Formulary Committee April 2017

Date of next review: April 2020

December 2017 version 1.1 – Monitoring parameters “Action to be taken if changed” amended to state refer to “specialist” rather than “rheumatologist / dermatologist” as gastroenterology indications have been added.

June 2018 version 1.2 – Title updated to “Prescribing and Monitoring of oral METHOTREXATE **in adults**”

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Methotrexate transfer form: from [Trust] to GP practice

Section A: to be completed by secondary care *Send to practice*

This document is to request the shared care pathway of your patient and comprises an agreement between the GP and named consultant. The patient will continue to be seen by the named consultant as regular follow up.

<i>Clinic stamp or give details below</i>	<i>Fix address label here (ensure inc. NHS no.)</i>
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Department

Please ensure consultant contact details are included within this request to enable the GP to contact the consultant for further support or advice if needed. Aim to respond to the GP within 24 hours of receiving a query.

Clinic phone Fax

Consultant Tel./ Bleep

Email (nhs.net only)

Indication for prescription

If the indication is <i>off-label</i> please tick:	<input type="checkbox"/> Juvenile idiopathic arthritis	<input type="checkbox"/> Systemic lupus erythematosus (SLE)	<input type="checkbox"/> Dermatomyositis
	<input type="checkbox"/> Crohn's disease	<input type="checkbox"/> Scleroderma	<input type="checkbox"/> Inflammatory myopathy
	<input type="checkbox"/> Sarcoidosis	<input type="checkbox"/> Vasculitis	<input type="checkbox"/> Pemphigoid
	<input type="checkbox"/> Psoriatic arthritis	<input type="checkbox"/> Atopic eczema	Any other off-label indication has not been approved for shared care

Drug prescribed

Date started Current dose mg ONCE a week

Relevant conditions

Monitoring variations

Section B: [Accept Shared Care] to be completed by practice *Send back **FAO referring consultant** above*

The above patient has been accepted into our monitoring service.

Practice date for next blood test

Practice stamp *Add fax no. below*

Signed /
Designation

Date

Date of next blood test

Next disease review due in months' time

Section B: [Reject Shared Care] to be completed by practice *Send back **FAO referring consultant** above*

The above patient has not been accepted into our monitoring service.

Reason

Practice stamp *Add fax no. below*

Signed /
Designation

Date