Clinical Guidance

Summary

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Keywords	Methotrexate, psoriasis
Relevant external law, regulation, standards	NPSA

Change History		
Date	Change details, since approval	Approved by

CONTENTS

Page No

1. CLINIC PROFILE

Clinic Name: systemic medicines for psoriasis and eczema; initiation and monitoring clinic

Supervising consultant:

Lead Nurses for clinic:

Nurse Job Title: Clinical Nurse Specialist, Dermatology

Clinic Code 1 :

Clinical Session frequency: Weekly

Clinic day/s:

Clinic Time:

Clinic Site:

No. of appointment slots:

2. REFERRAL PROCEDURE

Referral Sources: Referrals from **ANY** dermatologist/SpR/Consultant Nurse in department

Mode of referral: Booked as a follow up appointment using the clinic outcome form, tick the 'nurse led monitoring clinic' box*

Patient category: Patients with inflammatory dermatoses due to commence on methotrexate (MTX), ciclosporin, acitretin, azathioprine or fumaric acid esters** therapy that require monitoring for up to 12 weeks following initiation. Any referrals for systemic treatments with an unlicensed indication must be fully discussed with the nurse prior to an appointment in the clinic being booked.

- No referral letter is required but clear instructions on start dose, dose escalation and monitoring requirements of the systemic agent should be stated in the patient notes, along with initial prescription.
- IMPORTANT – when referring patients to the clinic, it is the referring Doctors responsibility:
  - to decide on the dose regimen
  - to write up the accurate prescription details for 14 weeks on planned dosing schedule
  - To file prescription details in the medical notes

- **Referrals for FAE only accepted from psoriasis clinic as this is an unlicensed medicine, and permission to use is only granted to psoriasis clinic consultants.

3. SCOPE AND PURPOSE OF CLINIC

3.1. To safely initiate either methotrexate, ciclosporin, acitretin, azathioprine or fumaric acid esters for the treatment of inflammatory dermatoses.

The Nurse will:

- Ensure that a prescriber has provided clear instructions on start dose, dose escalation and monitoring requirements of the systemic agent in the patient notes, and has also supplied a valid prescription
- Review pregnancy status and contraceptive status in women of child bearing potential, explaining risk of conception on therapy
- Review significant out of range screening investigations with the referring doctor.
- Explain the risks of conception to men receiving methotrexate and azathioprine
- Ensure pre-treatment patient information leaflet and/or NPSA oral methotrexate leaflet (if applicable) was supplied at screening and issue if not
- Ensure patient understanding/consent to treatment
- Reiterate possible side effects of treatment and give advice on managing these side effects
- Explain potential drug interactions and advise any action to be taken
- Explain need for alcohol avoidance with mtx
- Reiterate the importance of informing the relevant nurse/doctor immediately of severe side effects that indicate treatment cessation.
- If applicable, issue and complete relevant data fields in NPSA patient held monitoring document explaining its use
- If applicable, inform pharmacy by letter that booklet was issued to comply with NPSA alert
- Explain dosing schedule e.g. frequency, no. of tablets to take, how and when to take medication and common side effects
- Order all monitoring bloods required for the drug initiation period prior to next clinic appointment.
- Give the doctor's prescription (to last until next clinic appt with Dr i.e. 14/52) if safe to do so.
- Perform all applicable baseline skin disease scores (e.g. PASI, EASI, DLQI etc)
- Arrange all follow up appointments in nurse monitoring clinic as well as clinic appointment with referring Doctor
- Provide nurse contact numbers for patients
- Offer the patient opportunity to enter relevant research studies such as BADBIR and/or pharmacogenetics.

3.2. To provide early monitoring service for patients (review clinical status and side effects).

The nurse will:

- Review the patient in a booked clinic environment at **weeks 4, 8 and 12** by:
  - Reviewing side effects and giving advice as required
  - Ensuring patient is taking medicine as prescribed; if not, documenting reasons for non-compliance
  - Documenting any new side effects, medical problems and reviewing any potential interacting medicines e.g. NSAIDS and some antibiotics
  - Reviewing blood tests (entering details into patients NPSA hand held booklet, if applicable)
  - Performing relevant skin assessments e.g. DLQI and validated scoring system for inflammatory dermatoses
  - Instructing patient to increase drug dose as prescribed, as long as blood test results and patient review are satisfactory (entering new dose for methotrexate in the patient held monitoring book)
- Gradually increase the ciclosporin dose by 1mg/kg every 4 weeks, up to 5mg/kg - for patients on ciclosporin for a licensed indication, who are tolerating treatment well (satisfactory serum creatinine* and blood pressure*) but there is no improvement within one month. Ciclosporin will be administered in two equally divided doses, but the dose will not exceed 5mg/kg/day. As per guidelines, * creatinine must be no more than 30% above baseline; and *diastolic blood pressure reading must be below 95 mmHg (Hypertension is defined as a diastolic blood pressure of greater than or equal to 95mmHg on two separate occasions).
- **Remotely** review patient, if applicable, as per relevant treatment guidelines by

telephone consultation (please see appendices outlining drug specific pathways) by;

- Ordering & checking blood results
- Ringing the patient to advise dose increase (where necessary) and if all blood test results are satisfactory
- Assessing and monitoring side effects
- Document this review in medical notes or on 'EPR Telephone Consultation'

4. NURSE REFERAL FOR MEDICAL SUPPORT

4.1. The nurse will call the referrer or their teams designated SpR if:

- Screening or monitoring blood test tests are significantly out of range as per GSTT treatment guidelines
- The patient is pregnant
- The patient is experiencing severe side effects from their systemic agent that is outside of the nurses scope
- The patient presents medically unwell
- The patient's skin condition is deteriorating significantly

4.2. The nurse will bring forward the patients review with the referring doctor if the patient is experiencing significant side effects and needs a dose reduction/treatment discontinuation (see 4.1 above)

4.3. The nurse will write to the referring doctor (cc GP & Patient), following initiation of treatment and at discharge from nurse led service; or if there are changes of note or problems with the process that need to be highlighted by letter.

5. DNA Policy;

5.1. DNA Initiation appointment

- Telephone patient to establish reason for DNA, if in error, rebook into clinic for next available. If unable to get through, rebook appt anyway & send out appt letter
- If DNA for a second time, discuss with referring doctor.

5.2. DNA follow-up appointment

- Telephone patient to establish reason for DNA, if in error, rebook pt & organise blood tests that are required asap.
- If unable to make contact with patient, send standard DNA letter to GP, referrer & patient (Ask GP to follow-up patient & monitor bloods).
- Rebook next follow-up appointment.
- If patient repeatedly DNA's, discuss with referring doctor.

6. RESPONSIBILITIES OF THE REFERRING DOCTOR

- To order all pre-treatment investigations – this includes the appropriate blood tests (See Guidelines) and where appropriate a chest X-ray
- To complete a detailed medical history and perform medical examination
- To assess all absolute and relative contraindications and possible drug interactions prior to deciding to proceed with initiation of therapy AND prior to referring into nurse-led initiation and early monitoring clinic
- To provide patient with pre-treatment information leaflets NB. These must be supplied before treatment is commenced, allowing patient time to consider the information, discussing it with his/her family as necessary
- To provide a prescription for systemic agent to last between medical review appointments (this will be a 14 week prescription with details of specific dose escalation regime); and document and file details in the patient's notes.

7. MODE OF CORRESPONDENCE

All consultations are documented in patient hospital records and blood test monitoring will also be recorded in NPSA patient held monitoring booklet, where applicable. A letter will be sent to the referring doctor and copied to the patients' GP and the patient following the initiation of treatment. Every telephone consultation will be documented in the medical notes or on 'EPR Telephone Consultation' in the absence of the notes. Unless clinical problems arise at monitoring visits, no further formal correspondence will be sent until the patient is discharged from nurse led service (Week 12).

8. DISCHARGE POLICY

Patient will be seen as per the treatment pathway for initiation and for the first 12 weeks of therapy. Patients who have been referred from the severe psoriasis service will be discharged back to the severe psoriasis service and reviewed in the clinic at week 12. Patients referred from other clinics will be seen in the nurse led clinic at week 12 and will be discharged back to the referring dermatologist with an appointment to be seen within 2 - 4 weeks of last appointment in the nurse led monitoring clinic .

9. CLINICAL COVER

If one of the two nurses is on leave, their list will be cancelled and the second list will remain open and covered by the remaining nurse. In the rare event that both nurses are absent the nurse consultant will cover the booked clinical activity (one list only). Formal supervision is provided by the nurse consultant.

10. Glossary

MTX = Methotrexate

TPMT = Thiopurine methyltransferase

NPSA = National patient safety agency

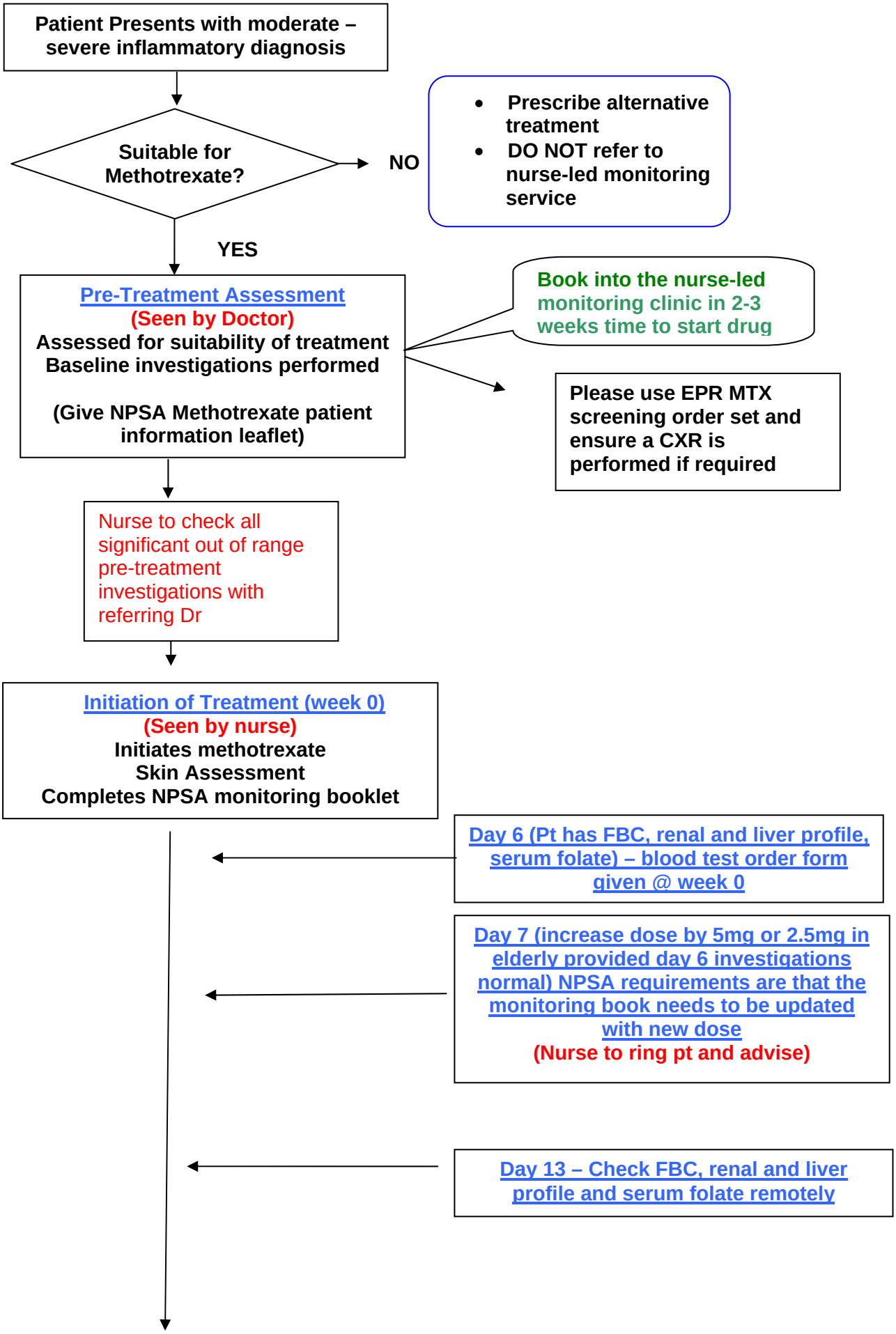
PASI = Psoriasis area and severity index

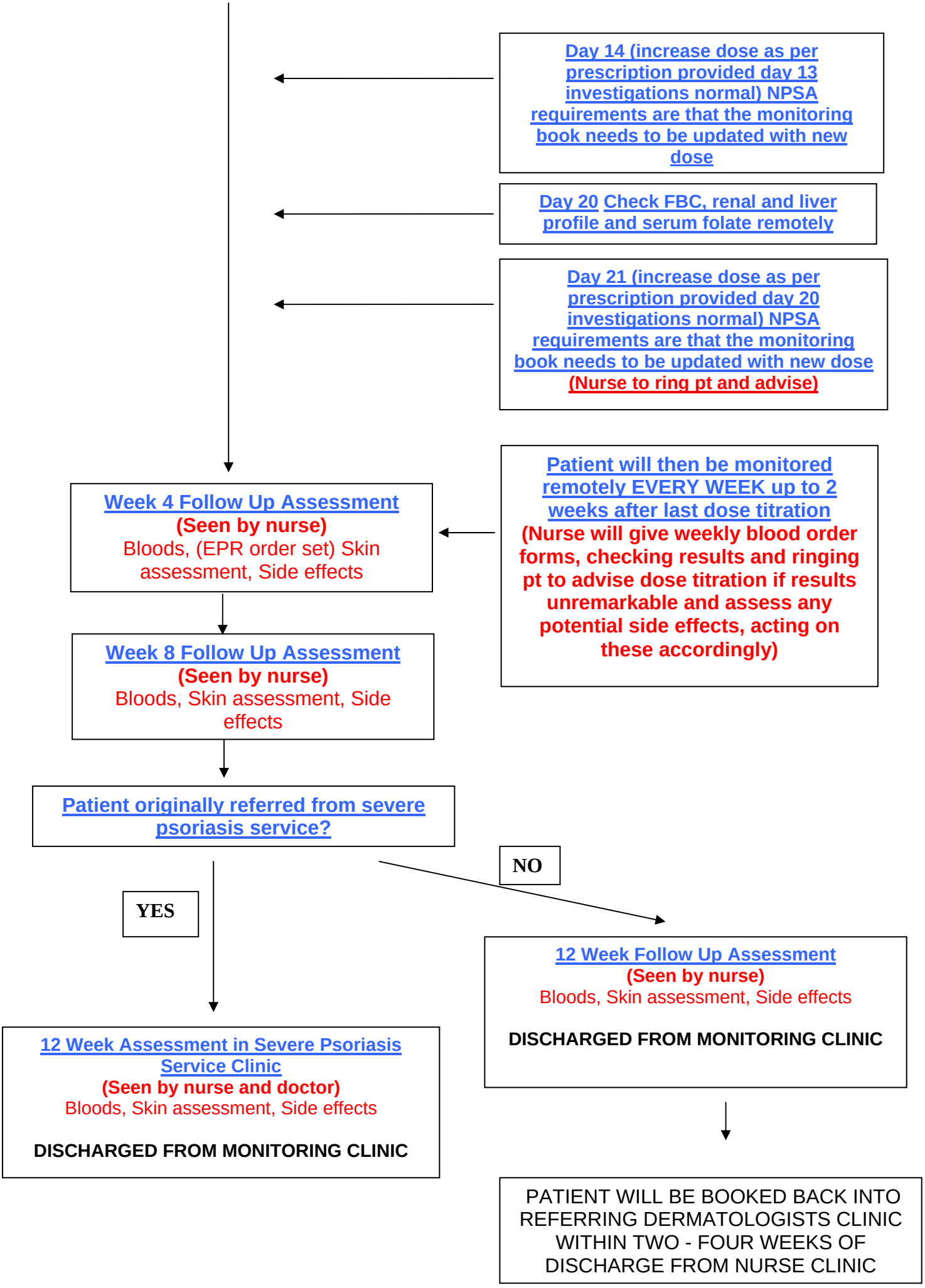
DLQI = Dermatology life quality index

EPR = Electronic patient record

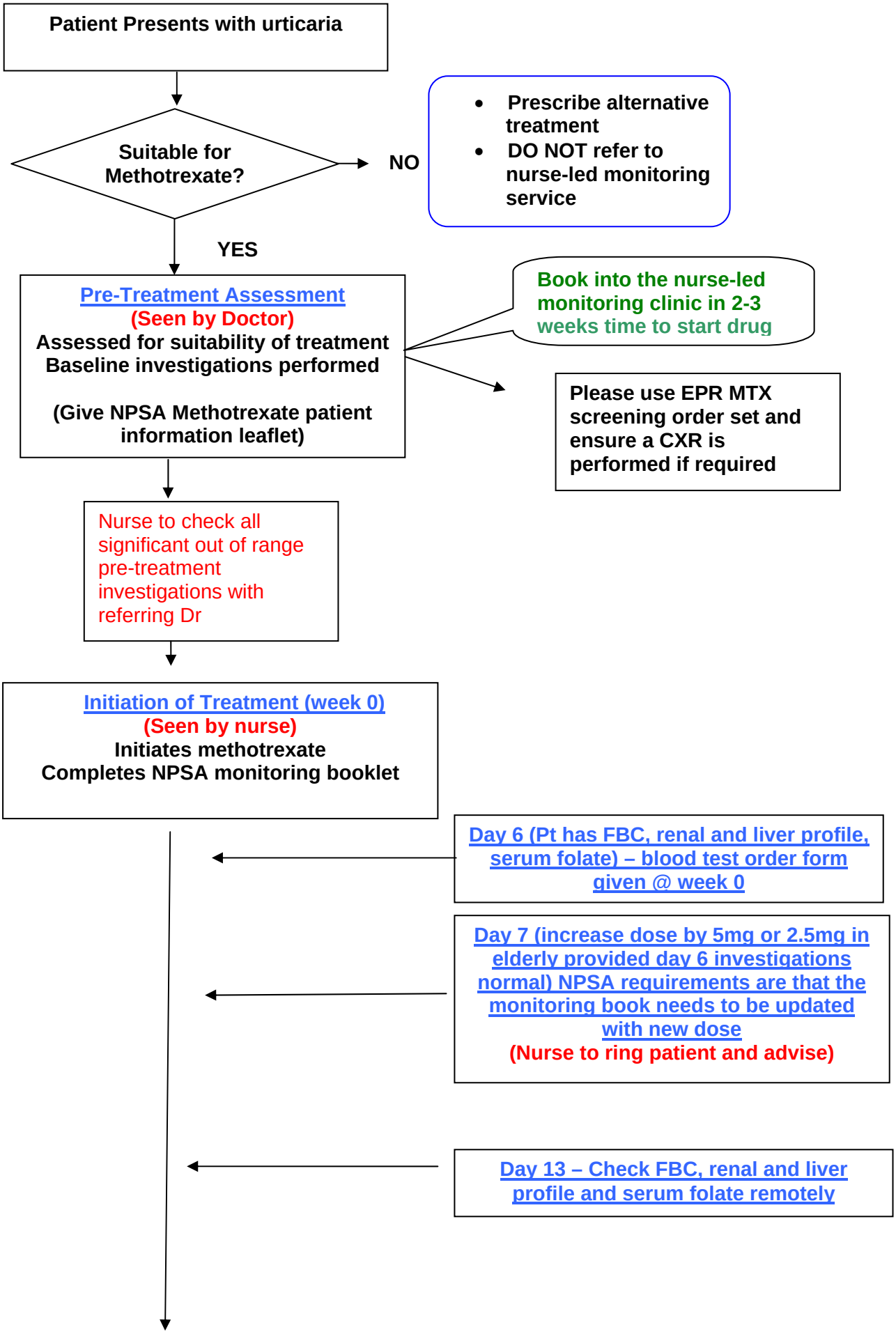
CXR = Chest Xray

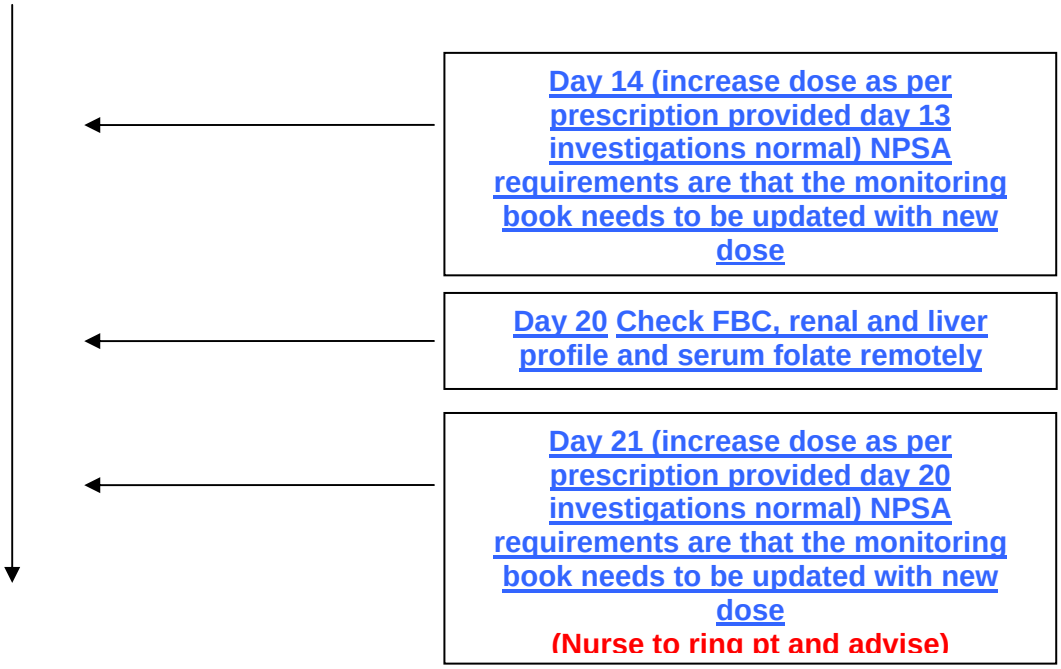
Appendix 1: Methotrexate pathway for patients with inflammatory dermatoses




Day 14 (increase dose as per prescription provided day 13 investigations normal) NPSA requirements are that the monitoring book needs to be updated with new dose
Day 20 Check FBC, renal and liver profile and serum folate remotely
Day 21 (increase dose as per prescription provided day 20 investigations normal) NPSA requirements are that the monitoring book needs to be updated with new dose
(Nurse to ring pt and advise)
Patient will then be monitored remotely EVERY WEEK up to 2 weeks after last dose titration
(Nurse will give weekly blood order forms, checking results and ringing pt to advise dose titration if results unremarkable and assess any potential side effects, acting on these accordingly)
Week 4 Follow Up Assessment
(Seen by nurse)
Bloods, (EPR order set) Skin assessment, Side effects
Week 8 Follow Up Assessment
(Seen by nurse)
Bloods, Skin assessment, Side effects
Patient originally referred from severe psoriasis service?
NO
YES
12 Week Follow Up Assessment
(Seen by nurse)
Bloods, Skin assessment, Side effects
DISCHARGED FROM MONITORING CLINIC
12 Week Assessment in Severe Psoriasis Service Clinic
(Seen by nurse and doctor)
Bloods, Skin assessment, Side effects
DISCHARGED FROM MONITORING CLINIC
PATIENT WILL BE BOOKED BACK INTO REFERRING DERMATOLOGISTS CLINIC WITHIN TWO - FOUR WEEKS OF DISCHARGE FROM NURSE CLINIC

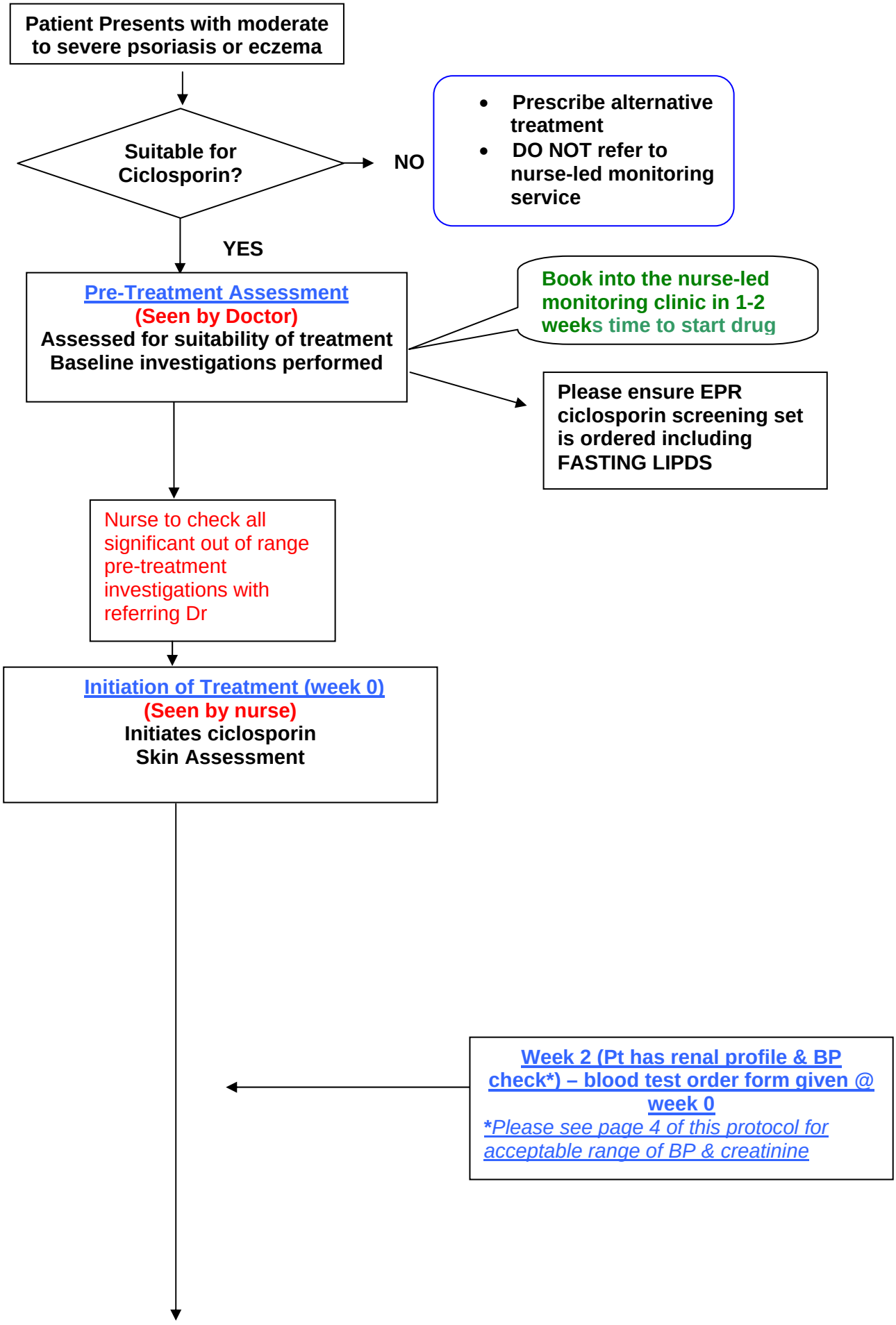
Appendix 2: Methotrexate pathway for patients with urticaria

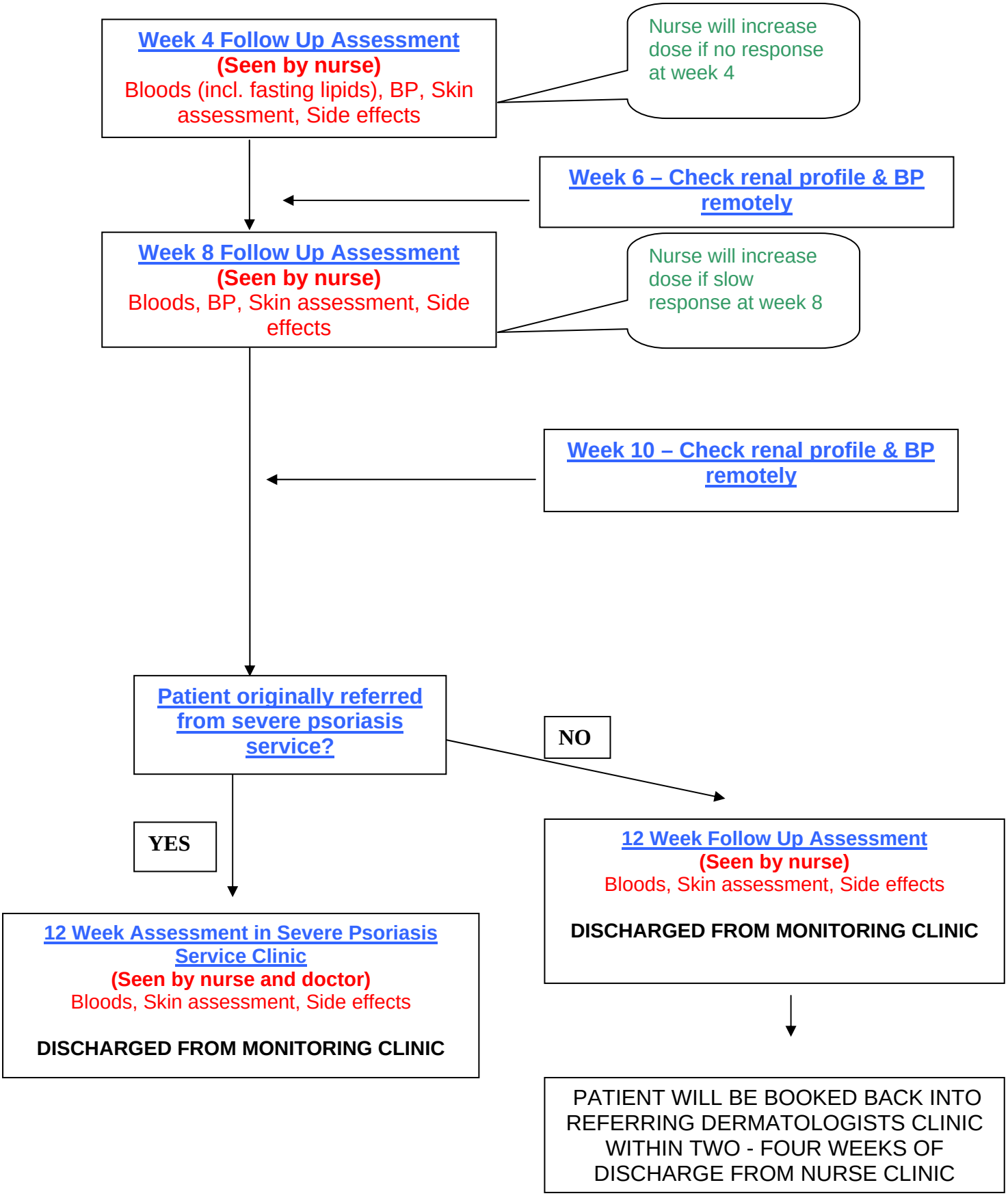




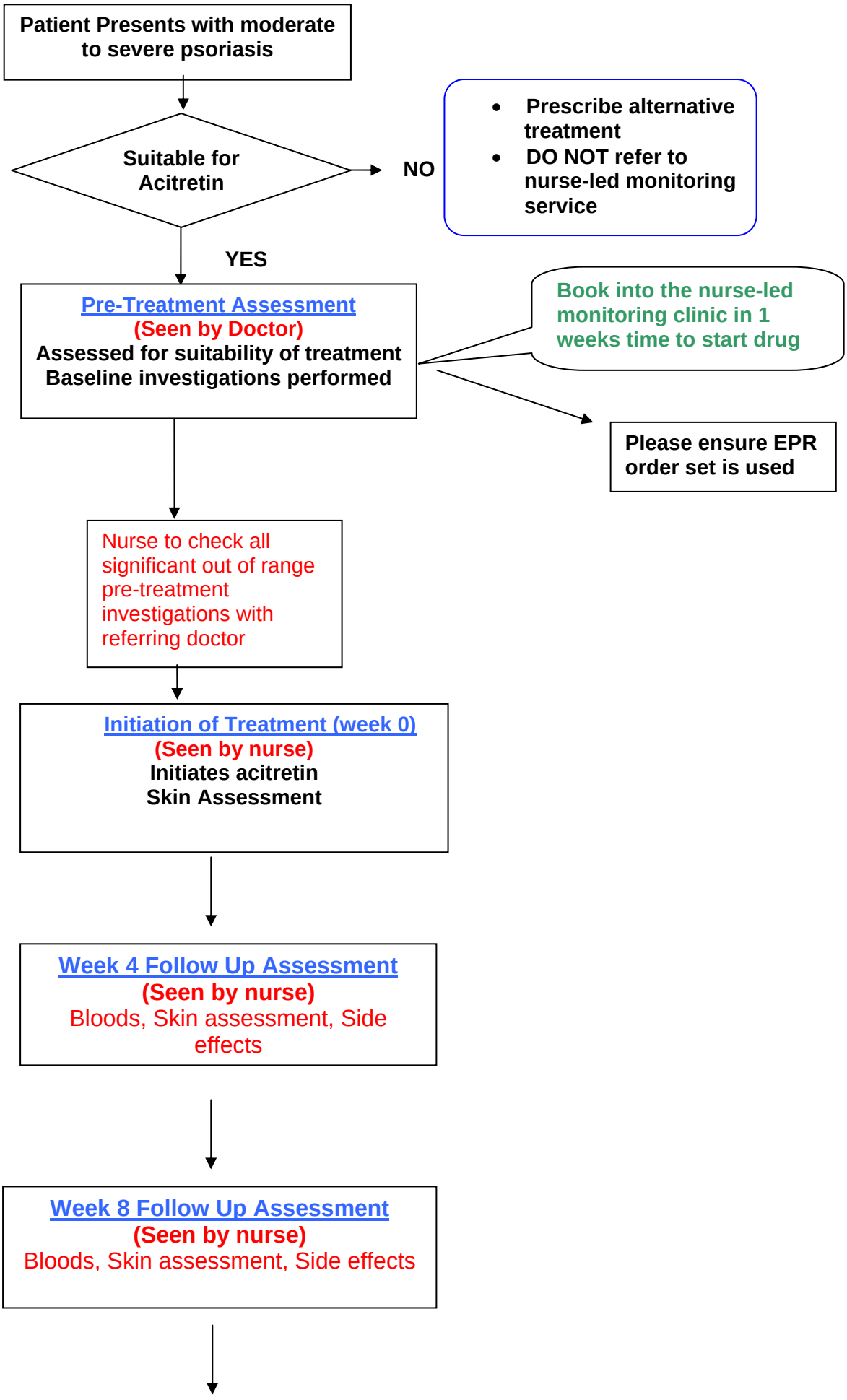
Patient is DISCHARGED from nurse-led service ensuring that patient has a review with referring doctor at WEEK 4 of treatment

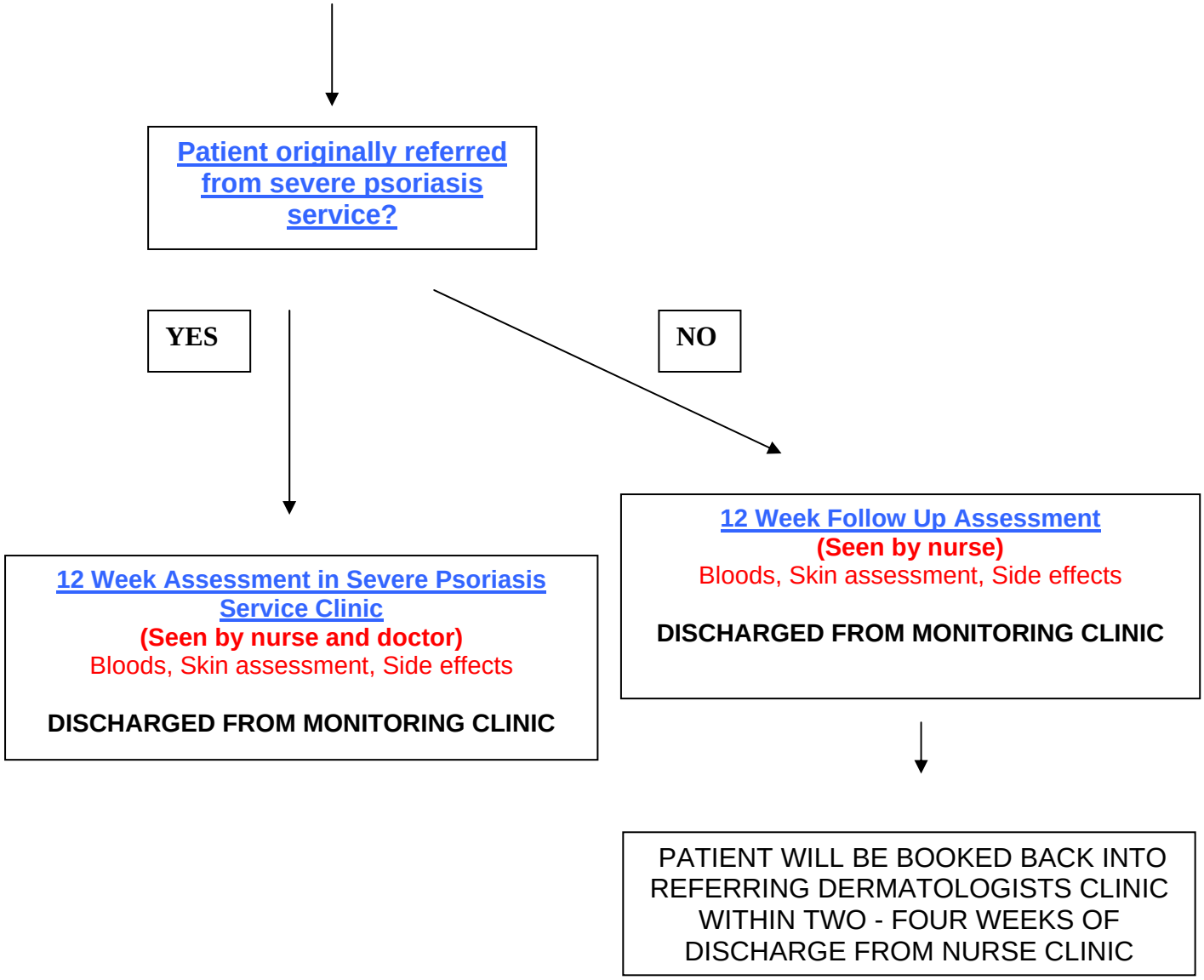
Appendix 3: Ciclosporin pathway for patients with inflammatory dermatoses



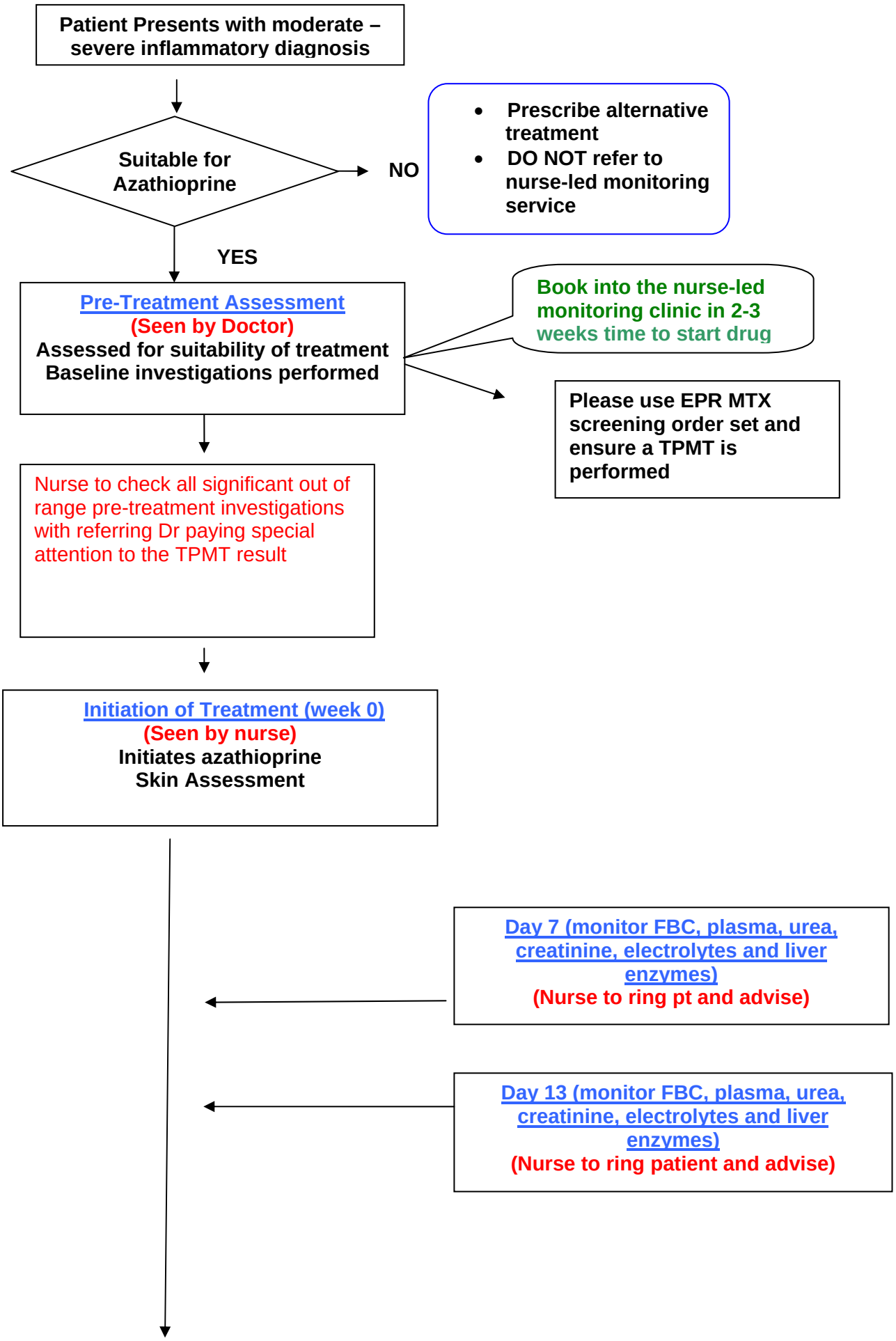

Week 4 Follow Up Assessment
(Seen by nurse)
Bloods (incl. fasting lipids), BP, Skin assessment, Side effects
Nurse will increase dose if no response at week 4
Week 6 – Check renal profile & BP remotely
Week 8 Follow Up Assessment
(Seen by nurse)
Bloods, BP, Skin assessment, Side effects
Nurse will increase dose if slow response at week 8
Week 10 – Check renal profile & BP remotely
Patient originally referred from severe psoriasis service?
NO
YES
12 Week Follow Up Assessment
(Seen by nurse)
Bloods, Skin assessment, Side effects
DISCHARGED FROM MONITORING CLINIC
12 Week Assessment in Severe Psoriasis Service Clinic
(Seen by nurse and doctor)
Bloods, Skin assessment, Side effects
DISCHARGED FROM MONITORING CLINIC
PATIENT WILL BE BOOKED BACK INTO REFERRING DERMATOLOGISTS CLINIC WITHIN TWO - FOUR WEEKS OF DISCHARGE FROM NURSE CLINIC

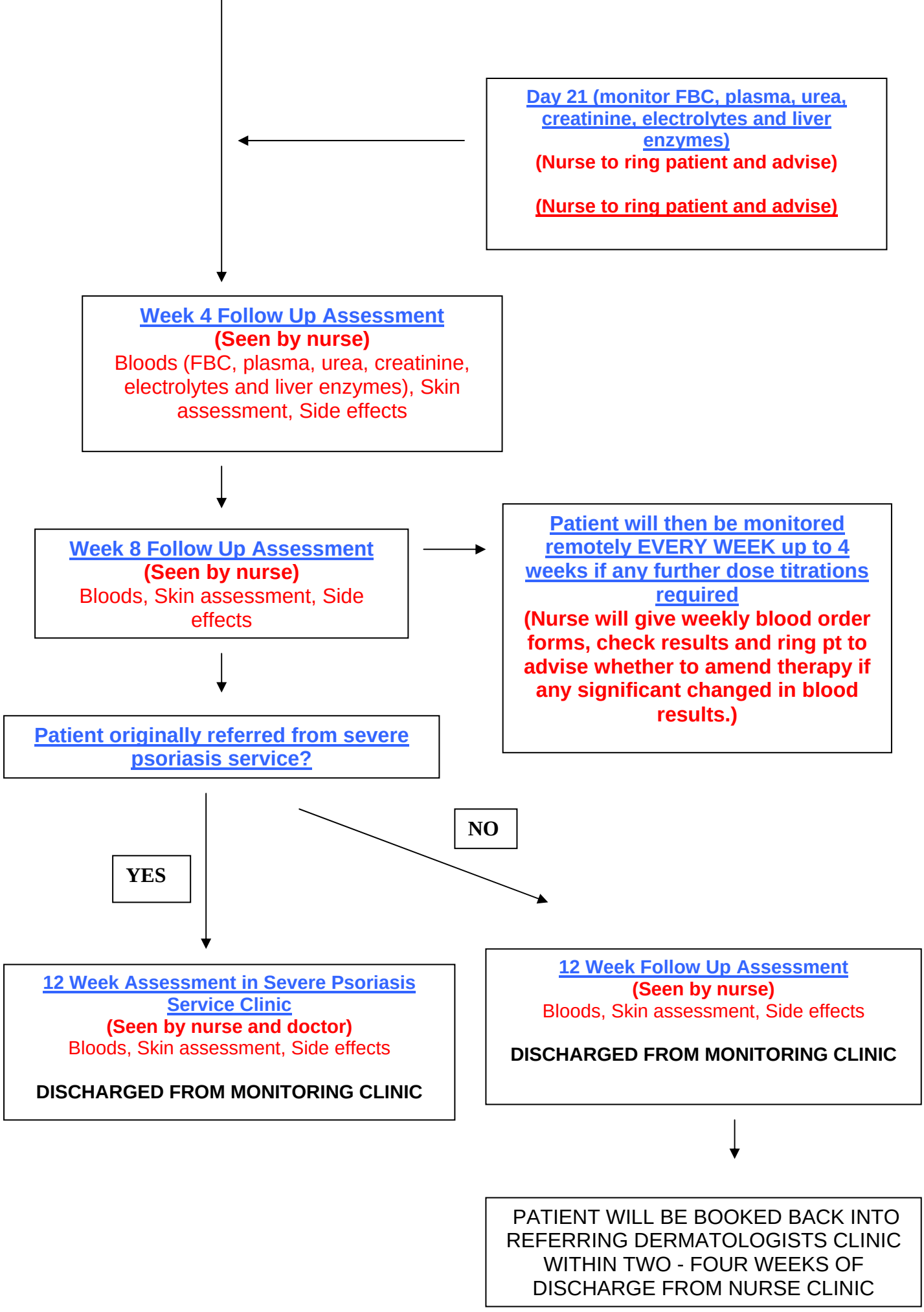
Appendix 4: Acitretin pathway for patients with moderate to severe psoriasis




Patient originally referred from severe psoriasis service?
YES
NO
12 Week Assessment in Severe Psoriasis Service Clinic
(Seen by nurse and doctor)
Bloods, Skin assessment, Side effects
DISCHARGED FROM MONITORING CLINIC
12 Week Follow Up Assessment
(Seen by nurse)
Bloods, Skin assessment, Side effects
DISCHARGED FROM MONITORING CLINIC
PATIENT WILL BE BOOKED BACK INTO REFERRING DERMATOLOGISTS CLINIC WITHIN TWO - FOUR WEEKS OF DISCHARGE FROM NURSE CLINIC

Appendix 5: Azathioprine pathway for patients with inflammatory dermatoses




Day 21 (monitor FBC, plasma, urea, creatinine, electrolytes and liver enzymes)
(Nurse to ring patient and advise)
(Nurse to ring patient and advise)
Week 4 Follow Up Assessment
(Seen by nurse)
Bloods (FBC, plasma, urea, creatinine, electrolytes and liver enzymes), Skin assessment, Side effects
Week 8 Follow Up Assessment
(Seen by nurse)
Bloods, Skin assessment, Side effects
Patient will then be monitored remotely EVERY WEEK up to 4 weeks if any further dose titrations required
(Nurse will give weekly blood order forms, check results and ring pt to advise whether to amend therapy if any significant changed in blood results.)
Patient originally referred from severe psoriasis service?
NO
YES
12 Week Assessment in Severe Psoriasis Service Clinic
(Seen by nurse and doctor)
Bloods, Skin assessment, Side effects
DISCHARGED FROM MONITORING CLINIC
12 Week Follow Up Assessment
(Seen by nurse)
Bloods, Skin assessment, Side effects
DISCHARGED FROM MONITORING CLINIC
PATIENT WILL BE BOOKED BACK INTO REFERRING DERMATOLOGISTS CLINIC WITHIN TWO - FOUR WEEKS OF DISCHARGE FROM NURSE CLINIC

Appendix 6: Fumaric Acid Esters pathway for patients with moderate to severe psoriasis