Defining the *Traffic Light* medicine status

Introduction

The ***traffic light*** system- **R**ed **A**mber **G**reen (**RAG**), double red and blue- classification offers guidance on the prescribing of drugs initiated in secondary care and aims to align the information provided in the NHS England guidance *Responsibility for prescribing between primary and secondary/tertiary care* (Jan 2018) which replaces EL(91)127 "Responsibility for Prescribing between Hospitals and GPs.", DH.

East Suffolk and North East Essex Foundation Trust, NHS Ipswich and East Suffolk CCG and NHS North East Essex CCG have classified medicines using the following colour framework:

- **DOUBLE RED:** Not recommended for prescribing by either primary or secondary care.
- **RED:** Not recommended for prescribing by primary care, prescribing responsibility to be retained in secondary care for Hospital Only Prescribing.
- **AMBER:** Initiated by specialist in secondary care, prescribing can be continued in primary care in conjunction with a Shared Care Agreement.
- **GREEN:** Initiated (if clinically urgent) or advised (if non-urgent) by specialist in secondary care, prescribing can be continued in primary care (shared care not required, but GP should be provided with sufficient information).
- **BLUE:** For routine prescribing in primary and secondary care.

This classification offers guidance to primary and secondary care providers on the prescribing of a drug and where clinical responsibilities should lie following its initiation. This ensures the provision of care is seamless and clinically safe.

The system is intended to encourage appropriate shifts in prescribing between hospital clinicians and general practitioners (GPs) consistent with clinical responsibility and supported by the most appropriate form of guidance or information (e.g. shared care guidelines) in order to provide assurance that the transfer of prescribing responsibilities is completed in a safe and effective manner

The criteria used for defining status is based on the specialist nature of the drug, the complexity of the assessment and monitoring arrangements required for the care of the patient, clinical responsibility and competency associated with the prescribing of a medicine and is not based on the cost of a medication.

It is important to note that these are not rigid. Where necessary, secondary and primary care prescribers should discuss the appropriate management of individual patients personally. On occasions both parties may agree to work outside of this guidance. In addition where appropriate pathways are in place some CCGs may have a variation to this list.

This is applicable to medicines which have been agreed by NHS Organisations and the CCGs in the East Suffolk and North East Essex area only. Some medicines may have a different position outside of the area and the primary care prescriber may wish to consider the out of area position of prescribing. The prescriber may wish to contact the local prescribing advisor (or equivalent) at the CCG for guidance.

Some medicines may exist under more than one Traffic Light + classification depending the indication which may require a different status decision depending on the monitoring and assessment required.

It is the responsibility of the applicant to clearly define the formulary position and of the medicines committees to ensure the position meets the criteria defined below.

Criteria for the *traffic light*

DOUBLE RED drugs

Double red drugs are those where prescribing is not generally recommended for any patient group in primary or secondary care.

Drugs which are not appropriate for prescribing by primary or secondary care may be due to one or more of these reasons:

1. Lack of data on effectiveness compared with standard therapy.
2. Lack of data on safety compared with standard therapy.
3. Known increase in risk of adverse events compared with standard therapy.
4. Lack of data on cost-effectiveness compared with standard therapy.
5. Less cost-effective than current standard therapy
6. NICE guidance which does not recommend the use of the drug

RED drugs

Not recommended for prescribing by primary care, prescribing responsibility to be retained in secondary care for Hospital Only Prescribing.

Drugs which should only be prescribed in secondary/tertiary care may be due to one or more of these reasons:

1. Unlicensed products where a large body of evidence for use of the medicine is not available- this excluding those unlicensed for the formulation or 'off label' paediatric use
2. The condition is considered rare
3. The medicine is a NHS England commissioned medicines listed either in the NHS England drug list (please click here) or NHS England Manual for Prescribed Specialised Services
4. Medicines by manufacturer's recommendation or without wholesale opinion as being specialist only
5. Medicines whose monitoring or control remains within secondary care (e.g. oncology)
6. The drug or condition requires specialist knowledge to ensure safe prescribing and monitoring. The safe management of patients in primary care **cannot** be supported through provision of comprehensive written information.
7. The individual GP is unable to monitor therapy sufficiently to oversee treatment or adjust the dose where necessary to ensure safety
8. IV drugs agreed as not an appropriate drug for primary care prescribing (some of these can appropriately be waived in certain situations e.g. palliative care, paediatrics or cystic fibrosis)
9. Medicines for which the funding is levied out with primary care- medicine, dressing or appliance is only available through a hospital.
10. The medicine appears on the Black List within the NHSBSA Drug Tariff
11. Similar but less familiar medicines to another recommended product
12. Medicines that have received a negative or "do not do" from NICE
13. Requiring long-term, on-going specialist monitoring of efficacy carried out by secondary/tertiary care
14. Requiring long-term, on-going specialist monitoring of toxicity (because the side-effect profile necessitates rigorous supervision by the hospital consultant or, the full range of possible side-effects, particularly long-term effects needs to be established) from secondary/tertiary care
15. That are hospital indicated clinical trial materials
16. Requiring specialist assessment to enable patient selection, initiation and continuation of treatment

When assigning Red status to a drug then commissioning implications should be considered. For example commissioning of provision of the drug from secondary care needs to be included as part of the pathway of care.

Appendix 1 aims to provide a flow diagram to help identify the key differences between RED and AMBER drugs.

Amber drugs

It is recommended that shared care arrangements should be drawn up following local discussion and agreement by prescribing parties. A shared care guideline details the respective clinical responsibilities of both parties. An example shared care template can be found in **appendix 2.**

Criteria for "Amber" classification:
Circumstances which meet all of the following criteria may allow a product to be used as part of a shared care arrangement (Amber Drug), following agreement by both prescribing parties involved.
A shared care guideline has been drawn up following joint discussion and agreement of the parties.

The shared care agreement:

1. Provides a comprehensive summary of treatment
2. Defines the responsibility of the consultant and the GP for monitoring and adjusting treatment
3. Defines the referral procedure from hospital to GP
4. Defines the back-up facilities available to the GP from hospital with which the agreement is made.
5. The GP is satisfied that he/she has all the information and support needed to prescribe and monitor the patient
6. If a product is not licensed for the proposed indication, full justification for its use is given by the consultant to the GP and this is documented in the patients notes

Principles for shared care

1. Patients should obtain care through their local GP practice whenever possible, where it is convenient for them to attend and the patients' illnesses and current medicines are best known.
2. Care should be provided by the doctor who is best placed to provide it safely and this can sometimes be in either primary or secondary care.
3. Consultants should usually advise on care rather than manage it and General Practitioners should usually manage their patients and their patients' illnesses and medicines.
4. By improving the communication between primary and secondary care the variability in approaches to treatment will diminish.
5. Prior research and discussion should enable a shared understanding and ensure that the optimum quality of evidence-based treatment is available to all patients.
6. It would not normally be expected that GPs should be asked to participate in a shared care arrangement where no appropriate protocol exists or where the drug or disease process falls out with the criteria defined as being suitable for inclusion in a shared care agreement.
7. Where there is dispute over arrangements for prescribing, responsibility for prescribing remains with the consultant until resolved.
8. Where community nurse involvement is required in the administration of drugs under a shared care guideline, they should be provided with adequate information and guidance by the prescriber or the hospital and arrangements should be made in good time for any potential problems to be resolved before patient care is compromised

Various considerations will lead to the decision that a medicine is suitable for inclusion in a shared care guideline, including:

- Is this truly shared care or is it just to shift prescribing into primary care?
- How often will cases be encountered?
- How often does the patient need to return to secondary care for monitoring of the disease?
- What is the complexity of the drug?
- How new is it to the market and to the consultants recommending it?
- Is it in a trial?
- Where the funding is held?
- How available and reliable is the information concerning the drug: its effectiveness?
- Who is responsible for adjusting the dose and/or making the decision to discontinue it?
- Is its monitoring safe and practical in Primary Care?
- Are there supply, handling or storage problems for Community Pharmacies?
- Is waste disposal a problem?
- What will the patient gain by the care being shared?
- When assigning Amber status to a drug then commissioning implications should be considered. For example costs around moving a drug from secondary to primary care need to be evaluated alongside the need for the patient to be reviewed in secondary care.

GREEN drugs

These are drugs that can be prescribed safely in primary care but require initiation or advice/ recommendation from secondary care

These drugs have:

- Little to no monitoring of the drug (e.g. requires blood pressure or creatinine checks)
- The condition is routinely manageable within primary care
- It is in line with NHS prescribing
- Ongoing monitoring and follow up can be safely manageable in primary care

Green drugs must be initiated by the specialist if the drug I required urgently. Specialists can advise or recommend a green drug when it does not to be started urgently.

Blue drugs

- The condition and drug do not require any specialist input to initiate/advise or continue.
- The management of the condition and monitoring of the drug is limited

Acknowledgement

Adapted from the NHS GMMMG Interface Prescribing Subgroup *Guidelines on defining RED/AMBER/GREEN medicines status* July 2014 (please click here)

Suffolk and North East Essex Area Prescribing Committee (SNE APC)

NHS Ipswich and East Suffolk CCG (IESCCG), NHS North East Essex CCG (NEECCG), NHS West Suffolk CCG (WSCCG)
East Suffolk and North Essex NHS Foundation Trust (ESNEFT), Norfolk and Suffolk NHS Foundation Trust (NSFT), West Suffolk NHS Foundation Trust (WSFT), Anglian Community Enterprise (ACE), Essex Partnership University Trust (EPUT)
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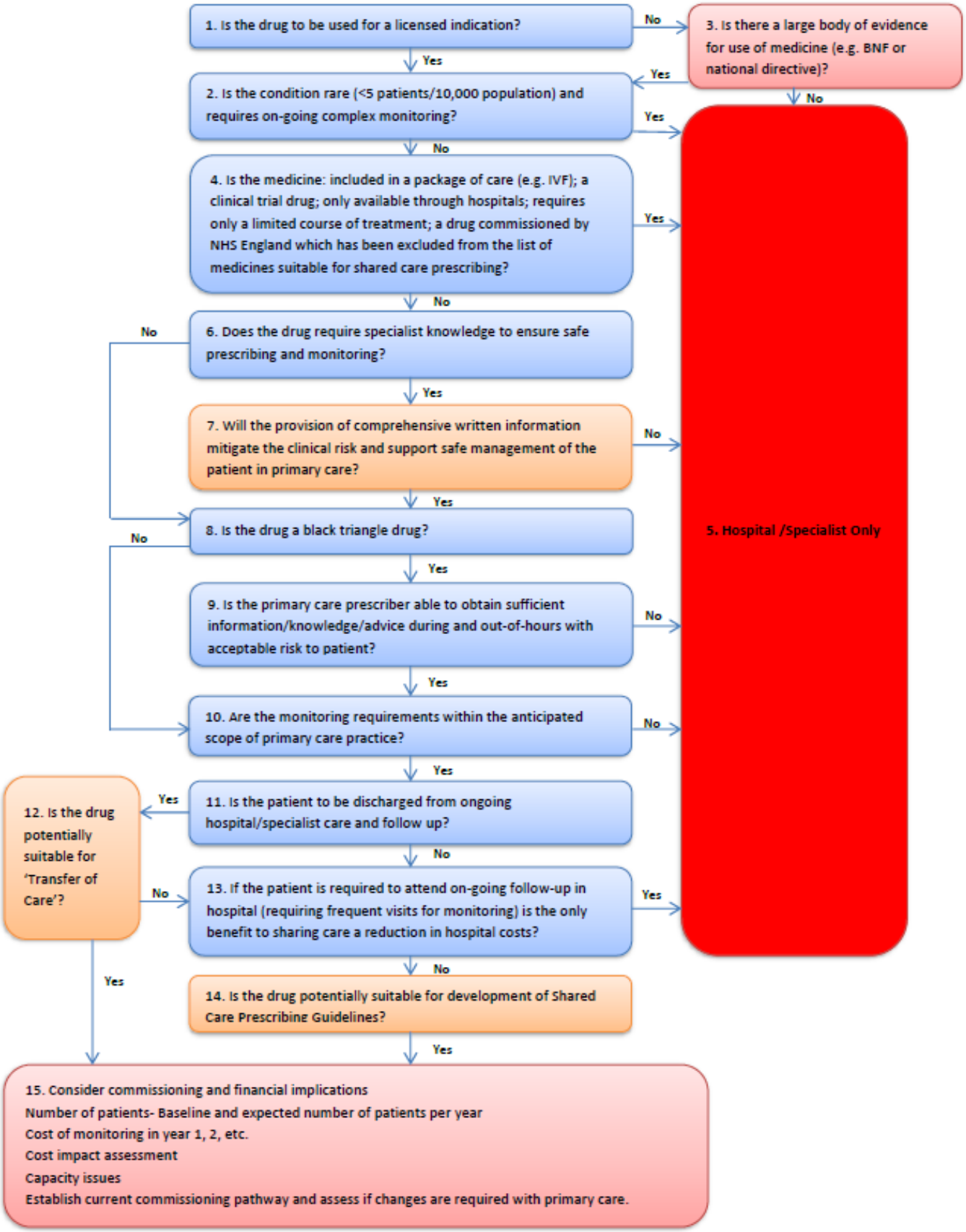
Appendix 1: Flow Chart to identify if a new medicine is RED or AMBER



Appendix 2: Shared Care Agreement Template

[DRUG] SHARED CARE AGREEMENT (SCA) FOR ADULTS/CHILDREN

FOR USE IN [INDICATION]

SPECIALIST RESPONSIBILITIES

1. Assess patient, confirm diagnosis and discuss benefits and risks of treatment with the patient.
2. Confirm women of childbearing age are not pregnant. Ensure that the requirement for contraception is understood and prolonged risk of conception after use of [INCLUDE DRUG NAME]. Pregnancy should be prevented for a minimum of 6 weeks after discontinuation of treatment.
3. Perform pre-treatment assessments and on-going monitoring as detailed.
4. Advise patient and GP if any **inactivated** vaccinations are required (e.g. influenza, pneumococcal).
5. Prescribers should familiarise themselves with the drug indication, dose, administration, contra-indications, cautions, side-effects, interactions and preparation by referring to the current version of the Summary of Product Characteristics (https://www.medicines.org.uk/emc) or the BNF (https://bnf.nice.org.uk/).
6. Initiate and titrate treatment with [INCLUDE DRUG NAME]. therapy and supply for x weeks.
7. Provide appropriate written information on [INCLUDE DRUG NAME]. to the patient.
8. Review efficacy of treatment and ensure any drug treatment changes are communicated to the GP.
9. Act on pathology lab results when initiated by the hospital.
10. Advise the GP on frequency of monitoring and what to do when the parameters change.
11. Communicate any changes in frequency of pathology testing to the GP if relevant.
12. Ensure clear back-up arrangements exist for GPs, including telephone number for advice and support and regularly checked e-mail account.
13. Discuss proposed SCA with the patient and provide the ***Shared Care Agreement: Information for patients*** to the patient.
14. Send a letter to the patient's GP to request participation in the SCA, along with this current SCA or a link to the SCA on the CCG website or traffic lights and the clinic letter (containing full details of the prescribing and treatment plan). The GP must respond to the specialist within 14 days if not willing to participate in shared care.
15. Full clinical responsibility for the patient and the prescribed treatment will remain with the specialist if the GP declines to participate.

Provided that the GP has not declined to participate in the SCA, the specialist will:

1. Make a record in the patient's secondary care notes that treatment is being given as part of an SCA.
2. Inform the patient of the aspects of care that will be provided by the specialist and by the GP.
3. Ensure ongoing treatment is provided before prescribing is transferred.
4. Inform the patient when to contact their GP practice.
5. Ask the patient to report any adverse effects about their treatment to the specialist or GP. Adverse events should be reported by the specialist or GP to the MHRA (http://yellowcard.mhra.gov.uk/). Female patients must be asked to inform the specialist or GP if they are pregnant or planning a pregnancy.
6. Review the patient as clinically appropriate and inform the GP of any changes to treatment, the next date for blood reviews and when the prescription is due.
7. Advise the GP of the on-going monitoring required as detailed on below.
8. Advise the GP of when and how to discontinue treatment (if necessary).
9. Ensure clear arrangements exist for GPs to obtain advice and support.

GP RESPONSIBILITIES

1. Offer flu and pneumococcal vaccination as required for patients on immunosuppressive agents.
2. Review request from the specialist to participate in the SCA and respond to the specialist as soon as possible (within 14 days) if you cannot accept the SCA due to clinical reasons. Prescribing should not be refused on the grounds of drug cost. [INCLUDE DRUG NAME] is/is not included in the local Shared Care Enhanced Service.

Once shared care is transferred to the GP, the GP will:

3. Make a record in the patient's primary care notes that treatment is being given as part of an SCA.
4. Familiarise themselves with the drug indication, dose, administration, contra-indications, cautions, side-effects, interactions and preparation by referring to the current version of the Summary of Product Characteristics (https://www.medicines.org.uk/emc) or the BNF (https://bnf.nice.org.uk/).
5. Prescribe [INCLUDE DRUG NAME] in accordance with the specialist prescribing and treatment plan.
6. Check for possible drug interactions when newly prescribing or stopping concurrent medication.
7. Report any adverse effects to the specialist and to the MHRA (http://yellowcard.mhra.gov.uk/).

8. Follow advice from the specialist regarding any changes required to treatment.
9. Perform on-going monitoring as advised by the specialist and detailed below.
10. Refer to the specialist if the patient's clinical condition deteriorates, if intolerance to treatment develops, or if contra-indications/cautions arise that prevent continued prescribing. Female patients must be asked to inform the specialist or GP if they are pregnant or planning a pregnancy.
11. Discontinue treatment (if necessary) on the advice of the specialist.
12. Contact the specialist for any necessary advice and support via the telephone helpline numbers provided.

Contact information

IPSWICH HOSPITAL CONTACT DETAILS		
COLCHESTER HOSPITAL CONTACT DETAILS		
WEST SUFFOLK HOSPITAL		

SHARED SPECIALIST & GP RESPONSIBILITIES: MONITORING

On-going monitoring will be transferred from the specialist to the GP after the specialist has stabilised the patient on treatment

	Parameter		Frequency
	In addition to absolute values for haematological indices, a rapid fall or rise and a consistent upward or downward trend in any value should prompt caution and extra vigilance		
	Parameter	**Frequency**	**Action to take if abnormal result**
Specialist moving to GP once shared care accepted			
	Symptoms that the patient may report		**Action for GP to take if symptom occurs**
Specialist and GP			•
			•
			•
			•

Shared Care Agreement: Information for patients

Patient Name: Patients NHS Number: Medicine: Indication

We would be grateful if you would take time to read this information as it will help us work with you to manage your condition and ensure safe prescribing of the specific medicine listed above.

What is a Shared Care Agreement (SCA)?

A Shared Care Agreement (SCA) enables the care you have for a specific condition to be shared between the hospital and your GP. The agreement means that the medicine the hospital has started, can be continued by your GP, so you won't have to visit the hospital to collect your medicine. The SCA gives information on your medicine, guidance on the prescribing and monitoring responsibilities for your consultant (in the hospital), your GP and you. For an SCA, to work everyone involved must understand it and communicate effectively. Your consultant and your GP will need to sign the agreement and if you agree to this approach, we would ask you to sign this letter, to indicate your agreement to have your care managed in this way.

How does Shared Care work?
The consultant is a specialist in your condition and will start prescribing your medicine, making sure it is suitable for you. There will come a point in your treatment when you may not need to be monitored by the consultant as often and this monitoring can be done by your GP. Once your GP has agreed to the SCA, they will be able to prescribe the same medicine for you at the dose recommended by the consultant.

The organisation which regulates GPs, the General Medical Council, says that 'when a GP prescribes a medicine, the GP needs to satisfy themselves that the prescription is needed, appropriate for the patient and within the limits of their competence'. So, your GP can only issue a prescription if the consultant and you keep to the responsibilities you have agreed (see below). If responsibilities are not kept or if the GP no longer feels it is safe to prescribe the medicine, he/she will explain the reasons to you and your consultant, then prescribing responsibilities will be transferred back to the hospital.

What do I need to do to ensure the SCA can continue?

Attend hospital outpatients
You must still attend the hospital for regular reviews as directed by your consultant (these may be less frequent than before and you may be seen by a specialist pharmacist or a specialist nurse). If you do not attend your hospital appointments, your GP will not be able to continue issuing prescriptions forthis medication.

Attend GP appointments
You must attend any appointments you have with your GP in relation to this medicine, so they can look after you effectively

Have blood tests as you have been advised to
Your consultant should have informed you if and how often you need to have blood monitoring tests. You can usually have your blood taken at an appropriate clinic and not need to go to the hospital.

If you do not have the blood monitoring tests as advised by your consultant, your GP will no longer be able to issue you with prescriptions as it would not be safe to do so.

What do I do if I am having side-effects to the medicine?
Your consultant should have informed you of the common side-effects to expect and what to do if you experience them. If you think you may be having side-effects from a medicine report these directly to your consultant. Your

GP may need to seek advice from your consultant before issuing you with another prescription; this is to ensure it is safe for you to continue on the medication.

What if my disease symptoms change or get worse?
Report any changes in disease symptoms or circumstances that could affect management of your disease to your consultant.

What about the other medicines I take?
Inform your GP and the consultant of all other medicines you are taking, including those you may have bought yourself. Do not take new medicines (including those you could buy) until you have discussed this with your pharmacist, GP or consultant. If you would like to go ahead with a shared care agreement for the specific medication identified on page 1, please sign below to confirm that you:

- Understand the shared care agreement.
- Are happy to have your care for this aspect of your health managed by a shared care agreement.
- Agree to attend regular review appointments as requested.
- Agree to have blood tests as required.

What happens if I change GP Practice?
If you register at a new GP Practice a new agreement needs to be put in place between your new GP and the specialist team. The specialist team can start this process if you provide them with information before you move to make sure there is a smooth handover.

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