Guidelines on the Red/Amber/Green (RAG) system for classifying medicines in Sunderland Joint Formulary

Background

The **R**ed/**A**mber/**G**reen **(RAG)** classification offers guidance on the prescribing of drugs initiated in primary and secondary care on the primary basis of patient safety.

Proposal

The RAG list is intended for use in conjunction with the agreed joint formulary, to ensure that the level of patient care and monitoring required for use of the drug is not compromised. By categorising drugs as red, amber, green+ or green, the list will clarify prescribing responsibilities and provide information as to whether the medicine should be supplied from hospital or the community. The 'traffic light' system is designed to encourage appropriate shifts in prescribing between primary and secondary care consistent with clinical responsibility and supported by shared care arrangements where applicable. The aims of the document are:

- to improve the safe and effective transfer of prescribing from secondary to primary care
- to address areas of concern relating to new or rarely prescribed medication, unlicensed or off-label use of medication and non-formulary prescribing
- to enhance the safe and effective use of medicines ensuring "seamless" continuity of treatment without inconvenience or distress to the patients involved
- to improve patient safety and care when prescribing is transferred between care providers

The criteria used for defining the RAG status of a drug are based on the following:

- 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

N.B. the RAG status of a drug is not based on the cost of the medication

It is important to note that these are not rigid guidelines, but the expectation is that the list will be adhered to in the vast majority of cases. Where necessary, secondary and primary care prescribers should discuss the appropriate management of individual patients personally. On occasion, and where appropriate, both parties may agree to work outside of this guidance, as long as appropriate arrangements are agreed and implemented by those involved.

A summary table of the RAG classification system is shown below; please see text for a further explanation of each category.

Drug Category	Definition
RED Drugs[1] R	Drugs for hospital use or use by a specialist within specialist centre only. Initiation and monitoring of treatment should remain under the total responsibility of the appropriate hospital clinician or specialist. These drugs should only be prescribed under the direct supervision of that clinician or specialist and are not suitable for shared care arrangements. The drug should be supplied via the hospital or specialist centre for the duration of treatment.
AMBER Drugs[2] A	These are specialist drugs which must be initiated by secondary care specialist prescribers, but with the potential to transfer prescribing to primary care within written and agreed shared care protocols and according to the agreed process for transfer of care. For these drugs, in order to ensure patient safety, some aspects of care must remain with the specialist due to their complexity e.g. monitoring of disease or drug response. Other more routine aspects can be transferred to the GP e.g. monitoring of adverse effects and supply of the medicine. The specific responsibilities of the specialist and GP are defined in the shared care agreement for each drug. Shared care agreements are still under development for some amber drugs. Until these are available, it would be expected that any shared care request from secondary care to a GP would be accompanied by written information which defines prescribing and monitoring responsibilities. The hospital specialist should also provide the GP with enough information and support to allow the safe transfer and ongoing management of prescribing into primary care.
GREEN+ Drugs[3] G+	Drugs which should usually be initiated in secondary care, or by a specialist clinician, but can be safely maintained in primary care with very little or no monitoring required. An information leaflet may be provided in order to facilitate ongoing prescribing in primary care.
GREEN Drugs[4]	These are defined as new and established drugs, which may be prescribed, initiated, changed or maintained on FP10 by the GP and, if appropriate, discontinued without recourse to secondary care or to a specialist.

Further information and guidance on the categories

[1]RED Drugs R

Guidance on items which should be classified as RED is as follows. This may include, but is not limited to, the following criteria:

- Drugs that require frequent, specialist, long-term monitoring of efficacy or toxicity by hospital clinicians or specialists within specialist centres. This may be because the side-effect profile necessitates rigorous supervision by the hospital consultant or specialist, or the full range of side effects, particularly long term effects, needs to be established.
- Drugs whose monitoring or control remains within secondary care or within the control of specialists within specialist centres
- Primary care is unable to monitor therapy with the drug sufficiently to oversee treatment, or is unable to adjust the dose of the drug where necessary to ensure safety
- Drugs without a substantial wholesale body of support unless in BNF or Children's BNF
- Drugs requiring secondary care or specialist facilities or high-cost environment for preparation or reconstitution.
- Drugs which are only available through a hospital
- Drugs specified as hospital only by product license, legislation or with wholesale opinion
- Unlicensed products, indications or doses without acceptance of authoritative body of recommended opinion
- IV drugs agreed as inappropriate for primary care prescribing
- Medicines which have been rejected by NICE
- Medicines that are hospital indicated clinical trial materials

There are some drugs which must be supplied by the hospital purely for commissioning reasons. These are:

- Medicines for which the funding is levied out with primary care e.g. PBR excluded drugs
- NHS England commissioned medicines – these should only be prescribed and supplied via secondary care specialist centres in line with NHS England Clinical Commissioning Policy for specialised services.

These will be clearly marked in the joint formulary to show that they must only be supplied in secondary care; however they will not be included in the RAG list.

[2]AMBER Drugs A

If circumstances meet all of the following criteria, the medication may be classified as amber and can be used as part of a shared care arrangement, providing that both prescribing parties are in agreement:

- A specialist is required to start the medication. This would be for an agreed indication, as stated in the joint formulary and as described in the shared care guideline.
- A shared care agreement is in place which defines the responsibilities of both the

specialist and the GP for monitoring and adjusting treatment. The shared care agreement is signed by both parties. The GP is satisfied that he/she has all the information and support needed to prescribe the medication and to monitor the patient.

- Both the specialist and GP may share the responsibility for stopping the medication.

The patient's condition and/or treatment should normally be stabilised before the GP is asked to participate in shared care. This time period can be variable dependent on the condition being treated and the individual patient's response to the treatment; this would be defined in the shared care agreement. A minimum of one month's stabilised dose would be expected to be provided by the specialist prescriber before considering transfer of prescribing.
Inherent in any shared care agreement is the understanding that participation is at the discretion of the GP subject to their clinical confidence; however it is the expectation that the GP will participate in shared care where the correct process is followed.
This is in line with guidance from the Department of Health:

"When clinical and / or prescribing responsibility for a patient is transferred from secondary to primary care, the primary care prescriber should have the appropriate competence to prescribe the necessary medicines. Therefore, it is essential that a transfer of care involving medicines that a primary care prescriber would not normally be familiar with, should not take place without the sharing of information with the primary care prescriber and their mutual agreement to the transfer of care."

Responsibility for prescribing between hospitals and GPs, EL(91)127 (1991), DH.

Any refusal to participate in a shared care agreement should be an exception, although it may occasionally be the case that a shared care agreement may be taken on with caveats. Any refusal by primary care to participate in shared care and any reports of deviation from the agreed shared care processes by secondary care will be monitored in order to identify problems and/or training requirements.

[3]GREEN+ Drugs G+

A minimum of one month's supply should be given to patients with their first prescription by the specialist clinician before transferring responsibility to primary care. In some case, the initiation of a **GREEN+** drug may not require the patient to be seen by the specialist clinician; an advisory phone call or letter from the specialist clinician to the GP may be sufficient. Shared care agreements are not required for **GREEN+** drugs; however the provision of an information leaflet may be appropriate in order to facilitate ongoing prescribing in primary care. If an information leaflet is available, a copy of the leaflet or a link to it must be provided.

[4]GREEN Drugs

Drugs not classified as red, amber or green+ will be classified **GREEN** as default.

References

This Guidance is based on the previous '*Policy for the Transfer of Prescribing Responsibilities between Primary and Secondary Care (SoTW)*' (March 2013), the Department of Health publication: EL(91)127 "Responsibility for Prescribing between Hospitals and GPs", and the GMMMG Interface Prescribing Subgroup document 'Guidelines on defining Red/Amber/Green Medicine Status (September 2015).