



Guidelines on defining RED/AMBER/GREEN/ MEDICINE Status

Background

The Red Amber Green (RAG) classification offers guidance on the prescribing of drugs initiated in primary and secondary care and reinforces the basic premise that:

“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.”

EL(91)127 “Responsibility for Prescribing between Hospitals and GPs.”, DH

Inherent in any shared care agreement is the understanding that participation is at the discretion of the GP subject to their clinical confidence.

AIM: The “traffic light” system defines where responsibility for prescribing between primary and secondary care should lie through categorising individual drugs as **red**, **amber** or **green**. The system is intended to encourage appropriate shifts in prescribing between hospital clinicians and general practitioners (GPs) consistent with clinical responsibility and supported by shared care arrangements.

The list provides a framework for defining where clinical and therefore prescribing responsibility should lie through categorisation of individual drugs. 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 guidelines and the GMMM Red, Amber Green list is an advisory list. 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.

Assigning RAG status

Following review of clinical data on efficacy, safety and cost-effectiveness by the GMMMG and its sub-groups – New Therapies and Formulary; drug treatments will either be **recommended** for the full indication or for a subset of patients or **not recommended** (see below)

Drugs will only be considered when there is deemed to be a need for clarification of prescribing responsibilities. All drugs are not routinely added to the list in order to keep the list at a manageable size.

In the interests of safety the group recommends that prescribing and monitoring of a drug should be carried out by the same prescriber. E.g. prescribing of a drug should not be carried out in primary care whilst monitoring is carried out in secondary care.

Recommended drugs

In order to link clinical and cost effectiveness information with RAG status only those treatments that have been **recommended** will be referred to the Interface Prescribing Subgroup for review, following which they will receive a “traffic light” category as follows:

- ❖ **Red** - for secondary or tertiary care initiation and long-term maintenance of prescribing
- ❖ **Amber**– drugs which are appropriate to be initiated and stabilised by a specialist in secondary or tertiary care, once stabilised the drug may be appropriate for responsibility to be transferred from secondary to primary care with the agreement of a GP and a formal ‘shared care’ agreement.
- ❖ **Green (following specialist initiation)** - for drugs that must be initiated in secondary care but can then be safely prescribed in primary care with very little or no monitoring required.
- ❖ **Green (following specialist recommendation)** – for drugs that can be initiated by primary care following written or verbal advice from a specialist and can then subsequently be safely prescribed in primary care with little or no monitoring required.
- ❖ **Green** – drugs which may be initiated, stabilised and maintained in a primary, secondary or tertiary care setting

Non- Formulary and Not Recommended Drugs

Non-formulary drugs may still be considered for a RAG status if they are recommended for use by GMMMG or the New Therapies Subgroup for a small subgroup ($\leq 20\%$) of patients.

Not recommended 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:

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

It should be noted that the decision around whether a drug is recommended or not will be made by GMMMG and or the Formulary or New Therapies Subgroups and not the Interface Prescribing Subgroup.

Where a drug is *not recommended* these will be included within the RAG list as a not recommended drug with a link to the recommendation.

There may be rare occasions where the use of a drug treatment that has been categorised as “not recommended” is considered clinically appropriate. This should be managed by NHS Trusts and Clinical Commissioning Groups on an individual patient basis and with regard to appropriate commissioning arrangements.

Unlicensed medicines

For unlicensed medicines the prescriber, patient and GP should be aware of the unlicensed nature of the drug. In general the prescribing of unlicensed medications should not be transferred to primary care; however off-label use may be suitable for transfer if there is a widespread acceptance of a national body of recommended opinion. Off label use for an indication where there is no established evidence base should not be transferred to primary care under any circumstances.

Please note if an indication is not stated on the RAG list then the classification relates to the licensed indication unless specifically defined on the list.

Paediatric Medicines

Drugs that have been assigned a RAG status and assessed for paediatric use will be listed separately to adults on the GMMMG RAG list to prevent confusion.

Where there is a substantial body of evidence to support the use of an unlicensed medicine or a licensed medicine outside of its licence for example in paediatrics the GP may be asked to prescribe. However the GP must be fully informed and made aware of the licensing status. The GP should refer to the [Children’s BNF](#) as a guide for prescribing of unlicensed medicines / licensed medicines outside of licence. The full agreement of the GP concerned must be obtained before prescribing is transferred.

Prescribers may wish to access the GMC guidance on prescribing off-label or unlicensed medications:

http://www.gmcuk.org/guidance/ethical_guidance/14327.asp

Specialist Commissioning & NHS England Commissioned Medicines

Details of the commissioner for all Payment by Results excluded medicines are available on the GMMMG website and the most up to date list will always be found on this page <http://gmmmg.nhs.uk/html/guidance.html>. Repatriation of specialist medicines commissioned by NHS England will only take place for post organ transplant immunosuppressants and nebulised antibiotics / mucolytics in cystic fibrosis. Repatriation should only take place under the direction of the Local Area Team and specialist centres. Those drugs that are currently prescribed in primary care should continue to be prescribed until appropriate safeguards are in place to allow a safe transfer of prescribing. There is no other primary care prescribing which is expected to be repatriated and there is still an expectation that GPs will continue to share care of other drugs used in conditions that are otherwise commissioned by NHS England using appropriate, locally agreed arrangements.

Guideline for Classification

RED DRUGS

Guidelines for “Red” classification:

1. Unlicensed products, indications or doses without acceptance of authoritative body of recommended opinion
2. Medicines without a substantial wholesale body of support unless in BNF or Children’s BNF
3. Medicines by manufacturer’s recommendation or with wholesale opinion as being specialist only
4. Medicines whose monitoring or control remains within secondary care
5. Primary Care is unable to monitor therapy sufficiently to oversee treatment or adjust the dose where necessary to ensure safety
6. 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.
7. Medicines for which the funding is levied out with primary care e.g. PBR excluded drugs.
8. The specialist medicine, dressing or appliance is only available through a hospital.
9. Medicines where a suitable licensed alternative is available.
10. Medicines that have been rejected by NICE.
11. Requiring long-term, on-going specialist monitoring of toxicity/efficacy (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)
12. That are hospital indicated clinical trial materials

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.

AMBER DRUGS

The Amber list is an advisory list where it is considered by the Interface Prescribing subgroup, that responsibility for prescribing may be transferred from secondary to primary care once the patient is stabilised and agreed shared care arrangements have been established. 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 on the GMMMG website here <http://gmmmg.nhs.uk/docs/ip/SCG%20template%20updated.doc>

Some medicines may exist under more than one code depending on the experience and skills of the individual practitioner involved. These will be listed as amber but could be used by some prescribers as green products.

Some drugs may have several indications which may require a different status decision depending on the monitoring and assessment required.

Guidelines 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:
 - ◇ Provides a comprehensive summary of treatment
 - ◇ Defines the responsibility of the consultant and the GP for monitoring and adjusting treatment
 - ◇ Defines the referral procedure from hospital to GP
 - ◇ Defines the back-up facilities available to the GP from hospital with which the agreement is made.
- The GP is satisfied that he/she has all the information and support needed to prescribe and monitor the patient
- 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

- 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.
- 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.

- Consultants should usually advise on care rather than manage it and General Practitioners should usually manage their patients and their patients' illnesses and medicines.
- By improving the communication between primary and secondary care the variability in approaches to treatment will diminish.
- Prior research and discussion should enable a shared understanding and ensure that the optimum quality of evidence-based treatment is available to all patients.
- 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.
- Where there is dispute over arrangements for prescribing, responsibility for prescribing remains with the consultant until resolved.
- 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

Guidelines for “Green” classification

These are drugs that can be prescribed by primary care.

There are three classifications of green drugs:

Green (following specialist initiation) this classification is for drugs that must be initiated in secondary care but can then be safely prescribed in primary care with very little or no monitoring required. (i.e. secondary care provide the initial prescription rather than asking GP to provide initial prescription)

Green (following specialist advice or recommendation) this classification allows initiation of the drug following written or verbal advice from the specialist outlining details around initiation and can then subsequently be safely prescribed in primary care with very little or no monitoring required.

Green drugs this classification allows initiation as well as follows up prescribing within primary care.

References

This Guidance is based the previous GMMMG Red Amber Green Guidance Document (July 2014), The National Institute of Clinical Excellence recommendations and the earlier Department of Health: EL(91)127 “Responsibility for Prescribing between Hospitals and GPs.”



APPENDIX 1
(Prescribing Guidance)

GMMMG IPS

Approved: September 2015