Guidelines on defining RED/AMBER/GREEN/BLACK/GREY MEDICINE Status

Background

The **R**ed **A**mber **G**reen **(RAG)** classification offers guidance on the prescribing of drugs initiated in primary and secondary care and reinforces the basic premise that:

"When decisions are made to transfer clinical and prescribing responsibility for a patient between care settings, it is of the utmost importance that the GP feels clinically competent to prescribe the necessary medicines. It is therefore **essential** that a transfer involving medicines with which GPs would not normally be familiar should not take place without **full local agreement**, and the **dissemination of sufficient, up-to-date information to individual GPs**. If the GP considers him- or herself unable to take on this responsibility, then this should be discussed between the relevant parties so that additional information or support can be made available, or alternative arrangements made."

NHS England: Responsibility for Prescribing between Primary and Secondary/Tertiary Care, 29th January 2018

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 shared care**, **amber SI/SR, green, grey or not approved (black)**. 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 RAG category assigned to a drug is 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 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.

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

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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

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

Guideline for Classification

GREEN DRUGS

GREEN Traffic Light – These GREEN medicines are appropriate for initiation in both primary and secondary care. Prescribing is appropriate within licensed or local recommendations. **Green Alternative** = Second line / alternative green drug

Guidelines for "Green" classification

Green Medicines must satisfy both of the following criteria:

1. Medicines for which Primary Care prescribers are able to take full responsibility for initiating and on-going prescribing. Local prescribing guidelines or NICE guidance may apply.
2. Medicines are in routine use and can be prescribed within Primary Care with no special restrictions, specialist knowledge or experience.

AMBER SPECIALIST RECOMMENDATION DRUGS

AMBER Specialist Recommendation Traffic Light – these medicines are considered suitable for GP prescribing following specialist recommendation of therapy, with ongoing communication between the primary care prescriber and specialist, if necessary. AMBER SR medicines require no specific shared care guideline as no or little monitoring is required. Ongoing prescribing by primary care includes titration of dose and assessment of efficacy. There is no need for ongoing monitoring other than for general adverse effects as listed in the BNF & SPC. However GPs must still be familiar with the drug to take on prescribing responsibility or must obtain the required information from the initial prescriber specialist.

Guidelines for "AMBER Specialist Recommendation" classification

These medicines are considered suitable for primary care prescribing following varied levels of specialist input as described below:

- Amber Specialist Recommendation requires specialist assessment and recommendation to GP to prescribe in Primary Care

Amber Specialist Recommendation medicines must meet both of the following:

1. Requires specialist assessment to enable patient selection.
2. Following specialist assessment, the medicine is suitable for prescribing in Primary Care.

AMBER SPECIALIST INITIATION DRUGS

AMBER Specialist Initiation Traffic Light – these medicines are considered suitable for GP prescribing following specialist initiation of therapy, with ongoing communication between the primary care prescriber and specialist, if necessary. AMBER SI medicines require no specific shared care guideline as no or little monitoring is required. Ongoing prescribing by primary care includes titration of dose (if appropriate) and assessment of efficacy. There is no need for ongoing monitoring other than for general adverse effects as listed in the BNF & SPC. Patients should ideally be initiated on therapy with a minimum of 28 days supply before transfer to primary care. However GPs must still be familiar with the drug to take on prescribing responsibility or must obtain the required information from the initial prescriber specialist.

Guidelines for "AMBER Specialist Initiation" classification

These medicines are considered suitable for primary care prescribing following varied levels of specialist input as described below:

- Amber Specialist Initiation requires specialist initiation of prescribing. Patients should ideally be initiated on therapy with a minimum of 28 days supply before transfer to primary care. In some circumstances prescribing to be continued by the specialist until stabilisation of the dose is achieved and the patient has been reviewed by the specialist.

Amber Specialist Initiation medicines must also meet both of the following:

1. Requires specialist assessment to enable patient selection.
2. Following specialist assessment, the medicine is suitable for prescribing in Primary Care.
3. Requires short to medium term specialist prescribing and monitoring of efficacy or toxicity, or depending on the drug until the patient's dose is stable.

AMBER SHARED CARE DRUGS

AMBER with SHARED CARE Traffic Light - These medicines are considered suitable for GP prescribing following specialist initiation of therapy and patient stabilisation, with ongoing communication between GP and Specialist. The Specialist is also required to retain the patient under their care as per the shared care guideline. AMBER with Shared Care medicines require significant monitoring and to qualify must be designated so by the APC. GPs are advised not to take on prescribing of these medicines unless they have been adequately informed by letter of their responsibilities with regards

to monitoring, side effects and interactions and are happy to take on the prescribing responsibility. A copy of the locally approved shared care guideline should accompany this letter which outlines these responsibilities. GPs should then inform secondary care of their intentions as soon as possible by letter, and then arrange the transfer of care as necessary.

RMOC defines medicines considered suitable for shared care as those which should be initiated by a specialist, but where prescribing and monitoring responsibility may be transferred to primary care. Due to their potential side effects, shared care medicines usually require significant regular monitoring and/or regular review by the specialist is needed to determine whether the medicines should be continued.

An example shared care template can be found on the APC website.

Guidelines for "AMBER with SHARED CARE " classification:

Circumstances which meet all of the following criteria may allow a product to be used as part of a shared care arrangement, following agreement by both prescribing parties involved. Implicit in any shared care agreement is the understanding that participation is at the discretion of the Primary Care prescriber subject to their clinical confidence.

- A shared care guideline has been drawn up following joint discussion and agreement of the parties using the RMOC approved template (if available).
- The shared care guideline:
    - ◊ 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

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 guideline 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

When assigning Amber Shared Care status to a drug then the APC will follow the principles and recommendations laid out in the RMOC - Shared Care for Medicines Guidance: A Standard Approach document.

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?
- 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.

RED DRUGS

RED Traffic Light – these **RED** medicines should be initiated by specialists only and prescribing retained within secondary care; primary care prescriber initiation or continuation of treatment is not recommended. These treatments require specialist knowledge, monitoring, dose adjustment or further evaluation in use. Intravenous medicines as well as unlicensed indications for specialist medicines would usually fall into this category. These treatments should be initiated by, or under the explicit direction of a relevant secondary care specialist (Consultant or Specialist Registrar – unless designated consultant prescribing only). GPs with a relevant specialist interest (GPwSI) working in the community may also commence such treatments under the agreed supervision of secondary care if the GPwSI is happy to take on the prescribing responsibility. (Where patients are already receiving a RED medicine from their primary care prescriber, and their primary care prescriber has particular specialist knowledge or prior experience of prescribing this drug, the primary care prescriber may continue prescribing in primary care provided their primary care prescriber is happy to continue to take on the prescribing responsibility). Primary care prescribers may prescribe RED

medicines in exceptional circumstances to patients to ensure continuity of supply while arrangements are made to obtain usual supplies from secondary care.

Guidelines for "Red" classification:

RED status will be allocated if **any one** of the following applies:

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. Where the administration requirements of a medicine makes it unsuitable for use in Primary Care.
8. Medicines for which the funding is levied out with primary care e.g. PBR excluded drugs, NHSE Commissioned drugs
9. The specialist medicine, dressing or appliance is only available through a hospital.
10. 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)
11. 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.

GREY DRUGS

GREY - restricted indications for use and not recommended for general use following assessment of safety data, efficacy and cost effectiveness.

Guidelines for "GREY" classification

These are items which are deemed not suitable for routine prescribing but may be suitable for a defined patient population. Whilst prescribers should think very carefully before prescribing or recommending any of the products on the grey list, there may be exceptional instances when the use of one of these products is necessary for a particular patient. A patient may be deemed exceptional if the patient has a clinical picture that is significantly different to the general population of patients with that condition and as a result of that difference the patient is likely to derive greater benefit from the intervention than might normally be expected for patients with that condition.

In addition to be assigned a GREY status these drugs will be also be assigned a RAG to define where prescribing responsibility should lie.

BLACK (NOT APPROVED) DRUGS *(Note these appear on the formulary website as purple)*

BLACK (NOT APPROVED) *(Note these appear on the formulary website as purple)* - These are medicines that have been reviewed and have been deemed less suitable for prescribing, and are therefore not recommended in primary or secondary care. This may be due to the lack of good clinical evidence, or due to the availability of more suitable alternatives (in addition to all medicines with a "not NHS" or "DLCV" classification in the BNF, those agents as included within the NICE "Do not do" list, and those agents included with the NHS England: Items which should not routinely be prescribed in primary care).

Guidelines for "BLACK" classification

BLACK status will be allocated if **any one** of the following applies:

1. Lack of data on clinical effectiveness compared with standard therapy
2. Lack of data on safety compared with standard therapy
3. Known excess of significant 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. Not accepted as cost effective compared to other service development opportunities
7. No significant advantage over currently supported therapy

References

NHS England Guidance: Responsibility for Prescribing between Primary and Secondary/Tertiary Care; 29th January 2018.

Shared Care for Medicines Guidance – A Standard Approach (RMOC) – 19th March 2021