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

Summary of Traffic light formulary classifications for North Yorkshire and York Drug formulary

Green	Medicines suitable for initiation and routine use within primary, secondary and tertiary care. Primary care prescribers take full responsibility for prescribing.
Amber Specialist recommendation	Medicines recommended by a specialist; this could offer a valuable alternative/addition to the patients' treatment. These are considered suitable for GP prescribing following specialist recommendation. Little or no monitoring is required. A brief prescribing guidance document may be available for these, but there is no requirement for full shared care guideline. No formal Shared Care Guideline is required.
Amber Specialist Initiation	Items initiated by a specialist where there is not a need for ongoing monitoring other than for general adverse effects (as listed in the BNF and SPC). These are considered suitable for GP prescribing following specialist initiation, including titration of dose and assessment of efficacy where appropriate. No formal Shared Care Guideline is required.
SCG	Medicines that should be initiated by a specialist in secondary/tertiary care, and which require significant monitoring on an ongoing basis. After a successful initiation period, including titration of dose and assessment of efficacy, a transition to primary care prescriber care can take place. Full agreement to undertake prescribing for each specific patient must be reached under the amber shared care agreement, and guidance must be provided to the primary care prescriber (available online). The amber shared care guidance will outline the specialist and primary care prescriber responsibilities (including monitoring requirements) and basic prescribing information.
Red	Medicines for secondary care/specialist commissioned service use only. The responsibility for initiation and monitoring treatment should rest with an appropriate secondary care/specialist commissioned service clinician. The drug should be supplied by secondary care/specialist commissioned service for the duration of the treatment course. Primary care prescriber initiation or continuation of treatment is not recommended.
Black	Medicines which the North Yorkshire and York Area Prescribing Committee has reviewed and does not recommend for use at present based on a review of clinical and/or cost effectiveness data in either primary or secondary care.
Grey	Medicines which the North Yorkshire and York Area Prescribing Committee have not yet reviewed. Initiation by primary or secondary care for grey listed drugs is not supported and request to use should come via NY&Y APC.

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, or black**. The system provides a framework for the safe use of medicine for patients.

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. Where necessary, secondary and primary care prescribers should discuss the appropriate management of individual patients personally taking into account monitoring requirements, drug interactions, frequency of routine patient visits to the Consultant and the specialist nature of the condition being treated. Clinical judgement should be used to arrive at the most reasonable outcome and consider where prescribing is best managed. On occasions both parties may agree to work outside of this guidance. However, if it is not possible to reach a consensus or a specific issue has arisen, please submit an application to the APC to assess or re-assess the RAG status.

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.

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, there are many situations where a unlicensed medicine may be used for routine practice and continuation by GP may be entirely appropriate. Off-label/unlicensed 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/prescribing in primary, secondary, and tertiary care. Prescribing is appropriate within their licensed or recognised unlicensed indication in accordance with nationally recognised formularies e.g. BNF, BNF for Children, Palliative Care Formulary, national guidelines (e.g. NICE) or within local recommendations. Primary care prescribers take full responsibility for prescribing.

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 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. 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 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
    - ◊ To say prescribing transferred after a defined time period individual to the SCG for the drug in a particular condition
    - ◊ 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.

RED DRUGS

RED Traffic Light –Medicines for secondary care/specialist commissioned service use only. The responsibility for initiation and monitoring treatment should rest with an appropriate secondary care/specialist commissioned service clinician. The drug should be supplied by secondary care/specialist commissioned service for the duration of the treatment course. Primary care prescriber initiation or continuation of treatment is not recommended.

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/specialist commissioned service.
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.

BLACK (NOT APPROVED) DRUGS

BLACK (NOT APPROVED) - These are medicines that have been reviewed and have been deemed less suitable for prescribing, and are therefore not recommended in primary, secondary or tertiary care. This may be due to the lack of good clinical evidence, cost-effectiveness, 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
8. Negative NICE Technology Appraisal
9. Negative NHS England Commissioning Policy (if applicable)

GREY DRUGS

GREY - No formal commissioning position at present

Guidelines for "GREY" classification

Medicines which the North Yorkshire & York APC have not yet reviewed. This usually means that an application is in progress. These drugs are not normally considered appropriate for prescribing in North Yorkshire & York until such time that a decision is taken by the APC on their formulary status. Initiation by primary or secondary care for grey listed drugs is not supported and request to use should come via NY&Y APC.

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