GMMMG Guidelines on Defining RED AMBER GREEN DNP and GREY Medicine Status

What is the RAG List?

The **GMMMG RED AMBER GREEN (RAG) List** provides guidance around the initiation of medicines in primary and secondary care. The list is based on a "traffic light" system which assigns medicines a colour-based status of **RED, AMBER, GREEN, DNP (do not prescribe), and / or GREY.**

It aims to:

- provide advice on the most appropriate care setting in which a medicine should be initiated (e.g. secondary care vs. primary care)
- clarify in which care setting the ongoing prescribing responsibility lies / support the safe transfer of prescribing responsibilities where clinically appropriate
- highlight any scenarios where prescribing should be restricted to a defined patient population (i.e. GREY listing); in these cases a RAG of RED, AMBER or GREEN will also be assigned to clarify in which care setting prescribing responsibility lies
- detail whether the status assigned applies to use in adults, paediatrics, or both

RAG, DNP or GREY classifications will mostly apply to medicines but will also apply to some medical devices.

What do the RAG classifications mean?

A summary of the RAG classifications is provided below:

Red	**Specialist only medicines.** It is recommended these medicines should only be initiated and prescribed by specialist teams. Supply of these medicines should occur via the hospital or specialist service (this may include via a home care company).
Amber	**Suitable for shared care arrangements.** Prescribing and monitoring responsibilities may be transferred from specialist teams to primary care prescribers in line with a shared care protocol. Shared care arrangements will usually be supported by a GMMMG shared care protocol (SCP). *See here for a list of GMMMG approved SCPs.*
Green following specialist initiation	**Following initiation by specialist service, suitable for continuation of prescribing by primary care.** Little or no monitoring required.
Green following specialist advice	**Suitable for initiation by primary care, following written or verbal advice from a specialist service to primary care prescriber.** Little or no monitoring required.
Green	**Suitable for initiation and continued prescribing within primary care.**
DNP	**Not recommended for prescribing in any setting. "Do Not Prescribe" status may relate to a specific medicine, or to prescribing for a particular indication.** This is in addition to all medicines with a "not NHS" or "Drugs of Low Clinical Value" classification in the BNF, and those medicines with a NICE "Do not do" recommendation.
Grey	**Not suitable for routine prescribing but suitable for exceptional use in a defined patient population**. Prescribers should ensure that more suitable alternatives have been considered and ruled out as not being appropriate before recommending or prescribing a medicine with a GREY list status. In these cases a RAG of RED, AMBER or GREEN will also be assigned to clarify in which care setting prescribing responsibility lies

How is RAG status assigned?

The following clinical aspects are taken into consideration when a GMMMG status is defined:

- the **specialist nature** of the medicine / indication for use
- the **complexity of assessment and monitoring** required for safe use
- the level of **clinical responsibility and competency** associated with prescribing (for example off-label use of a licensed medicine)
- the **clinical and cost-effectiveness** evidence for the medicine (e.g. when a GREY list or, DNP recommendation is made)

The RAG status of a medicine is not based on its cost. However, the route by which it is commissioned will be taken into account (including any recommendations from NICE relating commercial arrangements).

Medicines will be prioritised for a RAG status if they are included in the GMMMG Joint Formulary or if there is a need for clarification of prescribing responsibilities; for example if there are safety concerns or extensive monitoring requirements.

A medicine can be assigned a RAG status for one indication, or a group of indications. A medicine may have more than one RAG status depending on the indication or intended population (e.g. adults or paediatrics).

Any newly defined RAG status, or significant change to an existing status, will be opened for a period of GM-wide consultation prior to being finalised.

Guidance on the classification of GREEN medicines

A GREEN classification will be assigned if all of the following apply:

1. The medicine is considered safe, with little or no monitoring requirements
2. Dose adjustments can be undertaken with relative ease and are supported by readily available guidance (e.g. the product license / BNF)
3. The indication is non-specialist and is amenable to management in primary care
4. There are no service, commissioning or supply issues associated with primary care prescribing or dispensing of the medicine

In some cases a recommendation of "specialist initiation" or "specialist advice" will apply:

- if there is a need for specialist input around the initial diagnosis or management of the patient's condition (this may be in the form of written or verbal communication)

In some cases, supportive prescribing information for GPs may be developed, see existing GMMMG GREEN (following specialist initiation or advice) leaflets here.

Guidance on the classification of AMBER medicines

Amber drugs are those suitable for shared care arrangements. Prescribing and monitoring responsibilities may be transferred from specialist teams to primary care prescribers in line with a shared care protocol. Shared care arrangements will usually be supported by a GMMMG shared care protocol (SCP).

The RAG list aims to support primary care prescribers in responding to requests to take on prescribing responsibilities from specialist teams by reinforcing the following principles:

"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.

An AMBER classification will be assigned if GMMMG recommends that the prescribing of a medicine may be suitable for transfer from specialist care to primary care. An AMBER status will include the indication(s) for which shared care has been deemed appropriate.

An AMBER classification will only be assigned if the following conditions apply:

1. The medicine is being used for an established, licensed indication. Alternatively it is being used for an off-label indication that is considered to be standard therapy (i.e. supported by a consensus of recommended opinion or evidence base- BNF / BNFc, reputable clinical guideline etc.).
2. The medicine can be prescribed on FP10 and there are no issues around primary care procurement, supply (e.g. due to formulation or administration requirements), or commissioning.
3. During the initial treatment phase, the medicine requires to be initiated, titrated, efficacy reviewed and/ or monitoring to be managed by the specialist / specialist team. However these aspects can be safely and appropriately transferred to the primary care prescriber within the framework of a shared care protocol. To allow an AMBER status to be given, overarching specialist involvement must be retained and/or timely routes to obtain specialist input must be available.
4. Information is readily available to support primary care prescribing (e.g. information on cautions, interactions, monitoring, side effects, etc.) This should be in the form of a GMMMG SCP. A recommendation of AMBER can only be enacted on the RAG list once the SCP is available; the status will be RED in the interim. This will allow any commissioning or service implications of the proposed AMBER status to be identified and addressed as part of the development of the SCP.

Where there is a request to prescribe outside of the GM RAG framework, this should be a patient-specific request, as part of direct discussion/ correspondence between the relevant prescribers. On occasion, both parties may agree to work outside of the GM framework if the non-specialist prescriber feels competent and confident to do so. Any such agreement should be adequately documented in the patient's record held by both the specialist and the GP. Should there be a change in prescriber or clinical situation such that the prior agreement is no longer appropriate or in the best interest of the patient, prescribing may be transferred in line with the drug's current RAG status once agreed with the receiving prescriber/organisation.

Guidance on the classification of RED medicines

A RED classification will be assigned if any of the following apply:

1. The medicine is being used for an indication/ at doses that are not supported by a consensus of recommended opinion or evidence base (e.g. market authorisation, BNF/BNFc, reputable clinical guideline).
2. Where there is an accepted consensus of opinion that the drug is 'specialist only'- this may include manufacturers' opinion, DoH, MHRA, NICE, or GMMMG subgroup recommendation ratified following consultation.
3. The medicine requires initiation, ongoing review of efficacy and / or monitoring by specialist / specialist team. This includes where the side-effect profile necessitates rigorous supervision that is not safe/ practical to transfer to primary care.
4. The medicine or product is only available through the hospital and/or not on FP10- this includes 'borderline' products when used outside approved indications.
5. The medicine is unlicensed **and** cannot reasonably be sourced within primary care (e.g. concerns over continuity of supply/ significant delays in obtaining through community pharmacy, inability to source a clinically equivalent product to that available in secondary care).
6. Medicines for which the funding is levied outside of primary care (e.g. National Tariff excluded drugs) or where the only benefit of transferring care would be to provider costs.
7. Medicines used as part of hospital indicated clinical trials.
8. Newly licensed medicine or indication requiring specialist initiation and where place in therapy and/ or safety has not been established. Ongoing prescribing responsibility and monitoring to be retained by specialist team.
9. Medicines unsuitable for primary care prescribing as a result of their formulation or administration requirements.
10. Where a drug / indication has been assessed as AMBER but a GMMMG SCP is not yet available, a RED status will apply in the interim. This will allow any commissioning or service implications of the proposed AMBER status to be identified and addressed as part of the development of the SCP.

Specialist Commissioning & NHS England Commissioned Medicines

Commissioning and service implications should always be considered when assigning a RED RAG status: any new medicines that are specialist commissioned or NHS England commissioned are usually allocated RED status.

For patients who have historically received post organ-transplant immunosuppressants, or nebulised antibiotics/ mucolytics in cystic fibrosis, repatriation of care back to the specialist team is underway. Primary care prescribing of these medicines should continue until appropriate safeguards are in place to allow the safe transfer of prescribing back to the specialist centre. This should be done in line with locally agreed arrangements (e.g. shared care protocols provided by the specialist centre if a GMMMG protocol is not in existence). Two RAG statuses might apply in these circumstances: AMBER for existing patients and RED for new

patients being initiated on the medicine. Once all prescribing has been repatriated, the RAG status will be updated to RED for all patients.

For medicines used in conditions that are otherwise commissioned by NHS England but not subject to repatriation, there is an expectation that GPs will continue to share care using locally agreed arrangements (such as shared care protocols).

Guidance on the classification of GREY medicines

A GREY status is assigned to medicines that have been assessed and recommended by GMMMG as **not suitable for routine prescribing, but suitable for exceptional use in a defined patient population**. For example if the patient has a clinical picture that differs from the general population of patients with the same condition that makes them more likely to derive benefit from the intervention (than the benefit derived by the majority population with the same condition).

Prescribers should think carefully before recommending or prescribing a medicine with a GREY list status and ensure that more suitable alternatives have been considered and ruled out as being not appropriate. The reason for recommending or prescribing a GREY listed drug should be clearly documented in the patient's record.

A RAG status of RED, AMBER or GREEN will also be assigned to all GREY listed medicines in order to clarify where prescribing responsibility lies.

A GREY classification is based on one of the following criteria:

- Criterion 1: Products of low clinical effectiveness where there is a lack of robust evidence of clinical effectiveness, or there are significant safety concerns.
- Criterion 2: Products which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation.
- Criterion 3: Products which are clinically effective but due to the nature of the product or condition being treated, are deemed a low priority for NHS funding.

Guidance on the classification of Do Not Prescribe "DNP"

If an assessment has been made by GMMMG that prescribing is not recommended within Greater Manchester, a DNP status will be applied. This DNP status may relate to use of a specific medicine or to the prescribing of medicines for a particular indication.

‘DNP’ medicines*

A DNP status of a medicine may be specific to a particular indication. As a result, a medicine may have a different RAG status for different indications depending on the evidence base for each- e.g. liraglutide is DNP for obesity, but GREEN for type 2 diabetes.

A DNP status of a medicine may apply to all indications. If GMMMG deems that the evidence does not support prescribing of the medicine for any indication - e.g. homeopathic medicines.

‘DNP’ indications

A DNP status may be applied to specific indication (e.g. acute sore throat) if GMMMG have assessed that prescribing of any medicines should not be undertaken as part of its treatment. For example, GMMMG does not routinely support prescribing for conditions which are self-limiting or amenable to self-care in line with NHSE guidance: Items which should not routinely be prescribed in primary care. The GMMMG Commissioning Statement for over the counter items which should not routinely be prescribed in primary care can be found here.

As for GREY status, A DNP classification is based on one of the following criteria:

- Criterion 1: Products of low clinical effectiveness where there is a lack of robust evidence of clinical effectiveness, or there are significant safety concerns.
- Criterion 2: Products which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation.
- Criterion 3: Products which are clinically effective but due to the nature of the product or condition being treated, are deemed a low priority for NHS funding.

**This is in addition to all medicines with a “not NHS” or “Drugs of Low Clinical Value” classification within the BNF, and those medicines included the NICE “Do not do” list.*