TRAFFIC LIGHT SYSTEM - DOUBLE RED/RED/AMBER/GREEN/GREY

Criteria for inclusion of medicines on one of the traffic light lists, or for moving medicines between lists will be determined in the first instance by:

- Evidence base for clinical and cost effectiveness
- Clinical responsibility
- Patient safety
- Ensuring appropriate usage
- Ensuring efficient usage (clinical and cost)
- Willingness to provide shared care information
- Availability of suitable monitoring mechanisms in general practice
- Patient convenience and preference

In particular, attention will be paid to the introduction of new drugs, new uses of existing drugs and drugs whose use is under review in terms of shifting from predominantly being a drug normally prescribed within secondary care to a drug normally prescribed within primary care.

DOUBLE RED

These are medicines that are less suitable for prescribing and are not recommended in primary or secondary care due to the lack of good evidence for clinical- or cost-effectiveness, or due to the availability of more suitable alternatives. These medicines will not be included in the CCGs' formulary or Prescribing Guidelines or the Acute or mental health Trusts' formulary.

Prior Approval

Some double red drugs are available for prescribing if certain pre-defined criteria are met; a full list of double red drugs and the agreed pre-defined criteria for prior approval, where applicable, can be found at
http://nww.pathfinder-rf.northants.nhs.uk/nene/therapeutics/prior-approval/

The Prior Approval Drug request form can be found at

http://nww.pathfinder-rf.northants.nhs.uk/nene/therapeutics/prior-approval/

The clinician wishing to recommend or prescribe should complete and submit a Prior Approval Drug request form to Priorapproval.northants@nhs.net
or fax to 01604 745375 or post to Susan Barron Medicines Prior Approval Team NHS Nene CCG Francis Crick House Summerhouse road Northampton NN3 6BF.
Prior approval requests for double red drugs will be responded to within a week.
Requesting clinicians should ensure that the prior approval criteria are met and that this is demonstrated on the form before submitting.

Individual Funding Request
Other double red drugs are not routinely commissioned and will only be considered via the Individual Funding Requests (IFR) process. Where a double red drug is available via IFR only, clinicians must be able to demonstrate exceptionality as per the CCGs' IFR policy. Acute trust clinicians should follow the trust's internal processes prior to submission of the IFR to the CCG or NHSE.
If the patient is part of a cohort the IFR will be declined at triage. Clinicians are advised to consult appendix D for full details.
http://www.neneccg.nhs.uk/resources/uploads/files/IFR%20Policy%20Nene%20_%20Corby%20CCG%20v1.pdf

The clinician wishing to recommend or prescribe should complete and submit an IFR form (at appendix C to the policy) to ifr.northants@nhs.net
or fax to 01604 745377 or post to IFR Dept, Francis Crick House, Summerhouse Road, Moulton park, Northampton NN3 6BF.
If a secondary care consultant wishes to recommend or initiate a double red drug for a GP to continue to prescribe, it is the consultant's responsibility to complete the request.
If you have any queries regarding these processes please contact the CCGs' Prescribing and Medicines Management Team on 01604 651359RED and AMBER

RED

These are medicines that should be initiated by specialists only and prescribing retained within secondary care; prescribing, even with the support of written guidelines, is considered to be outside the scope of general practice Therefore, GP initiation or continuation of treatment of RED medicines is not recommended. A full list of red drugs can be found at:
http://nww.pathfinder-rf.northants.nhs.uk/nene/therapeutics/traffic-light-drugs/

Medicines **may** be included in the red list because they:

- Commissioned by NHSE under tariff excluded arrangements
- are only available through the Hospital Trust
- are part of a hospital Trust initiated clinical trial
- are not available on FP10
- require intravenous administration
- require long-term on-going specialist monitoring of efficacy
- require long-term on-going specialist monitoring of toxicity and are not suitable for shared care
- are specifically designated 'hospital only' by product licence or by the DoH.
- are a specialist medicine being used for a novel unlicensed indication for that medicine (not described in BNF or BNF for children)
- are new, or are an older medicine with a new indication, where there is at present no experience of use in general practice

Classification of a medicine under the Red List does not preclude the drug being administered by a health professional in the community, for patient convenience. The organisation and management of the administration service should be from the hospital

but may be provided by an outside agency that has entered into an agreement with the hospital.

AMBER

Medicines are classified as “Amber” if it has been decided they should only be prescribed under “shared care arrangements”. Such medicines should usually only be prescribed if they have been recommended after specialist referral. A full list of amber drugs can be found at:
http://nww.pathfinder-rf.northants.nhs.uk/nene/therapeutics/traffic-light-drugs/

The amber category can be split into two sections, defined as follows:

AMBER 1: These are medicines that require significant monitoring and the decision to treat with an AMBER medicine should be made by specialists only. Prescribing may be transferred to a GP under a shared care protocol. Therapy should either be initiated and the patient stabilised by the specialist, or the specialist may recommend the initial dose for the GP to prescribe while continuing to monitor the patient closely during the stabilisation phase; this will be specified in the shared care protocol e.g. for leflunomide and all other DMARDs. Amber 1 medicines attract a “near patient testing fee” under the GP Local Enhanced-Service Contract.

The request to share care should be made by the hospital consultant using a Shared Care Request Letter. If a Trust-approved shared care protocol is not available, then the letter should be accompanied by interim guidelines according to the NPAG Policy on Shared Care of Amber Medicines:
http://nww.pathfinder-rf.northants.nhs.uk/media/767112/shared-care-arrangements-for-amber-medicines-sept-14.pdf.

AMBER 2: These are medicines that require little or no monitoring by the GP, but should be prescribed in general practice only after they have been recommended following specialist referral**.** Shared care guidance will be available but a full shared care protocol is not required as little or no monitoring is required. However, GPs must still be provided with the required information by the hospital consultant; the duration of treatment must be specified and the possible consequences of treatment that would necessitate stopping treatment must be identified. Amber 2 medicines do NOT attract a “near patient testing fee” under the GP Local Enhanced-Service Contract.

Medicines may be included in the amber list because they:

- require short or medium term specialist monitoring of efficacy
- require short or medium term specialist monitoring of toxicity (difficulty in recognising side effects or high cost/availability of investigations to identify toxicity)
- are rarely used, such that individual GPs are unlikely to see sufficient patients and acquire a working knowledge of the drug
- require specialist assessment to enable patient selection and initiation of treatment

GREEN

These medicines are appropriate for initiation in both primary and secondary care. Prescribing is appropriate within licensed or local recommendations.

GREY

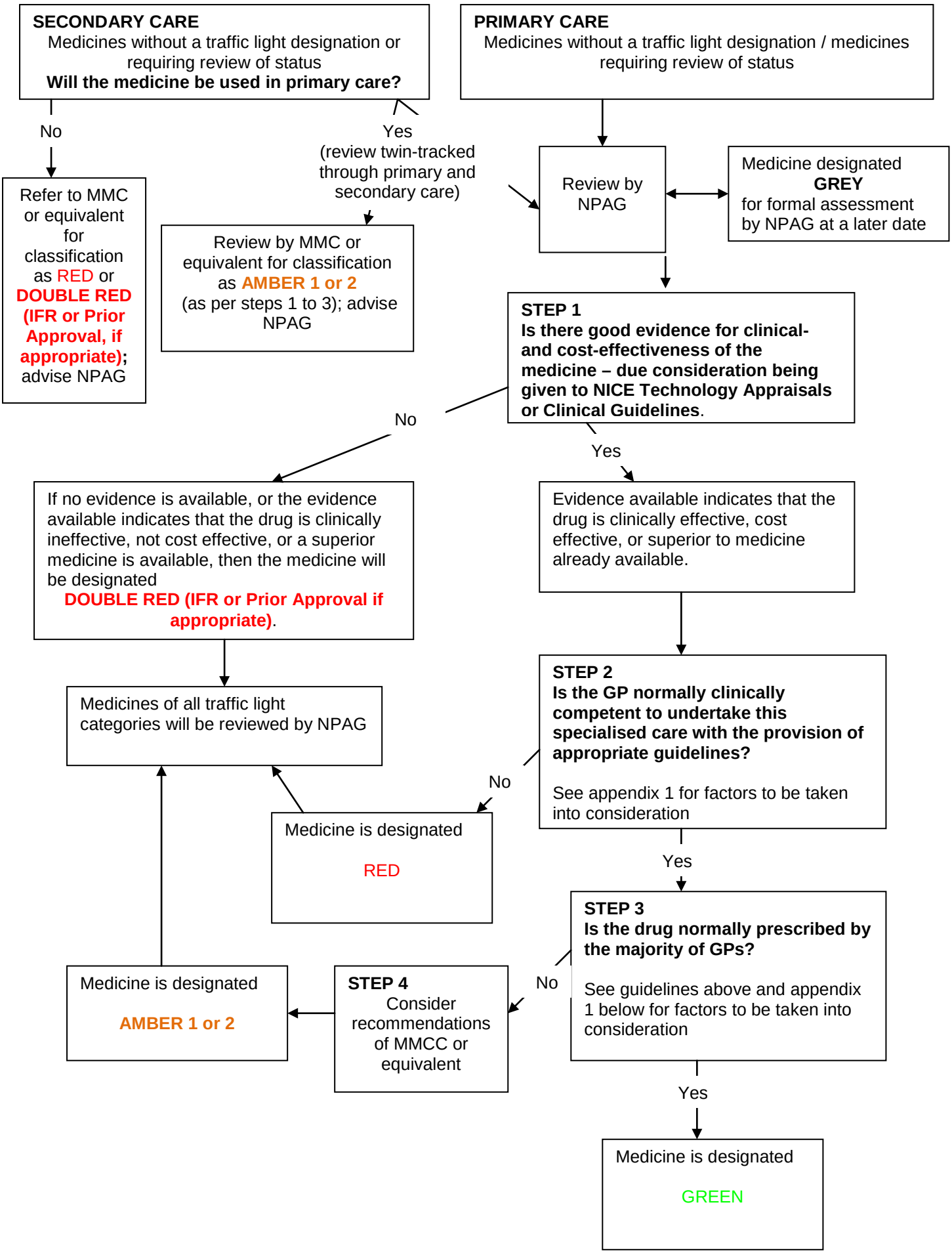
This is a holding category for drugs that have not been formally assessed by NPAG and awarded a traffic light designation. Grey medicines, or those not included elsewhere, are those that NPAG has not assessed for therapeutic use and prescribers should refrain from prescribing where possible.

REVIEW

The Traffic Light System is a dynamic tool to allow review and reclassification of medicines as evidence becomes available, which may be at the request of other bodies.

NPAG will review, or return to their author for review, all protocols and interim guidelines in accordance with the pre-determined review dates.

TRAFFIC LIGHTS PATHWAY



Appendix 1

RED LIST

Factors to be taken into considerations when deciding whether a medicine should be included in the red list:

- Is the GP truly taking full clinical responsibility for a patient's treatment? e.g. if monitoring is performed within secondary care and not by the GP it would normally be inappropriate for the GP to prescribe unless the GP took responsible for ensuring that monitoring had occurred before each new prescription is issued (e.g. DMARDs = AMBER 1)
- New medicines still marked with a black triangle, i.e. there is limited experience of use of the product; prescribing should perhaps remain in secondary care unless there is experience in the use of older medicines in the same class to which the newer medicine belongs that may indicate the appropriateness of use in primary care.
- New, specialised medicines should only move into primary care when a shared care protocol (if wide usage expected) or interim guidelines (if limited use) have been provided by the consultant for that indication and the opportunity for training provided if required.
- Patients attending the hospital frequently for complicated treatments and specialist investigations, and the consultant needs to monitor progress
- The convenience of the patient and in the patient's best interest
- Circumstances where GPs justifiably refuse to take clinical responsibility

AMBER LIST

- The GP must have a role in the care of the patient that is justifiable in terms of improvement in patient care and proper use of the GP's expertise. For medicines that they prescribe, GPs should have sufficient expertise to stop or restart treatment, or alter the dosage of the medicine appropriately as under the terms of the shared care arrangement described in the shared care protocol.
- It would generally be inappropriate for a GP to refuse to take clinical and prescribing responsibilities for an individual medicine where shared care for that medicine has become common practice and where a shared care protocol has been approved by MMC and NPAG / NPMG.
- Where a dispute arises, the Head of Prescribing and Medicines Management and the Chief Pharmacist will be consulted to seek a resolution. If a dispute arises over an invitation to share care, the Shared Care Request Letter should be returned to the consultant and copied as instructed. However, if a dispute arises over a request to prescribe, the Traffic Light Referral Letter should be returned to the consultant and copied as instructed.

- If a GP or consultant breaks the terms of the shared care agreement, resolution should be sought via the Head of Prescribing and Medicines Management and the Chief Pharmacist.