

DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC) The Derbyshire JAPC “Traffic Light” Classification

For Traffic Light Classification [click here](#)

The JAPC traffic light classification is in place to assist clinicians in making decisions about the medicines and some medical devices they prescribe. The overarching principles underpinning the decision to include a medicine or some prescribable medical devices in the traffic light classification include:

1. Evidence of clinical effectiveness
2. Evidence of cost effectiveness
3. Patient safety
4. Patient convenience and preference

The Derbyshire JAPC traffic light system is divided into five categories:

GREEN	Medicines or medical devices regarded as suitable for primary care prescribing
RED	Medicines or medical devices considered suitable for a consultant or specialist, usually within a secondary or tertiary care services, to initiate and continue prescribing
AMBER	Medicines or medical devices that are initiated in secondary care or other specialist setting but are suitable for GPs to continue on-going prescribing under a shared care protocol, once the patient has been stabilised or dose predictable. (See appendix 1 for circumstances where shared care is not appropriate)
GREY	Medicines or medical devices JAPC does not recommend for use except in exceptional circumstances
Do Not Prescribe (DNP)	Medicines or medical devices not recommended or commissioned*

*Clinicians should submit an individual funding request, and await a positive outcome, before initiation of treatment for a Do Not Prescribe medicine/treatment/medical device for NHS prescribing.

GREEN (which includes specialist/consultant initiation or recommendation – see below for definition)

Drugs/devices for which GPs (or non-medical prescribers in primary care) are able to take full responsibility for initiating and on-going prescribing

Definitions

- **Specialist/consultant initiation.**
Consultant/specialist issues the first prescription usually following a consultation because
 - a) The patient requires specialist assessment before starting treatment and/ or
 - b) Specialist short term assessment of the response to the drug/device is necessary. GPs will be asked to continue prescribing when the patient is stable or predictably stable
- **Specialist/consultant recommendation.**
The consultant/specialist requests GPs prescribe initial and on-going prescriptions, but ensures
 - a) There is no immediate need for the treatment and is in line with discharge policies and
 - b) The patient response to the treatment is predictable and safe

How to make an application to classify a drug/device

A medicine/prescribe-able medical device may be referred to Derbyshire JAPC by:

- Trust Drugs and Therapeutics committee
- Guideline group
- Individual prescriber
- Medicines management team

The Derbyshire JAPC will review all relevant factors and classify the medicine or prescribable medical device in line with JAPC traffic light classification.

Drugs/devices not yet classified

Not classified list contains new drug/device launches and new formulations which Derbyshire JAPC does not consider appropriate for inclusion into the local formulary. These are medicines or prescribable medical devices awaiting national or local evidence submissions.

Medicines or prescribable medical devices not included in the traffic lights

It is not possible to classify all medicines or medical devices listed in the BNF within the Derbyshire JAPC traffic light formulary. If a medicine or medical device is not listed on the traffic light system then advice should be sought from the Medicines Management Team and prescribing of these will be at the discretion of individual NHS Trusts and/or GP.

RED

Criteria for classification

- 1) Requires specialist assessment to enable patient selection, initiation and on-going treating
- 2) Requires long term on-going monitoring of efficacy by a specialist and not suitable for shared care
- 3) Requires long term on-going monitoring of toxicity by a specialist (either because of difficulty in recognising side effects, or problematic or high cost investigations to identify toxicity)
- 4) Specifically designated as "hospital only" by product licence or by DH/NICE
- 5) Is new to clinical practice and unfamiliar, necessitating a period of accumulation of experience, firstly (and most rapidly) by consultants/specialists
- 6) Is hospital initiated clinical trial material
- 7) Is unlicensed or prescribed "off-label" and unfamiliar to primary care

AMBER

Criteria for classification

- 1) Requires specialist assessment (for instance to enable patient selection and initiation of treatment)
- 2) Consideration of the drug/device is indicative of significant progression and a need for specialist input (usually as specified in a clinical guideline)
- 3) Requires short or medium term (e.g. 3-6 months) specialist monitoring of efficacy or until the patient is stable or predictable
- 4) Requires short or medium term specialist monitoring of toxicity
- 5) Is rarely used such that GPs are unlikely to see sufficient patients and acquire a working knowledge of the drug/device, thus requiring continued specialist support
- 6) Is relatively new but there is growing experience and can now begin to move into primary care where experience can be gained with support ('managed entry')
- 7) Requires specific long term monitoring for toxicity needing on-going specialist support

GREY

Criteria for classification

- 1) Lack of data on 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) NICE guidance
- 7) Not accepted as cost effective compared to other service development opportunities within the ICBs
- 8) Exceptionality where a small cohort of patients may benefit from prescribing can be identified

'GREY' Combination products

Derbyshire JAPC does not recommend the routine prescribing of ORAL COMBINATION PRODUCTS that are available as the separate constituents, the following reasons may apply:

- The dose of each individual medicines doses cannot be tailored to the patient's needs, potentially leading to risk of over or under dose
- In the event of an allergic /adverse drug reaction/ inefficacy to the combination product then it would be difficult to ascertain the drug molecule which has caused this reaction
- May not be cost effective

Do Not Prescribe (DNP)

Criteria for classification for DNP drugs include:

- 1) Are classified by the BNF as 'less suitable for prescribing', and includes anti-malarials (where a private prescription may be provided)
- 2) Have a lack of data on effectiveness compared with standard therapy
- 3) Have a lack of data on safety compared with standard therapy
- 4) Have known increase in risk of adverse events compared with standard therapy
- 5) Have a lack of data on cost-effectiveness compared with standard therapy
- 6) Less cost-effective than current standard therapy
- 7) Have NICE guidance that recommends they should not be used
- 8) Those that are deemed by national publications (e.g. by NHSE/NHS Clinical Commissioners) of limited value, unless agreed by local agreement.

For those drugs deemed to be classified as DNP, and where there is no suitable alternative for the patient, a Quality and Equality Impact Assessment (QEIA) needs to be part of the decision-making process. A [QEIA form](#) must be completed prior to JAPC ratification for a DNP drug classification or where a decommissioning policy has been produced (see notes below)#. This is only necessary where patients are already on NHS treatment and where there is no suitable alternative treatment.

Where an QEIA/ and Patient Public Involvement (PPI) is not necessary:

- JAPC will assign a DNP classification to medicines/treatments/medical devices that receive MHRA/safety alert where the safety and risk outweighs any benefit of the treatment.
- JAPC will actively horizon scan new medicines/treatments/medical devices and classify as DNP if not clinically effective/ safe or not cost-effective for the local health economy in the knowledge that no patients will be on treatment.
- In established treatments where legal duties are triggered, JAPC may classify these as DNP for example in terms of cost effectiveness, clinical effectiveness undertaking by the following process:
 - DNP will apply to all new patients from the date of decision.
 - Existing patients on DNP drugs for patients that are already on the medicine/treatment/medical device prior to the Do Not Prescribe (DNP) classification, this should not be withdrawn abruptly from patients, but should be continued until the next appropriate clinical review where their NHS clinician with the patient through shared decision making will decide whether it is appropriate to switch or stop. Clinicians who continue to prescribe a DNP treatment need to recognise the inequalities of this patient against the population of Derbyshire and document the rationale.

For prescribing DNP treatment outside of the above recommendations, a clinician should submit an individual funding request, and await a positive outcome, before initiation of treatment for a Do Not Prescribe (DNP) medicine/treatment/medical device for NHS prescribing. See [DNP guidance](#) for further detail.

Appendix 1 - Possible circumstances where shared care is not appropriate- hospitals/specialists would normally retain responsibility for prescribing:

- Medicines requiring ongoing specialist intervention and specialist monitoring
- Patients receive the majority of ongoing care, including monitoring, from the provider and the only benefit of transferring care would be to provider costs
- Medicines, which are unlicensed and/or are being used outside of product license (e.g. licensed medicine used for unlicensed indication or at an unlicensed dose) unless there is a recognised evidence base and/or it is standard treatment
- Individual treatment as part of specified packages of care often under specialised commissioning