Derbyshire Joint Area Prescribing Committee (JAPC)

New drug assessment / Traffic light allocation

1	**What is the drug?** *(Name, form, strength)*		
2	**Indication for use?** (*State the proposed indication and if appropriate comment if the drug is being off-label or is unlicensed)*		
3	**How effective is this drug?** *Summary of trial evidence, include grade of study, design, strengths and weaknesses. (include supporting references)* *Use appendix 1as examples for objective independent reviews*		
	The SORT classification **Level 1: good quality patient-oriented evidence** Systematic reviews (SRs) or meta-analyses (MAs) of randomised controlled trials (RCTs) with consistent findings related to POOs High quality individual RCTs which examine POOs All or none studies **Level 2: limited quality patient-oriented evidence** SRs or MAs of lower-quality studies related to POOs or of RCTs with inconsistent findings which examine POOs Lower-quality clinical trials which examine POOs Cohort studies which examine POOs Case-control studies which examine POOs **Level 3: other evidence** Any DOO study Case series Opinion Consensus guidelines Modelling from bench research		
4	**How does it compare with existing drugs, or non-drug therapies?**		
5	**How safe is the drug?** *Are there any published comparative safety data/ clinically important drug interactions/ monitoring requirements?*		
6	**Are there any special precautions?** *e.g. any particular groups of patients in which this drug is contra-indicated or where it should be used with caution*		
7	**What is its place in therapy?** *Consider advantages over current therapy/ other treatment options/ specific patient groups that may benefit/ considerations from the patients perspective/ national and/or local priorities*		
8	**Does this drug provide good value for money?** *Consider its cost effectiveness over other available interventions, benefits over costs involved. Give comparative costs and where possible budget impact across Derbyshire including patient numbers****. Include patient numbers and annualised costs***		
9	**Are there any service implications?** *(e.g., access, impact on other sectors etc)*		
10	**What is the balance of responsibility?** *(use Appendix 2 as a guide)*		
	Where the balance of prescribing lies	**BALANCE IN PRIMARY CARE**	**BALANCE IN SECONDARY CARE**

11	**Proposed traffic light classification** **What are the recommendations of Derbyshire JAPC?** *Traffic light classification* Why was this decision made? (use appendix 3 to guide and code)
12	**Prepared by:** **Designation:**

Green	Red	Amber	Grey	DNP	Not classified

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Appendix 1

Example of Organisations providing relevant resources on medicines

The Internet sites below are used to find the information contributing to literature searches carried out

All Wales Medicines Strategy Group

BNF

Cochrane Library

Drugs and therapeutics Bulletin

Electronic Medicines Compendium

EMBASE

European Medicines Agency

Manufacturers

Medicines and Healthcare products Regulatory Agency

Medline

Midlands Therapeutics Review and Advisory Committee

National Institute for Health Research – Horizon Scanning Centre

NHS Evidence

NICE

NICE Medicines Information

North East Treatment Advisory Group

Regional Drug & Therapeutics Centre

Scottish Intercollegiate Guidelines Network

Scottish Medicines Consortium

TRIP (Turning Research Into Practice)

UK Medicines Information

Appendix 2

Balance of responsibility

	Criteria		Primary Care	Secondary Care
(a)	The disease/condition		Familiar/common	Unfamiliar/rare
(b)	Efficacy & effectiveness	Initiation	No special requirements	Specialist diagnosis required Intense initial monitoring
		Maintenance	Benefit – measurable in primary care	Benefit measurable with specialist skills/equipment
		Dose titration	Simple	Complex depending on factors which can only be assessed in secondary care
		Withdrawal	Lack of benefit – measurable in primary care	Lack of benefit – Requires specialist skills/equipment, close monitoring required
(c)	Safety	Adverse events	Predictable Chronic	Unpredictable adverse events Acute and life threatening
		Knowledge base	Large	Limited
		Monitoring-skills equipment	Available in primary care	Specialised
(d)	Administration	Skill Equipment	Available in primary care	Specialist skills
		Training	Available in primary care	

Appendix 3

RED Drugs

A consultant or specialist, usually within secondary or tertiary care services, to undertake initiation and on-going prescribing.

High Cost drugs excluded from tariff that are locally commissioned are prescribed in secondary/ tertiary care settings only (the DH list can be found here (link) under tariff information). These drugs should not be prescribed in primary care.

Criteria for Classification

1. Requires specialist assessment to enable patient selection, initiation and ongoing 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 Drugs
Consultant initiated/recommended, then care shared between consultant and GP under a guideline agreed between primary and secondary care clinicians.

Criteria for Classification
1. Requires specialist assessment (for instance to enable patient selection and initiation of treatment).
2. Consideration of the drug 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.
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, 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 ongoing specialist support

GREY Drugs
JAPC does not recommend for use except in exceptional* circumstances. Seek advice from your prescribing adviser and record your reasons for prescribing. Drugs listed in the BNF are sometimes prescribed in an alternative, unlicensed formulation to meet the individual needs of a patient- these „specials" are considered to be BROWN drugs, and should only be prescribed on an exceptional basis when a licensed, cost-effective product is not available.

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 PCT's Local Operational Plan

Do Not Prescribe (DNP) Drugs
Not recommended or commissioned

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 PCT's Local Operational Plan

GREEN Drugs
Regarded as suitable for primary care prescribing but may not be first line and/or be governed by guidelines. Drugs for which GPs (or non-medical prescribers in primary care) are able to take full responsibility for initiating and on-going prescribing.