Erewash Clinical Commissioning Group
Hardwick Clinical Commissioning Group
North Derbyshire Clinical Commissioning Group
Southern Derbyshire Clinical Commissioning Group

ITEMS WHICH SHOULD NOT BE ROUTINELY PRESCRIBED ACROSS DERBYSHIRE

Better Value Prescribing: The Derbyshire CCGs policy on the use of low clinical value medicines (LCVMs)

1. Summary

This policy endorses the NHS England recommendations on items which should not be routinely prescribed in primary care.
This policy applies to all Derbyshire NHS providers and contractors (primary and secondary care).
To ensure that the NHS in Derbyshire continues to allocate its resources effectively, the Joint Area Prescribing Committee (JAPC) will review the guidance periodically to identify potential items to be retained, retired or added to the current guidance.

2. Introduction

In 2015/16, 1.1 billion NHS prescription items were dispensed to patients in primary care at a cost of £9.2 billion. With the number of prescriptions increasing by 1.9% a year, it is important that the NHS achieves the greatest value from the money that it spends. Clinical Commissioning Groups (CCGs) also have a legal duty around appropriate use of prescribing resources.
There is currently significant variation across England in what is being prescribed and to whom, with some patients receiving medicines now proven to be relatively ineffective or potentially harmful, or for which there are other more effective, safer or cheaper alternatives and products which are no longer appropriate to be prescribed on the NHS and could save the NHS up to £141 million a year.
The national guidance focused on an initial list of eighteen products which fall into one or more of the categories below:

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

Each product was assigned one or more of the following recommendations:

- Advise CCGs that prescribers in primary care should not initiate the product for any new patient;
- Advise CCGs to support prescribers in deprescribing the product in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change;
- Advise CCGs that if, in exceptional[3] circumstances, there is a clinical need for the item to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional;
- Advise CCGs that all prescribing should be carried out by a specialist; and/or
- Advise CCGs that this item should not be routinely prescribed in primary care but may be prescribed in named circumstances.

The recommendations on the 18 items within the NHS England guidance were publicly consulted on for 3 months, from 21st July – 21st October 2017. The draft guidance was revised in light of the consultation findings and the final recommendations set out in the national guidance document reflect the outcome of that consultation.
CCGs need to decide locally on the implementation of the national recommendations, taking into account their legal duties to advance equality and have regard to reducing health inequalities. This Policy outlines the current Derbyshire position on the NHS England guidance and aligns the Derbyshire Joint Area Prescribing Committee (JAPC) traffic light classification of the 18 drugs that should not be routinely prescribed in primary care.

3. Equality Statement

Erewash, Hardwick, North Derbyshire and Southern Derbyshire CCGs aim is to design and implement policy documents that meet the diverse needs of the populations to be served and the NHS workforce has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012.

The CCGs are committed to ensuring equality of access and non-discrimination, irrespective of age, disability (including learning disability), gender reassignment, and marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation.

It takes into account current UK legislative requirements, including the Equality Act 2010 and the Human Rights Act 1998, and promotes equality of opportunity for all. This document has been designed to ensure that no-one receives less favourable treatment owing to their personal circumstances.

4. Scope and purpose of the policy

The Better Value Prescribing Policy sets out the Derbyshire Clinical Commissioning Groups' approach to support prescribers in implementing NHS England recommendations on items which should not routinely be prescribed in primary care.

This policy will ensure equity of service for all residents of Derbyshire and will allow the same expectation of what will be provided from the GP Practice or other services.

This policy applies to all services contracted by or delivered by the NHS across Derbyshire including:

a) GP Practices – GPs and all other Prescribers
b) Out of hours and extended hours primary care providers
c) Acute Hospitals
d) Out-Patient Clinics
e) NHS Community Providers
f) Independent providers
g) Community pharmacies
h) Opticians
i) Dentists

This policy applies to all people (adults and children) who are registered with a GP in Derbyshire (permanent or temporary resident) or who access an NHS service in Derbyshire.
Derbyshire CCGs have a duty to ensure that the local NHS budget is spent in an appropriate way.
The Governing Bodies are responsible for ensuring that all agreed actions are carried out by healthcare professionals according to this policy.
Implementation of the policy will be monitored via ePACT data and other activity data.

5. Professional and contractual context for prescribers

During discussion with the patient, when considering what treatment and ongoing monitoring is required, prescribers are asked to be mindful of the following:

- Prescribers have clinical freedom to act in an individual patient's best interest where exceptional clinical circumstances exist that warrant deviation from this policy.
- That within their Primary Medical Services contract with NHSE, GPs have a contractual obligation relating to patients to make available such treatment (including any prescription deemed to be appropriate after discussion with the patient) as is necessary and appropriate, and to provide advice in connection with the patient's health, including relevant health promotion advice.
- That reference to local prescribing guidelines is good professional practice.
- That consideration of GMC professional obligations to use NHS resources wisely is good professional practice.

6. Current JAPC Traffic Light Definitions

6.1. BLACK Traffic Light Classification

Not recommended or commissioned*. This includes drugs/treatments/medical devices which:

- Are classified by the BNF as 'less suitable for prescribing', and includes anti-malarials (where a private prescription may be provided)
- Have a lack of data on effectiveness compared with standard therapy

- Have a lack of data on safety compared with standard therapy
- Have known increase in risk of adverse events compared with standard therapy
- Have a lack of data on cost-effectiveness compared with standard therapy
- Less cost-effective than current standard therapy
- Have NICE guidance that recommends they should not be used
- Those that are deemed by national publications (e.g. by NHSE/ NHS Clinical Commissioners) of limited value, unless agreed by local agreement

For patients that are already on the medicine/treatment/medical device prior to the BLACK classification, this should not be withdrawn abruptly from patients, but should be continued until the next clinical review where their NHS clinician will decide whether it is appropriate to switch or stop treatment or submit an individual funding request if in exceptional circumstances on-going prescribing is considered clinically appropriate.

*Clinicians should submit an individual funding request, and await a positive outcome, before initiation of treatment for a BLACK medicine/treatment/medical device for NHS prescribing.

6.2. BLACK Drugs: Action for prescribers

No new prescribing should be initiated. For patients that are already on the medicine/treatment/medical device prior to JAPC classification, treatment should not be withdrawn abruptly from patients, but should be continued until the next clinical review where their NHS clinician should decide whether it is appropriate to switch or stop treatment or submit a request for approval if in exceptional circumstances on-going prescribing is considered clinically appropriate.

6.3. BROWN Traffic Light Classification

JAPC does not recommend for use except in exceptional circumstances. Seek advice from your prescribing adviser and record your reasons for prescribing.

6.4. BROWN Drugs: Action for prescribers

For patients that are already on the medicine/treatment/medical device prior to JAPC classification, **and do not meet the defined exceptionality criteria**, treatment should not be withdrawn abruptly from patients, but should be continued until the next clinical review where their NHS clinician should decide whether it is appropriate to switch, stop treatment or submit a request under the BLACK drugs policy if in exceptional circumstances on-going prescribing is considered clinically appropriate. No new patients should be initiated on treatment unless they meet the exceptionality criteria.

6.5. RED Traffic Light Classification

Medicine/treatment/medical device considered suitable for a consultant or specialist, usually within a secondary or tertiary care service, to initiate and continue prescribing.

6.6. RED Drugs: Action for prescriber

No Primary care prescribing should be initiated. For patients that are already on the medicine/treatment/medical device prior to JAPC classification, patients should be referred to the appropriate secondary care specialist for review or on going treatment.

6.7. AMBER Traffic Light Classification

Initiated within a hospital/specialist setting but suitable for shared care with GP under a shared care agreement.

6.8. GREEN

Regarded as suitable for primary care prescribing

For a complete/comprehensive definition see
http://www.derbyshiremedicinesmanagement.nhs.uk/assets/japc/JAPC/JAPC_Traffic_Light_Classification_Criteria.pdf

NHSE RECOMMENDATION AND DERBYSHIRE CLASSIFICATION

Drug	NHSE Category	NHSE recommendation	Exceptions and/or further recommendations	JAPC Classification	Recommended Action
Co-proxamol	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.	• Advise CCGs that prescribers in primary care should not initiate co-proxamol for any new patient. • Advise CCGs to support prescribers in deprescribing co-proxamol in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.	No routine exceptions have been identified.	**BLACK** - Unlicensed - Re-classified from brown to black in April 14	See section 6.2 Trial of formulary alternatives e.g. Paracetamol +/- codeine
Dosulepin	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.	• Advise CCGs that prescribers in primary care should not initiate dosulepin for any new patient. • Advise CCGs to support prescribers in deprescribing dosulepin in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change. • Advise CCGs that if, in exceptional circumstances, there is a clinical need for dosulepin to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional	No routine exceptions have been identified.	**BLACK**	See section 6.2 Patients may require specialist review

Doxazosin MR	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation.	• Advise CCGs that prescribers in primary care should not initiate prolonged-release doxazosin for any new patient. • Advise CCGs to support prescribers in deprescribing Prolonged-release doxazosin in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.	No routine exceptions have been identified.	**BLACK** Modified release preparation: this is more costly than the immediate release preparation with only marginal benefits in relation to side effects	See section 6.2 Switch to standard release doxazosin
Immediate-Release Fentanyl	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation.	• Advise CCGs that prescribers in primary care should not initiate immediate release fentanyl for any new patient. • Advise CCGs to support prescribers in deprescribing immediate release fentanyl in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change. • Advise CCGs that if, in exceptional circumstances, there is a clinical need for immediate release fentanyl to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional.	**These recommendations do not apply to patients undergoing palliative care treatment** and where the recommendation to use immediate release fentanyl in line with NICE guidance (see below), has been made by a multi-disciplinary team and/or other healthcare professional with a recognised specialism in palliative care. **This recommendation does not apply to longer sustained release versions of fentanyl which come in patch form.**	**BROWN after palliative care specialist initiation: all non-transdermal preparations** (includes lozenges, tablets, buccal film and sublingual tablets) **classified as BROWN recognising limited use in cancer patients.** Not classified as **RED** to allow access in primary care if needed	See section 6.2 Patients may require specialist review

Glucosamine and Chrondroitin	Items of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.	• Advise CCGs that prescribers in primary care should not initiate Glucosamine and Chondroitin for any new patient. • Advise CCGs to support prescribers in deprescribing glucosamine and chondroitin in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.	No routine exceptions have been identified.	**BLACK:** All products: Lack of data on cost-effectiveness compared with standard therapy Not accepted as cost effective compared to other service development opportunities within the CCGs	Stop treatment. Patients may wish to purchase over the counter.
Herbal treatments	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.	• Advise CCGs that prescribers in primary care should not initiate herbal items for any new patient • Advise CCGs to support prescribers in deprescribing herbal items in all patients and where appropriate, ensure the availability of relevant services to facilitate this change.	No routine exceptions have been identified.	**BLACK**	Stop treatment. Patients may wish to purchase over the counter.
Homeopathy	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.	• Advise CCGs that prescribers in primary care should not initiate homeopathic items for any new patient • Advise CCGs to support prescribers in deprescribing homeopathic items in all patients and, where appropriate, ensure the availability of relevant services to facilitate this	No routine exceptions have been identified.	**BLACK**	Stop treatment. Patients may wish to purchase over the counter or consult a private homeopathic practitioner.

		change.			
Lutein and Antioxidants	Items of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.	• Advise CCGs that prescribers in primary care should not initiate lutein and antioxidants for any new patient • Advise CCGs to support prescribers in deprescribing lutein and antioxidants in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.	No routine exceptions have been identified.	**BLACK**	Stop treatment. Patients may wish to purchase over the counter.
Omega-3 Fatty Acid Compounds	Item of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns	• Advise CCGs that prescribers in primary care should not initiate omega-3 Fatty Acids for any new patient. • Advise CCGs to support prescribers in deprescribing omega-3 Fatty acids in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.	Consultant lipid specialist recommendation in patients with severe hypertriglyceridaemia (triglycerides >10mmol/L) after trial of fibrates +/- statins.	**BROWN:** after consultant lipid specialist recommendation in patients with severe hypertriglyceridaemia (triglycerides >10mmol/L) after trial of fibrates +/- statins	Review and stop prescribing in all patients, except those with severe hypertriglyceridaemia after trial of fibrates +/- statins.
Oxycodone and Naloxone Combination Product	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price	• Advise CCGs that prescribers in primary care should not initiate oxycodone and naloxone combination product for any new patient. • Advise CCGs to support prescribers in deprescribing oxycodone and naloxone	No routine exceptions have been identified.	**BLACK**	See section 6.2 Consider formulary alternatives e.g. morphine + laxative

	inflation.	combination product in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change. • Advise CCGs that if, in exceptional circumstances, there is a clinical need for oxycodone and naloxone combination product to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional.			
Paracetamol and Tramadol Combination Product	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation.	• Advise CCGs that prescribers in primary care should not initiate paracetamol and tramadol combination product for any new patient. • Advise CCGs to support prescribers in deprescribing paracetamol and tramadol combination product in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change	No routine exceptions have been identified.	**BLACK**	See section 6.2 Trial of formulary alternatives e.g. Paracetamol +/- codeine or tramadol
Perindopril Arginine	Items which are clinically effective but where more cost-effective products are	• Advise CCGs that prescribers in primary care should not initiate perindopril arginine for any new patient.	No routine exceptions have been identified	**BLACK** Black 4: Lack of data on cost-effectiveness	See section 6.2 Trial of formulary alternatives e.g.

	available, including products that have been subject to excessive price inflation	• Advise CCGs to support prescribers in deprescribing perindopril arginine in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.		compared with standard therapy Black 5: Less cost-effective than current standard therapy	Ramipril
Rubefacients (excluding topical NSAIDs)	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.	• Advise CCGs that prescribers in primary care should not initiate rubefacients (excluding topical NSAIDs) for any new patient. • Advise CCGs to support prescribers in deprescribing rubefacients (excluding topical NSAIDs) in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.	(note this does not include topical NSAIDs or capsaicin cream)	**BLACK** Lack of data on effectiveness compared with standard therapy All rubefacients are not recommended for prescribing	Stop treatment. Patients may wish to purchase over the counter.
Once Daily Tadalafil	Products which are clinically effective but where more cost-effective products are available this includes products that have been subject to excessive price inflation.	• Advise CCGs that prescribers in primary care should not initiate once daily tadalafil for any new patient • Advise CCGs to support prescribers in deprescribing once daily tadalafil in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change	No routine exceptions have been identified.	**BLACK:** NICE TA273: Terminated appraisal for benign prostatic hyperplasia **BLACK:** tadalafil (2.5mg & 5mg) once daily preparations - not recommended/commissioned**.** Less cost-effective than	See section 6.2 Trial of formulary alternatives e.g. sildenafil

				current standard therapy	
Trimipramine	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation.	• Advise CCGs that prescribers in primary care should not initiate trimipramine for any new patient. • Advise CCGs to support prescribers in deprescribing trimpramine in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.	No routine exceptions have been identified.	**BLACK** Not accepted as cost effective compared to other service development opportunities within the CCGs	See section 6.2 Trial of formulary alternatives e.g. amitriptyline
Lidocaine Plasters	Item of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns	• Advise CCGs that prescribers in primary care should not initiate lidocaine plasters for any new patient (apart from exceptions below) • Advise CCGs to support prescribers in deprescribing lidocaine plasters in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change. Advise CCGs that if, in exceptional circumstances, there is a clinical need for lidocaine plasters to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare	**These recommendations do not apply to patients who have been treated in line with NICE CG173 *Neuropathic pain in adults: pharmacological management in non-specialist settings*** but are still experiencing neuropathic pain associated with previous herpes zoster infection (post-herpetic neuralgia).	**BROWN:** for post herpetic neuralgia **BLACK:** for all other indications except PHN.	Consider formulary alternatives or specialist review

		professional.			
Liothyronine (including Armour Thyroid and liothyronine combination products) Note: The NHS E consultation and guidance only references liothyronine treatment in hypothyroidism and thyroid cancer. Derbyshire JAPC classification is for all indications including treatment resistant depression.	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation.	• Advise CCGs that prescribers in primary care should not initiate liothyronine for any new patient • Advise CCGs that individuals currently prescribed liothyronine should be reviewed by a consultant NHS endocrinologist with consideration given to switching to levothyroxine where clinically appropriate. • **Advise CCGs that a local decision, involving the Area Prescribing Committee (or equivalent) informed by National guidance (e.g. from NICE or the Regional Medicines Optimisation Committee), should be made regarding arrangements for on-going prescribing of liothyronine.** This should be for individuals who, in exceptional circumstances, have an on-going need for liothyronine as confirmed by a consultant NHS endocrinologist.	Patients treated with levothyroxine who continue to suffer with symptoms despite adequate biochemical correction, where levothyroxine has failed and in line with BTA guidance, endocrinologists providing NHS services may recommend liothyronine for individual patients after a carefully audited trial of at least 3 months duration of liothyronine. Where Liothyronine is used for patients with thyroid cancer, in preparation for radioiodine ablation, iodine scanning, or stimulated thyroglobulin test, it is appropriate for patients to obtain their prescriptions from the centre undertaking the treatment and not be routinely obtained from primary care prescribers.	**RED:** for all indications And as per BTA guidance for oncology treatment and for diagnostic purposes in line with the British Thyroid Cancer guidelines.	See section 6.2 Consider formulary alternative – levothyroxine or referral to appropriate specialist.
Travel Vaccines (vaccines administered exclusively for the purposes of travel)	Items which are clinically effective but due to the nature of the product, are deemed a low priority for NHS funding.	• Advise CCGs that prescribers in primary care should not initiate the stated vaccines exclusively for the purposes of travel for any new patient.	The following vaccines may still be administered on the NHS exclusively for the purposes of travel, if clinically appropriate, pending any future review:	**BLACK:** For travel this immunisation should not be given as part of an NHS service.	Patients should be advised that for travel, treatment is available through private travel clinic /GP practice

		• N.B This is a restatement of existing regulations and no changes have been made as a result of this guidance.
		• This guidance covers the following vaccinations which should not be prescribed on the NHS exclusively for the purposes of travel:
		  • Hepatitis B
		  • Japanese Encephalitis
		  • Meningitis ACWY
		  • OFFICIAL
		  • Yellow Fever
		  • Tick-borne encephalitis
		  • Rabies
		  • BCG
			- Cholera
			- Diphtheria/Tetanus/Polio
			- Hepatitis A
			- Typhoid
					provision on a private basis.

References

https://www.england.nhs.uk/wp-content/uploads/2017/11/items-which-should-not-be-routinely-precscribed-in-pc-ccg-guidance.pdf