ITEMS WHICH SHOULD NOT BE ROUTINELY PRESCRIBED ACROSS DERBYSHIRE

Better Value Prescribing: The Derbyshire ICBs 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

A total of 1.2 billion prescription items were dispensed in 2023-24, representing a 3% increase compared to the 2022-23 period, with costs amounting to £10.9 billion for the NHS. With the number of prescriptions increasing every year, it is important that the NHS achieves the greatest value from the money that it spends. Integrated Care Boards (ICBs) also have a legal duty around appropriate use of prescribing resources.

There is currently significant variation across England prescribing practices, , with some patients receiving medications that have been proven to be relatively ineffective or potentially harmful. Additionally, some of these medications have safer, more effective, or cheaper alternatives available. By eliminating the prescription of these items that are no longer appropriate to be prescribed on the NHS 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 ICBs that prescribers in primary care should not initiate the product for any new patient;
- Advise ICBs to support prescribers in deprescribing the product in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change;
- Advise ICBs 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 ICBs that all prescribing should be carried out by a specialist; and/or
- Advise ICBs 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, for the first iteration and 28th November 2018 – 28th February 2019 for the second iteration. This latter iteration included an update to one item from

the 2017 guidance and recommendations on eight new items 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.

ICBs 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

Derby and Derbyshire ICBs 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 ICBs 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 Integrated Care Boards' 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 ICBs 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. Do Not Prescribe (DNP) 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 DNP 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 DNP classification medicine/treatment/medical device for NHS prescribing.

6.2. DNP classification 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. Grey 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. Grey 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 DNP 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
Aliskiren [Updated 2023]	Items which are clinically effective but more cost-effective products are available, including products that have been subject to excessive price inflation.	• Do not initiate. • Deprescribe in patients currently prescribed this medicine. • Prescribe only if no other item or intervention is clinically appropriate. • Prescribe only if no other item or intervention is available.	No routine exceptions have been identified.	**Do Not Prescribe (DNP)**	Patients may require specialist review
	Background/rationale Aliskiren is a direct renin inhibitor; renin converts angiotensinogen to angiotensin. It is indicated for essential hypertension either alone or in combination with other antihypertensives. The patent expired April 2020 but no generics are available yet. NICE states there is insufficient evidence of its effectiveness to determine its suitability for use in resistant hypertension. While aliskiren has shown comparable efficacy to other antihypertensive agents in terms of blood pressure reduction, its effects on mortality and long-term morbidity are currently unknown.				
Amiodarone [Updated 2023]	Items of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or significant safety concerns.	• Do not initiate. • Deprescribe in patients currently prescribed this medicine. • Prescribe only if no other item or intervention is clinically appropriate. • Prescribe only if no other item or intervention is available. • Prescribe only if for a named indication in this guidance.	May be suitable in patients prior and post cardioversion or in specific patients who also have heart failure or left ventricular impairment. Must be initiated by a specialist and only continued under a shared care arrangement for patients where other treatments cannot be used, have failed or is in line with NICE Guidance CG180.	**Amber**	Requiring specialist assessment to enable patient selection and initiation of treatment

			Where there is an existing cohort of patients taking amiodarone who are not currently under shared care, it is recommended that these patients are reviewed to ensure that prescribing remains safe and appropriate, and a shared care arrangement is introduced.		
	Background/rationale Treatment of arrhythmias, particularly when other medicines are ineffective or contra-indicated, including paroxysmal supraventricular, nodal and ventricular tachycardias, atrial fibrillation and flutter, ventricular fibrillation and tachyarrhythmias associated with Wolff-Parkinson-White syndrome (initiated in hospital or under specialist supervision). Amiodarone has an important place in the treatment of severe cardiac rhythm disorders where other treatments either cannot be used or have failed. It has potential major toxicity and its use requires monitoring both clinically and via laboratory testing. NICE guidance on atrial fibrillation puts greater emphasis on rate rather than rhythm control and has clarified the place of amiodarone in the treatment pathway. NICE has issued the following 'do not do' recommendation: Do not offer amiodarone for long-term rate control.				
Bath and shower preparations for dry and pruritic skin conditions [Updated 2023]	Items of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or significant safety concerns.	• Do not initiate. • Deprescribe in patients currently prescribed this medicine. • Prescribe only if no other item or intervention is clinically appropriate. • Prescribe only if no other item or intervention is available. • Prescribe only if for a named indication in this guidance.	Substitute with leave-on emollients.	**Do Not Prescribe (DNP)**	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
	Background/rationale NICE guidance recommends that emollient bath additives should not be offered to children under the age of 12 for the management of atopic eczema, because they are not clinically- or cost-effective. 'Leave-on' emollient moisturisers can still be used for treating eczema. These emollients can also be used as a soap substitute.				

	It is recognised that this recommendation applies only to children; however, it was agreed that it is acceptable to extrapolate this recommendation to apply to adults until other good quality evidence emerges.				
Co-proxamol **[Updated 2023]**	Items of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or significant safety concerns.	• Do not initiate. • Deprescribe in patients currently prescribed this medicine.	No routine exceptions have been identified.	**Do Not Prescribe (DNP)** - Unlicensed - Re-classified from GREY to DNP in April 14	See section 6.2 Trial of formulary alternatives e.g. Paracetamol +/- codeine
	Background/rationale The Medicines and Healthcare products Regulatory Agency (MHRA) fully withdrew the painkiller co-proxamol from the UK market in 2007 due to safety concerns. All use in the UK is now on an unlicensed basis. Prescribing an unlicensed medicine should be in line with General Medical Council (GMC) guidance (Good practice in prescribing and managing and devices, 2021), which states suitably licensed alternatives need to be considered and the prescriber must be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy. Since 1985 advice aimed at the reduction of co-proxamol toxicity and fatal overdose has been provided, but this was not effective and resulted in withdrawal of co-proxamol by the MHRA. In 2011 MHRA reported that the withdrawal of co-proxamol from the UK had saved an estimated 300 to 400 lives each year from self-poisoning, around a fifth of which would have been accidental. Since the withdrawal, further safety concerns have been raised, resulting in co-proxamol being withdrawn in other countries. Due to the significant safety concerns, the joint clinical working group considered co-proxamol suitable for inclusion in this guidance. Co-proxamol is no longer manufactured or supplied in the UK and any use on an unlicensed basis requires it to be imported for individual use, at an increasing cost to the NHS and the environment. The average cost per item is £265 (January 2022), which is an increase of £44 since 2021.				
Dosulepin **(2017)**	Items of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or significant safety concerns.	• Do not initiate. • Deprescribe in patients currently prescribed this medicine. • Prescribe only if no other item or intervention is clinically appropriate. • Prescribe only if no other item or intervention is available. • Prescribe only if the decision has been made after a multidisciplinary team discussion.	No routine exceptions have been identified.	**Do Not Prescribe (DNP)**	See section 6.2 Patients may require specialist review

	Background/rationale Dosulepin, formerly known as dothiepin, is a tricyclic antidepressant. NICE guidance on depression in adults has a 'do not do' recommendation: Do not switch to, or start, dosulepin because evidence supporting its tolerability relative to other antidepressants is outweighed by the increased cardiac risk and toxicity in overdose. Due to the significant safety concerns advised by NICE, the joint clinical working group considered dosulepin suitable for inclusion in this guidance.				
Doxazosin MR **(2017)**	Items which are clinically effective but more cost-effective products are available, including products that have been subject to excessive price inflation.	• Do not initiate. • Deprescribe in patients currently prescribed this medicine	No routine exceptions have been identified.	**Do Not Prescribe (DNP)** 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
	Background/rationale Doxazosin is an alpha-adrenoceptor blocking drug that can be used to treat hypertension and benign prostatic hyperplasia. There are two oral forms of the medication (immediate release and prolonged release) and both are taken once daily. Prolonged-release doxazosin costs approximately six times more than doxazosin immediate release (NHS Drug Tariff). NICE guidance on hypertension recognises that doxazosin should be used in treatment but does not identify any benefits of prolonged release over immediate release. NICE guidance recommends doxazosin as an option in men with moderate to severe lower urinary tract symptoms. It does not identify benefits of prolonged release over immediate release. Due to the significant extra cost of prolonged-release doxazosin and the availability of once daily immediate-release doxazosin, the joint clinical working group considered prolonged-release doxazosin suitable for inclusion in this guidance.				
Dronedarone [2019]	Items of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or significant safety concerns.	• Do not initiate. • Deprescribe in patients currently prescribed this medicine. • Prescribe only if no other item or intervention is clinically appropriate. • Prescribe only if no other item or intervention is available.	Must be initiated by a specialist and only continued under a shared care arrangement for patients where other treatments cannot be used, have failed or is in line with NICE Guidance on atrial fibrillation.	**Amber -** See shared care guideline for the maintenance of sinus rhythm after successful cardioversion (Decision date - November 2017) Be aware of MHRA warnings	Requiring short or medium term (e.g. 3-6 months) specialist monitoring of efficacy or until the patient is stable

	Background/rationale Dronedarone is used for the maintenance of sinus heart rhythm after cardioversion in clinically stable patients with paroxysmal or persistent atrial fibrillation, when alternative treatments are unsuitable (initiated under specialist supervision). Dronedarone was originally approved to prevent atrial fibrillation from coming back or to lower the heart rate in adults who have had or have non-permanent atrial fibrillation. In September 2011 this indication was restricted to the maintenance of normal heart rhythm in 'persistent' or 'paroxysmal' atrial fibrillation after normal heart rhythm has been restored. This followed a review of data that became available since its authorisation, including data from the PALLAS study. NICE guidance puts greater emphasis on rate rather than rhythm control and clarifies the place of dronedarone in the treatment pathway.				
Immediate-Release Fentanyl **[Updated 2023]**	Items which are clinically effective but more cost-effective products are available, including products that have been subject to excessive price inflation.	• Do not initiate. • Deprescribe in patients currently prescribed this medicine. • Prescribe only if no other item or intervention is clinically appropriate. • Prescribe only if no other item or intervention is available. • Prescribe only if for a named indication in this guidance.	**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.**	**GREY – after palliative care specialist initiation: all non-transdermal preparations** (includes lozenges, tablets, buccal film. and sublingual tablets and nasal spray) **classified as GREY recognising limited use in cancer patients.** Prescribed by brand to avoid confusion. Requires specialist and a titration process. Not classified as RED to allow access in primary care if needed **DNP (Do Not Prescribe):** all non-transdermal preparations initiated outside palliative care.	See section 6.2 Patients may require specialist review Requires specialist and a titration process.

	Background/rationale Fentanyl is a strong opioid analgesic. It is available as an immediate-release substance in various dosage forms; tablets, lozenges, films and nasal spray. Immediate-release fentanyl is licensed for the treatment of breakthrough pain in adults with cancer who are already receiving at least 60mg oral morphine daily or equivalent. NICE CG140 Opioids in palliative care states: "Do not offer fast-acting fentanyl as first-line rescue medication". This recommendation does not apply to longer sustained release versions of fentanyl, which come in patch form. Due to the recommendations from NICE and immediate-release fentanyl only being licensed for use in cancer, the joint clinical working group considered immediate-release fentanyl was suitable for inclusion in this guidance with specific exceptions for people receiving palliative care, reflecting NICE and the terms of the product licence. The recommendations also reflect findings from the PHE Prescribed Review (September 2019), which outlined the risks of prescribing that can cause dependence or withdrawal and could cause problems for people taking them or coming off them, especially those who have been taking them for a long time.				
Glucosamine and Chrondroitin **(2017)**	Items of low clinical effectiveness, there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.	• Do not initiate. • Deprescribe in patients currently prescribed this medicine.	No routine exceptions have been identified.	**Do Not Prescribe (DNP):** All products:	Stop treatment. Patients may wish to purchase over the counter.
	Background/rationale Glucosamine and chondroitin are nutraceuticals used to improve pain associated with osteoarthritis. The BNF states: "The mechanism of action is not understood and there is limited evidence to show it is effective". NICE guidance on osteoarthritis care and management has the following 'do not do; recommendation: Do not offer glucosamine or chondroitin products for the management of osteoarthritis. Due to the recommendation from NICE and the lack of evidence as advised by the BNF, the joint clinical working group considered glucosamine and chondroitin suitable for inclusion in this guidance.				
Herbal treatments and other natural products [Updated 2023]	Items of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or significant safety concerns.	• Do not initiate. • Deprescribe in patients currently prescribed this medicine.	No routine exceptions have been identified.	**Do Not Prescribe (DNP)**	Stop treatment. Patients may wish to purchase over the counter.

	Background/rationale Under a traditional herbal registration (THR) there is no requirement to prove scientifically that a product works; the registration is based on longstanding use of the product as a traditional medicine. Due to the lack of scientific evidence required to register these products with the MHRA, the joint clinical working group felt that they were suitable for inclusion in this guidance. In addition to herbal treatments with a THR, other natural products without robust evidence of clinical effectiveness should not be prescribed at NHS expense and fall within these recommendations. These products do not have a THR, are not recognised as supplements in the NHS Drug Tariff and do not appear as in the BNF. These include: • natural oils, eg eucalyptus and almond • coenzyme Q10 (ubiquinone and ubidecarenone) • evening primrose (gamolenic acid). MHRA withdrew the licence for 2-gamolenic acid preparations in 2002 due to a lack of evidence of efficacy.				
Homeopathy (2017)	Items of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or significant safety concerns.	• Do not initiate. • Deprescribe in patients currently prescribed this medicine.	No routine exceptions have been identified.	**Do Not Prescribe (DNP)**	Stop treatment. Patients may wish to purchase over the counter or consult a private homeopathic practitioner.
	Background/rationale Homeopathy seeks to treat patients with highly diluted substances that are administered orally. During the consultation we received a range of submissions pertaining to homeopathy and it was deemed necessary to have a further review to include the up to date evidence; this was conducted by the Specialist Pharmacy Service. This review found no clear or robust evidence to support the use of homeopathy on the NHS.				
Lidocaine Plasters [Updated 2023]	Items of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or significant safety concerns	• Do not initiate. • Deprescribe in patients currently prescribed this medicine. • Prescribe only if no other item or intervention is clinically appropriate. • Prescribe only if no other item or intervention is available.	Prescribe to patients who have been treated in line with NICE guidance on chronic pain but are still experiencing neuropathic pain associated with previous herpes zoster infection (post-herpetic neuralgia, PHN).	**Grey-** for post herpetic neuralgia (Ralvo is the preferred, cost effective brand for lidocaine plaster) **DNP (Do Not Prescribe) -** for all other indications except PHN.	Consider formulary alternatives or specialist review See neuropathic pain guideline For topical treatment consider capsaicin cream first

		• Prescribe only if for a named indication in this guidance.	Prescribe only if the decision has been made after a multidisciplinary team discussion- *see local recommendation*		Patients initiated on lidocaine plasters should be reviewed 2-4 weeks after initiation and the on-going need assessed regularly and discontinued if ineffective. Lidocaine plasters for all other indications should be reviewed and discontinued.
	Background/rationale Lidocaine plasters are licensed for symptomatic relief of neuropathic pain associated with previous herpes zoster infection (PHN) in adults. NICE guidance on chronic pain does not recommend lidocaine plasters for treating neuropathic pain. The joint clinical working group also considered a PrescQIPP CIC review, and during the consultation more evidence was provided and an up to date evidence summary was deemed necessary and prepared by the Specialist Pharmacy Service to inform the joint clinical working group's recommendations. Based on this review, lidocaine plasters can be prescribed only for patients who are intolerant of first-line systemic therapies for PHN or where these therapies have been ineffective. Lidocaine plasters are not an alternative to an opioid-based medicine when concerned about dependence and withdrawal.				
Liothyronine (Including Armour Thyroid and liothyronine combination products) **[Updated 2023]**	Items which are clinically effective but more cost-effective products are available, including products that have been subject to excessive price inflation.	• Do not initiate. • Deprescribe in patients currently prescribed this medicine. • Prescribe only if no other item or intervention is clinically appropriate. • Prescribe only if no other item or intervention is available. • Prescribe only if for a named indication in this guidance.	The recommendations do not apply to patients who have already been reviewed by an NHS consultant endocrinologist. All other patients currently taking liothyronine should be reviewed by an NHS consultant endocrinologist to determine future treatment plans.	**Amber** (Liothyronine in combination with levothyroxine shared care agreement) **DNP (Do Not Prescribe) -** not to be initiated in new patients **RED:** when used as monotherapy, for resistant depression and in doses which exceed 60mcg per day.	For existing patients following review of benefit by an NHS Endocrinologist Specialist and the treatment dose have been stabilised for 3 months If there is an exceptional clinical need, such as difficulty in tolerating or absorbing levothyroxine, then a request to prescribe must be made via the IFR

			New patients with overt hypothyroidism whose symptoms persist on levothyroxine may be prescribed liothyronine after a 3-month or longer review by an NHS consultant endocrinologist.- *see local recommendation* Follow NHS England prescribing advice on liothyronine when initiating or reviewing the prescribing of liothyronine.		process and the request should be made by an NHS endocrinologist. Red: Requiring specialist assessment to enable patient selection, initiation and ongoing treating

Background/rationale

Liothyronine (sometimes known as T3) is used to treat hypothyroidism. It has a similar action to levothyroxine but is metabolised faster and has a quicker effect. It is sometimes used in combination with levothyroxine in products.

Prior to 2017, the price (NHS Drug Tariff) of liothyronine rose significantly and there is limited evidence for efficacy above levothyroxine for most patients. Since 2017, the price of liothyronine has fallen but it is still significantly higher than the price of levothyroxine tablets.

The British Thyroid Association (BTA) and Society for Endocrinologists 2023 joint consensus statement states “There is no convincing evidence to support routine use of thyroid extracts, L-T3 monotherapy, compounded thyroid hormones, iodine containing preparations, dietary supplementation and over the counter (OTC) preparations in the management of hypothyroidism”.
Due to the significant costs associated with liothyronine and the limited evidence to support its routine prescribing in preference to levothyroxine, the joint clinical working group considered liothyronine suitable for inclusion in this guidance. However, during the consultation, we heard and received evidence about a cohort of patients who require liothyronine, and the clinical working group felt it necessary to include some exceptions based on guidance from the BTA. These exceptions are clarified in the NHS England Liothyronine – advice for prescribers.
NHS England and the British Thyroid Association (BTA) advise that a small proportion of patients treated with levothyroxine continue to have symptoms despite adequate biochemical correction. Liothyronine may be appropriate for these patients.

Where symptoms persist on levothyroxine, and in line with NHS England and BTA prescribing advice on liothyronine, endocrinologists providing NHS services may initiate liothyronine for new patients after a carefully audited trial of liothyronine lasting at least 3 months.

<table>
<tr><td></td><td colspan="5">For patients currently prescribed liothyronine who have not already had a review, an NHS consultant endocrinologist should review them to consider switching to levothyroxine where clinically appropriate. Prescriptions for individuals already receiving liothyronine should continue until that review has taken place.

Liothyronine is used for patients with thyroid cancer, in preparation for radioiodine ablation, iodine scanning or stimulated thyroglobulin test. In these situations, it is appropriate for patients to obtain their prescriptions from the centre undertaking the treatment and not routinely obtained from primary care prescribers.</td></tr>
<tr><td rowspan="2">Lutein and Antioxidants

[Updated 2023]</td><td>Items of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or significant safety concerns.</td><td>• Do not initiate.
• Deprescribe in patients currently prescribed this medicine
• Only prescribe if no item or intervention is clinically appropriate
• Only prescribe if no item or intervention is available</td><td>No routine exceptions have been identified.</td><td>Do Not Prescribe (DNP)</td><td>Stop treatment.
Patients may wish to purchase over the counter.</td></tr>
<tr><td colspan="5">Background/rationale
The supplements lutein and antioxidants (e.g. vitamin A, C, E and zinc) are sometimes recommended for age-related macular degeneration (AMD). A variety of supplements are available to purchase in health food stores and other outlets where they are promoted to assist with ‘eye health’.
Two Cochrane reviews have been conducted on this topic:

1. Antioxidant vitamin and mineral supplements for preventing age-related macular degeneration. The authors conclude: “There is accumulating evidence that taking vitamin E or beta-carotene supplements will not prevent or delay the onset of AMD. There is no evidence with respect to other antioxidant supplements, such as vitamin C, lutein and zeaxanthin, or any of the commonly marketed multivitamin combinations”.

2. Antioxidant vitamin and mineral supplements for slowing the progression of age-related macular degeneration. The authors conclude: “People with AMD may experience delay in progression of the disease with antioxidant vitamin and mineral supplementation. This finding is drawn from one large trial conducted in a relatively well-nourished American population. The generalisability of these findings to other populations is not known”.

PrescQIPP CIC has issued a bulletin that did not find evidence to support prescribing of lutein and antioxidants routinely on the NHS.
NICE guidance on AMD includes a recommendation for research on the effectiveness and cost-effectiveness of lutein and antioxidants, which is currently a gap in the research.</td></tr>
</table>

Minocycline for acne **(2019)**	Items of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or significant safety concerns.	• Do not initiate. • Deprescribe in patients currently prescribed this medicine.	No routine exceptions have been identified.	**DNP (Do Not Prescribe)** - Not recommend for ACNE and its use in dermatology for other indications (e.g. bullous pyoderma) is no longer supported by dermatologists across Derbyshire.	Patients may require specialist review
	Background/rationale Minocycline is a tetracycline antibiotic that can be used for many indications. In primary care it is mainly used for acne. There are various safety risks associated with its use. NICE guidance on acne vulgaris management advises: "Minocycline is not recommended for use in acne as it is associated with an increased risk of adverse effects such as drug-induced lupus, skin pigmentation and hepatitis." A PrescQIPP CIC review found no evidence to support the use of one tetracycline over another in terms of efficacy for the treatment of acne vulgaris, and alternative once daily products are available.				
Needles for Pre-filled and reusable insulin pens **(2019)**	Items which are clinically effective but more cost-effective products are available, including products that have been subject to excessive price inflation.	• Do not initiate. • Deprescribe in patients currently prescribed this medicine. • Prescribe only if no other item or intervention is clinically appropriate. • Prescribe only if no other item or intervention is available. • Prescribe only if for a named indication in this guidance.	These recommendations do not apply to insulin pen needles that cost <£5 per 100 needles.	**Insulin Pen Needles:** **DNP (Do Not Prescribe)** - All other insulin pen needles with acquisition cost > £5 per 100 **Safety needles:** **DNP (Do Not Prescribe)** **–** All other insulin safety needles with acquisition cost > £20 per 100	
	Background/rationale Pen needles are available in sizes from 4mm to 12mm and cost from £3.95 to £30.08 for 100 (NHS Drug Tariff). Different needles will fit different pens, but some fit all major insulin delivery pen devices currently available. Rationalising use ensures that the most cost-effective options are used first line.				

<table>
<tr><td></td><td colspan="5">The Forum for Injection Technique (FIT) UK considers the 4mm needle to be the safest pen needle for adults and children, regardless of age, gender and body mass index (BMI).

Using shorter length needles helps prevent intramuscular injection of insulin. (IM injection of insulin can result in unpredictable blood glucose levels.) Therefore, the most cost-effective 4mm needle should be chosen.

For patients currently using longer pen needle lengths (8mm, 12mm), changing to a shorter length (6mm or less) is advised, but only after discussion with a healthcare professional to ensure they receive advice on the correct injection technique.
For patients who cannot self-administer, it may be appropriate for the healthcare professional to use a safety needle; however, this would not need to be supplied on prescription.</td></tr>
<tr><td rowspan="2">Omega-3 Fatty Acid Compounds [Updated 2023]</td><td>Items of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or significant safety concerns</td><td>• Do not initiate.
• Deprescribe in patients currently prescribed this medicine.</td><td>No routine exceptions have been identified. – see local recommendation</td><td>GREY: after consultant lipid specialist recommendation in patients with severe hypertriglyceridaemia (triglycerides >10mmol/L) after trial of fibrates +/- statins</td><td>Review and stop prescribing in all patients, except those with severe hypertriglyceridaemia after trial of fibrates +/- statins.</td></tr>
<tr><td colspan="5">Background/rationale

Omega-3 fatty acid compounds are essential fatty acids that can be obtained from the diet. They are licensed for adjunct to diet and statin in Type IIb or III hypertriglyceridaemia; adjunct to diet in Type IV hypertriglyceridaemia; adjunct in secondary prevention in those who have had a myocardial infarction in the preceding 3 months.

The summary of national guidance for lipid management (NHS Access Collaborative, December 2021) outlines the clinical pathway for primary and secondary prevention of cardiovascular disease (CVD). It states that omega-3 fatty acids should not be offered alone or in combination with a statin for the prevention of CVD. This pathway should be followed for lipid management.

NICE recommends that only one omega-3 fatty acid compound is recommended in specific clinical circumstances – icosapent ethyl [Vazkepa®] (NICE TA805), and that all other omega-3 fatty acid compounds are not suitable for prescribing:

Do not offer or advise people to use omega-3 fatty acid capsules or omega-3 fatty acid supplemented foods to prevent another myocardial infarction. If people choose to take omega-3 fatty acid capsules or eat omega-3 fatty acid supplemented foods, be aware that there is no evidence of harm.

Do not offer omega-3 fatty acid compounds for the prevention of cardiovascular disease to any of the following: people who are being treated for primary prevention, people who are being treated for secondary prevention, people with chronic kidney disease, people with type 2 diabetes, people with type 2 diabetes.</td></tr>
</table>

	Do not offer the combination of a bile acid sequestrant (anion exchange resin), fibrate, nicotinic acid or omega-3 fatty acid compound with a statin for the primary or secondary prevention of CVD. Do not offer omega-3 fatty acids to adults with non-alcoholic fatty liver disease because there is not enough evidence to recommend their use. Initiation of omega-3-acid ethyl esters supplements is not routinely recommended for patients who have had a myocardial infarction (MI) more than 3 months earlier. Do not use omega-3 fatty acids to manage sleep problems in children and young people with autism. People with familial hypercholesterolemia (FH) should not routinely be recommended to take omega-3 fatty acid supplements. Do not offer omega-3 or omega-6 fatty acid compounds to treat multiple sclerosis (MS). Explain that there is no evidence that they affect relapse frequency or progression of MS. The joint clinical working group agreed with NICE recommendations and considered omega-3 fatty acid compounds suitable for inclusion in this guidance.				
Oxycodone and Naloxone Combination Product **(2017)**	Items which are clinically effective but more cost-effective products are available, including products that have been subject to excessive price inflation.	• Do not initiate • Deprescribe in patients currently prescribed this medicine • Prescribe only if no other item or intervention is clinically appropriate • Prescribe only if no other item or intervention is available.	No routine exceptions have been identified. Prescribe only if the decision to prescribe has been made after a multidisciplinary team discussion.	**Do Not Prescribe (DNP)**	See section 6.2 Consider formulary alternatives e.g. morphine + laxative
	Background/rationale Oxycodone and naloxone combination product is used to treat severe pain and can also be used second line in restless legs syndrome. The opioid antagonist naloxone is added to counteract opioid-induced constipation by blocking the action of oxycodone at opioid receptors in the gut. PrescQIPP CIC has issued a bulletin, which does not identify a benefit of oxycodone and naloxone in a single product over other analgesia (with laxatives if necessary). Due to the significant cost of the oxycodone and naloxone combination product and the unclear role of the combination product in therapy compared with individual products, the joint clinical working group considered oxycodone and naloxone suitable for inclusion in this guidance.				
Paracetamol and Tramadol	Items of low clinical effectiveness, where there is a lack of robust	• Do not initiate.	No routine exceptions have been identified.	**Do Not Prescribe (DNP)**	See section 6.2 Trial of formulary alternatives e.g.

Combination Product **[Updated 2023]**	evidence of clinical effectiveness or significant safety concerns.	• Deprescribe in patients currently prescribed this medicine. • Prescribe only if no other item or intervention is clinically appropriate. • Prescribe only if no other item or intervention is available.			Paracetamol +/- codeine or tramadol
	Background/rationale Although the combination product has reduced in price since this guidance was first published in 2017, there is no further evidence that indicates significant advantages over individual products. A PrescQIPP CIC bulletin did not identify any significant advantages over individual products; however, it recognised that some people may prefer to take one product instead of two. While the strengths of tramadol (37.5mg) and paracetamol (325mg) in the combination product are lower than those in commonly available individual preparations of tramadol (50mg) and paracetamol (500mg), the PrescQIPP CIC review found no evidence that the combination product is more effective or safer than the individual preparations.				
Perindopril Arginine **(2017)**	Items which are clinically effective but more cost-effective products are available, including products that have been subject to excessive price inflation	• Do not initiate. • Deprescribe in patients currently prescribed this medicine. • Prescribe only if no other item or intervention is clinically appropriate. • Prescribe only if no other item or intervention is available.	No routine exceptions have been identified	**Do Not Prescribe (DNP)**	See section 6.2 Trial of formulary alternatives e.g. Ramipril
	Background/rationale Perindopril is an ACE inhibitor used in heart failure, hypertension, diabetic nephropathy, and prophylaxis of cardiovascular events. The perindopril arginine salt version is more stable in extremes of climate than the perindopril erbumine salt, which gives it a longer shelf-life. However, perindopril arginine is significantly more expensive than perindopril erbumine and a PrescQIPP CIC review of the topic found no clinical advantage for the arginine salt. NICE guidance on hypertension in adults recommends that prescribing costs are minimised. Due to the significant extra costs of the arginine salt and the availability of the erbumine salt, the joint clinical working group considered perindopril arginine suitable for inclusion in this guidance.				

<table>
<tr><td rowspan="2">Rubefacients, benzydamine, mucopolysaccharide and cooling products (excluding topical NSAIDs and capsaicin)

[Updated 2023]</td><td>Items of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or significant safety concerns.</td><td>• Do not initiate.
• Deprescribe in patients currently prescribed this medicine.
• Prescribe only if no other item or intervention is clinically appropriate
• Prescribe only if no other item or intervention is available.</td><td>(note this does not include topical NSAIDs or capsaicin cream)

No routine exceptions have been identified.</td><td>Do Not Prescribe (DNP)

All rubefacients are not recommended for prescribing (note this does not include topical NSAIDs or capsaicin cream)</td><td>Stop treatment.
Patients may wish to purchase over the counter.</td></tr>
<tr><td colspan="5">Background/rationale

Rubefacients are topical preparations that cause irritation and reddening of the skin due to increased blood flow. They are believed to relieve pain in various musculoskeletal conditions and are available on prescription and in OTC remedies. They may contain nicotinate compounds, salicylate compounds, essential oils and camphor.

The BNF states: “The evidence available does not support the use of topical rubefacients in acute or chronic musculoskeletal pain”.

NICE has issued the following ‘do not do’ recommendation: Do not offer rubefacients for treating osteoarthritis.

Due to limited evidence and NICE recommendations, the joint clinical working group considered rubefacients (excluding topical NSAIDs) suitable for inclusion in this guidance.

Other miscellaneous topical analgesics containing benzydamine, mucopolysaccharide polysulphate or cooling ingredients fall under this category. Benzydamine and mucopolysaccharide are weak prostaglandin inhibitors and are therefore pharmacologically different from those routinely referred to as NSAIDs in current practice (such as ibuprofen and diclofenac), so it cannot be presumed that the clinical evidence relating to NSAIDs can be extrapolated to benzydamine or mucopolysaccharide polysulphate containing products (Rubefacients and miscellaneous topical analgesics, PrescQIPP, July 2021).

The Clinical Knowledge Summary on sprains and strains (NICE, 2020) does not specifically discuss cooling sprays and gels, but does suggest ice is used for self-management strategies in the first 48–72 hours after injury.

Due to limited evidence and the NICE recommendations, the joint clinical working group considered these additional products suitable for inclusion in this category.</td></tr>
<tr><td>Silk Garments

(2019)</td><td>Items of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or</td><td>• Do not initiate.
• Deprescribe in patients currently prescribed this medicine.</td><td>No routine exceptions have been identified.</td><td>DNP (Do Not Prescribe)</td><td>Stop treatment.
Patients may wish to purchase over the counter.</td></tr>
</table>

	significant safety concerns.				
	Background/rationale Silk garments are typically prescribed for eczema or dermatitis. These products are knitted, medical grade silk clothing that can be used as an adjunct to normal treatment for severe eczema and allergic skin conditions. Four brands of knitted silk garments are currently listed as an appliance in part IX A in the NHS Drug Tariff and are relatively expensive. The PrescQIPP document on silk garments states that the evidence relating to their use is weak and is of low quality. In addition, due to limited evidence supporting the efficacy of silk clothing for the relief of eczema, the NIHR HTA programme commissioned the CLOTHES trial, to examine whether adding silk garments to standard eczema care reduced eczema severity in children with moderate to severe eczema, compared to use of standard eczema treatment alone. The trial concluded that using silk garments for the management of eczema is unlikely to be cost-effective for the NHS.				
Travel Vaccines (Vaccines administered exclusively for the purpose of travel) **(2017)**	Items which are clinically effective but due to the nature of the product, are deemed a low priority for NHS funding.	• Do not initiate. • Prescribe only for an indication named in this guidance.	The recommendations do not apply to the following vaccines when administered exclusively for the purposes of travel, if clinically appropriate:- Cholera - Diphtheria/ Tetanus/Polio - Hepatitis A - Typhoid	**Do Not Prescribe (DNP): (for travel) -** For all other indications, as outlined in Immunisation Against Infectious Disease – the green book – the vaccine remains free on the NHS.	These vaccines should continue to be recommended for travel, but the individual traveller will need to bear the cost of the vaccination (private travel clinic /GP practice provision on a private basis)
	Background/rationale This guidance covers the following vaccinations that should not be prescribed on the NHS exclusively for the purposes of travel: • hepatitis B • Japanese encephalitis • meningitis ACWY • yellow fever • tick-borne encephalitis • rabies • BCG. These vaccines should continue to be recommended for travel but the individual traveller will need to bear the cost of the vaccination.				

	For all other indications, as outlined in Immunisation Against Infectious Disease – the Green Book – the vaccine remains free on the NHS.				
Trimipramine **(2017)**	Items which are clinically effective but more cost-effective products are available, including products that have been subject to excessive price inflation.	• Do not initiate. • Deprescribe in patients currently prescribed this medicine. • Prescribe only if no other item or intervention is clinically appropriate. • Prescribe only if no other item or intervention is available.	No routine exceptions have been identified.	**Do Not Prescribe (DNP)**	See section 6.2 Trial of formulary alternatives e.g. amitriptyline
	Background/rationale The tricyclic antidepressant (TCA) trimipramine is significantly more expensive than other antidepressants. NICE guidance on depression in adults recommends selective serotonin reuptake inhibitor (SSRI) antidepressants first line if are indicated as they have a more favourable risk-to-benefit ratio compared to TCAs. However, if a TCA is required, more cost-effective TCAs than trimipramine are available. Due to the significant cost associated with trimipramine and the availability of alternative treatments, the joint clinical working group considered trimipramine suitable for inclusion in this guidance.				

References

https://media.nhsbsa.nhs.uk/news/prescriptions-cost-analysis-2#:~:text=The%20number%20of%20prescription%20items,1.18%20billion%20in%202022%2F23.

NHS England » Items which should not routinely be prescribed in primary care: policy guidance