NHS Clinical Commissioners
The independent collective voice of clinical commissioning groups

NHS

Items which should not routinely be prescribed in primary care: Guidance for CCGs

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NHS England and NHS Improvement

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Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the recommendations set out in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

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1 Background

This guidance was first published in November 2017 and included recommendations on 18 items which were consulted on from July – Oct 2017. In the Autumn of 2018 the guidance was reviewed, and further consultation was undertaken from Nov 2018 – Feb 2019 on an update to one of the 18 items (rubefacients) and 8 new items.

This updated CCG guidance therefore includes original recommendations for 17 items, an update to the recommendations for 1 of the original items and recommendations for 7 new items. Proposed recommendations for one of the new items (blood glucose testing strips) as outlined in the consultation document are not included in this version of the guidance and will be considered for addition at a later date.

Updated or new items are highlighted as [Updated 2019] or [New 2019]. Previous items are highlighted as [2017].

1.1 Who is this guidance for?

This guidance is addressed to Clinical Commissioning Groups (CCGs) to support them to fulfil their duties around appropriate use of their resources. We expect CCGs to take this guidance into account in formulating local policies, and prescribers to reflect local policies in their prescribing practice. Where appropriate there should be shared responsibility of prescribing and monitoring between primary and secondary care. Local areas should also take account of the NHS England guidance: Responsibility for prescribing between primary and secondary/tertiary care.

This guidance is issued as general guidance under s14Z10 and S2 of the NHS Act 2006 and is addressed to CCGs to support them to fulfil their duties around appropriate use of prescribing resources. The objective of this guidance is to support CCGs in their decision-making, to address unwarranted variation, and to provide clear national advice to make local prescribing practices more effective.

The guidance does not remove the clinical discretion of the prescriber in accordance with their professional duties.

1.2 Why have we developed this guidance?

Last year 1.1 billion prescription items[1] were dispensed in primary care at a cost of £8.8 billion[2]. This cost coupled with finite resources means it is important that the NHS achieves the greatest value from the money that it spends. We know that across England there is significant variation in what is being prescribed and to whom. Some patients are receiving medicines which have been proven to be relatively ineffective or in some cases potentially harmful, and/or for which there are other more effective, safer and/or cheaper alternatives; there are also products which are no longer appropriate to be prescribed on the NHS.

NHS England has partnered with NHS Clinical Commissioners to support Clinical Commissioning Groups (CCGs) in ensuring that they can use their prescribing

[1] An item is anything which can be prescribed on an NHS prescription. More information on what is prescribed on an NHS prescription is available in the Drug Tariff.
[2] NHS Digital Prescription Cost Analysis 2018

resources effectively and deliver best patient outcomes from the medicines that their local population uses. CCGs asked for a nationally co-ordinated approach to the creation of commissioning guidance, developed with and by CCGs. The aim was a more equitable basis on which CCGs can take an individual and local implementation decisions. CCGs will still need to take individual decisions on implementation locally, ensuring they take into account their legal duties to advance equality and have regard to reducing health inequalities.

1.3 How have the recommendations in this guidance been developed?

In response to calls from General Practitioners (GPs) and CCGs who were having to take individual decisions about their local formularies, NHSCC, surveyed their members during February and March 2017 to assess views as to whether a range of medicines and other products should be routinely available for prescription on the NHS.

NHS Clinical Commissioners asked NHS England to work with them to produce commissioning guidance to support their member organisations in taking decisions about prescribing of these products in primary care.

Together, NHS England and NHSCC established a clinical working group, chaired by representatives of these two organisations, with membership including GPs and pharmacists, CCGs, Royal College of General Practitioners, National Institute for Health and Care Excellence (NICE), Department of Health and Social Care, the Royal Pharmaceutical Society and others (full membership listed at appendix A). This clinical working group was tasked with identifying which products should no longer be routinely prescribed in primary care.

Work focused on developing guidelines for products which fall into one or more of the following categories:

In the joint clinical working group, items were considered for inclusion if they were:

- Items of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns;

- Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation; and/or

- Items which are clinically effective but, due to the nature of the product, are deemed a low priority for NHS funding.

The group assigned one or more of the following recommendations to items considered:

- Advise CCGs that prescribers in primary care should not initiate {item} for any new patient;
- Advise CCGs that prescribers in primary care should not initiate {item} that cost {price} for any new patient.

- Advise CCGs to support prescribers in deprescribing {item} in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change;
- Advise CCGs to support prescribers in deprescribing {item} that cost {price} in all patients and where appropriate ensure the availability of relevant services to facilitate this.
- Advise CCGs that if, in exceptional[3] circumstances, there is a clinical need for {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 {item} should not be routinely prescribed in primary care but may be prescribed in named circumstances such as {circumstance}.

Subsequently NHS England's Board considered the proposals prior to them being formally consulted upon publicly.

In reaching its recommendations for the 25 products listed in this guidance document, the group considered recommendations from NICE, where relevant, in order to support CCGs in implementing NICE guidance across the country; in particular it identified items which NICE consider to be "Do not do's[4]".

Where NICE guidance was not available, the group considered evidence from a range of sources, for example; the Medicines and Healthcare products Regulatory Agency (MHRA), the British National Formulary, the Specialist Pharmacist Service and PrescQIPP Community Interest Company (CIC) evidence reviews.

The group reviewed each product against the following criteria:

- **Legal Status** i.e. is it prescription only, or is it available over the counter in pharmacies and/or any retail outlet?
- **Indication** i.e. what condition is it used to treat?
- **Background** i.e. a general narrative on the drug including. pack size, tablet size, whether administered orally etc.
- **Patent Protection** i.e. is the drug still subject to a patent?
- **Efficacy** i.e. is it clinically effective?
- **Safety** i.e. is the drug safe?
- **Alternative treatments and exceptionality for individuals** i.e. do alternatives exist and if so, who would they be used for?
- **Equalities and Health Inequalities** i.e. are there groups of people who would be disproportionately affected?
- **Financial implications, comprising:**
    - **Commissioning/funding pathway** i.e. how does the NHS pay for the drug?
    - **Medicine Cost** i.e. how much does the drug cost per item?
    - **Healthcare Resource Utilisation** i.e. what NHS resources would be required to implement a change?
    - **Annual Spend** i.e. what is the annual spend of the NHS on this item?

[3] In this context, "exceptional circumstances" should be interpreted as: Where the prescribing clinician considers no other medicine or intervention is clinically appropriate and available for the individual.
[4] Practices NICE recommend should be discontinued completely or should not be used routinely.

- **Unintended consequences**

The group's recommendations on the original 18 items within this guidance were publicly consulted on for a period of 3 months, from 21st July 2017 – 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.

During both consultations, we heard from members of the public, patients and their representative groups, NHS staff, various Royal Colleges and the pharmaceutical industry, amongst others. Section 1.4 details the main findings from the consultations and the changes that have been made because of what we have heard. More detailed reports on both consultations can be found in *Items which should not routinely be prescribed in primary care: consultation report of findings (Nov 2017 and June 2019)*, published alongside this guidance. The final recommendations set out in this guidance document reflect the outcome of both consultations. Final guidance includes eighteen original items published in 2017, one of which was updated in 2019, along with the addition of seven new items. The potential impact of these recommendations on equality and health inequalities has also been considered and is outlined in the Equality and Health Inequalities Impact Assessment documents (Nov 2017 and June 2019) published alongside this guidance.

1.4 How have the recommendations in this guidance been developed following the results of the consultation?

We listened to what our stakeholders told us through the consultations and refined our draft guidance considering the written and survey responses, discussion through webinars and engagement exercises, as well as recommendations from the joint clinical working group which considered the feedback in detail.

There have been some important refinements and clarifications made in respect of several products because of the consultations. Details of each product are as follows:

July 2017 – October 2017 consultation:

Co-proxamol – We received a significant number of responses during the consultation around co-proxamol and the safety of continuing to prescribe this treatment emerged as the main theme. Because of what we heard, the joint clinical working group recommended that we keep our original recommendations.

Dosulepin – Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for dosulepin.

Prolonged-release Doxazosin - Because of what we heard the joint clinical working group did not feel it necessary to amend the proposed recommendations on deprescribing for prolonged-release doxazosin; however, the group felt that there would not be cases of exceptionality that would warrant referral to a multidisciplinary team so removed that recommendation.

Immediate release Fentanyl – During the consultation we heard from patients, healthcare professionals and others that it is important that immediate-release fentanyl

is available for use in palliative care. The joint clinical working group therefore decided that the three original proposed recommendations should remain but that a defined exemption and clarification should be provided for use as outlined in NICE guidance for palliative care.

Glucosamine and Chondroitin - Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for glucosamine and chondroitin.

Herbal Treatments - Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for Herbal treatments.

Homeopathy – During the consultation we heard a range of views both agreeing and disagreeing with our proposals on homeopathy. Due to the volume of evidence submitted a further review of the evidence was commissioned from the Specialist Pharmacy Service (SPS) by NHS England. The SPS review found that there was no clear or robust evidence base to support the use of homeopathy in the NHS and therefore, also considering responses received from medical and scientific bodies, the joint clinical working group did not feel it necessary to amend the proposed recommendations for homeopathy.

Lidocaine Plasters - During the consultation we heard from patients, healthcare professionals and others that there may be some specialist uses for this item which may be outside the terms of its license. We also received further submissions of evidence and a review of this evidence was commissioned from the Specialist Pharmacy Service (SPS) by NHS England. The joint clinical working group considered the consultation feedback and the SPS evidence review and decided that the three recommendations should remain, but that a defined exemption and clarification should be provided for the use of lidocaine plasters in Post Herpetic Neuralgia (PHN) only, for which it is licensed in adults and for which there is some evidence of efficacy.

Liothyronine - We received a significant number of responses during the consultation around liothyronine. The main recurring theme – particularly from patients and organisational bodies - is that liothyronine is an effective treatment which is invaluable to patient wellbeing, quality of life and condition management. We also heard that a small proportion of patients treated with levothyroxine continue to suffer with symptoms despite adequate biochemical correction. The joint clinical working group considered the consultation feedback and therefore decided that liothyronine should still be prescribed for a small cohort of patients. The joint clinical working group changed the recommendations so that initiation of prescribing of liothyronine in appropriate patients should be initiated by a consultant endocrinologist in the NHS, and that deprescribing in ‘all’ patients is not appropriate as there are recognised exceptions.

Lutein and Antioxidants – Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for lutein and antioxidants.

Omega-3 Fatty Acid Compounds - Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for omega-3 fatty acid compounds.

Oxycodone and Naloxone combination product - Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for oxycodone and naloxone combination product.

Paracetamol and Tramadol combination product - Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for paracetamol and tramadol Combination Product.

Perindopril Arginine - Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for perindopril arginine.

Rubefacients (excluding topical NSAIDs) - Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for rubefacients (excluding topical NSAIDs).

Once daily Tadalafil - Because of what we heard the joint clinical working group did not feel it necessary to amend the proposed recommendations for once daily tadalafil.

Vaccines administered exclusively for the purposes of travel - Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for vaccines administered *exclusively for the purposes of travel*. However, we did hear that confusion persists around travel vaccines and we have amended the wording of our guidance to reduce confusion.

Trimipramine - Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for deprescribing trimipramine however the group felt that there would not be cases of exceptionality that would warrant referral to a multidisciplinary team so removed that recommendation.

Whilst not a part of this consultation, the Department of Health consulted on the availability of Gluten free foods in primary care from August – October 2018. The Department of Health made recommendations in November 2018 and we removed references to Gluten free foods from this commissioning guidance. NHS England also published CCG guidance on Prescribing Gluten Free Food in Primary Care in November 2018.

November 2018 – February 2019 consultation:

Aliskiren - Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for aliskiren.

Amiodarone - Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for amiodarone.

Bath and shower preparations for dry and pruritic skin conditions - During the consultation we heard a range of views both agreeing and disagreeing with our proposals on bath and shower preparations. We also received further submissions of evidence and a review of this evidence was commissioned from the Specialist Pharmacy Service (SPS) by NHS England. The SPS review found that there was no clear or robust evidence base to support the use of bath and shower preparations for dry and pruritic skin conditions in the NHS. Having considered responses received

from medical and scientific bodies, the joint clinical working group did not feel it necessary to amend the proposed recommendations significantly but did make minor changes to the wording. The group recognises that the clinical evidence relied upon in reaching the recommendations refers primarily to children but the working group felt that in the absence of other good quality evidence (e.g. randomised controlled trials), it is acceptable to extrapolate the evidence pertaining to children to adults until good quality evidence emerges for adults.

Blood glucose testing strips for type 2 diabetes – Although the consultation was on the whole positive with regards to the recommendations, on advice of the NHS England & NHS Improvement Diabetes team, further work is being undertaken on the features of different testing meters available and how this may impact on the choice of blood glucose testing strip. It is therefore decided that the joint clinical working group await the outcome of this work before making any final CCG recommendations on blood glucose testing strips. The guidance therefore makes no recommendations on blood glucose testing strips for type 2 diabetes.

Dronedarone - Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for dronedarone.

Minocycline for acne - Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for minocycline.

Needles for pre-filled and reusable insulin pens - Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed recommendations for needles for pre-filled and reusable insulin pens. The joint clinical working group therefore decided that the two original proposed recommendations should remain but clarification should be provided for use of safety needles in particular settings.

Rubefacients (excluding topical NSAIDs and capsaicin) - Recommendations on rubefacients were issued in November 2017. The recommendation was updated to highlight that capsaicin cream can be prescribed in line with NICE guidance and would therefore be excluded from the recommendations for rubefacients. We consulted on this change only. Because of what we heard, the joint clinical working group did not feel it necessary to amend the proposed updated recommendation for rubefacients.

Silk garments - During the consultation we heard a range of views both agreeing and disagreeing with our proposals on silk garments. We also received further submissions of evidence and a review of this evidence was commissioned from the Specialist Pharmacy Service (SPS) by NHS England. The SPS review found that there was no clear or robust evidence base to support the routine use of silk garments in the NHS and therefore, also considering responses received from medical and scientific bodies, the joint clinical working group did not feel it necessary to amend the proposed recommendations.

2 How will this guidance be updated and reviewed?

To ensure that the NHS continues to allocate its resources effectively, the joint clinical working group will review the guidance at least annually (or more frequently if required) to identify potential items to be retained, retired, updated or added to the current guidance. There will be three stages:

Item identification
Organisations represented on the joint clinical working group will, considering previous feedback, identify items from the wide range of items that can be prescribed on NHS prescription in primary care in the categories defined in section 1.3.

Item prioritisation
The joint clinical working group will prioritise items based on the following criteria:

- Safety Issue
- Evidence of efficacy
- Degree of variation in prescribing
- Cost to the NHS
- Clinician or patient feedback

To seek initial views from interested parties, a draft list of items will be shared with the organisations detailed in Appendix 1 and others where appropriate. A consultation document will be made available and a public consultation will be undertaken. Feedback will be collated and then published on the NHS England website.

Item selection for inclusion or removal from the guidance
The joint clinical working group will consider the feedback and produce the updated list of recommendations for consideration by NHS England and NHS Clinical Commissioners to update the proposed commissioning guidance for items which should not be routinely prescribed in primary care.

3 Definitions

Annual Spend: This is the primary care spend from NHS Prescription Services at the NHS Business Services Authority. Prescriptions written by General Medical Practitioners and non-medical prescribers (nurses, pharmacists etc.) in England represent the clear majority of prescriptions included. Prescriptions written by dentists and hospital doctors which are dispensed in the community are not included. Prescriptions written and dispensed in Prisons or Hospitals, and Private prescriptions are not included. Prescriptions written in England but dispensed in Wales, Scotland, Guernsey/ Alderney, Jersey and Isle of Man are included. Prescriptions written in the rest of the UK but dispensed in England are not included. The figure quoted is the Actual Cost which is the basic price of the drug adjusted for the discount pharmacists receive and including container costs. It does not include any adjustment for income obtained where a prescription charge is paid at the time the prescription is dispensed or where the patient has purchased a prepayment certificate.

BNF: British National Formulary provides healthcare professionals with authoritative and practical information on the selection and clinical use of medicines.

Deprescribing: A collaborative process with the patient (or their carer) used to ensure the safe and effective withdrawal of medicines that are no longer appropriate, beneficial or wanted, which is guided by a person-centred approach and shared decision making.

Exceptional Circumstances: In the context of this guidance, "exceptional circumstances" should be interpreted as: Where the prescribing clinician considers no other medicine or intervention is clinically appropriate and available for the individual.

Item: An item is anything which can be prescribed on an NHS prescription. More information on what is prescribed on an NHS prescription is available in the Drug Tariff.

New patient: This refers to any patient newly initiated on an item listed in the guidance.

NICE: The National Institute for Health and Care Excellence. They provide the NHS with clinical guidance on how to improve healthcare.

MHRA: Medicines and Healthcare Products Regulatory Agency. They regulate medicines, medical devices and blood components for transfusion in the UK.

NHS Clinical Commissioners: NHSCC are the independent membership organisation for CCGs, providing their collective voice, facilitating shared learning and delivering networking opportunities for CCG members.

PHE: Public Health England. They protect and improve the nation's health and wellbeing, and reduce health inequalities.

PrescQIPP CIC (Community Interest Company): PrescQIPP are an NHS funded not-for-profit organisation that supports quality, optimised prescribing for patients. They produce evidence-based resources and tools for primary care commissioners, and provide a platform to share innovation across the NHS.

Routinely: The term routine can be defined as 'regularly, as part of the usual way of doing things rather than for any clinically exceptional reason.

4 Implementation

CCGs will still need to take individual decisions on implementation locally, ensuring they consider their legal duties to advance equality and have regard to reducing health inequalities. Effective implementation will involve engagement with secondary care and use of shared care arrangements where appropriate. Provision of support for patients who may review a change to their current prescription is recommended. Various resources are available to support implementation and monitoring of the guidance including patient leaflets.

There are dashboards illustrating current prescribing patterns available to CCGs to monitor prescribing data for the items included in this guidance. These are available from NHS BSA in ePACT 2, PrescQIPP and OpenPrescribing.net. Data on spend and volume is summarised by item and is available at regional, area team, STP, CCG and practice level. When monitoring, clinical exceptions defined in the guidance should be taken account of and care should be taken to ensure that targets of zero prescribing are not used inappropriately.

A Low Priority Prescribing (LPP) indicator will form part of the 2019/20 CCG Improvement and Assessment Framework (IAF). The CCG IAF technical specification will outline the methodology for this indicator. As part of the IAF process each CCG will be given a score based on their prescribing rates and this will contribute to the IAF CCG overall assessment. CCGs are encouraged to monitor prescribing data and demonstrate where appropriate, reduced prescribing over time.

Working closely with Integrated Care Systems (ICS) and Primary Care Networks (PCN), the Regional Medicines Optimisation Committees (RMOC) will monitor variance at each meeting, this will enable them to support CCGs with any challenges with local implementation.

5 Recommendations

5.1 Aliskiren [New 2019]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate aliskiren for any new patient. • Advise CCGs to support prescribers in deprescribing aliskiren in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been defined.
Category	Products which are clinically effective but where more cost-effective products are available this includes products that have been subject to excessive price inflation.
Annual Spend	£776,000 (BSA, 2018/19)
Background and Rationale	Aliskiren is a renin inhibitor which inhibits renin directly; renin converts angiotensinogen to angiotensin. It is indicated for essential hypertension either alone or in combination with other antihypertensives. NICE state there is insufficient evidence of its effectiveness to determine its suitability for use in resistant hypertension. Whilst 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.
Further Resources and Guidance for CCGs	Patient information leaflets

5.2 Amiodarone [New 2019]

Recommendation	• Advise CCGs that prescribers should not initiate amiodarone in primary care for any new patient. • Advise CCGs that if, in exceptional circumstances, there is a clinical need for amiodarone to be prescribed, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional.
Exceptions and further recommendations	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. It may also be suitable in patients prior and post cardioversion or in specific patients who also have heart failure or left ventricular impairment.
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
Annual Spend	£1,427,000 (BSA, 2018/19)
Background and Rationale	Treatment of arrhythmias, particularly when other drugs 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 clinical guideline on Atrial Fibrillation (AF) CG 180 puts greater emphasis on rate rather than rhythm control and has clarified the place of amiodarone in the treatment pathway: NICE have issued the following "Do not do" recommendation: **Do not offer amiodarone for long-term rate control.**
Further Resources and Guidance for CCGs	NICE CG180 Atrial fibrillation: management Patient information leaflets NHS England, Responsibility for prescribing between Primary & Secondary/Tertiary Care

5.3 Bath and shower preparations for dry and pruritic skin conditions [New 2019]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate bath and shower preparations for any new patient. • Advise CCGs to support prescribers in deprescribing bath and shower preparations in this category and substitute with "leave-on" emollients and, where appropriate, to ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been defined.
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
Annual Spend	£11,708,000 (BSA, 2018/19)
Background and Rationale	Emollient bath and shower preparations are routinely prescribed for dry and pruritic skin conditions including eczema and dermatitis. A multicentre pragmatic parallel group RCT looking at emollient bath additives for the treatment of childhood eczema (BATHE) showed that there was no evidence of clinical benefit for including emollient bath additives in the standard management of childhood eczema. Soap avoidance and 'Leave-on' emollient moisturisers can still be used for treating eczema. These emollients can also be used as a soap substitute. Patients should be counselled on the use of any emollients as soap substitutes and the risk of using bath and shower emollients should be fully explained. It is recognised that BATHE trial looked at use in children however in the absence of other good quality evidence it was agreed that it is acceptable to extrapolate this to apply to adults until good quality evidence emerges.
Further Resources and Guidance for CCGs	Specialist Pharmacy Service bath and shower preparations evidence review Patient information leaflets

5.4 Co-proxamol [2017]

Recommendation	• 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.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
Annual Spend (baseline)	£8,272,000 (BSA, 2016/17)
Annual Spend (current)	£3,237,000 (BSA, 2018/19)
Background and Rationale	Co-proxamol was a pain-killer which was previously licensed in the UK until being fully withdrawn from the market in 2007 due to safety concerns. All use in the UK is now on an unlicensed basis. 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. Since the withdrawal, further safety concerns have been raised which have resulted 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.
Further Resources and Guidance for CCGs	MHRA Drug Safety Update: November 2007, January 2011 PrescQIPP CIC Drugs to Review for Optimised Prescribing - Co-proxamol Patient information leaflets

5.5 Dosulepin [2017]

Recommendation	• 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.

Exceptions and further recommendations	No routine exceptions have been identified.
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
Annual Spend (baseline)	£2,342,000 (BSA, 2016/17)
Annual Spend (current)	£3,706,000 (BSA, 2018/19)
Background and Rationale	Dosulepin, formerly known as dothiepin, is a tricyclic antidepressant. NICE CG90: 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.
Further Resources and Guidance for CCGs	NICE CG90: Depression in Adults PrescQIPP CIC Drugs to Review for Optimised Prescribing - Dosulepin Patient information leaflets

5.6 Prolonged-release Doxazosin (also known as Doxazosin Modified Release) [2017]

Recommendation	• 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.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation.
Annual Spend (baseline)	£6,828,000 (BSA, 2016/17)
Annual Spend (current)	£5,009,000 (BSA, 2018/19)
Background and 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 is approximately six times the cost of doxazosin immediate release (NHS Drug Tariff). NICE CG127 Hypertension in adults: diagnosis and management recognises that doxazosin should be used in treatment but does not identify benefits of prolonged-release above immediate release. NICE CG97 Lower urinary tract symptoms in men: management recommends Doxazosin as an option in men with moderate to severe lower urinary tract symptoms. It does not identify benefits of Prolonged-release above 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.
Further Resources and Guidance for CCGs	NICE CG127 Hypertension in adults: diagnosis and management NICE CG97 Lower urinary tract symptoms in men PrescQIPP CIC Drugs to Review for Optimised Prescribing - Prolonged Release Doxazosin BNF - Doxazosin Patient information leaflets

5.7 Dronedarone [New 2019]

Recommendation	• Advise CCGs that prescribers should not initiate dronedarone in primary care for any new patient. • Advise CCGs that if, in exceptional circumstances, there is a clinical need for dronedarone to be prescribed, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional.
Exceptions	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.
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
Annual Spend	£1,519,000 (BSA 2018/19)
Background and 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 clinical guideline on Atrial Fibrillation (AF) CG 180 puts greater emphasis on rate rather than rhythm control and has clarified the place of dronedarone in the treatment pathway.
Further Resources and Guidance for CCGs	NICE CG180 Atrial fibrillation: management Patient information leaflets NHS England, Responsibility for prescribing between Primary & Secondary/Tertiary Care

5.8 Immediate Release Fentanyl [2017]

Recommendation	• 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.
Exceptions and further recommendations	**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.
Category	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation.
Annual Spend (baseline)	£10,185,000 (BSA, 2016/17)
Annual Spend (current)	£8,592,000 (BSA, 2018/19)
Background and 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 being only 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.
Further Resources and Guidance for CCGs	Opioids Aware: A resource for patients and healthcare professionals to support prescribing of opioid medicines for pain PrescQIPP CIC Drugs to Review for Optimised Prescribing - Immediate Release Fentanyl Faye's story: good practice when prescribing opioids for chronic pain Patient information leaflets

5.9 Glucosamine and Chondroitin [2017]

Recommendation	• 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.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Items of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
Annual Spend (baseline)	£405,000 (BSA, 2016/17)
Annual Spend (current)	£174,000 (BSA, 2018/19)
Background and Rationale	Glucosamine and Chondroitin are nutraceuticals which used to improve pain associated with osteoarthritis. The BNF states the following about glucosamine, "*The mechanism of action is not understood and there is limited evidence to show it is effective.*"

	NICE CG177: 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 due to the lack of evidence as advised by the BNF, the joint clinical working group considered glucosamine and chondroitin suitable for inclusion in this guidance
Further Resources and Guidance for CCGs and prescribers	BNF NICE CG177: Osteoarthritis care and management PrescQIPP CIC Drugs to Review for Optimised Prescribing - Glucosamine Patient information leaflets

5.10 Herbal Treatments [2017]

Recommendation	• 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.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
Annual Spend (baseline)	£111,000 (BSA, 2016/17)
Annual Spend (current)	£57,000 (BSA, 2018/19)
Background and Rationale	Under a Traditional Herbal Registration 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.
Further Resources and Guidance for CCGs and prescribers	GOV.UK Traditional herbal medicines: registration form and guidance GOV.UK Herbal medicines granted a traditional herbal registration (THR) Patient information leaflets

5.11 Homeopathy [2017]

Recommendation	• 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 change.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
Annual Spend (baseline)	£85,000 (BSA, 2016/17)
Annual Spend (current)	£47,000 (BSA, 2018/19)
Background and 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, up to date review of the evidence which was conducted by the Specialist Pharmacy Service. The review found that there was no clear or robust evidence to support the use of homeopathy on the NHS.
Further Resources and Guidance for CCGs and prescribers	Specialist Pharmacy Service homeopathy evidence review GOV.UK Register a homeopathic medicine or remedy Patient information leaflets

5.12 Lidocaine Plasters [2017]

Recommendation	• 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 professional.
Exceptions and further recommendations	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).
Category	Item of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns
Annual Spend (baseline)	£17,888,000 (BSA, 2016/17)
Annual Spend (current)	£16,206,000 (BSA, 2018/19)
Background and Rationale	Lidocaine plasters can be applied for pain relief and are licensed for symptomatic relief of neuropathic pain associated with previous herpes zoster infection (post-herpetic neuralgia, PHN) in adults. NICE CG173 Neuropathic pain in adults: pharmacological management in non-specialist settings 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 and non-inclusion, the lidocaine plasters are included with defined exceptions.
Further Resources and Guidance for CCGs and prescribers	NICE Clinical Knowledge Summaries - Post-herpetic neuralgia Patient information leaflets Specialist Pharmacy Service lidocaine plasters evidence review

5.13 Liothyronine (including Armour Thyroid and liothyronine combination products) [2017]

Recommendation	• 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.
Exceptions and further recommendations	The British Thyroid Association (BTA) advise that a small proportion of patients treated with levothyroxine continue to suffer with symptoms despite adequate biochemical correction. In these circumstances, 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. 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 be routinely obtained from primary care prescribers.
Category	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation.
Annual Spend (baseline)	£31,390,000 (BSA, 2016/17)
Annual Spend (current)	£23,184,000 (BSA, 2018/19)
Background and Rationale	Liothyronine (sometimes known as T3) is used to treat hypothyroidism. It has a similar action to levothyroxine but is more rapidly metabolised and has a more rapid effect. It is sometimes used in combination with levothyroxine in products. The price (NHS Drug Tariff) of liothyronine has risen significantly and there is limited evidence for efficacy above Levothyroxine.

	The British Thyroid Association, in their 2015 position statement, state "*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 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 British Thyroid Association.
Further Resources and Guidance for CCGs and prescribers	British Thyroid Association Guidelines UKMI Medicines Q&A - What is the rationale for using a combination of levothyroxine and liothyronine (such as Armour® Thyroid) to treat hypothyroidism? Patient information leaflets Regional Medicines Optimisation Committee guidance

5.14 Lutein and Antioxidants [2017]

Recommendation	• 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.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Items of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
Annual Spend (baseline)	£1,779,000 (BSA, 2016/17)
Annual Spend (current)	£723,000 (BSA, 2018/19)
Background and Rationale	Lutein and antioxidants (e.g. vitamin A, C E and zinc) are supplements which are sometimes recommended for Age Related Macular Degeneration. 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

	Antioxidant vitamin and mineral supplements for preventing age-related macular degeneration http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD000253.pub3/full 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".* **Antioxidant vitamin and mineral supplements for slowing the progression of age-related macular degeneration** https://www.cochrane.org/CD000254/EYES_antioxidant-vitamin-and-mineral-supplements-slow-down-progression-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 which did not find evidence to support prescribing of lutein and antioxidants routinely on the NHS. NICE have published draft consultation guidance on Age-Related Macular Degeneration and proposed that the effectiveness and cost-effectiveness of the use of lutein and antioxidants is currently a research recommendation.
Further Resources and Guidance for CCGs and prescribers	PrescQIPP CIC Drugs to Review for Optimised Prescribing - Lutein and Antioxidants NICE - Macular Degeneration Patient information leaflets

5.15 Minocycline for acne [New 2019]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate minocycline for any new patient with acne. • Advise CCGs to support prescribers in deprescribing minocycline in all patients with acne and, where appropriate, ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.

Annual Spend	£503,000 (BSA 2018/19)
Background and Rationale	Minocycline is a tetracycline antibiotic that can be used for many indications but is mainly used in primary care for acne. Minocycline is mainly used for acne however there are various safety risks associated with its use. NICE CKS 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 there is 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.
Further Resources and Guidance for CCGs and prescribers	NICE Clinical Knowledge Summaries - Acne vulgaris Patient information leaflets

5.16 Needles for Pre-Filled and Reusable Insulin Pens [New 2019]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate insulin pen needles that cost >£5 per 100 needles for any diabetes patient. • Advise CCGs to support prescribers in deprescribing insulin pen needles that cost >£5 per 100 needles and, where appropriate ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Products which are clinically effective but where more cost-effective products are available this includes products that have been subject to excessive price inflation.
Annual Spend	£24,802,000 (BSA, 2018/19)
Background and Rationale	Pen needles are available in a complete range of sizes from 4mm to 12mm; different needles will fit different pens; however, some pen needles will fit all major insulin delivery pen devices currently available. There are many different types of insulin pen needles available at a varying cost from £2.75 to £30.08 for 100[5].

[5] NHS Drug Tariff

	Rationalising use ensures that the most cost-effective options are used first line. In addition, 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 needles of a shorter length helps to prevent intramuscular injection of insulin. (IM injection of insulin should be avoided as it can result in unpredictable blood glucose levels). Therefore, needle choice should be the most cost effective 4mm needle. For patients currently using longer pen needle lengths (8mm, 12mm), it is advisable to change to a shorter needle length (6mm or less) but only after discussion with a healthcare professional, to ensure they receive advice on the correct injection technique. For patients that are not able to self-administer it may be appropriate that a safety needle is used by the health care professional, however this would not need to be prescribed on prescription.
Further Resources and Guidance for CCGs and prescribers	PrescQIPP CIC Drugs to Review for Optimised Prescribing - Needles for Pre-Filled and Reusable Insulin Pens Patient information leaflets

5.17 Omega-3 Fatty Acid Compounds [2017]

Recommendation	• 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.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Item of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns
Annual Spend (baseline)	£5,718,000 (BSA, 2016/17)
Annual Spend (current)	£3,813,000 (BSA, 2018/19)
Background and Rationale	Omega-3 fatty acid compounds are essential fatty acids which can be obtained from the diet. They are licensed for adjunct to diet and statin in type IIb or III hypertriglyceridemia; adjunct to diet in type IV hypertriglyceridemia; adjunct in secondary

	prevention in those who have had a myocardial infarction in the preceding 3 months. NICE have reviewed the evidence and advised they are not suitable for prescribing by making "Do not do" recommendations 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 1 diabetes, people with type 2 diabetes. 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.
Further Resources and Guidance for CCGs and prescribers	PrescQIPP CIC Drugs to Review for Optimised Prescribing - Omega 3 Fatty Acids Patient information leaflets

5.18 Oxycodone and Naloxone Combination Product [2017]

Recommendation	• 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 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.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation.
Annual Spend (baseline)	£4,589,000 (BSA, 2016/17)
Annual Spend (current)	£3,348,000 (BSA, 2018/19)
Background and 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 locally in the gut. PrescQIPP CIC have issued a bulletin and did 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.
Further Resources and Guidance for CCGs and prescribers	Opioids Aware: A resource for patients and healthcare professionals to support prescribing of opioid medicines for pain Faye's story: good practice when prescribing opioids for chronic pain PrescQIPP CIC Drugs to Review for Optimised Prescribing - Oxycodocne and Naloxone Combination Product Patient information leaflets

5.19 Paracetamol and Tramadol Combination Product [2017]

Recommendation	• 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.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation.
Annual Spend (baseline)	£1,766,000 (BSA, 2016/17)
Annual Spend (current)	£487,000 (BSA, 2018/19)
Background and Rationale	Paracetamol and tramadol combination products are more expensive than the products with the individual components (Drug Tariff). PrescQIPP CIC also issued a bulletin which did not identify any significant advantages over individual products, however it does recognise that some people may prefer to take one product instead of two. There are also different strengths of tramadol (37.5mg) and paracetamol (325mg) in the combination product compared to commonly available individual preparations of tramadol (50mg) and paracetamol (500mg), although the PrescQIPP CIC review found no evidence that combination product is more effective or safer than the individual preparations. Due to the significant extra cost of a combination product, the joint clinical working group considered paracetamol and tramadol combination products suitable for inclusion in this guidance.
Further Resources and Guidance for CCGs and prescribers	PrescQIPP CIC Drugs to Review for Optimised Prescribing - Paracetamol and Tramadol Combination Product Patient information leaflets

5.20 Perindopril Arginine [2017]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate perindopril arginine for any new patient. • 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.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation.
Annual Spend (baseline)	£1,441,000 (BSA, 2016/17)
Annual Spend (current)	£1,059,000 (BSA, 2018/19)
Background and Rationale	Perindopril is an ACE inhibitor used in heart failure, hypertension, diabetic nephropathy and prophylaxis of cardiovascular events. The perindopril arginine salt version was developed as it is more stable in extremes of climate than the perindopril erbumine salt, which results in a longer shelf-life. perindopril arginine is significantly more expensive than perindopril erbumine and a PrescQIPP CIC review of the topic found there was no clinical advantage of the arginine salt. NICE CG127: Hypertension in adults: diagnosis and management recommends that prescribing costs are minimised. Due to the significant extra costs with the arginine salt and the availability of the erbumine salt, the joint clinical working group considered perindopril arginine suitable for inclusion in this guidance.
Further Resources and Guidance for CCGs and prescribers	NICE CG127: Hypertension in adults: diagnosis and management PrescQIPP CIC Drugs to Review for Optimised Prescribing - Perindopril Arginine Patient information leaflets

5.21 Rubefacients (excluding topical NSAIDs[6] and capsaicin) [Updated 2019]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate rubefacients (excluding topical NSAIDs and capsaicin) for any new patient. • Advise CCGs to support prescribers in deprescribing rubefacients (excluding topical NSAIDs and capsaicin) in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
2019 update	Capsaicin cream is now excluded as well as topical NSAIDs. i.e. capsaicin can now be prescribed as per NICE guidance. Capsaicin cream falls within **NICE guidance** • Neuropathic Pain: Consider capsaicin cream for people with localised neuropathic pain who wish to avoid, or who cannot tolerate oral treatments. • Osteoarthritis: Topical capsaicin should be considered as an adjunct to core treatments for knee or hand osteoarthritis.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
Annual Spend (baseline)	£6,247,000 (BSA, 2016/17)
Annual Spend (current)	£3,887,000 (BSA, 2018/19)
Background and 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 over-the-counter 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 have 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.

[6] This does not relate to topical non-steroidal anti-inflammatory drug (NSAID) items such as Ibuprofen and Diclofenac.

Further Resources and Guidance for CCGs and prescribers	PrescQIPP CIC Drugs to Review for Optimised Prescribing – Rubefacients BNF: Soft-tissue disorders Patient information leaflets

5.22 Silk Garments [New 2019]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate silk garments for any patient. • Advise CCGs to support prescribers in deprescribing silk garments in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.
Annual Spend	£912,000 (BSA, 2018/19)
Background and Rationale	Silk garments are typically prescribed for eczema or dermatitis. These products are knitted, medical grade silk clothing which 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 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, which aimed to examine whether adding silk garments to standard eczema care could reduce eczema severity in children with moderate to severe eczema, compared to use of standard eczema treatment alone: The CLOTHing for the relief of Eczema Symptoms trial (CLOTHES trial). Overall the trial concluded that using silk garments for the management of eczema is unlikely to be cost-effective for the NHS.
Further Resources and Guidance for CCGs and prescribers	Specialist Pharmacy Service silk garments evidence review PrescQIPP CIC Drugs to Review for Optimised Prescribing – silk garments Patient information leaflets

5.23 Once Daily Tadalafil [2017]

Recommendation	• 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.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Products which are clinically effective but where more cost-effective products are available this includes products that have been subject to excessive price inflation.
Annual Spend (baseline)	£10,644,000 (BSA, 2016/17)
Annual Spend (current)	£6,311,000 (BSA, 2018/19)
Background and Rationale	Tadalafil is a phosphodiesterase-5-inhibitor and is available in strengths of 2.5mg, 5mg, 10mg and 20mg used to treat erectile dysfunction. In addition, 2.5mg and 5mg can be used to treat benign prostatic hyperplasia. Only 2.5mg and 5mg should be used once daily. 10mg and 20mg[7] are used in a "when required fashion". Tadalafil can be prescribed for erectile dysfunction in circumstances as set out in part XVIIIB of the Drug Tariff. Benign Prostatic Hyperplasia: NICE terminated their technology appraisal (TA273) due to receiving no evidence from the manufacturer. In NICE CG97: Lower Urinary Tract Symptoms in Men NICE state that there is not enough evidence to recommend phosphodiesterase inhibitors in routine clinical practice. Erectile Dysfunction: PrescQIPP CIC have reviewed the evidence for Tadalfil and although tadalafil is effective in treating erectile dysfunction, there is not enough evidence to routinely recommend once daily preparations in preference to "when required" preparations particularly as when required preparations are now available as a generic. Due to recommendations from NICE and that alternative tadalafil preparations are available, the joint clinical working group felt once daily tadalafil was suitable for inclusion in this guidance.

[7] There is also a 20mg once daily preparation, branded *Adcirca*, which is used to treat pulmonary hypertension. This recommendation does not apply to this product, however it should only be prescribed by specialist centres and not routinely prescribed in primary care.

Further Resources and Guidance for CCGs and prescribers	NICE CG97: Lower Urinary Tract Symptoms in Men NICE Clinical Knowledge Summaries - Erectile Dysfunction PrescQIPP CIC Drugs to Review for Optimised Prescribing - Once Daily Tadalafil Patient information leaflets

5.24 Travel Vaccines (vaccines administered exclusively for the purposes of travel) [2017]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate the stated vaccines exclusively for the purposes of travel for any new patient. **N.B This is a restatement of existing regulations and no changes have been made.**
Exceptions and further recommendations	The vaccines in this proposal are listed below and they may continue to be administered for purposes other than travel, if clinically appropriate. NHS England and NHS Clinical Commissioners recognise that the availability of vaccinations on the NHS for the purposes of travel can be confusing for prescribers and the public. The working group has recommended that Public Health England and Department of Health, working collaboratively with NHS England and NHS Clinical Commissioners, conduct a review of travel vaccination and publish the findings in Spring 2018.
Category	Items which are clinically effective but due to the nature of the product, are deemed a low priority for NHS funding.
Annual Spend (baseline)	£3,801,000 (BSA, 2016/17) Only some of this total will be administered for the purposes of travel.
Annual Spend (current)	£1,837,000 (BSA, 2018/19) Only some of this total will be administered for the purposes of travel.
Background and Rationale	To note the following vaccines may still be administered on the NHS exclusively for the purposes of travel, if clinically appropriate, pending any future review: • Cholera • Diphtheria/Tetanus/Polio • Hepatitis A • Typhoid

	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 • 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.
Further Resources and Guidance for CCGs and prescribers	The Green Book Travel Health Pro (NaTHNaC) PrescQIPP CIC Drugs to Review for Optimised Prescribing - Travel Guidance Patient information leaflets

5.25 Trimipramine [2017]

Recommendation	• Advise CCGs that prescribers in primary care should not initiate trimipramine for any new patient. • Advise CCGs to support prescribers in deprescribing trimipramine in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.
Exceptions and further recommendations	No routine exceptions have been identified.
Category	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation.
Annual Spend (baseline)	£19,961,000 (BSA, 2016/17)
Annual Spend (current)	£12,773,000 (BSA, 2018/19)
Background and Rationale	Trimipramine is a tricyclic antidepressant (TCA) however the price of trimipramine is significantly more expensive than other antidepressants.

	NICE CG90: Depression in Adults recommends selective serotonin reuptake inhibitor (SSRI) antidepressants first line if medicines are indicated as they have a more favourable risk to benefit ratio compared to TCA. However, if a TCA is required there are more cost-effective TCAs than trimipramine 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.
Further Resources and Guidance for CCGs and prescribers	NICE CG90: Depression in Adults NICE Clinical Knowledge Summaries – Depression Patient information leaflets

Appendix 1

Membership of the Joint Clinical Working group

Dr Graham Jackson (Co-chair)	NHSCC Co-chair	NHSCC
Dr Bruce Warner (Co-chair)	Deputy Chief Pharmaceutical officer	NHS England
Raj Patel	Deputy Director of Primary Care	NHS England
Julie Wood	Chief Executive	NHSCC
Michele Cossey	Regional Pharmacist	NHS England/NHS Improvement
David Geddes	Director of Primary Care Commissioning	NHS England
Jonathan Underhill	Medicines Clinical Adviser	NICE
Claire Potter	Medicines Regulation & Prescribing	Department of Health and Social Care
Carol Roberts	Chief Executive	PrescQIPP
Margaret Dockey	Information Services Manager	NHS BSA
Manir Hussain	Deputy Director of Primary Care & Medicines Optimisation & Chair of Pharmacy Local Professional Network	Staffordshire CCGs & NHS England
Clair Huckerby	Consultant Pharmacist Primary Care MO	Dudley CCG
Jane Freeguard	Head of Medicines Commissioning	Redditch and Bromsgrove South Worcestershire and Wyre Forest CCGs
Paul Gouldstone	Head of Medicines Management	Enfield CCG
Steve Pike	GP Medicines Optimisation Lead	Coastal West Sussex CCG
Jonathan Leach	Joint Honorary Secretary Royal College of GPs	Royal College of GPs
Ravi Sharma	Director for England	Royal Pharmaceutical Society
Andrew Green	Clinical and Prescribing Policy Lead.	GPC
Alex Williams	Deputy Director of Medicines Policy Team	NHS England
Margaret Williams	Chief Nurse	Morecambe Bay CCG
Jan MacDonald	Group Manager, Access & Information for Medicines & Standards	MHRA

Stakeholder Organisations

Association of the British Pharmaceutical Industry (ABPI)	NHS Clinical Commissioners
British Generic Manufacturers Association	NHS England
British Medical Association (General Practitioners Committee)	NHS Improvement
Care Quality Commission	NICE
Department of Health and Social Care	Patients Association
Enfield CCG	Pharmaceutical Services Negotiating Committee (PSNC)
General Medical Council	PrescQIPP
Healthwatch England	Public Health England
National Voices	Royal Pharmaceutical Society

Appendix 2

The working group considered the potential unintended consequences of its recommendations. These are set out in the table below. The group will be monitoring these on a regular basis, however these may also need to be considered locally when implementing this guidance.

Potential unintended consequences of issuing the proposed guidance	**Response**
Interactions with secondary care and consequent costs	This will need monitoring but is not inevitable. For some products, joint local guidance with secondary care providers may be appropriate.
Use of appointments in primary care	The group recognised that there could initially be increased use of appointments in primary care however this is not expected to be sustained.
Some alternative treatments may not be clinically identical, such as side-effect profile	Prescribers should make a shared decision with patients and CCGs should provide appropriate resources (e.g. decision-support tools) to facilitate this.
Alternative treatments could, in some cases, be prescribed with cost consequences.	This is an opportunity to review medication, and if appropriate to de-prescribe. Although alternatives may need to be considered including their cost impact. Guidance on suitable alternatives and the indication for use will be provided. In the implementation plan for the proposed guidance, monitoring of prescribing patterns would be undertaken and mitigations instigated if appropriate.
Individual prescribers' decision making.	Prescribers must recognise and work within the limits of their competence, as recommended by the GMC and other professional regulators/bodies. Nationally accessible resources (e.g. patient information leaflets) and local professional support should be provided to prescribers. The proposed guidance does dot remove the clinical discretion of the prescriber in deciding what is in accordance with their professional duties.
People currently on treatment stopping or altering their treatments	Prescribers should endeavour to explain the rationale for any proposed changes in treatments to come to a shared decision.
Complaints about general practice and associated administration time	The group discussed the potential for numbers of complaints to rise and the impact this would have on general

	practice workload and parts of the NHS. Therefore to support communication of the changes proposed in the guidance, educational aids will be produced.
Effect on medicines supply	The group recognised that by proposing guidance on individual items there is potential for alternative items to see increased demand. NHS England will work with Department of Health colleagues to ensure that pharmaceutical companies are aware of the proposed guidance and potential need for increased supply in some other products.