

# **Items which should not routinely be prescribed in primary care: an update and a consultation on further guidance for CCGs**

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Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited 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;
- 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

## 1.1 What is the issue we are trying to tackle?

It is important that the NHS achieves the greatest value from the money that it spends. In 2017, the cost of prescriptions dispensed in the community was £9.17 billion<sup>1</sup> and we know that across England there is significant variation in what is being prescribed and to whom.

In addition, patients continue to receive medicines which have been proven to be ineffective or in some cases dangerous, and/or for which there are other more effective, safer and/or cheaper alternatives.

Clinical Commissioning Groups (CCGs) therefore asked for a nationally co-ordinated approach to the development of commissioning guidance to ensure consistency and address unwarranted variation. As part of the review of medicines which could be considered to be of a 'low clinical priority', NHS England has continued to partner with NHS Clinical Commissioners to support CCGs in ensuring that they use their prescribing resources effectively and deliver the best patient outcomes from the medicines their local population use. To lead the work, NHS England hosted a clinical working group in partnership with NHS Clinical Commissioners, with prescriber and pharmacy representatives and relevant national stakeholders.

The aim is that our guidance will help support a more equitable process for making decisions about medicines; but CCGs will need to take individual decisions on implementation locally, ensuring they take into account their legal duties to advance equality and have regard to reduce health inequalities.

As a result of our work, NHS England and NHS Clinical Commissioners have identified a number of further products which fall under one or more of the criteria outlined in section 1.4 below. We are also using this document to provide an update to guidance issued in November 2017 for Rubefaciens (see section 4).

## 1.2 What is the objective of this work and what are we doing now?

The objective of this work is to support CCGs in their decision-making, to address unwarranted variation (see appendix 4 for details), and to provide clear national advice to make local prescribing practices more effective. The current financial situation means that CCGs need to make increasingly difficult decisions about how to spend the NHS budget and this means prioritising those things that will give patients the best clinical outcomes. Any savings from implementing the proposals will be reinvested in improving patient care.

Having completed the first stage of our work in 2017 and early 2018 (see section 1.4 for links to this work), we set out in this document, further proposed national guidance for CCGs on medicines which can be considered to be of low priority for NHS funding. This guidance is being sent out for consultation nationally, and we encourage CCGs to take part in this consultation by engaging with their communities and local professionals. Further information and guidance on how to do this can be found in section 1.7 and section 6.

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<sup>1</sup> [NHS Digital Prescription Cost Analysis 2017](#)

### 1.3 Who will the commissioning guidance be addressed to?

This guidance is addressed to CCGs to support them to fulfil their duties around appropriate use of their resources. We expect CCGs to take the proposed guidance into account in formulating local policies, and for prescribers to reflect local policies in their prescribing practice. The guidance does not remove the clinical discretion of the prescriber in accordance with their professional duties.

This guidance is issued as general guidance under 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.

### 1.4 How have these proposals been developed?

CCGs are regularly having to take difficult decisions about their local drug formularies and are supportive of wider national level guidance for their actions. The 'low value medicines project' (now re-termed 'low priority prescribing' project) and working group led jointly by NHS England and NHS Clinical Commissioners (NHSCC) was established in April 2017 as CCGs asked for a nationally co-ordinated approach to the creation of commissioning guidance. The aim was to reduce unwarranted variation and introduce a more equitable framework from which CCGs can take an individual and local implementation decision.

During 2017/18 CCG guidance was published by NHS England and NHSCC for:

- [Items which should not be routinely prescribed in primary care \(Nov 2017\); and](#)
- [Conditions for which over the counter items should not routinely be prescribed in primary care \(March 2018\)](#)

Feedback from CCGs via NHSCC demonstrates that this national co-ordinated approach and CCG guidance, outlining national recommendations, has been a helpful lever to initiate and support local decision making and to implement changes. It was agreed that NHS England should continue to work jointly with NHSCC to address further low priority items that should not routinely be prescribed. Further items from NHSCC's initial list were reviewed in line with the criteria as set out in section 1.6. This list was informed by the [PrescQIPP drop list](#).

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<sup>2</sup> 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.

## **1.5 Who has been involved in developing the proposal in this consultation?**

NHS England and NHS Clinical Commissioners established a joint clinical working group to develop these proposals. More detail on the membership of this working group is included in Appendix 1.

A stakeholder meeting was held in November 2018 to discuss the emerging recommendations outlined in this consultation document.

## **1.6 What evidence has been used in developing these proposals?**

The joint clinical working group considered information from various sources and organisations which are set out at the relevant parts of section 4. The group also 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"<sup>3</sup>.

Where NICE guidance was not available, the group considered evidence from a range of sources, for example; the MHRA, the British National Formulary, MTRAC – Center

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<sup>2</sup> 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.

<sup>3</sup> Practices NICE recommend should be discontinued completely or should not be used routinely.

for Medicines Optimisation and PrescQIPP CIC evidence reviews. In reaching its recommendations for the products identified in section 4, 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 incl. 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?
- **Unintended consequences** (see Appendix 2)

## 1.7 Who are we consulting and how can they respond?

This consultation, which is being nationally co-ordinated but which also encompasses a local element, is addressed to all CCGs, the public and patients, and any relevant interest group or body. **It will be open for 3 months from 28 November 2018 until 28 February 2019.**

Please see section 6: Next Steps for details on how to submit responses. If you are unable or unwilling to reply online, you may also reply by post to: NHS England, PO Box 16738, Redditch, B97 9PT.

During the national consultation phase individual CCGs can provide a response to the commissioning guidance, based on its own local consultation and engagement activities. This could include but is not limited to:

- The CCG's own perspective on the guidance;
- The outcome of any relevant local consultations; and/or
- Local engagement with patient participation groups, local community groups representing people with protected characteristics, Healthwatch and/or discussion with the local overview and scrutiny committee of the Local Authority

The potential equality impact of these proposals has been considered and is outlined in the Equality and Health Inequalities Impact Assessment document published alongside this consultation. We believe that the proposals are likely to have a neutral or positive impact on individuals with protected characteristics. If you do not agree,

and/or if you think there will be direct or indirect negative impact on people with protected characteristics, you can let us know by providing your views to the relevant consultation questions.

## **1.8 Confidentiality**

It is our intention to publish a summary of the responses we receive to this consultation on the NHS England website in due course. You can respond with your name and/or organisation, you can remain anonymous or ask that your details are kept confidential and excluded from the published summary of responses. If you would like any part of the content of your response (instead of or as well as your identity) to be kept confidential, please let us know and make it obvious by marking in your response which parts we should keep confidential.

Please also be aware that the summary may include details taken from any area of the consultation response, and so please bear this in mind when providing your comments. If you would prefer any particular comments are kept confidential (i.e. not published) please make this clear.

If you provide us with any personal information (i.e. name or email address) we will process, hold and store this in accordance with the General Data Protection Regulation and the Data Protection Act 2018. Your details will be kept for the minimum time necessary to allow us to complete the consultation exercise and use the outcomes of that consultation as part of our decision-making.



## 2 Definitions and scope

### 2.1 Definitions

**Annual Spend:** Unless otherwise indicated this is the total value from the Prescription Analysis for England 2018 produced by NHS Digital. Prescriptions written by General Medical Practitioners and non-medical prescribers (nurses, pharmacists etc.) in England represent the vast majority of prescriptions included. Prescriptions written by dentists and hospital doctors are also included provided that they were dispensed in the community. Also included are prescriptions written in Wales, Scotland, Northern Ireland and the Isle of Man but dispensed in England. Prescriptions written in England but dispensed outside England are not included. The figure quoted is the net ingredient cost which refers to the cost of the drug before discounts and does not include any dispensing costs or fees. 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.

**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](#).

**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.

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

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

**Routinely:** Regularly, as part of the usual way of doing things rather than for an exceptional reason.

### 2.2 Scope

The following chapter sets out the process for how NHS England and NHS Clinical Commissioners will conduct the process to review and update the guidance to CCGs as appropriate. Chapters 4 and 5 set out draft guidance on the products that have been identified as being of low priority prescribing for one or more of the reasons outlined in section 1.4. For each, this consultation provides advice to commissioners based on the latest available evidence and the clinical consensus that has been reached by our joint clinical working group. It seeks views on whether this advice can be implemented in practice and clinically sound. Full details of the questions can be seen on the online consultation form and in Appendix 3.

### 3 How will the guidance be updated and reviewed?

The NHS England and NHS Clinical Commissioners joint clinical working group will continue to meet and update the proposals as a result of this consultation.

The guidance will be reviewed at least annually; the joint clinical working group will identify potential items<sup>4</sup> to be retained, retired or added to the current guidance. There will be three stages:

#### **Item identification**

Organisations represented on the joint clinical working group will, taking into account 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 1.4.

#### **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
- Strong clinician or patient feedback

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 a final 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.

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<sup>4</sup> 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](#).

## 4 Proposals for updated CCG commissioning guidance

Guidance on rubefacients was issued in November 2017; this is an update to that guidance to consider exclusion of capsaicin cream in line with NICE guidance. We are consulting on the proposal to exclude capsaicin cream only and not the inclusion of rubefacients as a whole.

### 4.1 Rubefacients (excluding topical NSAIDs<sup>5</sup>)

Recommendation	<ul style="list-style-type: none"> <li>Advise CCGs that prescribers in primary care should not initiate rubefacients (excluding topical NSAIDs <i>and capsaicin</i>) for any new patient.</li> <li>Advise CCGs to support prescribers in deprescribing rubefacients (excluding topical NSAIDs <i>and capsaicin</i>) in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.</li> </ul>
2018 update	<p>The working group proposes to exclude capsaicin cream as well as topical NSAIDs. i.e. capsaicin can now be prescribed as per NICE guidance.</p> <p>Capsaicin cream falls within <b>NICE guidance</b></p> <ul style="list-style-type: none"> <li><a href="#">Neuropathic Pain</a>: Consider capsaicin cream for people with localised neuropathic pain who wish to avoid, or who cannot tolerate oral treatments.</li> <li><a href="#">Osteoarthritis</a>: Topical capsaicin should be considered as an adjunct to core treatments for knee or hand osteoarthritis.</li> </ul>
Exceptions and further recommendations	No routine exceptions have been found.
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	£5,481,000 (source: NHS BSA, 2017/18)
Background and Rationale	<p>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.</p> <p>The <a href="#">BNF states</a> <i>“The evidence available does not support the use of topical rubefacients in acute or chronic musculoskeletal pain.”</i></p> <p>NICE have issued the following “Do not do” recommendation:</p>

<sup>5</sup> This proposal does not relate to topical non-steroidal anti-inflammatory drug (NSAID) items such as ibuprofen and Diclofenac.

	<p><a href="#"><u>Do not offer rubefaciants for treating osteoarthritis.</u></a></p> <p>Due to limited evidence and NICE recommendations the joint clinical working group considered rubefaciants (excluding topical NSAIDS) suitable for inclusion in this guidance.</p>
Further Resources and Guidance for CCGs and prescribers	<p><a href="#"><u>PrescQIPP CIC Drugs to Review for Optimised Prescribing – Rubefaciants</u></a></p> <p><a href="#"><u>NICE CG177 Osteoarthritis: care and management</u></a></p> <p><a href="#"><u>BNF: Soft-tissue disorders</u></a></p> <p>Patient information leaflets:  <a href="https://www.prescqipp.info/media/1404/patient-information-changes-to-rubefaciants-prescribing.pdf"><u>https://www.prescqipp.info/media/1404/patient-information-changes-to-rubefaciants-prescribing.pdf</u></a></p>

## 5 Proposals for new Commissioning Guidance

### 5.1 Aliskiren

Recommendation	<ul style="list-style-type: none"> <li>Advise CCGs that prescribers in primary care should not initiate aliskiren for any new patient.</li> <li>Advise CCGs to support prescribers in deprescribing aliskiren in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.</li> </ul>
Exceptions	None
Background	<p>Aliskiren is a renin inhibitor which inhibits renin directly; renin converts angiotensinogen to angiotensin.</p> <p>It is indicated for essential hypertension either alone or in combination with other antihypertensives.</p>
Annual Spend	£939,300 (NHS BSA, 2017/18)
Rationale for recommendation	<p><a href="#">NICE state</a> there is insufficient evidence of its effectiveness to determine its suitability for use in resistant hypertension.</p> <p>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.</p>
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.

## 5.2 Amiodarone

Recommendation	<ul style="list-style-type: none"> <li>Advise CCGs that prescribers should not initiate amiodarone in primary care for any new patient.</li> <li>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.</li> </ul>
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 <a href="#">NICE Guidance CG180</a> . It may also be suitable in patients prior and post cardioversion or in specific patients who also have heart failure or left ventricular impairment.
Background	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).
Annual Spend	£1,095,700 (NHS BSA, 2017/18)
Rationale for recommendation	<p>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.</p> <p>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: <a href="https://www.nice.org.uk/guidance/CG180">https://www.nice.org.uk/guidance/CG180</a></p> <p>NICE have issued the following “Do not do” recommendation:  <b>Do not offer amiodarone for long-term rate control.</b></p>
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.

### 5.3 Bath and shower preparations for dry and pruritic skin conditions

Recommendation	<ul style="list-style-type: none"> <li>Advise CCGs that prescribers in primary care should not initiate bath and shower preparations for any new patient.</li> <li>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.</li> </ul>
Exceptions	None
Background	Emollient bath and shower preparations are routinely prescribed for dry and pruritic skin conditions including eczema and dermatitis.
Annual Spend	£15,800,000 (NHS BSA 2017/18)
Rationale for recommendation	<p><a href="#">A multicentre pragmatic parallel group RCT looking at emollient bath additives for the treatment of childhood eczema (BATHE)</a> showed that there was no evidence of clinical benefit for including emollient bath additives in the standard management of childhood eczema.</p> <p>‘Leave-on’ emollient moisturisers can still be used for treating eczema and these emollients can still be used as soap substitutes. Patients should be counselled on the use of any emollients as soap substitutes and the <a href="#">risk</a> of using bath and shower emollients should be fully explained.</p>
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.

## 5.4 Blood glucose testing strips for type 2 diabetes

Recommendation	<p>In patients with type 2 diabetes:</p> <ul style="list-style-type: none"> <li>Advise CCGs that prescribers in primary care should not initiate blood glucose testing strips that cost &gt;£10 for 50 strips for any new patient</li> <li>Advise CCGs to support prescribers in deprescribing blood glucose testing strips that cost &gt;£10 for 50 strips and where appropriate, ensure the availability of relevant services to facilitate this change.</li> </ul> <p>The intention of this recommendation is not that patients be de-prescribed blood glucose testing strips or not initiated on them. It is intended to encourage CCGs and prescribers to consider more cost-effective alternatives.</p>
Exceptions	Patients with type 2 diabetes who have been trained in carbohydrate counting and utilise an appropriate carb counting meter.
Background	There are currently over 40 different types of Blood Glucose Test (BGT) strips available in the UK.
Annual Spend	£173,110,700 (NHS BSA, 2017/18)
Rationale for recommendation	<p>BGT meters are classed as appliances and as such are not subjected to the same licensing arrangements as medicinal products. The quality of a meter is measured against a set international standard ISO 15197:2013.</p> <p>They range in price from £5.45 to £16.53<sup>6</sup> therefore promoting use of more cost effective test strips first line will enable savings to be made whilst not affecting patient care.</p> <p>Rationalising the amount of meters and test strips in use allows the education of healthcare professionals who in turn can better assist patients with their testing. Patients should therefore be switched from more expensive meters to cost effective options.</p> <p>NICE guidance outlines specific criteria for when self-monitoring of blood glucose may be suitable in patients with type 2 diabetes.</p> <p><a href="https://www.nice.org.uk/guidance/ng28/chapter/1-Recommendations#self-monitoring-of-blood-glucose">https://www.nice.org.uk/guidance/ng28/chapter/1-Recommendations#self-monitoring-of-blood-glucose</a></p>
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.

<sup>6</sup> NHS Drug Tariff 2018



## 5.5 Dronedarone

Recommendation	<ul style="list-style-type: none"> <li>Advise CCGs that prescribers should not initiate dronedarone in primary care for any new patient;</li> <li>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;</li> </ul>
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 <a href="#">NICE Guidance CG180</a> .
Background	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).
Annual Spend	£1,663,400 (NHS BSA 2017/18)
Rationale for recommendation	<p>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 <a href="#">PALLAS study</a>.</p> <p>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: <a href="https://www.nice.org.uk/guidance/CG180">https://www.nice.org.uk/guidance/CG180</a></p>
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.

## 5.6 Minocycline for acne

Recommendation	<ul style="list-style-type: none"> <li>Advise CCGs that prescribers in primary care should not initiate minocycline for any new patient.</li> <li>Advise CCGs to support prescribers in deprescribing minocycline in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.</li> </ul>
Exceptions	None
Background	Minocycline is a tetracycline antibiotic that can be used for many indications but is mainly used in primary care for acne.
Annual Spend	£ 637,400 (NHS BSA 2017/18)
Rationale for recommendation	<p>Minocycline is mainly used for acne however there are various safety risks associated with its use.</p> <p><a href="#">NICE CKS</a> advises <i>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.</i></p> <p>A <a href="#">PrescQIPP CIC</a> 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.</p>
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.

## 5.7 Needles for Pre-Filled and Reusable Insulin Pens

Recommendation	<ul style="list-style-type: none"> <li>Advise CCGs that prescribers in primary care should not initiate insulin pen needles that cost &gt;£5 per 100 needles for any new diabetes patient</li> <li>Advise CCGs to support prescribers in deprescribing insulin pen needles that cost &gt;£5 per 100 needles and, where appropriate ensure the availability of relevant services to facilitate this change.</li> </ul>
Exceptions	None
Background	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.
Annual Spend	£33,229,300 (NHS BSA, 2017/18)
Rationale for recommendation	<p>There are many different types of insulin pen needles available at a varying cost from £3.95 to £30.08 for 100<sup>7</sup>.</p> <p>Rationalising use ensures that the most cost effective options are used first line.</p> <p>In addition, the Forum for Injection Technique (FIT) UK considers the <b>4mm needle to be the safest pen needle</b> for adults and children regardless of age, gender and Body Mass Index (BMI).</p> <p>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.</p> <p>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.</p>
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.

<sup>7</sup> NHS Drug Tariff

## 5.8 Silk Garments

Recommendation	<ul style="list-style-type: none"> <li>Advise CCGs that prescribers in primary care should not initiate silk garments for any new patient.</li> <li>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.</li> </ul>
Exceptions	None
Background	<p>Silk garments are typically prescribed for eczema or dermatitis.</p> <p>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.</p> <p>Four brands of knitted silk garments are currently listed as an appliance in part IX A in the <a href="#">Drug Tariff</a> and are relatively expensive.</p>
Annual Spend	£1,204,000 (NHS BSA, 2017/18)
Rationale for recommendation	<p>The <a href="#">PrescQIPP document on silk garments</a> states that the evidence relating to their use is weak and is of low quality.</p> <p>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: <a href="#">The CLOTHing for the relief of Eczema Symptoms trial (CLOTHES trial)</a>.</p> <p>Overall the trial concluded that using silk garments for the management of eczema is unlikely to be cost-effective for the NHS.</p>
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns.

## 6 Consultation Format

NHS England and NHS Clinical Commissioners are grateful to individuals and organisations who take the time to respond to this consultation. During the 3 month consultation period, we will work with patient representative bodies, charities, Royal Colleges and industry to gather views across the range of stakeholders. We will also be asking CCGs to respond and undertake their own local engagement activities.

If you would like to respond to this consultation you can do so by:

- Using the online web-form [here](#). Questions from the online form are listed in appendix 3. Individuals may also want to contact their local CCG to inform a local response. You can find contact details for your local CCG on the [NHS website](#).
- Written enquiries can be submitted to [england.medicines@nhs.net](mailto:england.medicines@nhs.net) or to the postal address: NHS England, PO Box 16738, Redditch, B97 9PT. Please note that NHS England and NHS Clinical Commissioners will not be able to respond to every response individually.

Following the close of the consultation period, NHS England and NHS Clinical Commissioners will analyse and consider all responses received. A summary of the responses will be published on the NHS England and NHS Clinical Commissioners website to provide CCGs with an opportunity to reflect on what has been heard.

NHS England and NHS Clinical Commissioners, via the joint clinical working group, will review the responses received and develop finalised commissioning guidance. The finalised commissioning guidance will then be published with the expectation that CCGs should 'have regard to' it, in accordance with the NHS Act 2006.

Individual CCGs will then need to make a local decision on whether to implement the national commissioning guidance, with due regard to both local circumstances and their own impact assessments.

## Appendix 1 - Membership of the joint clinical working group

Dr Graham Jackson (Co-chair)	NHSCC Co-chair and Clinical Lead, Buckinghamshire ICS	NHSCC & Buckinghamshire ICS
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
Kate Arnold	Deputy Clinical Director, Medicines Management and Optimisation.	Birmingham and Solihull CCG
Paul Gouldstone	Head of Medicines Management	Enfield CCG
Steve Pike	GP Medicines Optimisation Lead	Coastal West Sussex CCG
David Paynton	National Clinical Lead	Royal College of GPs
Robbie Turner	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

## Appendix 2 – Unintended Consequences

The working group considered the potential unintended consequences of its recommendations. These are set out in the table below. Please consider unintended consequences when submitting responses to the consultation.

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 not 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.



## Appendix 3 - Consultation Questions

Please note this is an adapted version of a questionnaire designed for an internet web page. To view the questionnaire in its intended format and submit responses please visit

<https://www.engage.england.nhs.uk/consultation/items-routinely-prescribed-update/>

### **About you**

#### **Which age group are you in?**

Under 18/19 – 29/30 – 39/40 - 49/50 – 59/60 - 69/70 - 79/80+/Prefer not to say

#### **Please indicate your gender**

Male/Female/Intersex/Trans/Non-binary/Prefer not to say

#### **Do you consider yourself to have a disability?**

Yes/No/Prefer not to say

#### **Please select what you consider your ethnic origin to be. Ethnicity is distinct from nationality.**

##### **White**

- Welsh/English/Scottish/Northern Irish/British
- Irish
- Gypsy or Irish Traveller
- Any other White background

##### **Asian or Asian British**

- Indian
- Pakistani
- Bangladeshi
- Any other Asian background

##### **Other ethnic group**

- Chinese
- Any other ethnic group

##### **Mixed**

- White and Black Caribbean
- White and Black African
- White and Asian
- Any other mixed background

##### **Black or Black British**

- Black - Caribbean
- Black - African
- Any other Black background

**Please indicate your religion or belief**

No religion/Muslim/Buddhist/Sikh/Christian/Atheist/Hindu/Any other religion/Jewish/Prefer not to say

**Please indicate the option which best describes your sexual orientation**

Heterosexual/Gay/Lesbian/Bisexual/Prefer not to say

**Introduction**

**In what capacity are you responding?**

Patient/Family member/Friend or carer of patient/Member of the public/Patient representative organisation/Voluntary organisation or charity/Clinician/Clinical Commissioning Group/NHS Provider organisation/Industry/Other NHS Organisation/Other Healthcare Organisation/Professional Representative Body/Regulator/Other (please specify)

**Name** (optional)

**Email address** (optional)

**Have you read the document *Items which should not routinely be prescribed in primary care: an update and a consultation on further guidance for CCGs?***

- Yes
- No

**Equality and Health Inequalities**

NHS England has legal duties which require giving 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 having 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. An initial Equality and Health Inequalities Assessment (EHIA) has been carried out on these proposals and this can be read here. Further information on our duties can be read at <https://www.england.nhs.uk/about/equality/>

**Do you feel there are any groups, protected by the Equality Act 2010, likely to be disproportionately affected by this work?**

Yes (please tick all that apply)/No

Age/disability/gender reassignment/race/religion or belief/sex/sexual orientation/marriage and civil partnership/pregnancy and maternity

Please provide further information on why you think this might be the case.

**Do you feel there is evidence we should consider in our proposals on the potential impact on health inequalities experience by certain groups e.g. people on low incomes; people from black and minority ethnic (BME) communities?**

Yes/No

Please provide further information on why you think this might be the case

**Section 3: How will the guidance be updated and reviewed?**

**Thinking about the process for future update and review of the guidance:**

**How do you feel about the proposed process for identification of items for possible addition to the guidance or indeed possible removal, from the guidance?**

Agree/Neither agree or disagree/Disagree/Unsure

If needed, please provide further information.

**Section 4 & 5: Proposals for CCG commissioning guidance**

**Please select which items you would like to share your views on (please select)?**

**Reviewed item**

Rubefacients (excluding topical NSAIDs)

**New items**

Aliskiren

Amiodarone

Bath and shower preparations for dry and pruritic skin conditions

Blood glucose testing strips for type 2 diabetes

Dronedarone

Minocycline

Needles for Pre-Filled and Reusable Insulin Pens

Silk Garments

**Rubefacients (excluding topical NSAIDs)**

**Do you agree with the proposed recommendations for Rubefacients (excluding topical NSAIDs)?**

On the webform for each of the 9 medicines, each of the proposed recommendations will be included and for each recommendation one of the following options can be selected.

Agree/Neither agree or disagree/Disagree/Unsure

If needed, please provide further information

**Aliskiren**

**Do you agree with the proposed recommendations for Aliskiren?**

Agree/Neither agree or disagree/Disagree/Unsure  
If needed, please provide further information

**Amiodarone**

**Do you agree with the proposed recommendations for Amiodarone?**

Agree/Neither agree or disagree/Disagree/Unsure  
If needed, please provide further information

**Bath and shower preparations for dry and pruritic skin conditions**

**Do you agree with the proposed recommendations for bath and shower emollient preparations?**

Agree/Neither agree or disagree/Disagree/Unsure  
If needed, please provide further information

**Blood glucose testing strips for type 2 diabetes**

**Do you agree with the proposed recommendations for blood glucose testing strips?**

Agree/Neither agree or disagree/Disagree/Unsure  
If needed, please provide further information

**Dronedarone**

**Do you agree with the proposed recommendations for Dronedarone?**

Agree/Neither agree or disagree/Disagree/Unsure  
If needed, please provide further information

**Minocycline**

**Do you agree with the proposed recommendations for Minocycline?**

Agree/Neither agree or disagree/Disagree/Unsure  
If needed, please provide further information

**Needles for Pre-Filled and Reusable Insulin Pens**

**Do you agree with the proposed recommendations for needles for pre-filled and reusable insulin pens?**

Agree/Neither agree or disagree/Disagree/Unsure  
If needed, please provide further information

**Silk Garments**

**Do you agree with the proposed recommendations for silk garments?**

Agree/Neither agree or disagree/Disagree/Unsure  
If needed, please provide further information

## Appendix 4 - Prescribing variation data

Cost as measured by Net Ingredient Cost per 1,000 patients registered to CCG.











