NHS Clinical Commissioners
The independent collective voice of clinical commissioning groups

NHS England

Items which should not routinely be prescribed in primary care: A Consultation on guidance for CCGs

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Version number: 1

First published: 21 July 2017

NHS England Gateway publication number: 07040

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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; 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

1 Background

1.1 What is the issue we are trying to tackle?

Last year 1.1 billion prescription items were dispensed in primary care at a cost of £9.2billion[1]. This growing 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. Often patients are receiving 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.

NHS England has partnered with NHS Clinical Commissioners to support Clinical Commissioning Groups (CCGs) in ensuring that they can use their prescribing 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 development of commissioning guidance in this area to ensure consistency and address unwanted variation. The aim is that this will lead to a more equitable process for making decisions about guidance on 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.

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. Any savings from implementing the proposals will be reinvested in improving patient care.

Having completed the first stage of the work, we set out in this document, proposed national guidance for CCGs on medicines which can be considered to be of low priority for NHS funding. This guidance is being set 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.

1.3 Who will the commissioning guidance be addressed to?

The commissioning guidance, upon which we are consulting, will be addressed to CCGs to support them to fulfil their duties around appropriate use of prescribing resources. It is proposed that the guidance will be statutory guidance issued under S14ZG of the NHS Act. We expect CCGs to take the proposed guidance if and when issued into account in formulating local polices, and for prescribers to reflect local policies in their prescribing practice. The proposed guidance does not remove the clinical discretion of the prescriber in accordance with their professional duties.

[1] NHS Digital Prescription Cost Analysis 2016

1.4 How have these proposals been developed?

NHS Clinical Commissioners is the national representative organisation for CCGs. Working with their members NHS Clinical Commissioners developed a list of items that they consider need not be routinely prescribed in primary care. This process was supported by PrescQIPP CIC, who provide support on medicines optimisation to 90% of CCGs in England. PrescQIPP CIC have an established process for making recommendations which can be viewed here.

Subsequently NHS Clinical Commissioners asked NHS England to work with them to produce commissioning guidance to support their member organisations in taking action in addressing these issues on a national basis. This is in order to coordinate a national consultation, reduce duplication and reduce unwarranted variation. NHS England established a joint clinical working group in partnership with NHS Clinical Commissioners, with prescriber and pharmacy representatives, and relevant national stakeholders. This joint clinical working group met to produce these recommendations.

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; 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 to support prescribers in deprescribing {item} in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change;
- Advise CCGs that if, in exceptional[2] circumstances, there is a clinical need for the item to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional;
- Advise CCGs that all prescribing should be carried out by a specialist; and/or
- Advise CCGs that this item should not be routinely prescribed in primary care but may be prescribed in named circumstances such as {item}.

[2] 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

Subsequently NHS England's Commissioning Committee and Board considered the proposals prior to them being formally consulted upon publically.

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 in included Appendix 1.

An extended stakeholder meeting was held in June 2017 to discuss the emerging recommendations outlined in this consultation document. A full list of the organisations, which also included organisations representing patient perspectives, can also be found in Appendix 1.

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 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[3]".

Where NICE guidance was not available the group considered evidence from a range of sources, for example; the MHRA, the British National Formulary and PrescQIPP CIC evidence reviews. In reaching its recommendations for the eighteen 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?

[3] Practices NICE recommend should be discontinued completely or should not be used routinely

        - **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 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 21 July until 21 October 2017.

Please see section 6: Next Steps for details on how to submit responses.

During the national consultation phase individual CCGs can provide a response to the national consultation on 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 Data Protection Act 1998. Your details will be kept for the minimum time necessary.

2 Definitions and scope

2.1 Definitions

Annual Spend: Unless otherwise indicated this is the total value from the Prescription Analysis for England 2016 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.

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.

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

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.

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. Chapter 4 sets out draft guidance on 18 products that have been identified as being of low clinical value and/or comparatively expensive 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 is implementable and clinically sound. Full details of the questions can be seen on the online consultation form and in Appendix 3.

As part of the work to date, we have also identified a range of further items which could also be considered of low priority for prescription on the NHS. Chapter 5 sets out such conditions and products and seeks views to inform the next phase of the review which will consider these categories.

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.

In future, the joint clinical working group will review the guidance annually to identify potential items[4] 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 draft list of items will be made available online through the NHS England website for a four week period when comments will be sought from interested parties. Organisations detailed in Appendix 1 will be sent an e-mail inviting them to comment. 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.

[4] 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 Our proposals for CCG commissioning guidance

4.1 Co-proxamol

Background	Co-proxamol was a pain-killer which was previously licensed in the UK until being fully withdrawn, in 2007, from the market due to safety concerns. All use in the UK is now on an unlicensed basis.
Annual Spend	£9,002,824 (NHS Digital)
Rationale for recommendation	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 group considered co-proxamol suitable for inclusion in the proposed guidance.
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns
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. • Advise CCGs that if, in exceptional circumstances, there is a clinical need for co-proxamol to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional

4.2 Dosulepin

Background	Dosulepin, formerly known as dothiepin, is a tricyclic antidepressant.
Annual Spend	£2,651,544 (NHS Digital)
Rationale for recommendation	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

	group considered dosulepin suitable for inclusion in the proposed guidance.
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns
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

4.3 Prolonged-release Doxazosin (also known as Doxazosin Modified Release)

Background	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.
Annual Spend	£7,769,931 (NHS Digital)
Rationale for recommendation	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 group considered prolonged-release doxazosin suitable for inclusion in the proposed guidance.
Category	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation

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. • Advise CCGs that if, in exceptional circumstances, there is a clinical need for Prolonged-release Doxazosin to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional

4.4 Immediate Release Fentanyl

Background	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. This recommendation does not apply to longer sustained release versions of fentanyl which come in patch form.
Annual Spend	£10, 952,130 (NHS Digital)
Rationale for recommendation	NICE CG140 Opioids in Palliative Care states *Do not offer fast-acting fentanyl as first-line rescue medication.* Immediate release fentanyl products are licensed for treating adults with cancer who have breakthrough pain and are receiving opioid therapy, equivalent to at least 60mg of oral morphine. Consensus of the working group was that there was a small number of people who this would apply to and therefore does not justify current prescribing volumes. Due to the recommendations from NICE and immediate release fentanyl being only licensed for use in cancer, the group considered immediate release fentanyl was suitable for inclusion in the proposed guidance.
Category	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation
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

4.5 Glucosamine and Chondroitin

Background	Glucosamine and Chondroitin are nutraceuticals which used to improve pain associated with osteoarthritis.
Annual Spend	£444,535 (NHS Digital)
Rationale for recommendation	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 group considered Glucosamine and Chondroitin suitable for inclusion in the proposed guidance.
Category	Items of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns
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.

4.6 Herbal Treatments

Background	In the UK, the MHRA allows herbal products to be marketed for minor health conditions that don't require medical supervision, upon receipt of a traditional herbal registration (MHRA detailed guidance)
Annual Spend	£100,009 (Source: NHS Business Services Authority)
Rationale for recommendation	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 evidence provided in registering these products the group felt that they were suitable for inclusion in the proposed guidance.
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns
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.

4.7 Homeopathy

Background	Homeopathy seeks to treat patients with highly diluted substances that are administered orally. (MHRA detailed guidance)
Annual Spend	£92,412 (NHS Digital)
Rationale for recommendation	In 2010 a report by the House of Commons Science and Technology Committee, found that the use of homeopathy was not evidence based and any benefits to patients was down to placebo effect. The group agreed with the findings of the committee for the lack of evidence and considered homeopathy suitable for inclusion in the proposed guidance.
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns
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.

4.8 Lidocaine Plasters

Background	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.
Annual Spend	£19,295,030 (NHS Digital)
Rationale for recommendation	NICE CG173 Neuropathic pain in adults: pharmacological management in non-specialist settings does not recommend lidocaine plasters for treating neuropathic pain. The group also considered a PrescQIPP CIC review, and due to its non-inclusion in NICE guidance the group considered lidocaine plasters suitable for inclusion in the proposed guidance.
Category	Item of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns
Recommendation	• Advise CCGs that prescribers in primary care should not initiate Lidocaine plasters for any new patient • 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

4.9 Liothyronine

Background	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;
Annual Spend	£34,802,312 (NHS Digital) In addition £1,000,049 is spent on Liothyronine + Levothyroxine combination products e.g. armour thyroid
Rationale for recommendation	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". 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. Due to the significant costs associated with Liothyronine and the limited evidence to support its routine prescribing in preference to levothyroxine, the group considered Liothyronine suitable for inclusion in this guidance.
Category	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation
Recommendation	• Advise CCGs that prescribers in primary care should not initiate Liothyronine for any new patient • Advise CCGs to support prescribers in deprescribing Liothyronine 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 Liothyronine to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional

4.10 Lutein and Antioxidants

Background	Lutein and antioxidants (e.g. vitamin A, C E and zinc) are supplements 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".
Annual Spend	£1,500,000 (NHS Digital)
Rationale for recommendation	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** http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD000254.pub3/full 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 have issued a bulletin which did not find evidence to support prescribing of lutein and antioxidants routinely on the NHS.
Category	Items of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns
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.

4.11 Omega-3 Fatty Acid Compounds

Background	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.
Annual Spend	£6,317,927 per annum (NHS Digital)
Rationale for recommendation	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 working group agreed with NICE recommendations and considered Omega-3 Fatty Acid compounds suitable for inclusion in the proposed guidance.
Category	Item of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns
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

4.12 Oxycodone and Naloxone Combination Product

Background	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.

Annual Spend	£5,062,928 (NHS Digital)
Rationale for recommendation	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 group considered Oxycodone and Naloxone suitable for inclusion in the proposed guidance.
Category	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation
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

4.13 Paracetamol and Tramadol Combination Product

Background	Paracetamol and Tramadol are both commonly available painkillers. This recommendation relates to where both chemical ingredients are used together in a single combination product.
Annual Spend	£1,980,000 (NHS Digital)
Rationale for recommendation	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 (325mgmg) 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 group considered Paracetamol and Tramadol combination products suitable for inclusion in the proposed guidance.
Category	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation
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.

4.14 Perindopril Arginine

Background	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. The arginine is significantly more expensive than the erbumine salt, for example 28 days supply of Perindopril arginine costs £6.28 versus £1.07 for an equivalent 28 days treatment with perindopril erbumine.
Annual Spend	£529,403 (NHS Digital)
Rationale for recommendation	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 group considered Perindopril Arginine suitable for inclusion in the proposed guidance.
Category	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation
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.

4.15 Rubefacients (excluding topical NSAIDs[5])

Background	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.
Annual Spend	£4,301,527 (source: NHS BSA)
Rationale for recommendation	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 group considered rubefacients (excluding topical NSAIDS) suitable for inclusion in the proposed guidance.
Category	Products of low clinical effectiveness, where there is a lack of robust evidence of clinical effectiveness or there are significant safety concerns
Recommendation	• Advise CCGs that prescribers in primary care should not initiate Rubefacients (excluding topical NSAIDs) for any new patient • Advise CCGs to support prescribers in deprescribing Rubefacients (excluding topical NSAIDs) in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change.

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

4.16 Once Daily Tadalafil

Background	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* 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. *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.
Annual Spend	£11,474,221 (NHS Digital)
Rationale for recommendation	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. Due to recommendations from NICE and that alternative Tadalafil preparations are available, the group felt once daily Tadalafil was suitable for inclusion in the proposed guidance.
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.
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.

4.17 Travel Vaccines

Background	Some travel vaccines are available on the NHS and others are not available on the NHS. For travel vaccines not available on the NHS, they are sometimes inappropriately administered for the purposes of travel, due them being available for prevention of illness in other circumstances.
Annual Spend	£4,540,351 (NHS Digital) Only some of this total will be administered for the purposes of travel.
Rationale for recommendation	The following vaccinations should not be prescribed on the NHS for the purposes of travel • Hepatitis B • Japanese Encephalitis • Meningitis ACWY • Yellow Fever • Tick-borne encephalitis • Rabies • BCG Some of these are administered on the NHS for the purposes of travel in error and due to complicated vaccination reimbursement. These items are not commissioned on the NHS currently so the group considered these travel vaccines suitable for inclusion in the proposed guidance.
Category	Items which are clinically effective but due to the nature of the product, are deemed a low priority for NHS funding
Recommendation	• Advise CCGs that prescribers in primary care should not initiate the stated travel vaccines for any new patient

NHS England has asked PHE to conduct a review of travel vaccines currently available on the NHS to assess their appropriateness for prescribing on the NHS. These vaccines include;

- Cholera
- Diptheria/Tetanus/Polio
- Hepatitis A
- Typhoid

4.18 Trimipramine

Background	Trimipramine is a tricyclic antidepressant (TCA) however the price of timipramine is significantly more expensive than other antidepressants.
Annual Spend	£19,835,783 (NHS Digital)
Rationale for recommendation	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: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 group considered Trimipramine suitable for inclusion in the guidance.
Category	Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation
Recommendation	• Advise CCGs that prescribers in primary care should not initiate Trimipramine for any new patient • Advise CCGs to support prescribers in deprescribing Trimpramine in all patients and, where appropriate, ensure the availability of relevant services to facilitate this change. • Advise CCGs that if, in exceptional circumstances, there is a clinical need for Trimipramine to be prescribed in primary care, this should be undertaken in a cooperation arrangement with a multi-disciplinary team and/or other healthcare professional

4.19 Gluten Free Foods

The Department of Health has recently consulted on proposals to make changes to the availability of gluten free (GF) foods that are prescribed in primary care.

NHS England and NHS Clinical Commissioners support this consultation and as such, it would not be appropriate for NHS England or NHS Clinical Commissioners to further consult on the availability of GF foods on prescription in this document. It is anticipated that CCGs will take the outcome of that consultation into account as and when it becomes available.

5 Items that are prescribed in primary care and are available over the counter

In addition to the detailed recommendations made by the joint clinical working group for the list of 18 products in section 4, another area of NHS prescribing that has been suggested for consideration are those products which can also be purchased over the counter. We know that there is variation in prescribing practice across the country and so NHS England and NHS Clinical Commissioners propose as a next phase of this review to look at over 3,200 products which could otherwise be purchased over the counter from a pharmacy and/or other outlets such as petrol stations or convenience stores. The NHS in England spends approximately £645million p.a. on such medicines.

These include products that:

- can be purchased over the counter, and sometimes at a lower cost than that that would be incurred by the NHS;
- treat a condition that is considered to be self-limiting and so does not need treatment as it will heal/be cured of its own accord; and/or
- treat a condition which lends itself to self-care, i.e. that the person suffering does not normally need to seek medical care and/or treatment for the condition.

These conditions include but are not limited to the following, which in most cases are minor and/or self-limiting conditions:

Diarrhoea	Cold sores
Constipation	Teething
Acute Pain	Nappy rash
Athlete's foot	Mouth ulcers
Fever	Haemorrhoids
Oral and vaginal thrush	Ear wax
Head lice	Warts and verrucae
Insect bites and stings	Soft tissue injury/musculoskeletal joint injury
Conjunctivitis	Viral upper respiratory tract infections
Contact dermatitis	Scabies
Sore throat	Ring worm
Headache	Mild acne
Indigestion and heartburn (Dyspepsia)	Minor burns and scalds

Examples of products which are currently prescribed on the NHS and which can be used to treat some of the conditions above include:

Painkillers (analgesics) and medicines for fever (antipyretics), such as paracetamol and ibuprofen	Laxatives
Antifungal creams	Lubricating eye drops
Nasal sprays	Eczema creams and ointments
Coughs and cold remedies	Antiviral creams
Sunscreens	Ear wax removal liquid

NHS England and NHS Clinical Commissioners have identified three separate categories of product which are available over the counter and may be considered appropriate for restriction, such that the product is not routinely prescribed in primary care. These categories are:

a. further medicines additional to those identified in Chapter 4 above which are relatively clinically ineffective;

b. medicines which are used to treat generally time-limited/short term conditions that are suitable for self-care (this will include many conditions which are self-limiting). Medicines within this category account for approx. £50m - £100m p.a. of NHS spend. In this category, we mean conditions which are episodic and which do not require ongoing or long term treatment. By self-limiting, we mean conditions which without treatment to alleviate symptoms, would normally heal of their own accord, for example the common cold; and

c. medicines which are used for longer term, chronic conditions but which are being prescribed at an estimated cost of approx. £545m p.a. For example, some but not all of the £70m spent annually on paracetamol might fall into this category, as may antihistamines on which the NHS spends £14m p.a.

Having identified products which are considered to fall into the above categories, it is then proposed that detailed consideration is given to each product using the criteria as outlined in this consultation document. Namely, that each product, is assessed against:

- **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)

Using these criteria, the NHS England and NHS Clinical Commissioners joint clinical working group will consider items available for purchase over the counter in the coming months and where appropriate will develop detailed guidance for further consultation.

At this stage we are seeking views generally on this area and evidence that will inform our future programme of work.

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 but to also 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 NHS Choices.

- Written enquiries can be submitted to england.medicines@nhs.net 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 Health and Social Care Act.

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

Graham Jackson (Co-chair)	NHSCC Co-chair and Clinical Chair Aylesbury CCG	NHS Clinical Commissioners & Aylesbury Vale CCG
Bruce Warner (Co-chair)	Deputy Chief Pharmaceutical Officer	NHS England
Arvind Madan	Director of Primary Care and Deputy Medical Director	NHS England
Julie Wood	Chief Executive	NHS Clinical Commissioners
David Webb	Regional Pharmacist	NHS England
David Geddes	Director of Primary Care Commissioning	NHS England
Paul Chrisp	Programme Director, Medicines and Technologies Programme	NICE
Claire Potter	Medicines and Pharmacy	Department of Health
Carol Roberts	Chief Executive	PrescQIPP CIC
Margaret Dockey	Information Services Manager	NHS Business Services Authority
Manir Hussain	Local professional Network Chair & Assoc Director Medicines Optimisation	NHS England & North Staffs/Stoke on Trent CCGs
Duncan Jenkins	Pharmaceutical Public Health	Dudley Public Health/CCG
Kate Arnold	Head of Medicines and Primary Care Development	Solihull CCG
Paul Gouldstone	Head of Medicines Management	Enfield CCG
Steve Pike	Clinical Lead Medicines Management	Coastal West Sussex CCG
David Paynton	National Clinical Lead for Commissioning	Royal College of GPs
Robbie Turner	Director for England	Royal Pharmaceutical Society
Lauren Hughes	Director, Clinical Policy and Operations	NHS England

Organisations represented at a Stakeholder Engagement Event

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

Appendix 2 – Unintended Consequences

The working group considered potential unintended consequences of Section 4: Our Proposals for CCG commissioning guidance. 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	**Working Group**
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 (e.g. using oral analgesia versus topical)	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 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.

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/

Introduction Questions

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: A Consultation on 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 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: Proposals for CCG commissioning guidance

Please select which items you would like to share your views on (please select)?
Co-proxamol/Dosulepin/Glucosamine and Chondroitin/Herbal Treatments/Homeopathy/Immediate Release Fentanyl/Lidocaine Plasters/Liothyronine/Lutein and Antioxidants/Omega-3 Fatty Acid Compounds/Once Daily Tadalafil/Oxycodone and Naloxone Combination Product/Paracetamol and Tramadol Combination Product/Perindopril Arginine/Prolonged-release Doxazosin/Rubefacients (excluding topical NSAIDs)/Travel Vaccines/Trimipramine

Co-proxamol
Do you agree with the proposed recommendations for Co-proxamol?
On the webform for each of the 18 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

Dosulepin
Do you agree with the proposed recommendations for Dosulepin?
Agree/Neither agree or disagree/Disagree/Unsure
If needed, please provide further information

Prolonged-release Doxazosin
Do you agree with the proposed recommendations for Prolonged-release Doxazosin?
Agree/Neither agree or disagree/Disagree/Unsure

If needed, please provide further information

Immediate Release Fentanyl
Do you agree with the proposed recommendations for Immediate Release Fentanyl?
Agree/Neither agree or disagree/Disagree/Unsure
If needed, please provide further information

Glucosamine and Chondroitin
Do you agree with the proposed recommendations for Glucosamine and Chondroitin?
Agree/Neither agree or disagree/Disagree/Unsure
If needed, please provide further information

Herbal Treatments
Do you agree with the proposed recommendations for herbal treatments?
Agree/Neither agree or disagree/Disagree/Unsure
If needed, please provide further information

Homeopathy
Do you agree with the proposed recommendations for homeopathy?
Agree/Neither agree or disagree/Disagree/Unsure
If needed, please provide further information

Liodcaine Plasters
Do you agree with the proposed recommendations for Lidocaine Plasters?
Agree/Neither agree or disagree/Disagree/Unsure
If needed, please provide further information

Liothyronine
Do you agree with the proposed recommendations for Liothyronine?
Agree/Neither agree or disagree/Disagree/Unsure
If needed, please provide further information

Lutein and Antioxidants
Do you agree with the proposed recommendations for Lutein and Antioxidants?
Agree/Neither agree or disagree/Disagree/Unsure
If needed, please provide further information

Omega-3 Fatty Acid Compounds
Do you agree with the proposed recommendations for Omega-3 Fatty Acid Compounds?Agree/Neither agree or disagree/Disagree/Unsure
If needed, please provide further information

Oxycodone and Naloxone combination product
Do you agree with the proposed recommendations for oxycodone and naloxone?
Agree/Neither agree or disagree/Disagree/Unsure
If needed, please provide further information

Paracetamol and Tramadol Combination Product
Do you agree with the proposed recommendations for Paracetamol and Tramadol Combination product?
Agree/Neither agree or disagree/Disagree/Unsure
If needed, please provide further information

Perindopril Arginine
Do you agree with the proposed recommendations for Perindopril Arginine?
Agree/Neither agree or disagree/Disagree/Unsure
If needed, please provide further information

Rubefacients (excluding topical NSAIDs)
Do you agree with the proposed recommendations for Rubefacients (excluding topical NSAIDs)?
Agree/Neither agree or disagree/Disagree/Unsure
If needed, please provide further information

Once Daily Tadalafil
Do you agree with the proposed recommendations for Once Daily Tadalafil?
Agree/Neither agree or disagree/Disagree/Unsure
If needed, please provide further information

Travel Vaccines
Do you agree with the proposed recommendations for Travel Vaccines?
Agree/Neither agree or disagree/Disagree/Unsure
If needed, please provide further information

Trimipramine
Do you agree with the proposed recommendations for Trimipramine?
Agree/Neither agree or disagree/Disagree/Unsure
If needed, please provide further information

Section 5: Items that are prescribed in primary care and are available over the counter

Please provide your views and/or any relevant evidence that we should consider when developing proposals to potentially restrict items that are available over the counter.

Do you agree with our proposed criteria to assess items for potential restriction? These criteria are:

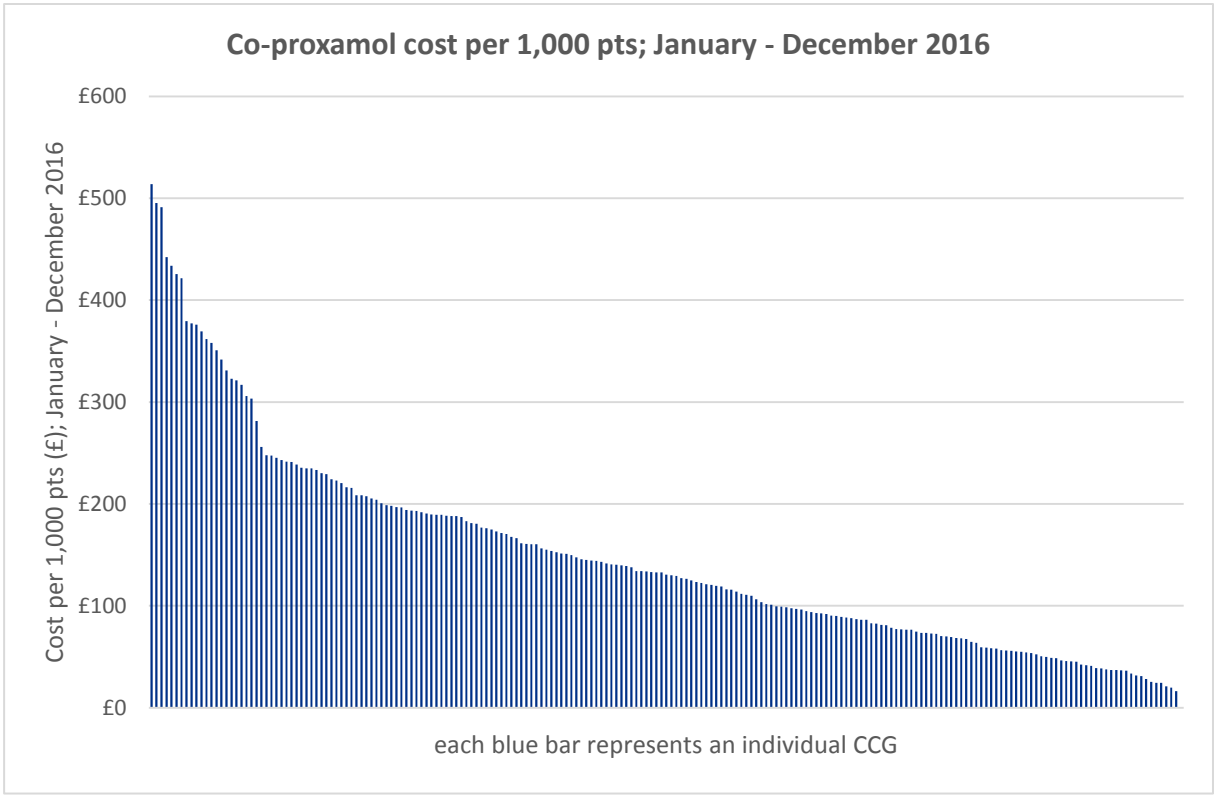
- **Legal Status** i.e. is it prescription only, or is it available over the counter in pharmacies and/or any retail outlet?
- **Indication** i.e. what condition is it used to treat?
- **Background** i.e. a general narrative on the drug incl. pack size, tablet size, whether administered orally etc.
- **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)

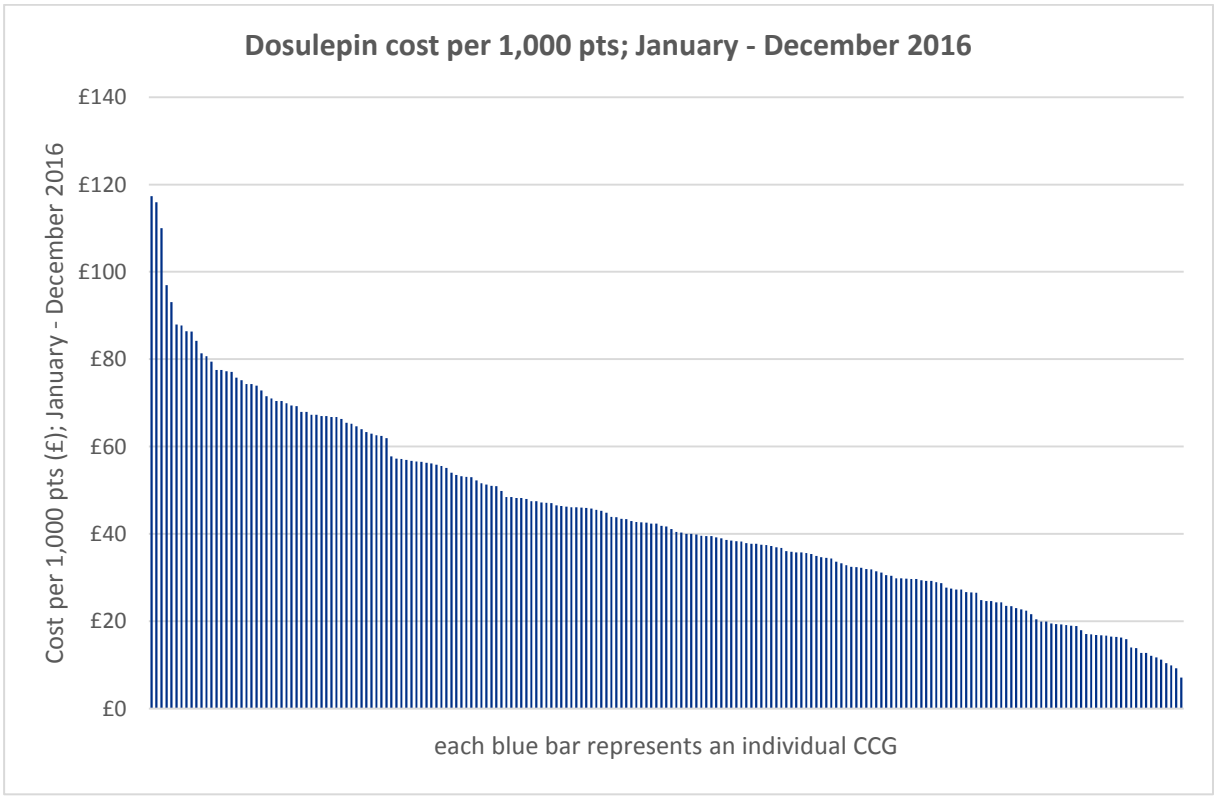
Agree/Neither agree or disagree/Disagree/Unsure

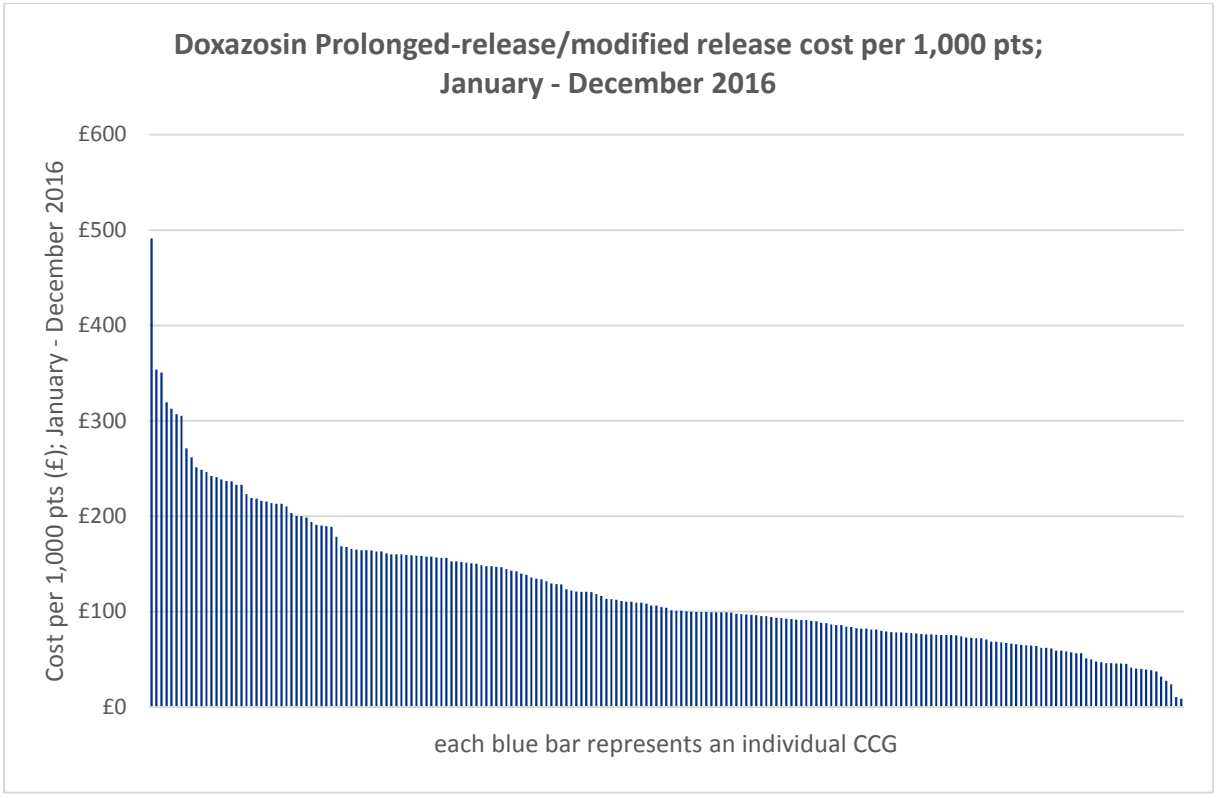
If needed, please provide further information

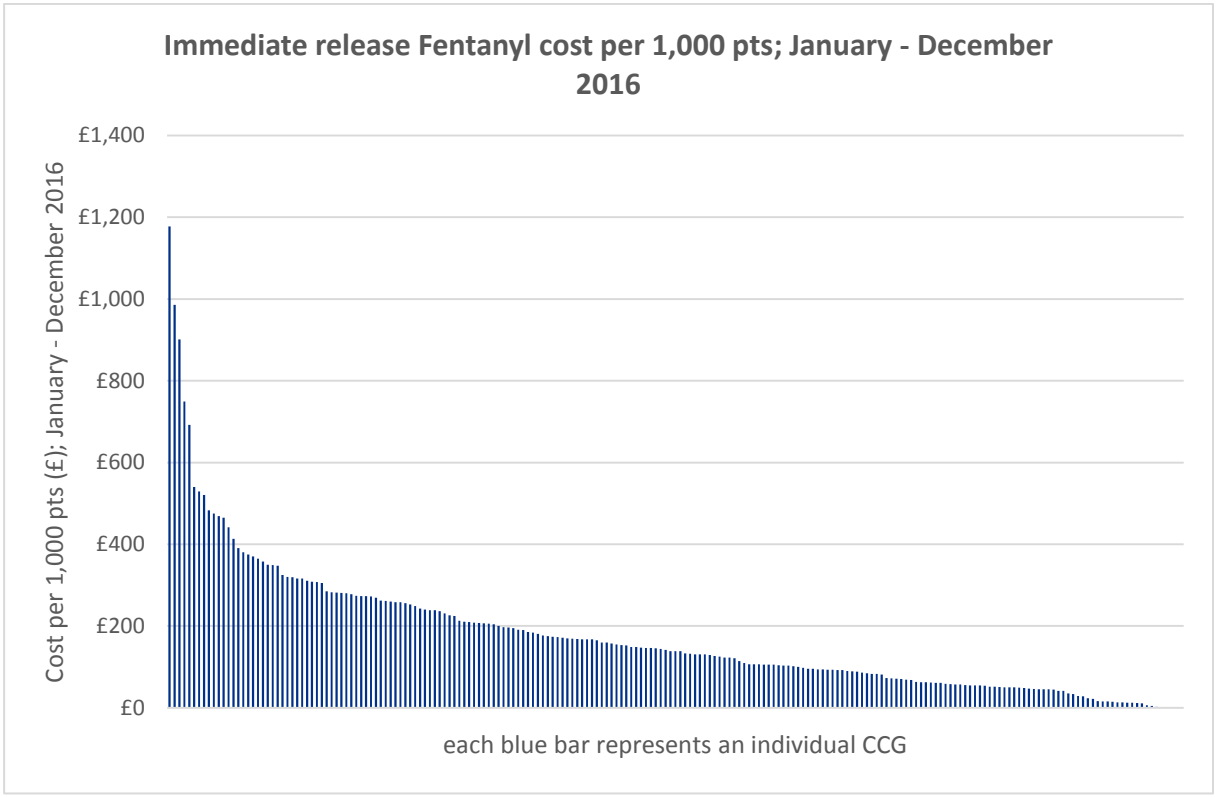
Are there individual products, which are either clinically ineffective or available over the counter which you believe should be prioritised for early review? Please give detailed reasons for your response.

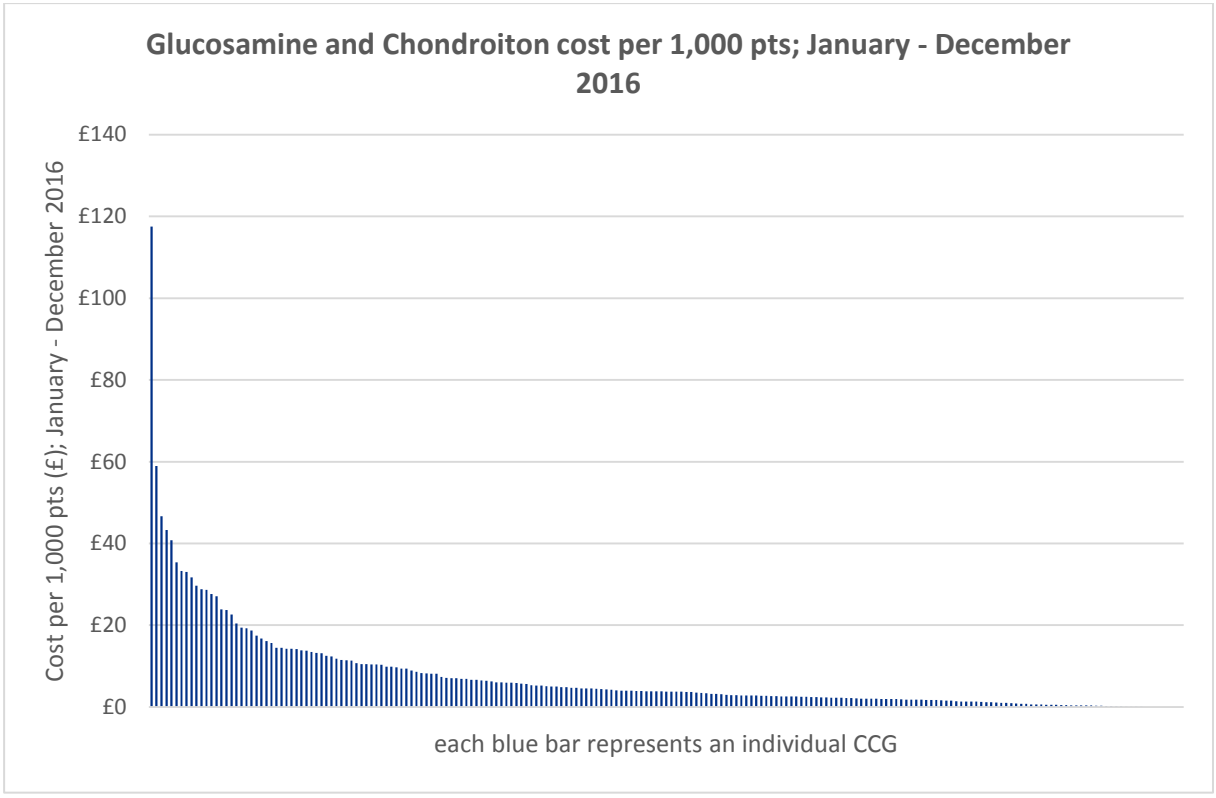
Appendix 4 - Prescribing variation data

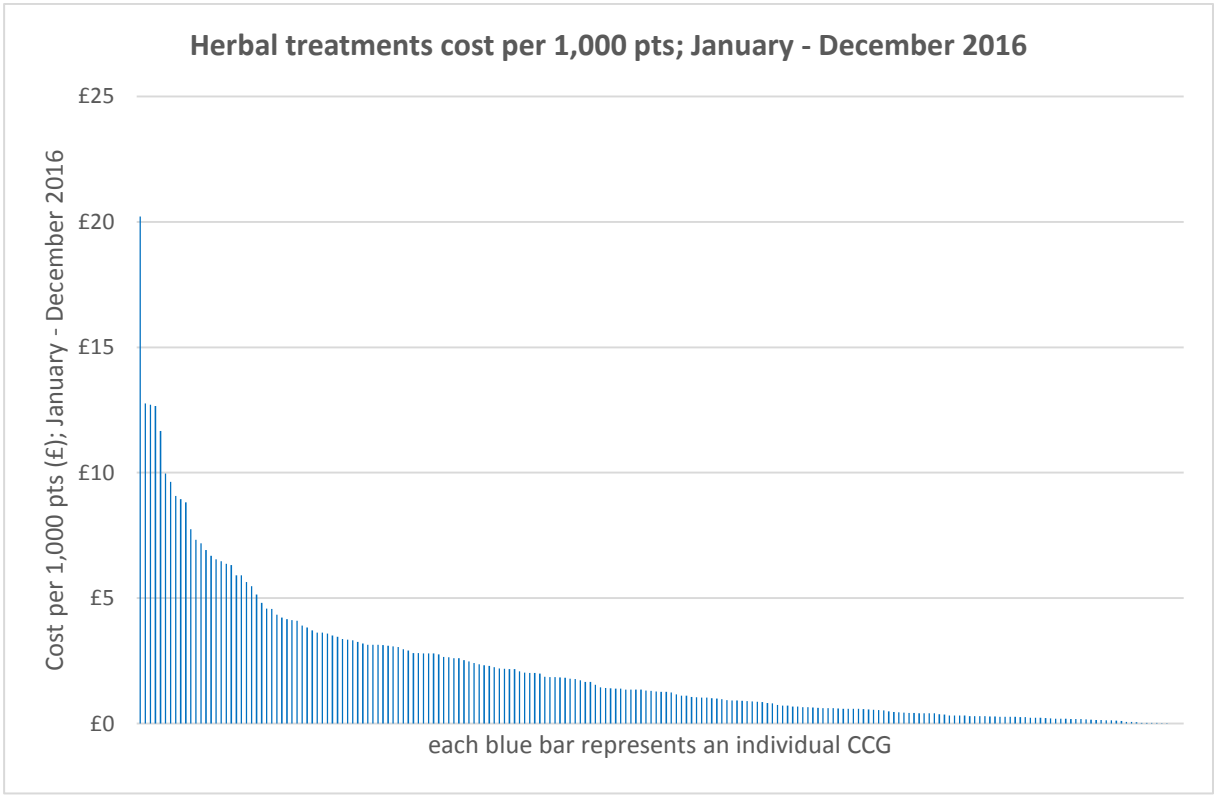


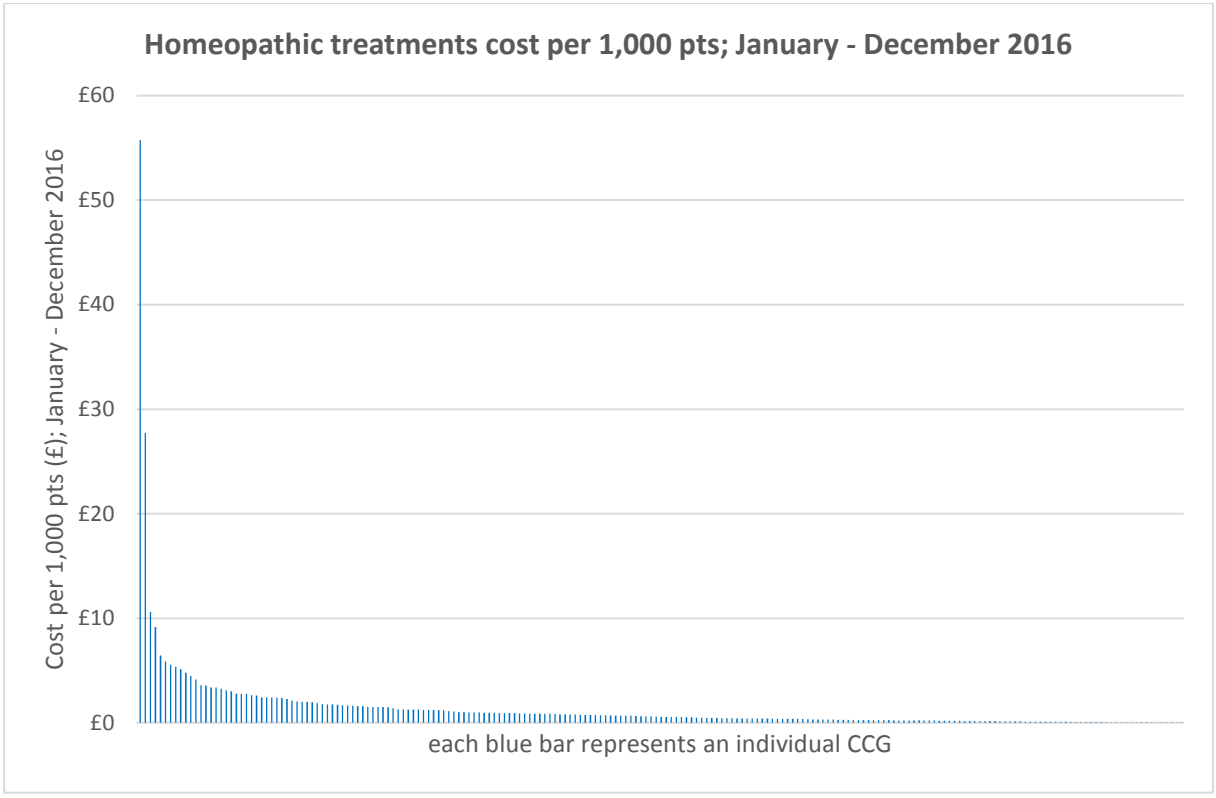


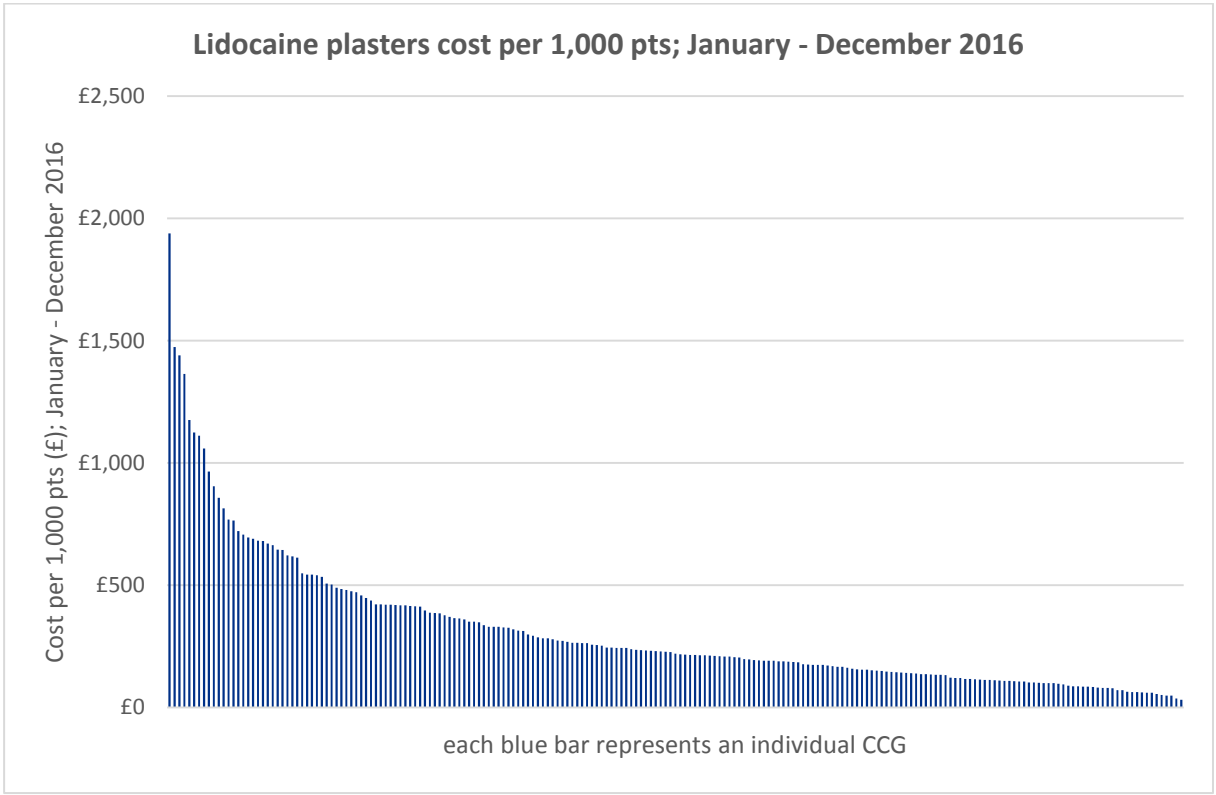

Doxazosin Prolonged-release/modified release cost per 1,000 pts; January - December 2016
Cost per 1,000 pts (£); January - December 2016
£600
£500
£400
£300
£200
£100
£0
each blue bar represents an individual CCG

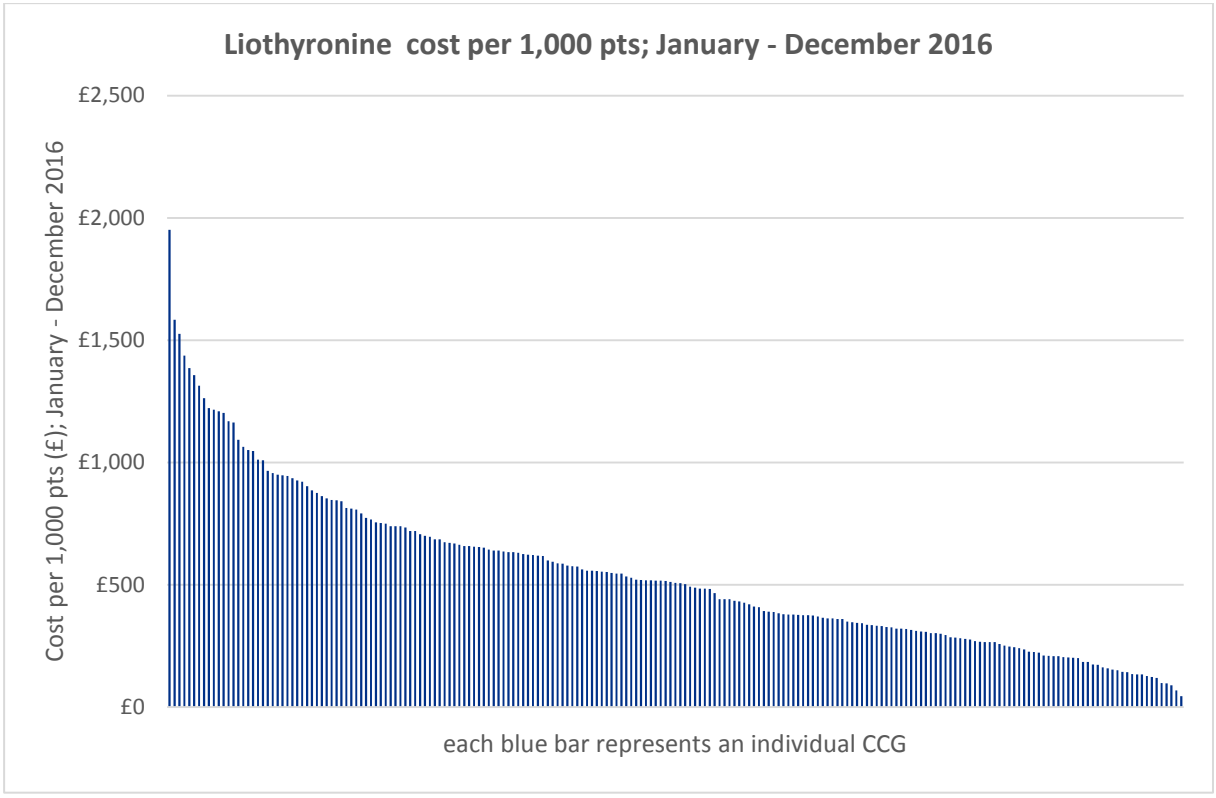

Immediate release Fentanyl cost per 1,000 pts; January - December 2016
Cost per 1,000 pts (£); January - December 2016
£1,400
£1,200
£1,000
£800
£600
£400
£200
£0
each blue bar represents an individual CCG

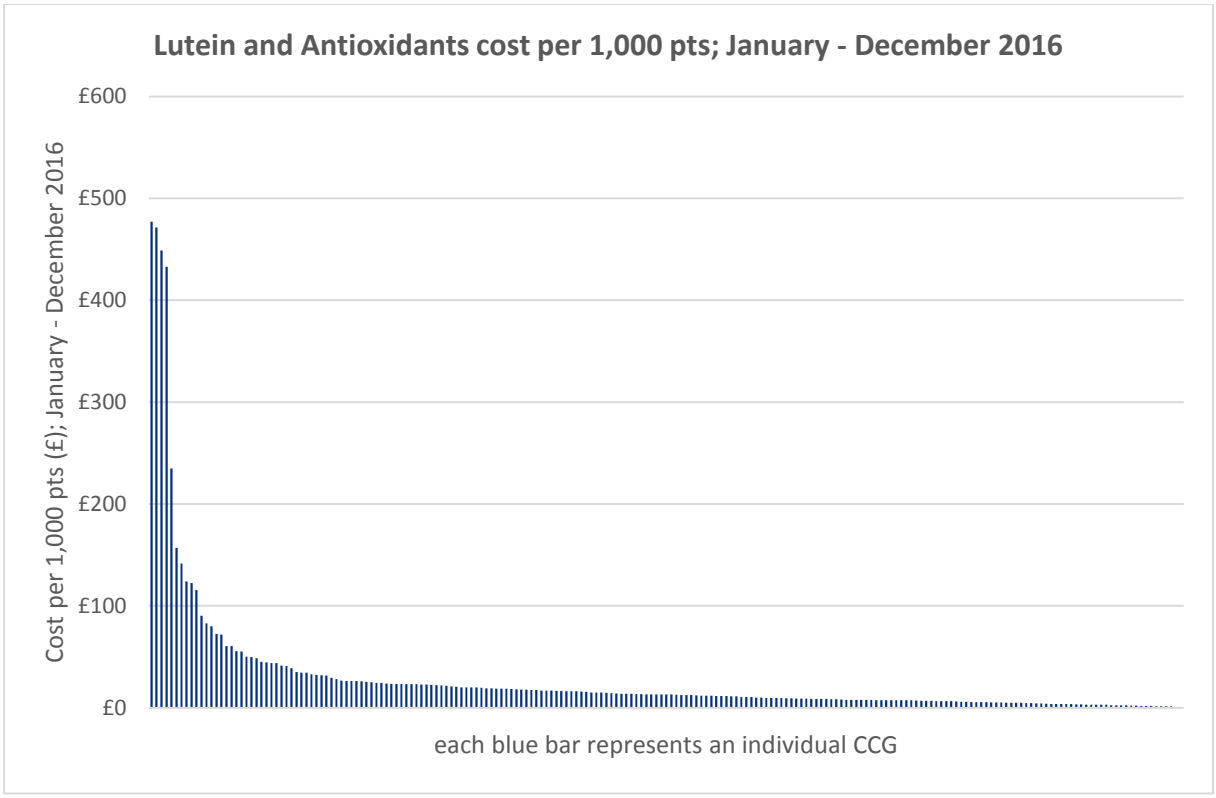

Glucosamine and Chondroiton cost per 1,000 pts; January - December 2016
Cost per 1,000 pts (£); January - December 2016
£140
£120
£100
£80
£60
£40
£20
£0
each blue bar represents an individual CCG

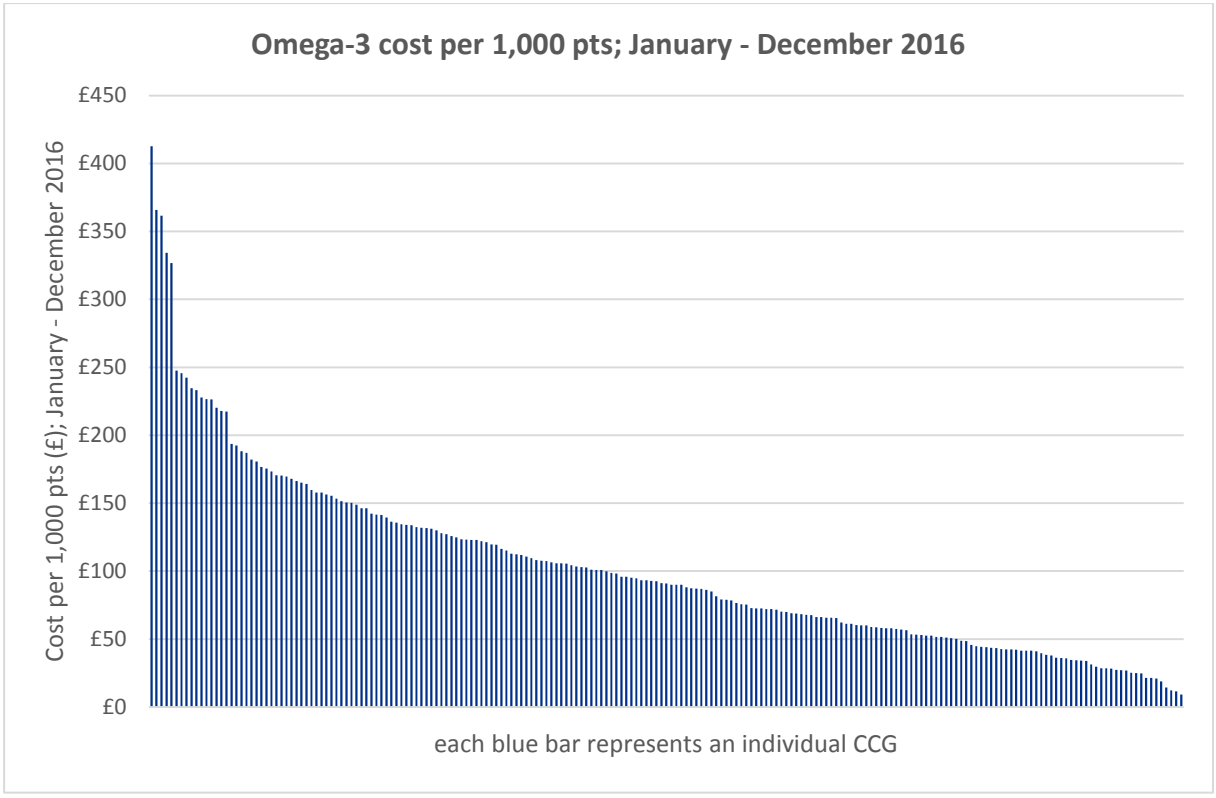

Herbal treatments cost per 1,000 pts; January - December 2016
Cost per 1,000 pts (£); January - December 2016
£25
£20
£15
£10
£5
£0
each blue bar represents an individual CCG

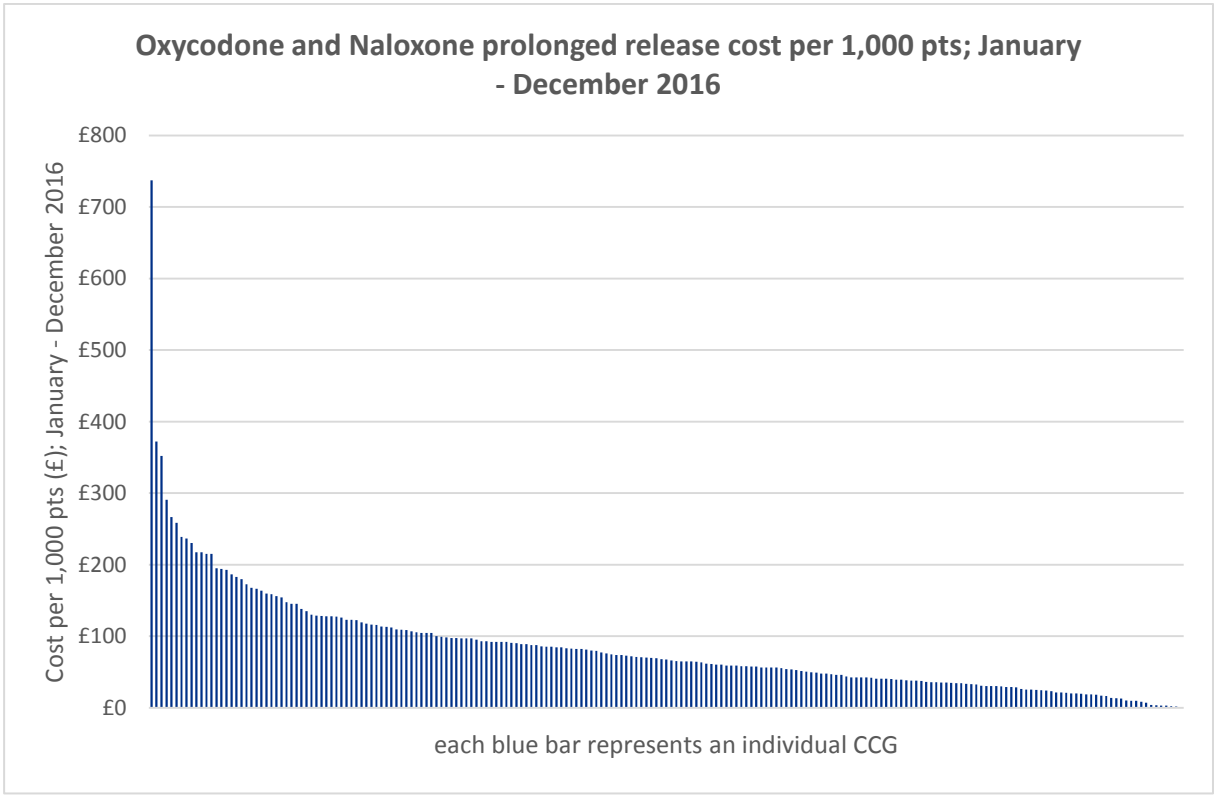

Homeopathic treatments cost per 1,000 pts; January - December 2016
£60
£50
£40
£30
£20
£10
£0
Cost per 1,000 pts (£); January - December 2016
each blue bar represents an individual CCG

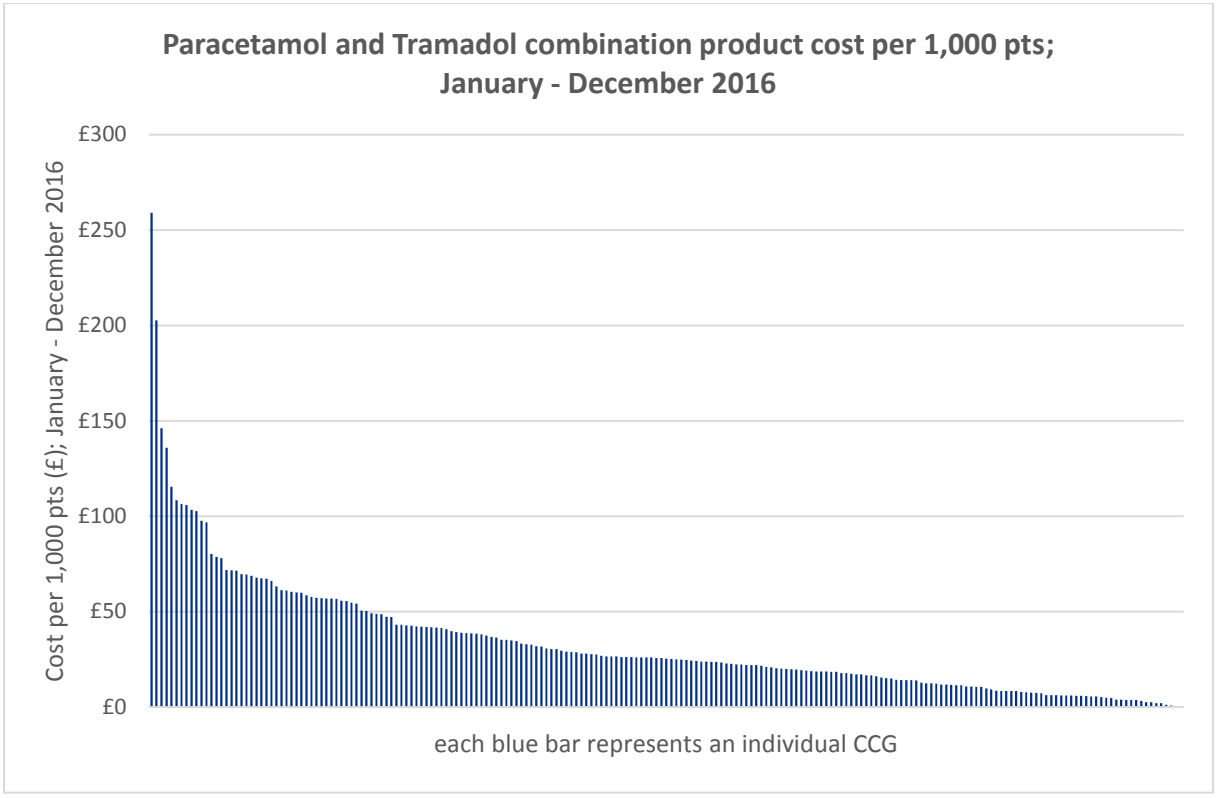

Lidocaine plasters cost per 1,000 pts; January - December 2016
£2,500
£2,000
£1,500
£1,000
£500
£0
Cost per 1,000 pts (£); January - December 2016
each blue bar represents an individual CCG

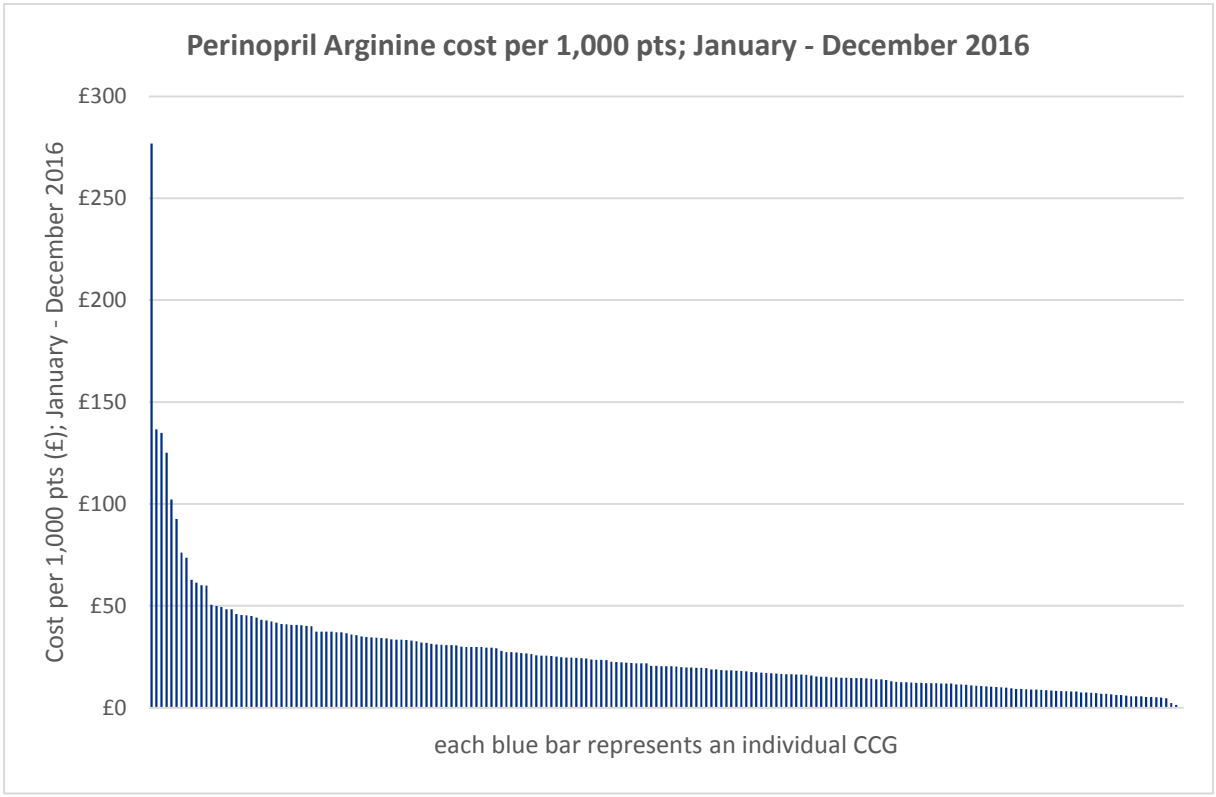

Liothyronine cost per 1,000 pts; January - December 2016
£2,500
£2,000
£1,500
£1,000
£500
£0
Cost per 1,000 pts (£); January - December 2016
each blue bar represents an individual CCG

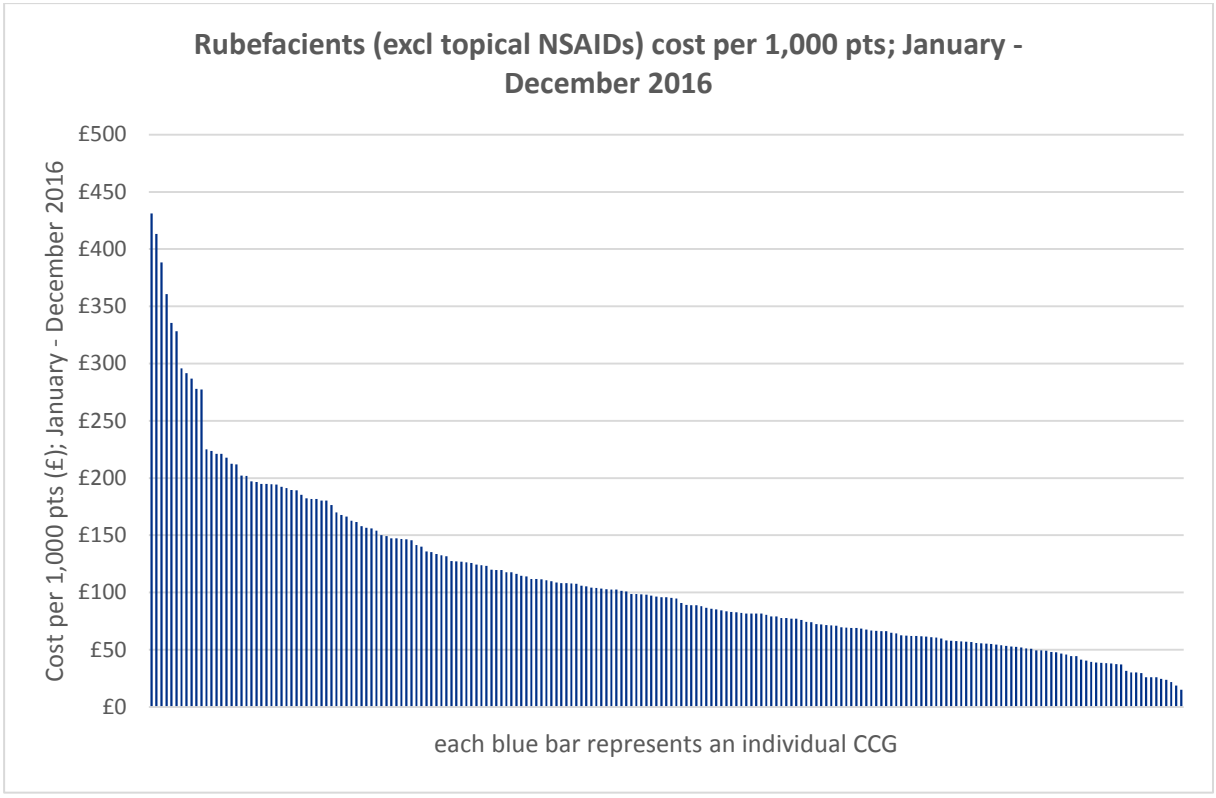

Lutein and Antioxidants cost per 1,000 pts; January - December 2016
£600
£500
£400
£300
£200
£100
£0
Cost per 1,000 pts (£); January - December 2016
each blue bar represents an individual CCG

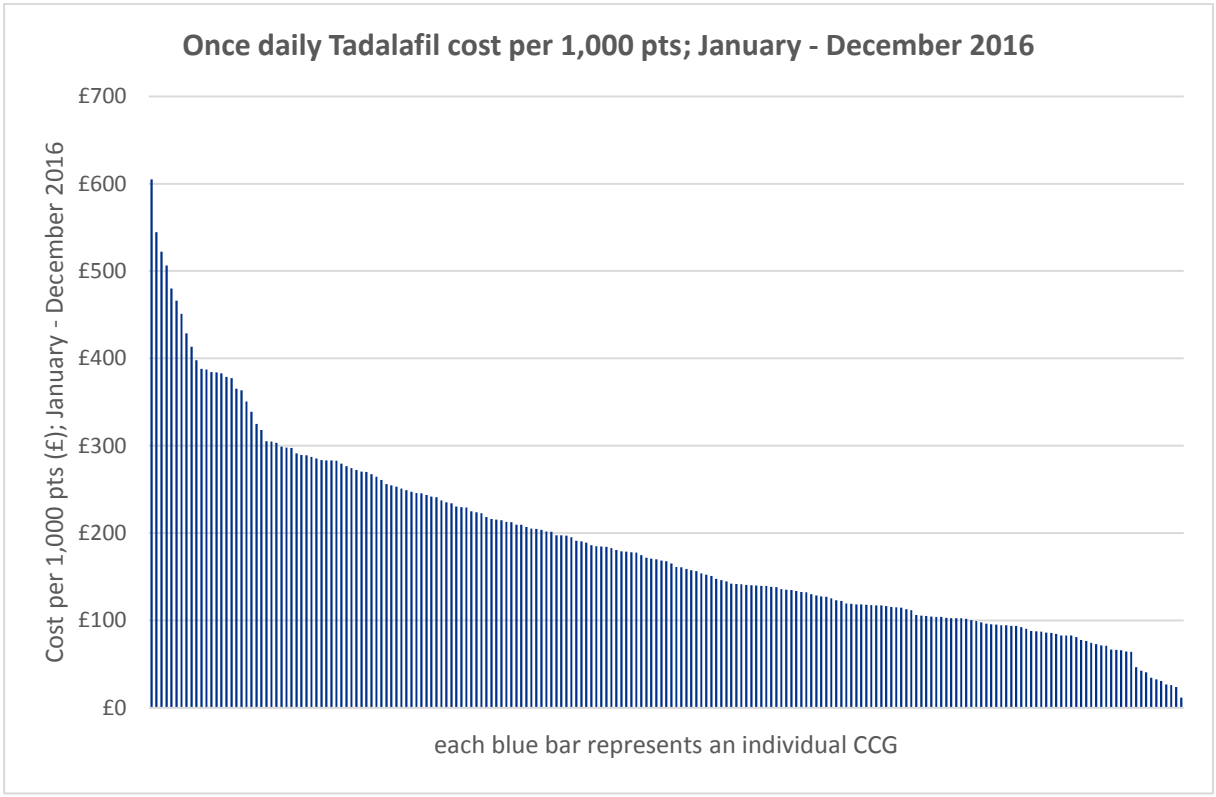

Omega-3 cost per 1,000 pts; January - December 2016
Cost per 1,000 pts (£); January - December 2016
£450
£400
£350
£300
£250
£200
£150
£100
£50
£0
each blue bar represents an individual CCG

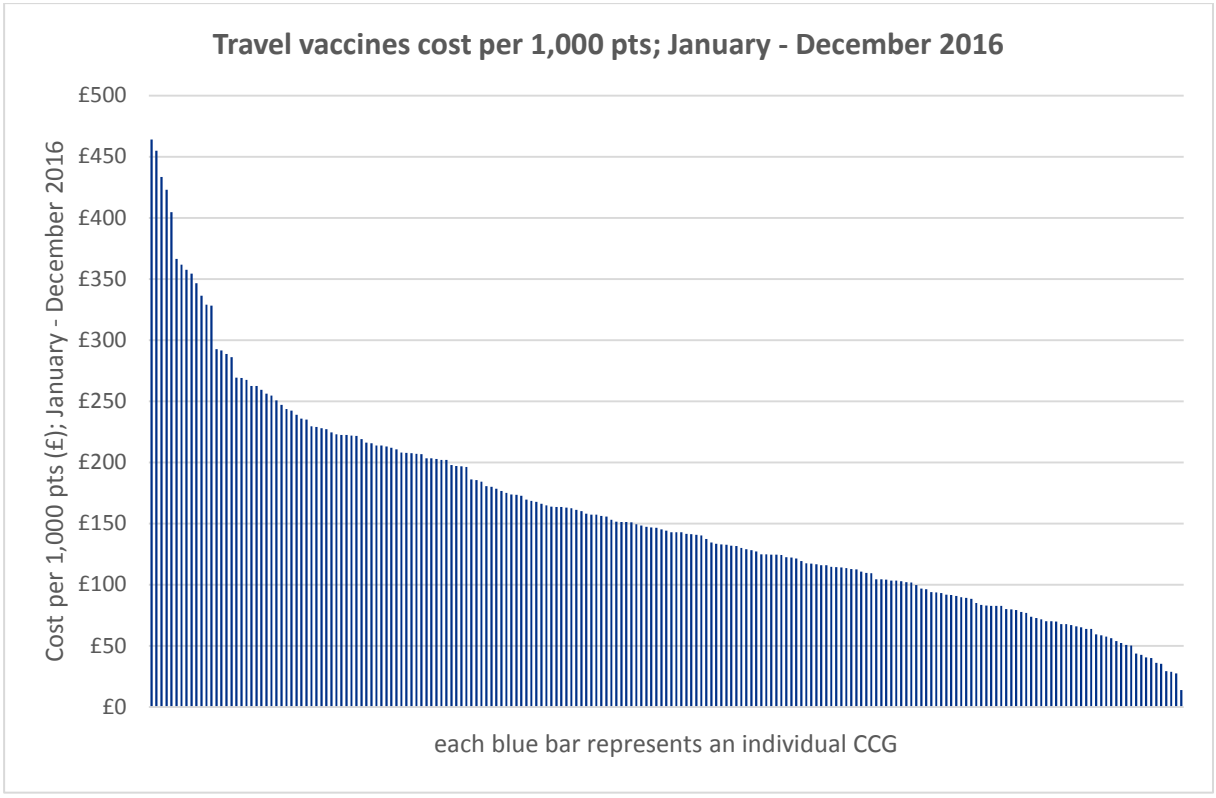

Oxycodone and Naloxone prolonged release cost per 1,000 pts; January - December 2016
Cost per 1,000 pts (£); January - December 2016
£800
£700
£600
£500
£400
£300
£200
£100
£0
each blue bar represents an individual CCG

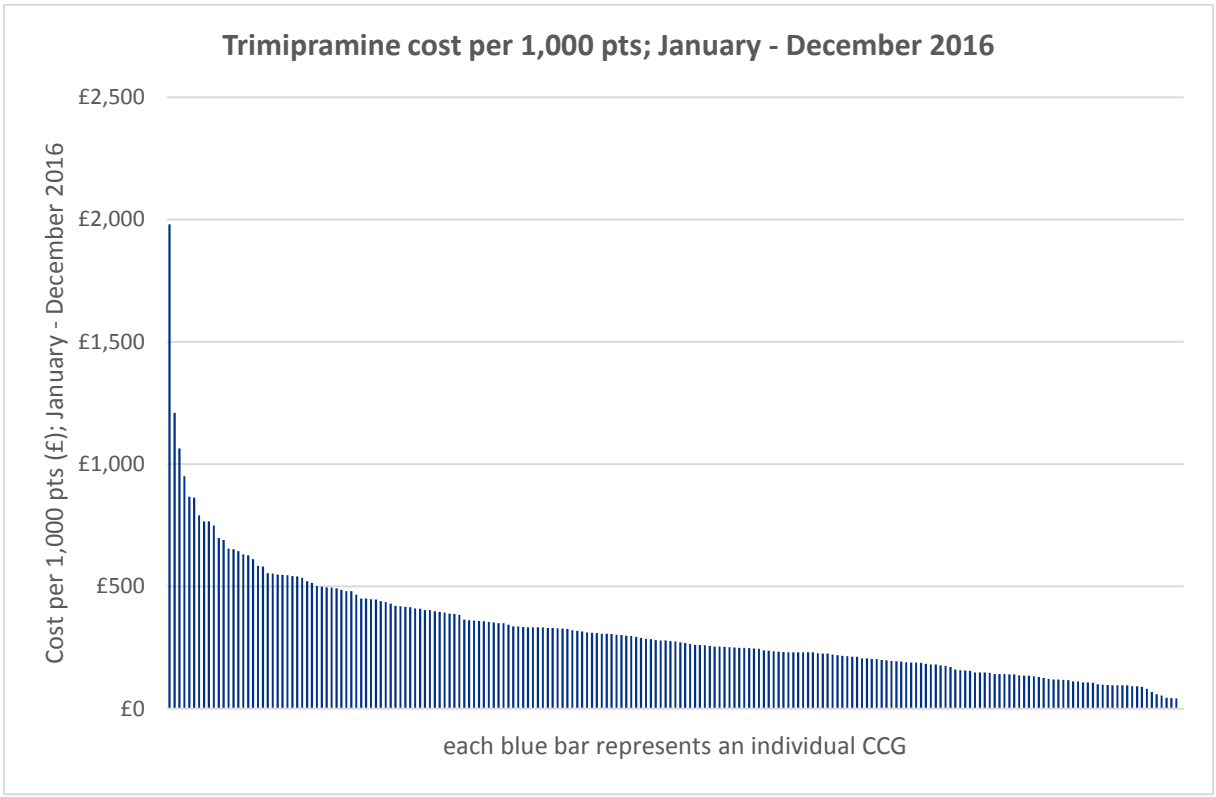

Paracetamol and Tramadol combination product cost per 1,000 pts; January - December 2016
Cost per 1,000 pts (£); January - December 2016
£300
£250
£200
£150
£100
£50
£0
each blue bar represents an individual CCG

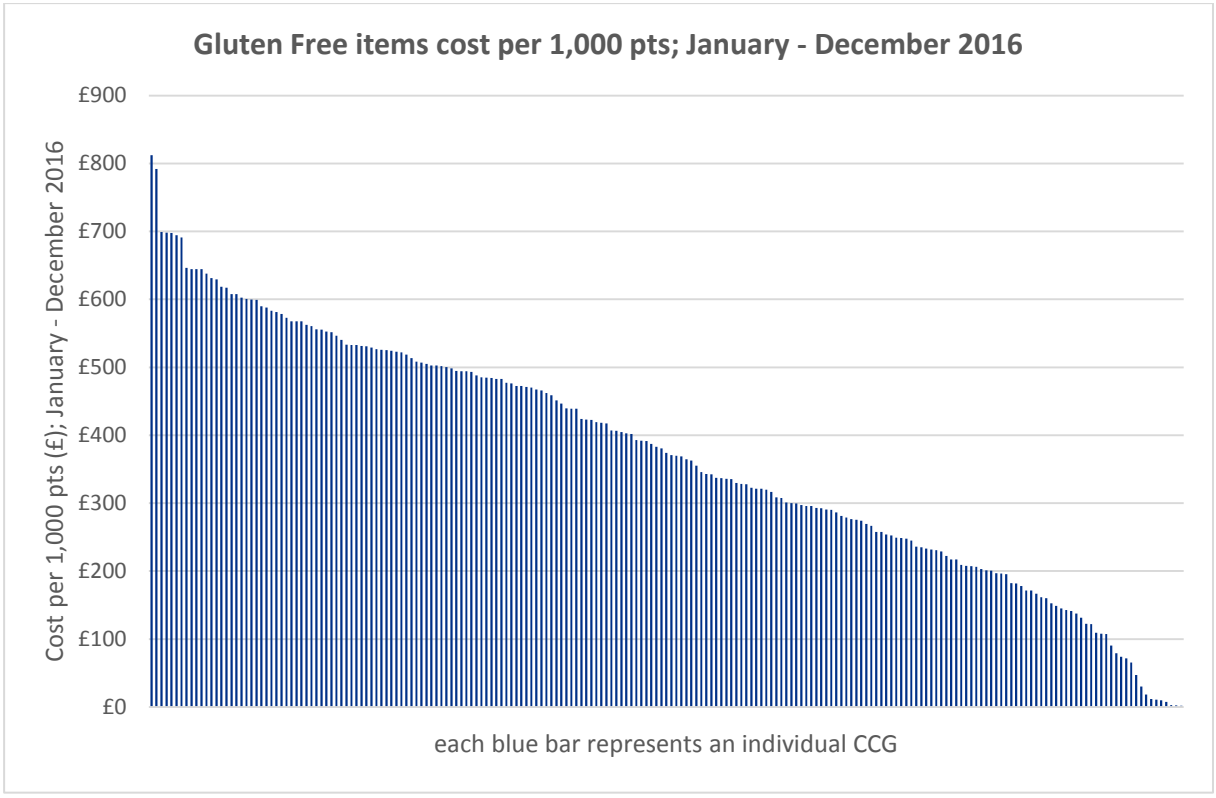

Perinopril Arginine cost per 1,000 pts; January - December 2016
Cost per 1,000 pts (£); January - December 2016
£300
£250
£200
£150
£100
£50
£0
each blue bar represents an individual CCG


Rubefacients (excl topical NSAIDs) cost per 1,000 pts; January - December 2016
Cost per 1,000 pts (£); January - December 2016
£500
£450
£400
£350
£300
£250
£200
£150
£100
£50
£0
each blue bar represents an individual CCG


Once daily Tadalafil cost per 1,000 pts; January - December 2016
Cost per 1,000 pts (£); January - December 2016
£700
£600
£500
£400
£300
£200
£100
£0
each blue bar represents an individual CCG


Travel vaccines cost per 1,000 pts; January - December 2016
£500
£450
£400
£350
£300
£250
£200
£150
£100
£50
£0
Cost per 1,000 pts (£); January - December 2016
each blue bar represents an individual CCG


Trimipramine cost per 1,000 pts; January - December 2016
£2,500
£2,000
£1,500
£1,000
£500
£0
Cost per 1,000 pts (£); January - December 2016
each blue bar represents an individual CCG


Gluten Free items cost per 1,000 pts; January - December 2016
£900
£800
£700
£600
£500
£400
£300
£200
£100
£0
Cost per 1,000 pts (£); January - December 2016
each blue bar represents an individual CCG