PrescQIPP Community Interest Company

# Medical devices DROP-List

The PrescQIPP DROP-List (Drugs to Review for Optimised Prescribing) incorporates medicines prescribed across the NHS that are considered low priority and poor value for money. Some of the National Institute for Health and Care Excellence (NICE) 'Do Not Do' items that can be easily measured using prescribing data are included. It also incorporates medicines that could potentially be provided as self care, with advice and support from community pharmacists, and discusses the potential to support medicines optimisation for the products listed. This bulletin reviews the potential medical devices/ appliances that could be considered as DROP-List items. It looks at the evidence to support the use of selected devices and makes commissioning recommendations for CCGs to consider for local adoption. As well as drawing attention to low priority treatments, the DROP-List for medical devices also considers the need for local pathways and waste minimisation strategies, where treatments are offered.

## Recommendations

- Review all patients prescribed a product listed in this medical device DROP-List bulletin.
- Determine whether to:
  - Continue treatment if the patient fulfils circumstances in which use is appropriate.
  - Change the treatment to a more appropriate, cost-effective choice.
  - Stop prescribing the medicine or medical device.
  - Recommend self care and purchase of over-the-counter (OTC) medicines or medical devices with support and advice from the community pharmacist wherever appropriate.
- Products included in part IX –Appliances of the Drug Tariff should be subject to local formulary restrictions in the same way that medicines are.
- Products not listed in part IX-Appliances of the Drug Tariff should not be prescribed on FP10 even though they are marked with a CE mark.
- Medical devices not included in local formularies should not be routinely prescribed on FP10 prescription, and advice should be sought from the CCG medicines management team when considering prescribing.
- Local patient pathways should be available to ensure that medical devices are prescribed appropriately. Pathways should ensure that initial prescribing is accompanied by appropriate instruction and counselling.
- The route of procurement of medical devices should be agreed in contract negotiations and be clear to practitioners delivering care.
  - Where a medical device is recommended or initiated by a specialist, the specialist should generally prescribe or provide the device, unless alternative arrangements have been agreed locally.
  - It is reasonable for GPs to prescribe consumables and replacement devices only.
- Many medical devices are reusable and do not need to be reordered on a monthly basis. Such devices should not be added to repeat prescribing systems.

# Background

The Medicines and Healthcare products Regulatory Agency (MHRA) provides information on and determines whether a product falls within the definition of a medicine – 'medicinal product' or a medical device.[1] A medicinal product will have a marketing authorisation (formerly a product licence) from the MHRA.

## A medicinal product is:

- Any substance or combination of substances presented as having properties of preventing or treating disease in human beings,
- Any substance or combination of substances that may be used by or administered to human beings with a view to restoring, correcting or modifying a physiological function by exerting a pharmacological, immunological or metabolic action, or making a medical diagnosis.

## A medical device is defined as:[2]

- Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:
  - Diagnosis, prevention, monitoring, treatment or alleviation of disease or compensation for an injury or handicap,
  - Investigation, replacement or modification of the anatomy or of a physiological process,
  - Control of conception,
  - And which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means.

Manufacturers need to demonstrate that their medical device meets the requirements in the Medical Devices Directive by carrying out a conformity assessment. When the device passes the conformity assessment, a CE mark can be then placed on the product to show that the medical device has met the requirements.[3] All medical devices on the UK market have to have received a CE mark (apart from the lowest risk devices). The manufacturers of the medical devices are responsible for obtaining a CE mark from a third part conformity assessment organisation which are approved by the MHRA.

Whether or not a medical device is prescribable on FP10 prescription is determined by whether or not it is included in part IX –Appliances of the Drug Tariff. If a product is listed then it could be prescribed on FP10 prescription. If a device is not listed in part IX of the Drug Tariff then it cannot be prescribed on an FP10.[4] As is the case for medicinal products, just because a medical device could be prescribed on FP10, NHS organisations may recommend that they are not recommended as cost-effective choices. This medical devices DROP-List bulletin provides information on medical devices to support commissioning decision making on medical devices which are viewed in general as low priority and poor value for money for the NHS.

If a product is not classified as a medicinal product or a CE marked medical device, then it could be a food, toiletry or cosmetic and may also be classed as a borderline substance and included in Part XV of the Drug Tariff as an (Advisory Committee on Borderline Substances) ACBS product. Some of these products will be covered in the DROP-List available at https://www.prescqipp.info/droplist

# Medicines optimisation

Medicines optimisation is key to achieving the best outcomes for patients. The Royal Pharmaceutical Society Good Practice Guide on Medicines Optimisation suggests a number of principles, along with the outcomes they are intended to influence, that are key in helping support patients to get the most out of their medicines.[5] These are also important considerations and aims when reviewing drugs or devices in the DROP-List and include the following:

- Treatments of limited clinical value are not used and medicines or medical devices no longer required are stopped.
- Optimal patient outcomes are obtained from choosing medicines or medical devices using best evidence (for example, following NICE guidance, local formularies etc.) and these outcomes are measured.
- Wastage is reduced.
- The NHS achieves greater value for money invested in medicines or medical devices.
- Patients are more engaged, understand more about their medicines or medical devices and are able to make choices, including choices about prevention and healthy living.
- It becomes routine practice to signpost patients to further help with their medicines or medical devices and to local patient support groups.
- Incidents of avoidable harm from medicines or medical devices are reduced.

Table 1 shows the total items and spend in England and Wales for selected medical devices in part IX of the Drug Tariff. Table 2 is an alphabetical list of these products and looks at these in more detail and considers where their use might be reviewed in the context of the evidence base and guideline recommendations. It includes commissioning recommendations for CCGs to consider adopting locally.

**Table 1. Summary of items and spend for selected products in the part IX of the Drug Tariff for England and Wales (ePACT July to September 2016)**

| Drug Tariff grouping | Total annual spend in England and Wales (ePACT July to September 2016) |
|---|---|
| Lymphoedema garments | £15,489,981 |
| Anal irrigation system | £13,898,500 |
| Deodorants | £1,683,047 |
| Dry mouth products | £1,410,586 |
| Silk garments | £1,365,135 |
| Ostomy underwear | £1,332,609 |
| Inhalation solutions | £1,243,375 |
| Plantar pressure offloading devices | £1,029,537 |
| Nasal products | £811,448 |
| Ear wax softening medical devices | £705,320 |
| Oscillating positive expiratory pressure device | £123,659 |
| Belladonna adhesive plaster | £118,357 |
| Potassium hydroxide solution | £97,937 |
| Insert for female stress incont | £69,112 |
| Auto inflation device | £66,436 |
| Cycloidal vibration accessories | £53,507 |
| Head lice device | £45,585 |
| Pelvic toning devices | £23,180 |
| Eye compress | £17,583 |
| Needle-free insulin delivery system | £16,372 |
| Bacterial decolonisation products | £6,648 |
| Acne treatment | £4,966 |
| Inspiratory muscle training devices | £4,131 |
| **Total** | **£39,617,011** |

The lowest spend categories have been excluded. The majority of dressings, emollients, test strips, needles, lancets and continence and stoma products have also been excluded, with some exceptions (where they are not covered by other workstreams).

Products such as spacer devices where use is considered a priority and good value for money have also been excluded from the DROP list for devices and are not discussed further in table 2.

N.B. There is currently nil prescribing for 'Devices For Adjunctive Treatment Of Hypertension'- Resperate®

**Table 2. DROP-List for medical devices: Summary of recommendations for the use of selected medical devices (sorted alphabetically) listed in part IX-Appliances of the Drug Tariff December 2016**

N.B. Some of the indicative savings may be offset by the prescribing of appropriate alternatives.

| Drug Tariff grouping | Recommendation(s) | National guidance and evidence | Suggested alternatives/comments | Indicative annual saving |
|---|---|---|---|---|
| Acne treatment<br>(Aknicare® cream and lotion, aknicare® sr skin roller) | **Not recommended for prescribing.**<br>Those who wish to try Aknicare® products should be directed to purchase them for self care. They should however be advised that benzoyl peroxide-containing OTC products are generally preferred because of the substantial clinical trial evidence to support their use. | NHS clinical knowledge summaries (CKS) recommend providing self care advice about the use of OTC topical benzoyl peroxide products in managing acne.<br>Benzoyl peroxide is a useful topical drug for which there is substantial placebo-controlled trial evidence to support the treatment of acne.<br>There is a lack of or limited evidence of benefit for other OTC drugs.[6] | Other OTC acne treatments are available (many are licensed medicines), but the only ones listed in the Drug Tariff as medical devices are Aknicare® cream, Aknicare® lotion and Aknicare® SR skin roller.<br>Self care recommended for topical benzoyl peroxide products.<br>Aknicare cream, lotion and skin roller ingredients include triethyl citrate, ethyl linoleate and salicylic acid.[7] | Assuming an 80% reduction in prescribing £4,000 annually.<br>Further savings will be available by reviewing prescribing of products for acne which are not classed as medical devices. |

| Drug Tariff grouping | Recommendation(s) | National guidance and evidence | Suggested alternatives/comments | Indicative annual saving |
|---|---|---|---|---|
| Anal irrigation system<br><br>(Anal irrigation is also known as rectal irrigation or trans-anal irrigation) | Rectal irrigation is a specialist management option and should only be considered as part of an appropriate local bowel care pathway. If prescribed, ensure the patient is trained on how to use the system and is monitored regularly.<br><br>Products should not be added to GPs repeat prescribing systems at initiation. Once a consistent routine of irrigation has been established (often on alternate days[8]) it may be appropriate to add only items that need to be ordered on a monthly basis to the repeat prescribing system.<br><br>Treatment should be reviewed regularly. | There is a limited evidence base for this procedure at present.[8-10] The only indication for which there is randomised controlled trial evidence (from one study, n=87) supporting anal irrigation is neurogenic bowel dysfunction in adults.[11]<br><br>NICE advise that adults who continue to have episodes of faecal incontinence after initial management should be considered for specialised management. This may involve referral to a specialist continence service and rectal irrigation may be considered.[12] | Rectal irrigation should only be tried if other less invasive methods of bowel management have failed to adequately control constipation and/or faecal incontinence. This can include dietary measures, adjusting fluid intake, bowel habit, ensuring toilet access, evacuation techniques, medication and pelvic floor muscle training.[8]<br><br>Irrigation systems can be re-used and therefore a new prescription is not needed every month, e.g. Peristeen irrigation system has 90 uses so would last six months if the patient was irrigating every other day.[8] | Assuming a 20% reduction in prescribing (reducing wastage and any inappropriate prescribing) £2.8 million annually. |

| Drug Tariff grouping | Recommendation(s) | National guidance and evidence | Suggested alternatives/comments | Indicative annual saving |
|---|---|---|---|---|
| Auto inflation device (Otovent®) | Autoinflation may be considered during or after an active observation period following diagnosis of otitis media with effusion (OME, or glue ear), in children who are likely to cooperate with the procedure.<br><br>Adults wishing to use the device to equalise the air pressure in the middle ear, e.g. for air travel, can purchase the device for self care. | NICE found four randomised controlled trials (n= 565 children in total) that showed statistically significant improvements in middle ear function with Otovent® compared with standard care, as determined by tympanometry and pneumatic otometry. The comparator was not always fully described in the studies.[13]<br><br>In their guidance on surgery for OME in the under twelves, NICE advise that autoinflation may be considered during the active observation period for children with OME who are likely to cooperate with the procedure.[14] | The Otovent kit® consists of a nose piece and five latex balloons (sufficient for 2-3 weeks treatment). The normal duration of treatment is two weeks; review is recommended before treatment is repeated.[15]<br><br>The manufacturer states that it can be used from three years of age.[16]<br><br>A reasonable amount of dexterity and co-ordination is necessary to blow the balloons up using one nostril while keeping the other occluded; not all small children are likely to be able to do this.[15] | Assuming a 20% reduction in prescribing (by ensuring appropriate use in children likely to co-operate with the procedure, and purchase for self care in adults) £13,000 annually. |

| Drug Tariff grouping | Recommendation(s) | National guidance and evidence | Suggested alternatives/comments | Indicative annual saving |
|---|---|---|---|---|
| Bacterial decolonisation products<br><br>(Prontoderm® foam and Prontoderm® nasal gel). | Not recommended for routine use; current randomised controlled trial evidence is limited and suggests that a single Prontoderm® decolonisation course is not effective in eradicating methicillin-resistant staphylococcus aureus (MRSA) carriage.[17]<br><br>However, it is recognised that local resistance patterns to other bacterial decolonisation agents may require policy makers to consider alternatives (which may include Prontoderm®).<br><br>Selection and prescribing of products for bacterial decolonisation should be in accordance with local guidelines. | A double-blind, placebo-controlled randomised controlled trial (n=146) evaluated Prontoderm® for topical decolonisation of MRSA carriers in a teaching hospital. Patients were randomised to Prontoderm® (ten day course) or placebo. The primary outcome was MRSA decolonisation at day 28. In the Prontoderm® group 33.8% achieved MRSA decolonisation, compared with 29.3% of the placebo group (risk difference 4.5%; 95% CI -10.6% to 19.5%, P=0.56). The results suggest that a single Prontoderm® decolonisation course is not effective in eradicating MRSA carriage. Further studies are needed.[17] | For MRSA decolonisation, Public Health England suggest nasal mupirocin 2% and chlorhexidine gluconate 4% body-wash/shampoo (alternatives povidone iodine 7.5% or triclosan 2%) for five days. However they do state that local policies should be followed.[18]<br><br>Various products are used for bacterial decolonisation (many are licensed medicines), but the only ones listed in the Drug Tariff as medical devices are Prontoderm® foam and Prontoderm® nasal gel. | Assuming a 20% reduction in prescribing (reducing inappropriate prescribing) £1,300 annually |

| Drug Tariff grouping | Recommendation(s) | National guidance and evidence | Suggested alternatives/comments | Indicative annual saving |
|---|---|---|---|---|
| Belladonna adhesive plaster | Not recommended; there is insufficient evidence to recommend the use of belladonna adhesive plasters.<br>Prescribing on FP10 should be discontinued.<br>Those prescribed belladonna adhesive plasters should have their therapy reviewed.<br>Consider recommending or prescribing an effective alternative treatment if appropriate.<br>Do not initiate new prescriptions for belladonna adhesive plasters. | Belladonna liniments and plasters have been used as counter-irritants for the relief of pain but there is little evidence that they have a beneficial effect and adverse effects have occurred.[19] | The recommendations are consistent with recommendations on topical rubefacients (see PrescQIPP bulletin 114). https://www.prescqipp.info/-rubefacients/category/224-rubefacients-drop-list<br>Rubefacients have also been used for pain relief as counter-irritants, however evidence supporting their use is also lacking.<br>NICE state that rubefacients should not be offered for treating osteoarthritis.[20] | Assuming an 80% reduction in prescribing £95,000 annually. |

| Drug Tariff grouping | Recommendation(s) | National guidance and evidence | Suggested alternatives/comments | Indicative annual saving |
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| Cycloidal vibration accessories<br>(Vibro-pulse® accessories) | Not recommended; there is currently insufficient evidence to recommend the use of cycloidal vibration therapy.[21,22] | Cycloidal vibration (CV) therapy with Vibro-Pulse® is promoted as a therapy for cellulitis, venous leg ulcers and lower limb oedema.<br>A small prospective, company-sponsored, non-blinded, randomised controlled trial (n=36) has been published of Vibro-Pulse® in the management of cellulitis. The hospital based study compared standard therapy (intravenous or oral antibiotics plus bed rest) to standard therapy plus CV therapy three times daily. A difference in full recovery within seven days favouring CV therapy was reported (67% in the intervention group vs 11% in the control group).[23]<br>A Cochrane review of treatments for cellulitis concluded that there was insufficient evidence on CV therapy to form a conclusion about the efficacy of such treatment.[21]<br>No comparative trials for CV therapy for venous leg ulcers or other wounds have been identified. | See the Trent Medicines Information Service summary on Vibro-Pulse® for cellulitis and venous leg ulcers for further information.[22]<br>The device itself is not prescribable on FP10, but the disposable covers are. | Assuming an 80% reduction in prescribing £43,000 annually. |

| Drug Tariff grouping | Recommendation(s) | National guidance and evidence | Suggested alternatives/comments | Indicative annual saving |
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| Deodorants (stoma) | Not recommended for routine use; deodorants should not be required. If correctly fitted, no odour should be apparent except when bag is emptied or changed. Household air-fresheners are sufficient in most cases and are widely available to buy. If odour is present at times other than changing or emptying, refer the individual for review.[24]<br><br>Prescribing may be considered where it is deemed to be clinically necessary by a specialist stoma nurse, after individual review. The reason why household air-fresheners are insufficient must be documented.<br><br>Do not add to repeat prescribing systems. | It is recognised that specialist stoma nurses may occasionally recommend prescribed deodorant products for specific clinical problems, e.g. deodorant lubricant drops for 'pancaking' (where stool sits at the top of the bag), which can lead to leaking of the appliance and subsequent skin issues.[25] | Requests for prescriptions for items seen in magazines or received as samples should not be processed unless a review has been undertaken and the product has been assessed as being clinically indicated.[26] | Assuming an 80% reduction in prescribing £1.4 million annually. |

| Drug Tariff grouping | Recommendation(s) | National guidance and evidence | Suggested alternatives/comments | Indicative annual saving |
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| Dry mouth products | Dry mouth products such as artificial saliva or salivary stimulants should only be prescribed if simple measures alone have been inadequate.<br><br>Where known, address the underlying cause (including drug causes) where possible/clinically appropriate.[27]<br><br>Initiate dry mouth products as a trial and discontinue if no perceived benefit.<br><br>In dentate people, artificial saliva should:<br>• Be of neutral pH (acidic pH can cause dental caries).<br>• Ideally contain fluoride (otherwise a daily fluoride mouthwash is also needed).[28] See UKMi Q&A on saliva substitutes for further details. http://www.medicinesresources.nhs.uk/ GetDocument.aspx?pageId=504026§<br>• | Dry mouth products such as sprays, lozenges, mouth rinses, gels, oils, chewing gum or toothpastes have been evaluated in a Cochrane review. No strong evidence was found to support efficacy in relieving the sensation of dry mouth. Chewing sugar-free gum appears to increase saliva production in those with residual secretory capacity and may be preferred by patients, but there is no evidence that gum is better or worse than saliva substitutes.[29] | Simple measures for managing dry mouth include:<br>• Regular sips of water or an unsweetened drink<br>• Sucking sugar-free sweets or chewing sugar-free gum<br>• Sucking on ice cubes<br>• Avoiding alcohol, caffeine and smoking; all make dry mouth symptoms worse.[27]<br><br>Good oral hygiene to avoid dental problems is essential.<br><br>Some dry mouth products are borderline substances (for those with dry mouth due to radiotherapy or sicca syndrome – endorse 'ACBS').<br><br>Products can be purchased from a pharmacy; most cost the same or less than a prescription charge. | Assuming a 20% reduction in prescribing (ensuring simple measures are first line, stopping if no perceived benefit) £282,000 annually. |

| Drug Tariff grouping | Recommendation(s) | National guidance and evidence | Suggested alternatives/comments | Indicative annual saving |
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| Ear wax softening medical devices | Ear wax softening drops should be purchased for self care, or obtained via NHS minor ailments schemes through participating community pharmacies.<br><br>If self care treatment doesn't work the person should be advised to contact their GP surgery.[30] | Ear wax softening drops may reduce the need for mechanical removal of wax (e.g. with ear irrigation), although this is sometimes necessary.[31]<br><br>Using drops of any sort appears to be better than no treatment, but it is uncertain if one type of drop is any better than another.[32]<br><br>Drops containing simple remedies such as olive oil, almond oil and sodium bicarbonate are available. Proprietary products containing ingredients such as docusate sodium and urea-hydrogen peroxide can also be obtained. However the simple remedies above are generally preferred as they are less likely to cause ear irritation. Sodium bicarbonate may cause dryness of the ear canal.[31] | Wax is a normal bodily secretion which provides a protective film on the meatal skin and need only be removed if it causes hearing loss or interferes with a proper view of the ear drum.[31]<br><br>Drops containing nut oil should be avoided by those with nut allergy.[33] | Assuming an 80% reduction in prescribing £564,000 annually |

| Drug Tariff grouping | Recommendation(s) | National guidance and evidence | Suggested alternatives/comments | Indicative annual saving |
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| Electrical stimulating wound device<br>(Accel-heal®)<br>Note: Although there was nilspend when the data pack was done using July to Sept 2016 data, there was some spend when the initial scope for DROP-devices data was done so this information has been left in. | Not recommended; there is currently insufficient evidence to recommend the use of the Accel-Heal® electrical stimulating device. | A company sponsored prospective study (n=30 wounds) reported improved venous leg ulcer healing with use of the Accel-Heal® electrical stimulating device. There were limitations in the study design, which was non-blinded, non-randomised and did not have a prospective comparator group. Further study is needed to generate robust clinical data regarding this treatment.[34]<br>Further data supporting this treatment is limited to a small uncontrolled study (n=22)[35] and three case series (n=9 in total).[36-38] | Accel-Heal® is the only electrical stimulating wound device listed in the Drug Tariff.<br>The manufacturer's website states that a randomised, double blind, placebo controlled study of Accel-Heal® in the treatment of recalcitrant venous leg ulcers has concluded in September 2015 and is due to report in Q4 of 2016.[39] | Assuming an 80% reduction in prescribing £4,200 annually<br>Although the current total spend is low, the individual unit cost for a course of treatment is relatively high at £240. |

| Drug Tariff grouping | Recommendation(s) | National guidance and evidence | Suggested alternatives/comments | Indicative annual saving |
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| Eye compress | Not recommended; there is no evidence of additional benefit compared to using a clean flannel and warm water as an eye compress.<br><br>Those that find commercially available eye compresses more convenient to use may purchase them from a pharmacy or on-line. | Warm eye compresses may be recommended in managing some eye conditions, including dry-eye syndrome,[40] meibomian cysts, styes and blepharitis.[41-43]<br><br>A warm compress can be applied using a flannel soaked in warm water. The flannel requires resoaking in warm water periodically to prevent it becoming cold.[40]<br><br>Eye compresses that can be heated in a microwave and lose their heat more slowly are available. No evidence comparing their clinical effectiveness with using the flannel method was located. | Three eye compresses are listed in the Drug Tariff:<br>• Hot Eye Compress®<br>• Meibopatch®<br>• MGDRx Eye Bag®<br><br>Information about dry-eye syndrome, including self-help advice regarding the use of warm compresses is available at NHS Choices via http://www.nhs.uk/Conditions/Dry-eye-syndrome/Pages/Prevention.aspx | Assuming an 80% reduction in prescribing £14,000 annually. |

| Drug Tariff grouping | Recommendation(s) | National guidance and evidence | Suggested alternatives/comments | Indicative annual saving |
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| Head lice treatment devices<br><br>(Bug buster kit, Chemists' own head lice spray, Full marks solution, Hedrin once liquid gel, hedrin once spray gel, Linicin lotion 15 mins, Nitcomb-m2, Nitcomb-s1, Nitlotion, Nitty gritty comb, Nyda, Portia head lice comb, Vamousse) | Treatments for head lice should be purchased for self care, or obtained via NHS minor ailments schemes through participating community pharmacies.<br><br>Assessment of the infected individual by a GP is not generally necessary.<br><br>Referral to a GP or other appropriate action may be appropriate in certain circumstances, e.g. where there is scalp inflammation[44] or excoriation and skin infection (such as impetigo or furunculosis) caused by scratching,[45] or where severe and persistent head lice infections may be cause for considering child neglect.[46] | If a live head louse is found, the NICE CKS on head lice recommend treatment with one of the following:<br><br>A physical insecticide e.g. dimeticone 4% lotion (Hedrin®), dimeticone 92% spray (NYDA®), and isopropyl myristate and cyclomethicone solution (Full Marks Solution®).<br><br>A traditional insecticide e.g. Malathion 0.5% aqueous liquid (Derbac-M®).<br><br>Wet combing, the systematic combing of wet hair with a nit comb (e.g. the Bug Buster® comb) to remove head lice.<br><br>Essential oil based treatments, herbal treatments and products marketed as head lice repellents are not recommended.[45] | A variety of head lice treatments are available. Some are licensed medicines and some are medical devices – all are available OTC.<br><br>Community pharmacists are well placed to support people in selecting an appropriate, effective treatment, and provide advice on their correct use.<br><br>Sources of information for patients on head lice infections include the British Association of Dermatology via http://www.bad.org.uk/for-the-public/patient-information-leaflets/head-lice) and NHS Choices (http://www.nhs.uk/conditions/Head-lice/Pages/Introduction.aspx | Assuming an 80% reduction in prescribing £37,000 annually.<br><br>Further savings may be achieved with head lice treatments classed as licensed medicines. |

| Drug Tariff grouping | Recommendation(s) | National guidance and evidence | Suggested alternatives/comments | Indicative annual saving |
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| Inhalation solutions<br><br>(This category refers to hypertonic sodium chloride solutions for nebulisation. It does not include sodium chloride 0.9% w/v used for dilution of solutions for nebulisation). | Use outside of hospital considered for those with cystic fibrosis (CF) or non-CF bronchiectasis, where recommended by a specialist.<br><br>Initiation must take place in secondary care to ensure safety and suitability for the individual.[47] | Evidence from a Cochrane review supports the use of nebulised hypertonic sodium chloride in CF. Treatment resulted in a small improvement in FEV1 at four weeks, but this was not sustained at 48 weeks. Treatment improved some aspects of quality of life and reduced pulmonary exacerbations.[48]<br><br>A Cochrane review on use in non-CF bronchiectasis was unable to draw firm conclusions from the data.[49]<br><br>Guidelines from the British Thoracic Society recommend considering nebulised hypertonic sodium chloride in CF and non-CF bronchiectasis, before airway clearance.[47] | Hypertonic sodium chloride should be nebulised prior to airway clearance. Where it is prescribed for administration more than twice daily, confirm that the frequency matches the number of airway clearance sessions.<br><br>Products come in 4ml vials. Doses greater than 4ml (e.g. 5ml) that necessitate the use of two vials per session should be queried as costs are doubled for uncertain additional benefit.<br><br>Query prescriptions for hypertonic saline as an unlicensed special rather than the commercially available preparations, which are preferable where suitable.<br><br>When making formulary decisions, policy makers should consider the cost difference in primary care of the available 7% strength products. | Assuming a 10% reduction in costs (due to medicines optimisation) £125,000 annually.<br><br>This figure could be greater if unlicensed specials are being prescribed. |

| Drug Tariff grouping | Recommendation(s) | National guidance and evidence | Suggested alternatives/comments | Indicative annual saving |
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| Insert for female stress incontinence | Not recommended; there is currently insufficient evidence to recommend the use of the Contiform® device, or other intravaginal or intraurethral devices for female stress incontinence. NICE do not recommend their routine use.[50]<br><br>There is a risk of side-effects with the use of intravaginal or intraurethral devices for female stress incontinence. They include urinary tract infections, insertion trauma, vaginal irritation, haematuria, spotting, and device migration.[51] | NICE guidance on urinary incontinence in women recommend that intravaginal or intraurethral devices should not be used for the routine management of urinary incontinence. They state that these devices may be used occasionally (such as during physical exercise).[50]<br><br>However NICE-CKS do not recommend the routine or occasional use of these devices because the evidence for their efficacy is poor (five case series and one cross-over randomised controlled trial) and a high number of urinary tract infections (up to 47%) were reported in these studies, as well as insertion trauma, vaginal irritation, haematuria, spotting, and device migration.[51]<br><br>Evidence (which was not considered by NICE) for the Contiform® device specifically is extremely limited and includes two small case series (n=41 and n=37 that completed the protocol).[52,53] | The only insert for female stress incontinence listed in the Drug Tariff is Contiform®. | Assuming an 80% reduction in prescribing £55,000 annually. |

| Drug Tariff grouping | Recommendation(s) | National guidance and evidence | Suggested alternatives/comments | Indicative annual saving |
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| Inspiratory muscle training devices | Not recommended for routine use,but inspiratory muscle training may be considered in those with COPD, non-CF bronchiectasis and upper spinal cord injuries.<br><br>For other indications, commissioners should engage with local stakeholders including respiratory specialists to determine if there are circumstances in which the intervention will be offered. Criteria for use (e.g. trials of other treatments) and an approval process should be agreed where applicable.<br><br>Inspiratory muscle training should be provided only after individual assessment by an appropriately skilled therapist.<br><br>Treatment should not be initiated by GPs or other non-specialists.<br><br>Some devices are promoted for fitness/sports use. In these circumstances the device should be purchased rather than prescribed. | Cochrane reviews on inspiratory muscle training for asthma, for CF and after stroke found insufficient evidence to support the intervention.[54-56] A Cochrane review on respiratory muscle training for cervical spinal cord injury found evidence from a small number of trials of increasing respiratory muscle strength.[57]<br><br>Guidelines from the British Thoracic Society recommend considering inspiratory muscle training in those with COPD, non-CF bronchiectasis and upper spinal cord injuries. They state that further research is required regarding this intervention in those with CF and those with asthma.[47] The statement on asthma is consistent with SIGN/ BTS guidance on asthma.[58] | Three inspiratory muscle training devices are listed in the Drug Tariff:<br>• POWERbreathe® Medic<br>• Threshold IMT®<br>• Ultrabreathe®<br><br>The most cost effective interventions in COPD are considered to be flu vaccination in ‘at risk’ populations, followed by stop smoking support with pharmacotherapy, and pulmonary rehabilitation.[59] | Dependent on local pathways and whether prescribing is via primary or secondary care. |

| Drug Tariff grouping | Recommendation(s) | National guidance and evidence | Suggested alternatives/comments | Indicative annual saving |
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| Lymphoedema garments | Ensure the use of compression garments is part of a local pathway. They should only be prescribed after a full assessment of the individual by an appropriately trained practitioner.[60]<br><br>Care must be taken when ordering lymphoedema garments to ensure that the correct item is selected. Where there is uncertainty, confirm items with the lymphoedema service before they are ordered, to avoid wastage. | Single or multi-layered garments providing static compression are the mainstay of conservative treatment of lymphoedema.[61]<br><br>The main use of compression garments is in the long-term management of lymphoedema, usually following a period of intensive therapy. Compression garments are also used for prophylaxis or as part of initial treatment.[60] | It can be difficult to identify the intended lymphoedema garment on GPs prescribing systems, as they are not currently Dictionary of Medicines and Devices (DM&D) coded.<br><br>Lymphoedema garments are costly. All reasonable steps to ensure the correct items are ordered should be undertaken. Local systems and processes for ordering lymphoedema garments may need review if waste is an issue.<br><br>Two of each garment should be provided (one to wear, one to wash).[60]<br><br>Garments should be washed frequently according to the manufacturer's instructions. They should be replaced every three to six months, or when they begin to lose elasticity.[60] | Assuming a 20% reduction in prescribing (by reducing wastage) £3 million annually. |

| Drug Tariff grouping | Recommendation(s) | National guidance and evidence | Suggested alternatives/comments | Indicative annual saving |
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| Nasal products<br><br>(The majority of prescribing is for saline nasal sprays, e.g. Sterimar®, Aqua maris®.) | Not recommended; limited evidence favours a different treatment (see below).<br><br>Saline nasal sprays should not generally be prescribed:<br><br>Where indicated, large volume saline douches are thought to be more effective than saline nasal sprays.[62-64]<br><br>For managing the nasal symptoms of self-limiting conditions, saline nasal sprays can be purchased OTC for self care by those that wish to try them. | Saline nasal irrigation has a role in managing chronic rhinosinusitis.[62,65-67]<br><br>There is evidence to support the use of large volume saline nasal irrigation in the management of chronic rhinosinusitis, but it is generally of poor quality.[67,68]<br><br>Large volume saline douches are thought to be more effective than nasal sprays.[62-64]<br><br>Limited evidence has also shown potential benefit in managing upper respiratory tract infection symptoms.[69] | Health care professionals recommending nasal douching should ensure they are familiar with the procedure so that they can advise patients of an appropriate method to use.<br><br>Information for health care professionals on nasal douching can be found at http://www.bsaci.org/Guidelines/SOPs (see SOP on nasal douching.[70] | Assuming an 80% reduction in prescribing (by recommending saline douches or self care instead, where clinically appropriate) £650,000 annually |

| Drug Tariff grouping | Recommendation(s) | National guidance and evidence | Suggested alternatives/comments | Indicative annual saving |
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| Needle-free insulin delivery system | Not routinely recommended unless there is a confirmed diagnosis of needle phobia which would result in the patient not injecting insulin.[71]<br><br>Where use is deemed to be appropriate, treatment should be initiated and stabilised by an appropriate specialist. | NICE advise that adults with type 1 diabetes who have special visual or psychological needs be provided with injection devices or needle-free systems that they can use independently for accurate dosing.[72]<br><br>Limited data from two small pharmacokinetic studies in healthy volunteers (n=18)[73] and people with diabetes (n=24)[74] have demonstrated some pharmacokinetic differences in insulin aspart delivered via InsujetTM compared with conventional pen injection. | Needle-free insulin delivery systems deliver insulin via a fine stream of fluid (under pressure) that penetrates the surface of the skin.<br><br>They are promoted as possible options for people with true and severe needle phobia (which is rare).<br><br>These systems are more expensive than insulin injections, can be cumbersome to use, and may not be completely pain free.[75]<br><br>Two needle-free delivery systems have been available on the NHS: Injex® and InsuJet®. However, the distributors of Injex® have stated that for commercial reason they are unable to support supply through the NHS for the foreseeable future. Injex® remains available to purchase privately.[76] | Dependent on local pathways and whether prescribing is via primary or secondary care. |

| Drug Tariff grouping | Recommendation(s) | National guidance and evidence | Suggested alternatives/comments | Indicative annual saving |
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| Oscillating positive expiratory pressure device | Recommended for consideration when selecting an appropriate airway clearance technique in those with CF and non-CF bronchiectasis.[47]<br><br>For non-CF bronchiectasis commissioners should be aware that the supporting evidence is much more limited.[77] They should engage with local stakeholders including respiratory specialists to determine in what circumstances treatment with oscillating positive expiratory pressure (OPEP) is to be offered. Criteria for use (e.g. disease severity, prior trials of other treatments) and an approval process should be agreed where applicable.<br><br>OPEP treatment should be provided only after individual assessment by an appropriately skilled therapist.<br><br>Treatment should not be initiated by GPs or other non-specialists.<br><br>Although several devices may be required per year, they should not be added to repeat prescribing systems. | There is limited evidence in relation to OPEP devices. Evidence in people with non-CF bronchiectasis is very limited.<br><br>Evidence from a Cochrane review of oscillating devices in people with CF (n=1050 patients) found no clear evidence that oscillation was more or less effective overall than other forms of physiotherapy.[78]<br><br>A systematic review (n=146 patients) assessed OPEP compared with other airway clearance techniques or control in people with stable non-CF bronchiectasis. OPEP resulted in greater sputum expectoration than no treatment, but had equivalent benefits to other airway clearance techniques.[77]<br><br>Guidelines from the British Thoracic Society recommend considering oscillation devices in those with CF and non-CF bronchiectasis.[47] | The manufacturer's washing and replacement advice should be followed.<br><br>The following OPEP devices are listed in the Drug Tariff:<br><br>• Acapella® – estimated device lifetime six months.[79]<br>• Flutter® - several probably needed each year with regular use.[80]<br>• Lungflute® - replace reed about every two weeks.[81]<br>• Pari O-PEP – replace device at least once a year.[82]<br>• RC-Cornet® - replace silicone valve tube every six months.[83] All other components are guaranteed to perform as designed for a period of 12 months.[84] | Dependent on local pathways and whether prescribing is via primary or secondary care. |

| Drug Tariff grouping | Recommendation(s) | National guidance and evidence | Suggested alternatives/comments | Indicative annual saving |
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| Ostomy underwear | Not recommended for routine use; Specific ostomy underwear for general use is not needed. There is currently insufficient evidence to recommend routine use of support ostomy underwear for parastomal hernia prevention after stoma surgery.<br><br>Support ostomy underwear or support belts/girdles should be prescribed where they have been recommended by a specialist stoma nurse for managing parastomal hernias.[25]<br><br>Specialist stoma nurses may recommend support belts for the prevention of parastomal hernias in some individuals, e.g. those undertaking strenuous activities.[85]<br><br>Do not add to repeat prescribing systems. | There is limited evidence from three studies that prevention programmes including the use of abdominal support belts or garments after stoma surgery may reduce the incidence of parastomal hernias.[86] In two of the studies support belts were only used for heavy work, rather than worn routinely.[87] Abdominal exercises and education about parastomal hernias were also part of the preventative programmes, so it is not possible to determine the impact of the interventions individually. Further research on parastomal hernia prevention is needed.[86] | It has been noted that adherence to the wearing of hernia support garments can be poor. Education, along with correct measurement and fitting of garments by an appropriately trained practitioner may be important in improving adherence and reducing waste.[86] | Assuming a 30% reduction (by stopping prescribing ostomy underwear for general use, and prescribing products only after recommended by a specialist stoma nurse) £399,000 annually.<br><br>There could be a large variation in potential saving depending on current local practice. |

| Drug Tariff grouping | Recommendation(s) | National guidance and evidence | Suggested alternatives/comments | Indicative annual saving |
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| Pelvic toning devices | Not recommended; there is no evidence of additional benefit compared to undertaking pelvic floor exercises alone.<br><br>Those that wish to use pelvic toning devices may purchase them from a pharmacy or on-line. | Several NICE guidelines, including those on urinary incontinence in women, make recommendations about pelvic floor exercises.[88]<br><br>A small trial (n=40) investigated the use of the PelvicToner device to aid pelvic floor muscle training, compared with standard pelvic floor muscle training, in women with stress urinary incontinence. No significant difference between the groups regarding improvement in stress urinary incontinence was seen at 16 weeks in the per protocol analysis.[89]<br><br>No evidence for Kegel8® or Aquaflex® confirming additional benefits over pelvic floor exercises alone was located. | Pelvic toning devices are either egg or cone shaped devices that are inserted into the vagina to assist with pelvic floor exercises. They can be weighted devices (e.g. Kegel8® and Aquaflex®) or incorporate a hinge and spring mechanism to provide passive resistance (PelvicToner®).[71]<br><br>Several pelvic toning devices are available, but only three are listed in the Drug Tariff:<br>• PelvicToner®<br>• Kegel8®<br>• Aquaflex® | Assuming an 80% reduction in prescribing £19,000 annually. |

| Drug Tariff grouping | Recommendation(s) | National guidance and evidence | Suggested alternatives/comments | Indicative annual saving |
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| Plantar pressure offloading device | Ensure the use of plantar pressure offloading devices is part of a robust and clear local pathway for the prevention and management of diabetic foot problems.<br><br>Plantar pressure offloading devices should only be prescribed after individual assessment by an appropriately skilled practitioner. This is likely to be via a foot protection service or a multidisciplinary foot care service.<br><br>When deciding about offloading, the clinical assessment of the wound and the person's preference should be taken into account, and the devices with the lowest acquisition cost appropriate to the clinical circumstances should be used.[90]<br><br>Prescribable plantar pressure offloading devices are reusable and should not be added to repeat prescribing systems. | NICE advise that those with diabetic foot problems should be referred to a foot protection service or a multidisciplinary foot care service.<br><br>Foot care services may recommend offloading of plantar pressure for diabetic foot ulcer treatment, or where there is suspicion of acute Charcot arthropathy.<br><br>They may also consider the need for preventative use of specialist footwear and orthoses in those at moderate or high risk of developing a diabetic foot problem.[90]<br><br>Non-removable casts are more effective in healing diabetes related plantar foot ulcers than removable casts.[91] They are the preferred option, where clinically appropriate.[90,92]<br><br>Removable offloading devices may be needed in the following circumstances:<br>• Until casting can be provided.[90]<br>• Where it is more appropriate for the person's clinical or personal circumstances (e.g. where ischaemia or infection are present).[90,92] | The following plantar pressure offloading devices are listed in the Drug Tariff:<br>• BeneFoot® Medical Shoe<br>• Cellona® Shoe<br>• Kerraped® All Purpose Boot<br>• Kerraped® Plantar Ulcer Shoe System<br>• Liqua Care® Diabetic FlowGel Orthotics<br><br>Other types of removable plantar pressure offloading devices are also available, such as removable cast walkers.[92] However they are not listed in the Drug Tariff so cannot be provided via prescription. | Assuming a 10% reduction in prescribing (by ensuring local pathways govern appropriate use) £103,000 annually. |

| Drug Tariff grouping | Recommendation(s) | National guidance and evidence | Suggested alternatives/comments | Indicative annual saving |
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| Potassium hydroxide solution<br>(For treating molluscum contagiosum) | Not recommended in primary care; there is currently insufficient evidence of efficacy and a risk of side-effects.<br>The National Institute for Health and Care Excellence Clinical Knowledge Summary (NICE CKS) on molluscum contagiosum recommends giving reassurance that molluscum contagiosum is a self-limiting condition that usually resolves spontaneously within 18 months, together with advice to avoid sharing towels, clothing and baths, and to avoid scratching the lesions. Exclusion from school, gym or swimming is not necessary.[93]<br>There are some circumstances where specialist referral is indicated, and a specialist may consider the use of potassium hydroxide solution (see CKS for further information). | A Cochrane review of interventions for molluscum contagiosum included two small studies of topical potassium hydroxide solutions compared with saline (n=30 and n=10). Neither the individual studies nor the pooled data showed a statistically significant difference in clinical cure at 12 weeks.[94]<br>In 2014 the DTB considered the evidence for this treatment and similarly concluded that clinical trials have been small and have not shown a convincing effect. Prescribing was not recommended.[95]<br>Potassium hydroxide is caustic. Burning or stinging is the most common adverse effect. Other effects included erythema, itching, pain, erosion, crusting and hyperpigmentation.[95] | MolluDab® 5% and Mollutrex® 5% are listed in the Drug Tariff.<br>In their patient information leaflet on molluscum contagiusum the British Association of Dermatologists state that it is almost always better to avoid painful non-essential treatment in children because of the risk of hurting the child and making them frightened of doctors.[96]<br>Information for patients can also be found on NHS Choices at http://www.nhs.uk/Conditions/molluscum-contagiosum/Pages/Introduction.aspx | Assuming an 80% reduction in prescribing £79,000 annually. |

| Drug Tariff grouping | Recommendation(s) | National guidance and evidence | Suggested alternatives/comments | Indicative annual saving |
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| Silk garments | Not recommended; there is currently insufficient evidence to recommend the routine use of silk garments.<br><br>CCGs may wish to consider prescribing in exceptional circumstances through assessment by a dermatologist. For such cases, CCGs should agree a process for prescribing locally (individual funding request, prior approval etc).<br><br>Where prescribing is considered appropriate, provide the minimum quantity of garments necessary to meet people's needs. Do not add to repeat prescribing systems.[97]<br><br>A PrescQIPP bulletin on Silk and antimicrobial garments will be published in 2017.[97] | Evidence from randomised controlled trials supporting the use of silk garments is currently limited.[98]<br><br>A systematic review of silk garments in atopic dermatitis in 2012 concluded that the evidence of effectiveness is weak and of low quality.[99]<br><br>NICE CG57 states that whole-body wet wrap therapy and whole-body dry bandages (including tubular bandages and garments) should not be used as first-line treatment for atopic eczema in children. They should only be initiated by a healthcare professional trained in their use.[100] | Elasticated viscose stockinette (tubular and garments) are available for use in managing skin conditions or for dressing retention. See PrescQIPP bulletin 148 on Support bandages and stockinette for further information (www.prescqipp.info/resources/category/322-wound-care-support-bandages-and-stockinette).<br><br>Both silk and viscose garments should be washed and reused in accordance with the manufacturer's instructions. | Assuming an 80% reduction in prescribing (reducing wastage and inappropriate prescribing) £1.1 million annually. |

## Summary

A number of medical devices are listed in part IX –Appliances of the Drug Tariff, and can therefore be prescribed on FP10. In England and Wales the NHS spends in excess of £39 million annually on such items (ePACT July to September 2016). Like medicines, medical devices should be subject to local formulary recommendations. Reviewing the prescribing of medical devices to ensure that they are prescribed appropriately, only where there is reasonable evidence to support their use and cost-effectively has the potential to release significant savings of approximately £10.8 million to the NHS annually. This equates to £17,733 per 100,000 patients.

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## Additional PrescQIPP resources

Data pack

Available here: https://www.prescqipp.info/resources/category/353-medical-devices-drop-list

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**Contact help@prescqipp.info with any queries or comments related to the content of this document.**

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