Bedfordshire, Luton and Milton Keynes Health and Care Partnership

NHS

BLMK ICB Area Prescribing Committee

Recommendations for medical devices

Approved for use: July 2023

Date of review: July 2026

Belladonna adhesive plaster DNP
• Not recommended; there is insufficient evidence to recommend the use of belladonna adhesive plasters. • Prescribing on FP10 should be discontinued. • Those prescribed belladonna adhesive plasters should have their therapy reviewed. • Consider recommending or prescribing an effective alternative treatment if appropriate. • 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. The recommendations are consistent with national recommendation on topical rubefacients, which have also been used topically for pain relief as counter-irritants. However, evidence supporting their use is also lacking. NICE state that rubefacients should not be offered for treating osteoarthritis. Guidance from NHS England classifies rubefacients as items which should not be routinely prescribed in primary care. Patient information about managing back pain, sciatica and neck pain can be found at: https://www.nhs.uk/conditions/back-pain/ https://www.nhs.uk/conditions/sciatica/ https://www.nhs.uk/conditions/neck-painand-stiff-neck/
Cycloidal vibration accessories (Vibro-Pulse®) DNP
Not recommended; there is currently insufficient evidence to recommend the use of cycloidal vibration therapy for cellulitis, venous leg ulcers and lower limb oedema.

Stoma deodorants (Not for routine use)

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.

It is recognised that 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.

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.

Do not add to repeat prescribing systems.

Requests for prescriptions for items seen in magazines or received as samples should not be processed unless an individual review has been undertaken by a stoma care nurse and the product has been assessed as being clinically indicated

Dry mouth products SpA

To be advised by specialist only where simple measures have failed to provide relief. Products can also be purchased from a pharmacy; most cost the same or less than a prescription charge.

Simple measures for managing dry mouth include:

- Regular sips of water
- Sucking on ice cubes or ice lollies
- Sucking sugar-free sweets or chewing sugarfree gum
- Applying petroleum jelly on the lips if they are dry. However, if a person is on oxygen apply a water-soluble lubricant (e.g. example K-Y Jelly®).
- Avoiding alcohol, caffeine and smoking; all make dry mouth symptoms worse.
- Good oral hygiene to avoid dental problems is essential.

Where known, address the underlying cause (including drug causes) where possible/clinically appropriate.

Initiate dry mouth products as a trial and discontinue if no perceived benefit.

Some dry mouth products are borderline substances (for those with dry mouth due to radiotherapy or sicca syndrome – endorse 'ACBS').

In dentate people, artificial saliva should:

- Be of neutral pH (acidic pH can cause dental caries).
- Ideally contain fluoride (otherwise a daily fluoride mouthwash is also needed).

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.

Electrical stimulating wound device (Accel-Heal) DNP

Not recommended; there is currently insufficient evidence to recommend the use of the Accel-Heal® electrical stimulating device.

Hypertonic sodium chloride for inhalation (3%, 6% and 7%) SpA

Use outside of hospital may be considered for those with cystic fibrosis (CF) or non-CF bronchiectasis, where recommended and initiated by a specialist.

Initiation (with a bronchoconstriction trial) should be done by an appropriate professional to ensure safety and suitability for the individual.

Cystic Fibrosis: NICE recommend considering nebulised hypertonic saline as a 2nd line mucoactive agent in those with clinical evidence of lung disease.

A Cochrane review on use in non-CF bronchiectasis was unable to draw firm conclusions from the data.

BTS guidance (2018) on the management of bronchiectasis in adults states that the evidence for hypertonic saline suggests that it may improve QoL outcomes and sputum clearance in individuals with bronchiectasis, however it is unclear if this benefit is over and above that of isotonic saline.

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.

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.

Query prescriptions for hypertonic saline as an unlicensed special rather than the commercially available preparations, which are preferable where suitable.

Insert for female stress incontinence DNP

Not recommended; there is currently insufficient evidence to recommend the use of these devices for female stress incontinence. NICE do not recommend their routine use. Side-effects reported in clinical trials include urinary tract infections, vaginal bleeding and discomfort. NICE advise that women with stress or mixed UI should be offered a trial of supervised pelvic floor muscle training of at least 3 months' duration as first-line treatment.

NICE guidance on urinary incontinence (UI) in women recommend that intravaginal or intraurethral devices should not be used for the routine management of UI. They state that women should not be advised to consider such devices other than for occasional use (e.g. during physical exercise).

Inspiratory muscle training devices RED

Not recommended for routine use, but inspiratory muscle training may be considered in those with COPD, non-CF bronchiectasis and upper spinal cord injuries Inspiratory muscle training should be provided only after individual assessment by an appropriately skilled therapist. Treatment should not be initiated by GPs or other non-specialists Some devices are promoted for fitness/ sports use. In these circumstances the device should be purchased rather than prescribed.
Nasal douches (Sterimar®, Aqua Maris®) DNP
Not recommended for prescribing. 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. It should be explained that there is not enough evidence to show they relieve nasal congestion and recommend their use. For chronic rhinosinusitis: large volume saline douches are thought to be more effective than saline nasal sprays. Health care professionals recommending nasal douching (for over the counter purchase) should ensure they are familiar with the procedure so that they can advise people of an appropriate and safe method to use. Information for health care professionals on nasal douching is available on the British Society for Allergy and Clinical Immunology (BSACI) website: see SOP on nasal douching. The document above from the BSACI also notes that using a proprietary product for children under twelve years or adults that are unsure may make nasal douching more acceptable and safer where there is uncertainty about mixing up a homemade solution
Needle-free insulin delivery system (Not for routine use)

Not routinely recommended unless there is a confirmed diagnosis of needle phobia which would result in the person not injecting insulin. 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
Oscillating positive expiratory pressure device (OPEP device) RED **(including specialist respiratory service (AIRS))**
Recommended as an option under physiotherapy in the NICE COPD guideline. People with COPD who have excessive sputum should be taught how to use positive expiratory devices Recommended for consideration when selecting an appropriate airway clearance technique (ACT) for those with CF and non-CF bronchiectasis (NB: the supporting evidence is much more limited and considered to be low quality for non-CF bronchiectasis). OPEP treatment should be provided only after individual assessment by an appropriately skilled therapist. Treatment should not be initiated by GPs or other non-specialists. Although several devices may be required per year, they should not be added to repeat prescribing systems.
Ostomy underwear/support belts
Parastomal hernia prevention (Not recommended for routine use) Not recommended for routine prescribing Specific ostomy underwear is not generally necessary, as high waisted support underwear (with Lycra®) is readily available from high-street stores or can be purchased from specialist ostomy manufacturers if preferred. The exception is where a clinical need is identified, e.g. • Where a stoma nurse recommends a garment with a higher level of support (2/3) because of risk factors present.

- Where the stoma nurse or GP feel that prescribing of a lightweight support garment is necessary for comfort and discretion due to significant psychosocial impact affecting the person's wellbeing.

For prevention, the Association of Stoma Care Nurses (ASCN) recommend that stoma nurses identify predisposing factors for parastomal hernias and provide education and prevention advice, including:

- Hernia prevention exercise information.
- Advice to purchase lightweight support underwear from a high street store or obtain a prescribed garment if necessary.

Those at higher risk should be advised of how to reduce their risk where possible (e.g. smoking/weight/lifestyle). A higher level of support garment could be considered.

Parastomal hernia management SpIS

Support ostomy underwear/ garments should be prescribed where recommended by a stoma nurse. Specialist is responsible for arranging measuring and fitting and all details regarding type and size of support must be specified.

Do not add to repeat prescribing systems.

Support wear should not be viewed as a standalone intervention. The limited supporting evidence used a package of hernia prevention measures, which also included education, core exercises and regular follow-up.

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.

Where prescribing is appropriate, suggested maximum quantities are:

- three belts per year
- three girdles per year
- six pairs of briefs or boxers per year.

Pelvic toning devices DNP

Not recommended for prescribing; there is no evidence of additional benefit compared to undertaking pelvic floor exercises alone. Those that wish to use pelvic toning devices may purchase them from a pharmacy or on-line.
Plantar pressure offloading devices
Prevention and management of diabetic foot problems 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. 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. 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. Foot care services may recommend offloading of plantar pressure for diabetic foot ulcer treatment, or where there is suspicion of acute Charcot arthropathy. 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. Non-removable casts are more effective in healing diabetes related plantar foot ulcers than removable casts. They are the preferred option, where clinically appropriate. Removable offloading devices may be needed in the following circumstances: Until casting can be provided. Where it is more appropriate for the person's clinical or personal circumstances (e.g. where ischaemia or infection are present). Kerraped® Plantar Ulcer Shoe System/Cellona shoes may be required for patients with foot ulcer dressings and should be recommended for prescribing by DNs/TVNs.

RED The true off-loading devices are supplied podiatry.

SpA Shoes used for leg ulcers are prescribed – not available on NHS supplies.

Potassium hydroxide solution for treating molluscum contagiosum (MolluDab® 5% and Molutrex® 5%) (Not for routine use)

Molluscum contagiosum does not usually require treatment in immunocompetent people.

Unless there is an indication for urgent referral, NICE-CKS recommend giving reassurance that molluscum contagiosum is a self-limiting condition that usually resolves spontaneously within 18 months in otherwise healthy individuals. Advice to avoid sharing towels, clothing and baths, and to avoid scratching the lesions should also be provided. Exclusion from school, gym or swimming is not necessary.

There are some circumstances where specialist referral is indicated; including where lesions continue to be troublesome, are extensive or where there is diagnostic uncertainty. Urgent referral should be considered for extensive problematic lesions in children, a person is known to be immunocompromised, eyelid margin or ocular involvement, HIV positive patients, or adults with anogenital lesions.

See the NICE CKS Summary for further information.

A specialist may consider the use of potassium hydroxide solution, but other treatment options may be available.

Information for patients on molluscum contagiosum can be found on the NHS website.

The British Association of Dermatologists produce a range of patient information leaflets, including one, on molluscum contagiosum.

Pulsed electromagnetic stimulator (ActiPatch®) DNP

Not recommended for routine prescribing; evidence for ActiPatch® is yet to be evaluated by a national body.

Silk garments DermaSilk®, DreamSkin®, SkinniesTM silk and Skintoskin® DNP
Not recommended - there is currently insufficient evidence to recommend the routine use of silk garments.
Rectal irrigation systems
Faecal incontinence: SpIS **In adults:** NICE advise considering specialised management in those that continue to have episodes of faecal incontinence after initial management. This may involve referral to a specialist continence service and rectal irrigation may be considered. Peristeen® rectal irrigation system: NICE state that the evidence supports the case for adopting its use in people with bowel dysfunction. **In children with bowel dysfunction**, NICE state that despite limitations in the published evidence, anecdotal experience suggests that Peristeen® may offer significant benefits. Rectal irrigation is a specialist management option. Where treatment is considered appropriate, it should be offered as part of a supportive bowel care programme. People using rectal irrigation should have training and ongoing support from a specialist health care professional. Rectal irrigation may not be suitable for all people with bowel dysfunction and should only be considered 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. 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) it may be appropriate to add only items that need to be ordered on a monthly basis to the repeat prescribing system.

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 person was irrigating every other day.

Rectal catheters are single use and the water bag needs changing every 15 uses so the average patient will need at least one accessory unit pack per month.

For those taking laxatives before starting irrigation, it is prudent to continue these in the usual dose until irrigation is established. They may subsequently be able to gradually stop taking laxatives.

Constipation in children: (**Not recommended)**

NICE guidance does not currently include rectal irrigation as a treatment option. NICE state that there is uncertainty around the safety and efficacy of rectal irrigation in this population. After NICE published guidance on Peristeen®, they undertook surveillance of the clinical guideline on managing constipation in children (CG99), as the Peristeen® guidance could cover this population. NICE decided not to update CG99 at present, as the evidence on rectal irrigation had not substantially progressed since it was last checked, although they did acknowledge that this is an area of research showing promising results for the treatment of constipation in this population.

Safety needles and safety lancets (Not for routine use)

Not recommended for routine prescribing: Safety needles and lancets (also known as ‘safer sharps’) are primarily for the benefit of healthcare workers to avoid needle stick injury, rather than for use by patients for self administration. Therefore they should not routinely be prescribed by GPs on FP10s

There may be exceptions where prescribing is appropriate to ensure medication can be given/monitored safely where a person is not able to self administer.

To ensure that insulin can be given safely where a patient is not able to self-administer, NICE advise that staff, and where appropriate, patients who use pen devices, should be routinely provided with safety needles and access to equipment capable of safely removing and disposing of used insulin pen needles. It is essential that users are trained to use safety needles correctly. Community Trusts are responsible for supply of safety needles to their staff where required.

Waterproof limb covers (LimbO®, Seal-Tight® and BUDDY®)
Not generally recommended for prescribing; people should be advised to purchase an appropriate product if required. **Protection of PICC lines** RED **Wound care (e.g. bandaged leg / foot ulcers)** – Not for routine use **Casts on a fractured limb:** Not generally recommended for prescribing; people should be advised to purchase an appropriate product if required.
Adjunctive treatment of hypertension e.g. Resperate® DNP
Not recommended
Vaginal dilators or trainers e.g. Femmax®, Amielle Care®, and Amieille Comfort® SpA
Recommended for women following vaginal reconstruction surgery or following pelvic radiotherapy when recommended by an appropriate Secondary Care Specialist. (Local supply recommendation – GP to prescribe on recommendation of the Specialist).
Jaw rehabilitation device, e.g. Therabite RED

Recommended for patients following head and neck radiotherapy or head and neck surgery
Vacuum pumps for erectile dysfunction (ED) RED
Recommended. For Bedfordshire and Luton the supply and training would be in Secondary Care. For Milton Keynes, Vacuum pumps for ED are usually given by Northampton hospital from the ED clinic.
Lymphoedema garments (TVN and oncology use) RED
Should only be prescribed after a full assessment of the individual by an appropriately trained practitioner All reasonable steps to ensure the correct items are ordered should be undertaken. If uncertain; confirm items with the lymphoedema service before they are ordered, to avoid wastage. Provide two of each garment (one to wear, one to wash). Replace every three to six months, or when they begin to lose elasticity. The person should be re-measured first. Lymphoedema garments are often used in the long-term phase of lymphoedema management, usually following a period of intensive therapy (which may include multilayer lymphoedema bandaging). They are also sometimes used as part of the initial treatment, or for prophylaxis. **Lymphoedema as a complication of advanced breast** cancer: NICE advise considering multilayer lymphoedema bandaging for volume reduction as a first treatment option before compression hosiery. People should be provided with at least two suitable compression garments of the appropriate class and size, when their use commences. A choice of fabrics and colours are be available. **Liposuction for chronic lymphoedema guidance**: NICE note the role of compression garments in the conservative treatment of lymphoedema. Custom-made compression garments also need to be worn after this procedure

SpIS **For re-supply**: GPs can be asked to re-supply garments provided patients were re-measured (by the lymphoedema service) as appropriate and clear advice on products to be prescribed provided to GPs.

References and superseded documents:

- The above recommendations are adapted from PrescQipp Bulletin 235 PROP List v2.0 2021

Other previous documents considered in the review:

- EoE PAC Recommendations – Evidence review and commissioning recommendations for specified medical devices (v3 July 2018)
- JPC Medical Devices DROP List Bulletin 249 (Updated May 2019) – To be retired
- PrescQipp Bulletin B160 Feb 2017 – Silk and antimicrobial garments
- PrescQipp Bulletin 192: Lymphoedema garments April 2019