

# Medical Devices – Commissioning Position

## General principles

The World Health Organisation define a medical device as, an article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved 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. All medical devices on the UK market have to have received a CE mark.

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.

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.

- Products included in part IX – Appliances of the Drug Tariff should be subject to local formulary restrictions in the same way that medicines are and go through the APC formulary approval process if they have in impact on the primary care prescribing budget with the exception of:
  - Part IXB – incontinence appliances – local approved list of products managed separately.
  - Part IXC – stoma appliances – local approved list of products managed separately.
  - Dressings, catheters, hosiery - local approved list of products managed separately.
- 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 the North Yorkshire and York formulary should not be routinely prescribed on FP10 prescription, and advice should be sought from the NY&Y medicines management team when considering prescribing.
- 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.
- 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.

Device	APC Recommendation	RAG Status	Cost excluding VAT (dm&d)	Rationale
OPEP [Oscillating positive expiratory pressure] devices (e.g. Flutter® and Acapella®)	For initiation by a Specialist Physiotherapist. Training and the first device will be supplied by the Hospital. These devices can be prescribed on FP10 prescription. Primary care to prescribe replacement devices only in the event of breakage or when the device starts to "fail".	Amber	Flutter® - £40.50 Acapella® - £40.50 RC Cornet £39.95	The British Thoracic Society (BTS) Guideline for Bronchiectasis in Adults (January 2019) recommends offering active cycle of breathing techniques or oscillating positive expiratory pressure to individuals with bronchiectasis.
Resperate®	Not commissioned as British Hypertensive Society state that there is not sufficient evidence for this equipment to be recommended.	Black	£132.00	Efficacy of the RESPeRATE Device for Lowering Blood Pressure Statement from the British Hypertension Society April 2012 states that there is not sufficient evidence for this equipment to be recommended.
Needle free insulin devices (Insujet™ and InJex™)	Not commissioned. Evidence indicates devices being associated with pain and bruising. Local diabetes specialist opinion does not support use.	Black	Costs are dependent on system and how often they are used.	NICE recommend that adults with type 1 diabetes who have visual or psychological needs should be provided with needle-free systems that they can use independently for accurate dosing. However, there is only limited evidence from pharmacokinetic studies to support their use.
Vaginal Dilators or Trainers (Femmax®, Amielle Care®, Amielle Comfort®)	Not recommended for routine use due to limited published clinical evidence. These products can be purchased OTC.	Black	Femmax® - £16.48 Amielle Care® - £28.34 Amielle Comfort® - £37.79	The British Association Sexual Health and HIV (BASHH) recommend the use of vaginal trainers in the treatment of localised provoked vulvodynia (vestibulodynia). (Evidence III b)  Ref: 2014 UK national guideline on the management of vulval conditions
Potassium hydroxide solution	Not commissioned for molluscum contagiosum.	Black	MolluDab® - £14.78 Molutrex® - £10.51	There is limited evidence for the use of potassium hydroxide solution. The natural resolution of molluscum contagiosum remains a strong method for dealing with the condition.  Ref: The PrescQIPP PROP-List (Products to Review for Optimised Prescribing) 2021

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Pelvic toning devices	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.	Black	Aquaflex® - £13.95 Kegel8® - £15.00 Pelvic Toner® - £15.00	A Cochrane review investigating weighted vaginal cones for UI found some evidence, from mainly small trials, that cones are better than no active treatment in women with stress UI. However, no clear differences were evident when vaginal cones/weights were compared with other treatments, such as pelvic floor muscle training alone (i.e. exercises without the devices).  Ref: The PrescQIPP PROP-List (Products to Review for Optimised Prescribing) 2021
Jaw rehabilitation device (TheraBite®)	Not recommend due poor evidence base.	Black	Adult device - £239.19 Replacement pads x 4 - £11.17	A small randomised study (n=71) found that the Therabite device was no more effective than wooden spatulas for the treatment of trismus in patients who had received radiotherapy.  Ref: GMMMG DNP Listing September 2018
ActiPatch®	Not routinely commissioned	Black	£13.95	In a small RCT in patients with osteoarthritis of the knee, one month of treatment with the ActiPatch® device was associated with a reduction in pain compared with placebo. Other evidence to support its use is restricted to registry studies and unpublished trial findings.  Ref: The PrescQIPP PROP-List (Products to Review for Optimised Prescribing) 2021 and RDTC Evaluation report: ActiPatch for the management of localised musculoskeletal pain (January 2019)
Spacers	Included in formulary as per BTS guidance.	Green	AeroChamber Plus® - £5.21 Volumatic® - £3.88 AeroChamber Plus Flow-Vu® - £5.22	The British Thoracic Society recommends in children, a pMDI and spacer as the preferred method of delivery of $\beta$ 2 agonists and inhaled corticosteroids. In addition a pMDI and spacer is at least as good as a nebuliser at treating mild and moderate asthma attacks in children and adults.  Ref: BTS/Sign Asthma Guidelines 2019
Eye drop compliance aids	Not routinely commissioned as can be purchased OTC Many similar devices are already not available to be prescribed on the NHS.	Black	ComplEye® - £2.00 Opticare® and Opticare Arthro® - £4.95	ComplEye® - For use with Hylotears and Hyloforte bottles only. Opticare® can be used for 2.5-15mL eye drop bottles. Other devices that are not available to be prescribed on the NHS include; Autodrop®, Autosqueeze®, Drop Aid®, Eyot – Thea Eyot®, Eyot – Alcon Eyot®.

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				Ref: Drug Tariff July 2023
Silk Garments	Not routinely commissioned	Black	Depending on preparation and size. Varies from £10-£80	The CLOTHES trial found that the addition of silk garments to standard atopic eczema care is unlikely to improve atopic eczema severity. Or to be cost-effective compared with standard care alone, for children with moderate or severe AE.  Ref: NHS Items which should not routinely be prescribed in primary care: Guidance for CCGs Version 2, June 2019
Transanal irrigation	Approved and used currently when all other treatment options for chronic constipation been exhausted.	Amber SI	Costs are dependent on system and how often they are used. See below for more information.	One small (n=87) 10 week randomised trial which had a small risk of bias. Participants used the Peristeen® system daily or every other day in addition to conservative bowel care or conservative bowel care alone. Statistically significant constipation, neurogenic bowel disease and faecal incontinence sores were found in the TAI group compared to the conservative group. TAI also resulted in a significantly reduced time for bowel care and increased satisfaction.
Stoma deodorants	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.	Black	LiMone deodorant spray (1x50ml) - £5.51  Adapt® lubricating deodorant (1x236ml) - £10.35	No odour should be apparent expect from when the stoma bag is emptied. It is recommended that patients are referred for a review if there is an odour at times other than changing or emptying. Household air fresheners can be used to mask odours when emptying bags.  Ref: The PrescQIPP PROP-List (Products to Review for Optimised Prescribing) 2021
Dry mouth products	AS Saliva Orthana® spray and Biotene Oralbalance® gel are included in formulary. Glandosane® is a non-formulary product.	Green	AS Saliva Orthana® (1x50ml) - £4.92 Biotene Oralbalance® gel (1x50g) - £5.30	No strong evidence was found to support the efficacy of dry mouth products. Dry mouth products can be bought OTC from pharmacies without a prescription.  Ref: The PrescQIPP PROP-List (Products to Review for Optimised Prescribing) 2021

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Ear wax softening medical devices	Self-treatment should be with olive oil or sodium bicarbonate 5% (OTC) ear drops used twice daily for 2 weeks. Agreed should not routinely prescribed on NHS prescription.	Green	Olive Oil ear drops (1x10ml) – £1.42 Sodium Bicarbonate ear drops (1x10ml) - £1.25	Using drops of any type appears to be better than no treatment. However there is no evidence to suggest one type of treatment is more effective than another. Drops are all available from community pharmacies without a prescription and may reduce the need for mechanical removal of wax.  Ref: NHS England - Conditions for which over the counter items should not routinely be prescribed in primary care: Guidance for CCGs. March 2018
Head Lice Treatment Devices	Agreed not should not routinely be prescribed on NHS prescription as per current CCG policy. Available OTC. Agreed may be circumstances when appropriate to prescribe in hospital.	Red	Full Marks solution (1x100ml) - £3.47  Hedrin® Once spray gel (1x100ml) - £6.83  Linicin Lotion (1x100ml) - £5.49	Hedrin 4% lotion and Derbac M liquid® are licensed medicines. Other products are classed as devices. NICE CKS recommends the following if a head louse is found; dimeticone 4% gel, lotion, or spray (Hedrin® Once or Lotion; Chemists' Own® Head Lice Spray); dimeticone 92% spray (NYDA®); dimeticone > 95% lotion (Linicin® Lotion); isopropyl myristate and cyclomethicone solution (Full Marks Solution®); and isopropyl myristate and isopropyl alcohol aerosol (Vamousse® Head Lice Treatment). These are available OTC products from community pharmacies.  Ref: NHS England - Conditions for which over the counter items should not routinely be prescribed in primary care: Guidance for CCGs. March 2018
IQoro® device for stroke-related dysphagia or hiatus hernia	Recommended not be prescribed on prescription based on quality of evidence base presented in NICE Medtech briefings for IQoro®.	Black	The cost of a single IQoro device is £116 (excluding VAT)	Ref: IQoro for hiatus hernia, NICE Medtech innovation briefing [MIB176] Published: 06 March 2019 IQoro for stroke-related dysphagia, NICE Medtech innovation briefing [MIB175] Published: 06 March 2019