

Medical devices: Evidence review and commissioning recommendations for specified medical devices

Basildon and Brentwood CCG and Thurrock CCG recommendations:

To support the East of England Priorities Advisory Committee (PAC) policy statement and recommendations (See attachment)

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The East of England
**Priorities Advisory
Committee**

A function of the **PrescQIPP**
Programme

GUIDANCE STATEMENT

Medical devices: Evidence review and commissioning recommendations for specified medical devices

PAC recommendation

- Medical devices listed in the Drug Tariff (DT) are subject to local formulary restrictions.
- 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 prior to prescribing.
- Table 1 lists commissioning recommendations for specified medical devices. Decisions on patient pathways and prescribing responsibility should be agreed locally.
- Local patient pathways should ensure that initial prescribing of a medical device is accompanied by appropriate instruction and counselling.

Introduction

A medical device is defined as:¹

Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for

diagnostic and/or therapeutic purposes and 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.

A range of medical devices are available, some of which are listed in Drug Tariff (DT) and therefore could be prescribed on FP10 prescription.

Formulary restrictions apply equally to the prescribing of medical devices as they do to drugs.

This review looks at the evidence to support the use of selected devices and makes commissioning recommendations for CCGs to consider for local adoption. Patient pathways and prescribing responsibility are to be agreed locally.

Advice should be sought from the CCG Medicines management team prior to prescribing of any device on an FP10.

Summary of commissioning recommendations

Table 1: Summary of PAC recommendations for the commissioning of specified medical devices

Device	PAC commissioning recommendations
<ul style="list-style-type: none"> Oscillating positive expiratory pressure (OPEP) device, e.g. Flutter® and Acapella® (listed in DT), Cornet® (not listed in DT). 	Recommended for cystic fibrosis patients only, where PEP alone has proved ineffective.
<ul style="list-style-type: none"> Resperate® - Adjunctive treatment of hypertension 	Not recommended as the British Hypertension Society consider that the small effect over short durations do not provide sufficient evidence for this equipment to be recommended.
<ul style="list-style-type: none"> Needle free insulin devices, e.g. Insujet® and Injex®. 	Not routinely recommended unless there is a confirmed diagnosis of needle phobia which would result in the patient not injecting insulin.
<ul style="list-style-type: none"> Vacuum pumps for erectile dysfunction (ED) 	Recommended - arrangements for supply and appropriate training should be agreed locally.
<ul style="list-style-type: none"> Normal saline nasal sprays, e.g. Sterimar®, Aqua Maris® 	Not recommended.
<ul style="list-style-type: none"> Vaginal dilators or trainers, e.g. Femmax®, Ameille Care® and Ameille Comfort® 	Recommended for women following vaginal reconstruction surgery or following pelvic radiotherapy when recommended by an appropriate Secondary Care Specialist.
<ul style="list-style-type: none"> Potassium hydroxide solution, e.g. MolluDab® 5%, Molutrex® 5% 	Not recommended as this is a limited clinical value treatment. Patients may purchase from a pharmacy or on-line directly from the manufacturers if wanted.
<ul style="list-style-type: none"> Jaw rehabilitation device, e.g. Therabite® 	Recommended for patients following head and neck radiotherapy or head and neck surgery when recommended by an appropriate Secondary Care Specialist.
<ul style="list-style-type: none"> Pelvic toning devices, e.g. PelvicToner® 	Not recommended as there is no evidence of additional benefit compared to undertaking pelvic floor exercises alone. Patients may purchase from a pharmacy or on-line if wanted.

Evidence summary

1. Oscillatory positive expiratory pressure (OPEP) devices

Chest Physiotherapy (CPT) is an essential part of the management of cystic fibrosis (CF).^{2,3}

The amount of treatment needed depends on the individual and a number of airways clearance techniques (ACT) are currently available.^{2,3} These include:

- **Active cycle breathing techniques (ACBT)** - breathing control, thoracic expansion exercises, forced expiration technique.
- Positioning.
- Percussion and vibration.
- Autogenic drainage.
- **High frequency chest wall oscillation (HFCWO)** - also known as vest therapy as it uses a vest to externally vibrate the chest wall and lungs.
- **Positive expiratory pressure (PEP)** - uses device which apply a back pressure as the patient breathes out, which helps open up the airways and move the secretions.
- **Oscillating positive expiratory pressure** these devices combine vibration with PEP.

Oscillatory positive expiratory pressure devices including the Flutter®, Acapella® and Cornet® have been advocated as a more effective alternative to CPT for patients with medical conditions where there is excessive production of mucus and/or where mucus clearance is reduced, such as CF and bronchiectasis^{3, 4}.

These handheld devices generally consist of a steel ball in a plastic holder that either resembles a smoker's pipe or a spacer device. Exhaling into the device causes the steel ball to oscillate and vibrate in the casing. The resulting vibrations that are set up are thought to travel back into the lungs, vibrating the walls of the lungs and encouraging loosening of mucus. This then facilitates clearance of mucus by coughing. It is normally used for five to 15 minutes at a time, twice daily.³

The Flutter® and the Acapella® devices are listed in the Drug Tariff and cost £40.50. Cost of purchase by a patient would be higher as it would involve the addition of VAT. A third device called the RC Cornet® is not currently listed in the Drug Tariff. All three devices are available to purchase directly from the manufacturers. More details can be found on the manufacturers' respective websites:

Flutter®: <http://www.clement-clarke.com/>

Acapella®: <http://www.smiths-medical.com/catalog/bronchial-hygiene/acapella/acapella.html>

RC-Cornet®: http://www.curaplex.com/rc_cornet.asp

It is unclear how long an oscillating PEP device lasts and several would probably be needed each year with regular use.⁴

Evidence

There is limited evidence in relation to the oscillating PEP devices particularly in comparison to other ACTs. No data have been published on long term clinical outcomes. However, overall there is a paucity of well controlled long term studies of all ACTs in CF patients and more studies are required to confirm the evidence base and place in therapy of all ACTs in relation to both CF and non CF patients.

Guidelines from the British Thoracic Society support the teaching of an ACT to patients with CF and have confirmed that no ACT technique has been demonstrated to be superior to another, with overall choice of ACT being decided by the patient and their physiotherapist.^{2,3} In addition, The International Physiotherapy Group for Cystic Fibrosis recommends a number of ACTs; including ACBT, PEP, oscillating PEP, autogenic drainage, and postural drainage and percussion.⁶ A recent report has suggested that 22.8% of CF patients who require an airways clearance technique are using oscillating PEP with 28.1% using forced expiratory techniques and 15% using exercise.⁷

A Cochrane review, originally published in 2009 and updated in 2014 included 1050 CF patients' in 35 trials.^{4,8} The trial lengths varied from one week to one year and the device studied was variable. Furthermore data were not published in sufficient detail in most of these studies, so meta-analysis was limited.^{4,8}

Forced expiratory volume in one second was the most frequently measured outcome however only one long-term study (seven months) compared oscillatory devices with either conventional physiotherapy or breathing techniques and found statistically significant differences in some lung function parameters in favour of oscillating devices.

One study identified an increase in frequency of exacerbations requiring antibiotics whilst using high frequency chest wall oscillation when compared to positive expiratory pressure.^{4,8} There were some small but significant changes in secondary outcome variables such as sputum volume or weight, but not wholly in favour of oscillating devices. Participant satisfaction was reported in 15 studies but this was not specifically in favour of an oscillating device, as some participants preferred breathing techniques or techniques used prior to the study interventions.^{4,8} The review authors concluded that there was no clear evidence that oscillation was a more or less effective intervention overall than other forms of physiotherapy; furthermore there was no evidence that one device is superior to another.^{4,8}

Although the evidence is weak, feedback from East of England clinicians has indicated that there is a place for using OPEP devices for cystic fibrosis patients where PEP alone has proved ineffective

There is very limited evidence of benefit for patients with non CF related bronchiectasis.

A randomised trial of 17 patients with bronchiectasis compared ACBT for mucus clearance with the Flutter device for four weeks. No significant differences between the treatments were identified in lung function, health status measured by questionnaire, sputum weight or breathlessness, although 11 of the 17 patients said they preferred the Flutter device.^{4,9}

A systematic review, involving seven studies and a total of 146 patients, which assessed oscillating PEP therapy and other ACT therapies reported that oscillating PEP resulted in greater sputum expectoration than no treatment, but had equivalent benefits to other assisted techniques. Oscillating PEP had a similar effect on lung volumes, gas exchange and breathlessness and improved disease specific and cough related QoL scores, but did not show an improvement in exacerbation rates compared to other ACTs.¹⁰

Guidelines produced by the British Thoracic Society regarding non-cystic fibrosis bronchiectasis recommend that oscillation devices should be considered for use with postural drainage and forced expiration when helping patients develop effective mucus clearance techniques.¹¹

2. Resperate

This electronic device uses device-guided breathing to reduce blood pressure.¹² It produces musical tones that encourage a reduction in breathing rate (particularly exhalation rate), which after some training produces a decrease in blood pressure. It is thought to utilise a physiological mechanism that decreases sympathetic nervous system activity and sensitises arterial and cardiopulmonary baroreceptors, resulting in an increase in parasympathetic activity and consequent reduction of blood pressure. According to the manufacturer, respiratory rate needs to be decreased to 10 breaths/minute to be effective at lowering blood pressure. Use of the device is advised for 15 minutes a day, it is suggested that reduction in blood pressure is related to time spent on slow breathing. The rechargeable electronic device is accompanied by ear phones and a waist band that is used to detect respiratory rate.

The current price listed in the Drug Tariff is £1,325. More details can be found on the manufacturer's website at www.resperate.co.uk

Evidence

A systematic review of studies with the device was published in 2012 which identified 494 hypertensive patients in eight studies from three countries. Seven studies compared the Resperate® with another electronic musical device or standard BP monitoring unit, one study compared the device with 'usual care'.^{12,13}

The length of trials varied between four and nine weeks. Meta-analysis of the results found a small decrease in systolic and diastolic BP: change in systolic BP was -2.46mm Hg (95% CI -4.74 to -0.18, P=0.03) and diastolic BP -2.22mmHg (95% CI -3.74 to -0.66, P=0.005). There was no overall effect on resting heart rate. Blinding in the trials was not possible, so the authors of the meta-analysis carried out a sensitivity analysis which excluded all trials sponsored by the manufacturer. This left three trials with a total of 100 patients. Meta-analysis of this data found no significant effect on either systolic or diastolic blood pressure. The authors conclude that longer term independent trials of the device are needed to investigate this intervention further.^{12,13}

No long term data is available on efficacy of the device on outcomes for people who use the device instead of conventional therapy. There is no data for patients who do not continually use the device for 15 minutes daily.^{12,13}

The British Hypertension Society (BHS) commented in April 2012 that: 'In the opinion of the BHS, such small effects (on blood pressure, heart rate and quality of life) over very short durations of time do not provide sufficient evidence for this equipment to be recommended.'^{12,14}

An NHS Evidence update (March 2013) concluded that further research was desirable and that 'the available evidence does not seem to support the use of this device for the treatment of hypertension and is not likely to influence the recommendations in NICE CG127'.^{12,15}

It is unclear how long a device would last, but it would probably need to be replaced if dropped accidentally.¹²

3. Needle free insulin devices (Insujet™ and Injex™)

Two needle-free devices to deliver insulin are available - Insujet™ and Injex™. Both utilise jet injector technology to fire a jet of insulin at high velocity into the subcutaneous tissue. They are promoted as a possible option for patients with needle phobia. There are practical differences between the devices.¹⁷

Insujet™

Any 10ml vial or 3ml cartridge of 100units/ml insulin can be attached to the device using a disposable adapter. A nozzle is attached and the dose of insulin (range 4-40 units) can be dialled up. The device is then placed against the skin and the dose is delivered by pressing a button. It is recommended that the nozzle is replaced every 1-2 weeks and every time a new vial or cartridge is used. A new adaptor is also required every time a new vial or cartridge is used. A different Insujet™ device is required for each type of insulin used.¹⁷ More details are available on the Insujet™ website.

Injex™

The appropriate dose of insulin (range 3-30 units) is drawn into what is described as an 'ampoule', although this looks similar to a syringe barrel; an appropriate adapter is purchased to transfer the insulin from the cartridge/vial or pen device into the 'ampoule'. Note that only the 10ml vial adapter can be prescribed on the NHS. The 'ampoule' is then attached to the Injex™ device which is placed against the skin and the dose is delivered by pressing a trigger. A new 'ampoule' is required for each injection. A vial adapter is required for each new vial used.¹⁷ More details are available on the Injex™ website.

Evidence

Jet injectors were first developed more than 50 years ago to deliver vaccinations. A variety of jet injectors have been designed over this period, with emphasis on nozzle diameter, velocity and jet power. However, their development and more widespread use have been hindered by their use being associated with pain and bruising. It has been suggested that pain and bruising is due to deep penetration of the jet and minimising the penetration depth may reduce the incidence of bruising.^{17,18}

There are no controlled clinical trials of these products in patients with diabetes.¹⁷

One pharmacokinetic study compared delivery of a specified dose of insulin aspart (0.2 units/kg), either by Insujet™ or conventional pen injection, to 18 healthy volunteers using a double-blind, double-dummy cross-over design.¹⁹ After the insulin injection, plasma glucose was maintained at approximately 5mmol/L for eight hours by a variable infusion of 20% dextrose. The time to peak insulin concentration was shorter (31+/-3 vs. 64+/-6 minutes, $P>0.0001$) and the peak plasma insulin concentration was higher (108+/-13 vs. 79 +/-7mU/L, $P=0.012$) with Insujet™ as compared with conventional pen injection. There were no statistically significant differences in maximal glucose-lowering effect or the total amount of glucose administered, however the duration of glucose lowering effect was approximately 40 minutes shorter with Insujet™. Thus patients would need to monitor blood glucose levels carefully if switching to this method.

The Injex™ website includes results of an unpublished pharmacokinetic study in 25 patients with diabetes (type 1 and 2). Patients were injected on two occasions with insulin lispro using either the Injex™ device or conventional needle and syringe on consecutive days. There was no attempt to conceal which device was used. There was no statistically significant difference in the mean free insulin level at baseline, 20, 40 or 60 minutes after the injection between the devices.¹⁷

There is no information on incidences of bruising or pain with either device. The trial comparing Insujet™ with conventional pen injection reported that neither device resulted in haematomas or redness, although some participants reported that the firm pressure required for the Insujet™ device was unpleasant.¹⁷

Annual costs

Approximate annual costs of the devices and consumables are given below for a range of dosing regimens. These assume each device will last approximately three years and does NOT include the cost of the insulin itself.^{5,17}

Table 2: Comparison of approximate annual costs of insulin devices and consumables

Device	Cost per annum			
	One basal long-acting insulin 20 units/day and three short-acting doses of seven units per day (total daily dose 41 units)	One basal long-acting insulin 20 units/day and three short-acting doses of 15 units per day (total daily dose 65 units)	Twice daily dosing - 40 units of mixed insulin in the morning and 30 units of mixed insulin in the evening (total daily dose 70 units)	Once daily dosing - 40 units of long-acting insulin (total daily dose 40 units)
Insujet™ (using 3ml cartridges)	£263	£363	£335	£211
Insujet™ (using 10ml vials)	£162	£187	£142	£126
Injex™ (using 10ml vials) NB. Costing based on new 'ampoule' for each administration	£395	£395	£305	£216
Injectable insulin (including cost of pen device(s) for 3ml cartridges) NB. Costing based on a new needle for each dose (range 7p - 12p per needle) plus sharps bins.	£126 - £204	£126 - £204	£69 - £108	£44 - £64

4. Vacuum pumps for erectile dysfunction (ED)

Vacuum pumps have a long history and have been commercially available since 1985.^{20,21} The principle of vacuum erection devices is simple. A cylinder is placed over the penis, air is pumped out with an attached pump. The penis becomes filled up with blood and, when hard enough for intercourse, a plastic ring is slipped from the end of the cylinder around the base of the penis. This traps blood in the penis and the erection can be safely maintained for up to 30 minutes. Some people prefer to use two constriction rings to obtain a stronger and better maintained erection. Thus, erections with these devices are not normal because they do not use physiological erection pathways.²⁰⁻²²

Efficacy, in terms of erections satisfactory for intercourse, is reported as high as 90%, regardless of the cause of ED and satisfaction rates range between 27% and 94%.²³ Men with a motivated, interested, and understanding partner report the highest satisfaction rates. Long-term use of vacuum pumps decreases to 50-64% after two years. Most men who discontinue use of vacuum pumps do so within three months.²⁴⁻²⁷

Vacuum devices are contraindicated in men with bleeding disorders or those taking anticoagulant therapy. They work best if the man and his partner have a positive attitude to them and sufficient time has been spent demonstrating their use. The commonest adverse events include pain, inability to ejaculate, petechiae, bruising, and numbness, which occur in <30% of patients.²⁰⁻²² Serious adverse events (skin necrosis) can be avoided if patients remove the constriction ring within 30 minutes.²⁰⁻²²

Vacuum pumps are currently recommended as a second line treatment option for ED management by Guidance produced by the European Association of Urology²⁰ the British Society for Sexual Medicine and a NICE Clinical Knowledge Summary, and may be the treatment of choice in well-informed older patients with infrequent sexual intercourse and comorbidity requiring non-invasive, drug-free management of ED.²⁰⁻²²

Vacuum pumps can be supplied on a FP10 prescription in accordance with Schedule 2 prescribing restrictions which state that NHS supplies can only be obtained for erectile dysfunction for men with certain medical conditions. Full details can be found in the current NHS Drug Tariff.⁵ See Part IXA, appliances.⁵

In addition, in the UK the pump can be purchased tax free with a private prescription.²¹ The Sexual Advice Association produces a number of factsheets, including one on vacuum pumps that provides details of companies that supply them.²¹ The cost of individual vacuum pumps varies and ranges between £95 and £220 each.⁵

5. Normal saline nasal sprays (Sterimar®, Aqua Maris®)

Nasal irrigation with saline solutions and saline nasal sprays have been suggested as possible treatment options for patients with various nasal conditions, including acute and chronic rhino sinusitis, allergic rhinitis and upper respiratory tract infections.²⁸⁻³¹

Daily nasal irrigation or lavage with saline solution is recommended as a possible adjunctive treatment strategy, along with other measures such as oral antihistamines.²⁸⁻³¹ Nasal lavage (with at least 200ml warmed saline per side) can be performed as needed only, daily, or multiple times daily, depending on the severity of symptoms.³² Homemade nasal douches using distilled or boiled and cooled water have also been advocated, however nasal irrigation with tap water is not recommended for nasal douching as it has been associated with amoebic encephalitis.³² Washing the nasal cavities with saline reduces postnasal drainage, removes secretions, and rinses away allergens and irritants.³²

Saline nasal sprays such as Sterimar® and Aqua Maris® are generally considered to be less effective than with higher volume nasal irrigation.^{33,34} Other alternatives include normal saline nasal drops.¹⁶

Systematic reviews of studies employing various forms of saline sprays and irrigation (performed one to four times daily) found that nasal saline is an effective adjunctive treatment for chronic rhinosinusitis, although less effective as monotherapy than topical glucocorticoids.^{35,36} A Cochrane review published in 2007 identified eight trials, three of which, compared topical saline against no treatment, one against placebo, one as an adjunct to and one against an intranasal steroid spray. Two studies compared different hypertonic solutions against isotonic saline. The review authors concluded that saline is not as effective as an intranasal steroid but is well tolerated. Although minor side effects are common, the beneficial effect of saline appears to outweigh these drawbacks for the majority of patients. Some evidence suggests that hypertonic solutions improve objective measures but the impact on symptoms is less clear.³⁵

Both Sterimar® and Aquamaris® are registered as medical devices and can be prescribed on FP10 with appropriate ACBS endorsement.⁵ The reimbursement price for Sterimar® is currently £2.49-£2.89 and £2.49 and £2.77 for Aqua Maris®.⁵

Both products are available to buy over the counter, with Sterimar® costing between £6.77-£7.43 and Aquamaris® £5.15-£7.26 and more details are available on the Sterimar and Aquamaris websites.

6. Vaginal dilators or trainers (Femmax®, Ameille Care® and Ameille Comfort®)

There are currently three brands of vaginal trainer/dilators listed in the current Drug Tariff: Femmax®, Ameille Care® and Ameille Comfort® with a NHS reimbursement cost of between £15.26-£35.06.⁵

Vaginal trainers or dilators are a set of four smooth, plastic penis-shaped objects in different sizes which are used to help women with vaginal problems particularly vaginismus which is the term used to describe recurrent or persistent involuntary tightening of muscles around the vagina whenever penetration is attempted.³⁷ Vaginal dilators are also used following vaginal reconstructive surgery and to help with the side effects of pelvic radiation therapy being received for gynaecological cancers. Guidance produced by recommends vaginal trainers as a possible treatment option for the management of vulva pain.³⁸

For women with vaginismus, vaginal trainers help women learn to tolerate vaginal penetration by gradually getting the patient used to having something inserted into the vagina. The size of the trainer used by the patient is increased gradually over several weeks or months. Treatment in this way is also known as desensitisation training.

There is limited evidence to support the effectiveness of vaginal dilators in practice, however as there are limited alternative strategies the use of vaginal trainers are firmly established in clinical practice.³⁷⁻⁴⁰

Two Cochrane reviews have been published which confirm this lack of evidence.³⁹⁻⁴⁰ In the first, published in September 2014, regarding the use of vaginal dilators for vaginal rehabilitation following pelvic radiotherapy, no studies were identified which met the inclusion criteria.³⁹ The excluded trials included one randomised trial (RCT), which showed no improvement in sexual scores associated with encouraging women to practise dilation therapy; a recent small RCT that did not show any advantage to dilation over vibration therapy during radiotherapy; two non-randomised comparative studies; and five correlation studies. One of these showed that objective measurements of vaginal elasticity and length were not linked to dilation during radiotherapy, but the study lacked power. One study showed that women who dilated tolerated a larger dilator, but the risk of objectivity and bias with historical controls was high. Another study showed that the vaginal measurements increased in length by a mean of 3cm after dilation was introduced six to ten weeks after radiotherapy, but there was no control group; another case series showed the opposite. Three studies showed less stenosis associated with prophylactic dilation after radiotherapy. One small case series suggested that dilation years after radiotherapy might restore the vagina to a functional length.³⁹ The review authors concluded that women who want to preserve the length of their vagina after radiotherapy should consider dilation. There are limited data from observational studies that suggest regular stretching of the vagina, once radiotherapy treatment is completed, might reduce the risk of scarring by a small amount. There is no evidence to support dilation therapy during radiotherapy. There are also case reports and one case series suggesting that dilation months or years after radiotherapy might help restore vaginal length. In addition, randomised trial design has not, and may never, obtain high-quality evidence to assess vaginal dilation therapy. The available studies suggest, but cannot prove, that dilation works. However, this only applies once the radiotherapy has finished. There is an association between vaginal dilation after radiotherapy and less vaginal stenosis, but this is not proof that the benefit is due to dilation. The link between dilation and less stenosis could either be due to a beneficial effect of dilation or because women with stenosis (or who self-report stenosis) are less able to use the dilator.³⁹

The second review, published in 2012 regarding possible interventions for vaginismus including desensitisation training with vaginal dilators identified five studies.⁴⁰ Four trials, with a total of 282 participants provided data. All studies were considered to be at either moderate or high risk of bias. The results of this systematic review indicate that there is no clinical or statistical difference between systematic desensitisation and any of the control interventions (either waiting list control, systematic desensitisation combined with group therapy or in vitro desensitisation with women under instruction by the therapist) for the treatment of vaginismus. The study authors concluded

that a clinically relevant effect of systematic desensitisation when compared with any of the control interventions cannot be ruled out. None of the included trials compared other behaviour therapies (e.g. cognitive behaviour therapy, sex therapy) to pharmacological interventions. The findings are limited by the evidence available and as such conclusions about the efficacy of interventions for the treatment of vaginismus should be drawn cautiously.⁴⁰

7. Potassium hydroxide solution (MolluDab® 5%, Molutrex® 5%)

Molluscum contagiosum (MC) is a common skin condition caused by a poxvirus. It is characterised by small, discrete, waxy, skin-coloured dome-shaped papules, 3–5mm in diameter and is transmitted through direct contact with an infected person or an object (such as a shared towel).⁴¹ When the lesions are squeezed or traumatised, a creamy, grey-white material can be extruded. In immunocompetent people there are usually fewer than 20 papules. The condition is common in children and generally presents with asymptomatic papules, although they can sometimes present with itching, redness and occasionally bacterial superinfection leading to inflammation and pain.⁴¹ The incidence has been estimated as 15–17/1,000 children aged 1–4 years in the UK, with girls and boys similarly affected.⁴¹ In adults it can be sexually transmitted and affect the genitalia.⁴¹

MC can cause considerable anxiety among parents and treatment is not routinely recommended because most cases clear up in around six to 18 months without the need for treatment.⁴¹ If left alone, MC does not usually result in scarring or cause any symptoms other than spots.⁴¹ Exclusion from school, gym or swimming is not necessary. Treatment, if used, is intended to accelerate resolution through destruction of the lesions or to induce an inflammatory response and options include simple physical trauma (which, following a bath involves gentle squeezing with fingernails while wearing gloves and discarding the curd-like material inside, or pricking with a sterile needle). Cryotherapy and curettage in older children and adults, may be considered by a specialist but may cause pain and scarring.^{41,42}

Symptomatic treatment involving an emollient to help relieve itching, and/or a mild topical corticosteroid (e.g. hydrocortisone 1%) which may be used if eczema or inflammation develop around lesions, may be more appropriate than the physical or chemical treatment designed to destroy the lesions. A topical antibacterial such as fusidic acid 2% may be needed if secondary skin infection occurs.⁴²

Topical preparations with an irritant or keratolytic effect that have been used to induce a local inflammatory response include salicylic acid, podophyllotoxin, liquefied phenol, tretinoin, cantharidin and potassium hydroxide. Other proposed treatments have included immune response modifiers such as imiquimod and cidofovir, and systemic therapy with cimetidine (for its immunomodulatory effect). Pulsed dye laser therapy has also been.^{41,42}

Potassium hydroxide is a powerful caustic that has been used to remove warts. And is marketed as Molludab® (Alliance Pharmaceuticals) and Molutrex® (Espere). It is recommended that the patient or parent dabs the solution on the Molluscum contagiosum bumps twice daily.⁴¹ The product is believed to work by breaking down the skin cells which encase the virus which enables the immune system to recognise the virus and respond to it. After around four to six days' treatment; once this inflammatory response has cleared the virus, the skin begins healing and the molluscum contagiosum lesions disappear after 1–5 weeks.⁴¹

Both can be prescribed on an FP10, and MolluDab® costs £13.50 for 2ml and Molutrex® is £9.99 for 10ml. Alternatively both products can be purchased by patients directly from the manufacturers at a cost of £23.49 for Molludab® and £19.95 for Molutrex®. More details are available on the specific websites for Molludab® and Molutrex®.

A Cochrane systematic review investigated randomised controlled trials for the treatment of MC (excluding patients with genital infection or immunodeficiency). The reviewers included 11 studies (involving a total of 495 patients) that examined the effects of topical (nine studies), systemic and homeopathic interventions (one study each). No single intervention was shown to be convincingly effective in the treatment of MC.⁴³

Two of the trials included in the Cochrane review assessed potassium hydroxide. One study, a randomised double-blind study compared potassium hydroxide 10% with placebo (saline) in 20 children aged 2–12 years for three months.⁴⁴ Nearly all patients on potassium hydroxide reported mild stinging, and one withdrew because of severe stinging. Among those who received the treatment, the complete clearance rate (the primary outcome measure) was 70% compared with 20% with placebo. However, after intention-to-treat analysis, the result was not statistically significant, possibly due to the small size of the trial. The other trial (which is unpublished and the date of which is unknown) included 30 children aged two–12 years and compared potassium hydroxide 5% with saline for three weeks.⁴³ The treatments were randomised to the left or right side of a participant's body. Only 20 patients completed the trial. In both groups 17 out of 20 patients were 'cured'. The authors of the systematic review combined the results of the two trials and calculated the effect size risk ratio as 1.68 (95% CI 0.36 to 7.75); however, they state that this meta-analysis was hampered by the different randomisation methods in the two trials.

A randomised controlled trial published since the systematic review assessed 5% vs. 2.5% potassium hydroxide. The trial included 29 participants aged 15 months to 18 years with two–50 lesions. The treatment was applied twice daily. After three months, there was complete clearance of lesions in 67% of those on the 5% solution vs. 23% with 2.5% solution ($p < 0.047$).⁴⁵ 5% potassium hydroxide has also been compared with 0.05% tretinoin cream; and 10% potassium hydroxide with salicylic acid plus lactic acid; cryotherapy; and imiquimod; all the trials were open-label with small numbers of patients (26-50 participants). No one treatment showed a clear benefit.⁴⁶⁻⁴⁹

8. Jaw rehabilitation device (TheraBite®)

A jaw rehabilitation device (TheraBite®) is a hand-held device, specifically designed to help open and stretch your jaw, without putting strain upon the surrounding jaw muscles and is advocated for the treatment of trismus and mandibular hypomobility.⁵⁰ Trismus is a term used to describe painful and/or limited jaw movement. Trismus can occur for a variety of reasons including radiotherapy and/or surgery to the head and neck area. The system utilizes repetitive passive motion and stretching to restore mobility and flexibility of the jaw musculature, associated joints, and connective tissues.⁵⁰ More details about how the device works are available on the TheraBite® website and in the TheraBite® Quick Reference Guide.⁵⁰

Both the device itself and the replacement mouthpiece pads are prescribable on FP10. The device itself has a current reimbursement cost of £221 for the device, initial bite pads and accessories. The replacement pads, which protect the user's teeth and should be replaced when necessary, cost £10.34/4 pads.⁵ A set of four replacement pads are expected to last around six months.

The device has only recently become allowed on NHS FP10 prescription and up until now has been supplied by Speech and Language Therapists directly to the patient.

Passive movement therapy appears to be an established technique for the management of trismus, however there is currently limited evidence for the effectiveness of TheraBite®, particularly in relation to more basic methods, on which to base a definitive conclusion.

One study enrolled seven patients with oropharyngeal carcinoma who underwent resection and radial forearm flap reconstruction. Five had midline mandibulotomy procedures for exposure. Six who had radiation therapy (two pre, four post) were given a TheraBite® mechanical jaw mobilization device,⁵¹ were instructed in its proper use, and began using it within six weeks postoperatively. The primary outcome measure was maximal interincisor opening (MIO) measured at the beginning of use and at the most recent postoperative visit. A five-question self-assessment telephone survey was administered on study completion. Total study duration is unknown. The average MIO was 30 mm (range, 21-38 mm) at the beginning of the study and 40 mm (range, 30-57 mm) at the last visit. Average gain in MIO was 10 mm (range, 1-21 mm). Four of five assessable patients had minimal or no limitation on overall quality of life relative to jaw opening. No complications were associated with use of the device. Two patients could not be located for follow-up. The study authors concluded that the TheraBite® mechanical stretching device is effective and safe for the management of

trismus in a select group of head and neck cancer patients after extensive ablation and complex reconstruction. Specifically, there were no adverse effects in the five patients who had undergone midline mandibulotomy.⁵¹

A second study was designed to compare the effectiveness of a passive jaw motion device, the TheraBite®, and wooden tongue depressors (WTD), in patients with temporomandibular joint and muscle disorders, who did not improve after manual manipulation of the mandible and flat bite plane therapy.⁵² 43 patients were enrolled in the study and were classified as joint or muscle groups according to the Research Diagnostic Criteria for TMD. 24 were assigned to the joint group, and 19 patients were assigned to the muscle group. The patients were assigned at random to three treatment subgroups: passive jaw motion device therapy (TheraBite®); wooden tongue depressors therapy (WTD); and control group. All subjects received flat bite plane appliance therapy throughout the treatment period. Mandibular range of motion was measured for maximum opening, right and left lateral and protrusive movements. Pain level was also assessed at the beginning and at the end of the treatment. The study authors concluded that the results suggested that a passive jaw motion device is effective in increasing range of motion in both groups of temporomandibular disorder patients, joint (intracapsular) and muscle (extracapsular) and also appears to decrease pain in patients with temporomandibular disorders. Pain was relieved to a greater degree in the muscle group than the joint group.⁵²

A further trial comparing TheraBite® to wooden spatulas is currently being conducted, although it is now closed to new patients.⁵³

Gibbons and Albohoul have advocated the use of the TheraBite® device following coronoidectomy. However further details are unavailable.⁵⁴

The total number of patients and the overall cost implications for the East of England are currently unknown.

9. Pelvic toning devices (e.g. PelvicToner®, Aquaflex®, Kegel 8®)

Daily pelvic floor exercises or Kegel exercises are routinely recommended to all women, particularly following childbirth to help prevent stress incontinence and vaginal and uterine prolapse.⁵⁵ Several pelvic toning devices are available, however the only devices PelvicToner® available on FP10 prescription⁵ are PelvicToner®, Aquaflex® and Kegel8® with reimbursement costs of £15.00 for PelvicToner® and Kegel8® and £13.95 for Aquaflex®.

Pelvic toners are weighted cone or egg shaped devices which are inserted in to the vagina and may help strengthen the pelvic floor muscles. The PelvicToner® has an innovative design which has an elongated cone shape incorporating a hinge and spring mechanism which is inserted into the vagina and provides passive resistance during daily pelvic exercises. The manufacturers claim that it is the best way to make sure that pelvic floor exercises are done correctly and effectively. More details are available on the Aquaflex®, Kegel8® and PelvicToner® websites respectively.

There appears to be no evidence for the Kegel8® and Aquaflex® devices which confirms they provide no additional benefit over pelvic floor exercises alone. There is very limited efficacy data for the effectiveness and safety of the PelvicToner® device.

In one small trial, which aimed to determine the feasibility of using the pelvic toner device (PTD) in aiding pelvic floor muscle training (PFMT), 40 women, aged at least 18 years with symptoms of pure stress urinary incontinence (SUI) or stress-predominant mixed urinary incontinence were randomly assigned to standard PFMT (ST group), or to PFMT and additional PTD (PTD group). They were evaluated throughout a treatment period of 16 weeks, and followed up six months after the active treatment period, using International Consultation on Incontinence Questionnaires (ICIQ), bladder diaries, and other subjective outcome measures for symptom improvement.⁵⁶ 24 women were randomised to ST and 28 to PTD. 12 women did not complete therapy and analysis was performed on 19 randomised to ST and 21 randomised to PTD on a per protocol basis. The two groups showed statistically significant symptom improvement in ICIQ responses, both at 16 weeks and at six months. There was no significant difference between the groups regarding improvement in SUI (ST 52.6%,

PTD 52.4%) at 16 weeks. At six months after the active treatment period, 60% of women (50%, 8 in the PTD group and 71.4 %, 10 in the ST group) were still doing pelvic floor exercises. The sample difference observed was not statistically significant. Some women reported that the device helped with confidence that the correct muscles were being contracted, and helped motivation to sustain PFMT.⁵⁶

Document history

PAC approval date	V1 September 2013
	V2 13th April 2015
	V2b 1st June 2015
Version	2b
Document history	V1 revised to include full evidence reviews for specified devices V2 revised decision on OPEP devices in CF patients
Consultation process	Local stakeholders via PAC members
QA process	Katie Smith – Director of East Anglia Medicines Information Service, 11th June 2015

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