Kent and Medway Policy Recommendation and Guidance Committee
Policy Recommendation

Policy:	**PR 2014-06: Hyperhidrosis**
Issue date:	**May 2014**
Review date:	**May 2017**

Recommendation:

The Kent and Medway Policy Recommendation and Guidance Committee (PRGC) considered the evidence, baseline position, other CCG policies and the views and opinions of local experts. All decisions were made with reference to the Ethical Framework. Taking these into account the PRGC recommended that:

- Patients with a HDSS[1] score of 1–2 should be treated in primary care and not referred to secondary care (see Appendix 1 for treatment algorithm)
- Refer to a dermatologist if there is evidence that treatment (first-line: topical aluminium chloride; second-line: oral systemic anticholinergics [oxybutynin or propantheline; see below regarding glycopyrrolate]) in primary care have been provided and proved unsuccessful (or are contra-indicated) and the patient has an HDSS score of 3–4.
- Prescribing of oral systemic glycopyrrolate is not routinely commissioned (in primary or secondary care) for newly diagnosed patients with hyperhidrosis. Existing patients receiving oral glycopyrrolate should be assessed and switched to oxybutynin or propantheline whenever possible, or referred as appropriate (see below).
- Tap-water iontophoresis is commissioned for palmoplantar and axillary hyperhidrosis provided:
    - Patient has an HDSS score of 3–4 AND there is evidence that treatment in primary care (as outlined above) has been provided and proved unsuccessful

  Patients receive initial treatment (7 sessions) in the hospital setting. Maintenance therapy varies according to the individual. The addition of anticholinergic drugs (e.g. glycopyrrolate) to water is not routinely funded.
- BTX-A is commissioned for axillary hyperhidrosis provided:
    - Patient has an HDSS score of 3–4 AND there is evidence that treatment in primary care (as outlined above) has been provided and proved unsuccessful

  If successful, treatment may be repeated when sweat production is back to 50% of baseline (or HDSS score of 3 or 4), with a minimum treatment interval of 6 months (i.e. maximum of two BTX-A treatments per year).
- BTX-A is not routinely funded for palmar, plantar or craniofacial hyperhidrosis
- Endoscopic Thoracic Sympathectomy (ETS) is not routinely commissioned

This policy recommendation will be reviewed in light of new evidence or national guidance.

Commissioners in Kent and Medway will always consider appropriate individual funding requests (IFRs) through their IFR process.

[1]HDSS = Hyperhidrosis Disease Severity Scale. See Box 3 of treatment algorithm for more information.

Supporting documents

- Health Care Intervention Appraisal and Guidance (HCiAG) team (2014) *Management of hyperhidrosis – Briefing note*

Key findings and rationale

Why was this topic identified for review?
There are inequities in the provision of hyperhidrosis treatments across Kent and Medway, and local clinicians have questioned the wording, eligibility criteria and rationale of the current RaTC policy.

What is primary hyperhidrosis?
Hyperhidrosis can be defined as sweating in excess of the body's homeostatic requirements, and can range from moderate moisture to severe dripping. It can be classified by the presence of an underlying cause (primary or secondary).

Primary hyperhidrosis only affects certain parts of the body, most commonly the armpits, then the feet and hands or more rarely, the face or scalp; some patients exhibit primary hyperhidrosis at more than one location. Symptoms typically start during childhood or adolescence and peak in the third decade. It is a chronic condition requiring long-term treatment. Hyperhidrosis can lead to substantial emotional and physical impairment, affecting professional and social activities and significantly reducing health-related quality of life (HRQoL).

What is the prevalence of hyperhidrosis?
The prevalence of hyperhidrosis was 2.8% in a large US national survey. Applying this value to the Kent and Medway population, around 47,100 people have hyperhidrosis, although only a small minority of these would be expected to present for treatment.

How is hyperhidrosis treated?
Treatment depends on disease severity, focal location and patient preferences, but usually follows a step-by-step approach moving from conservative to more invasive interventions. A literature review indicated topical aluminium chloride preparations, iontophoresis[1], botulinum toxin (BTX-A), systemic anticholinergics and surgery have all been studied for hyperhidrosis.

What does the evidence say?
The level of evidence to support the use of each intervention at different anatomical sites varies considerably.

<u>Topical aluminium chloride</u>
Although the evidence for topical aluminium salts is limited, it is widely recommended by experts for the initial management of primary focal hyperhidrosis.

<u>Oral anticholinergics</u>
Propantheline bromide is the only oral anticholinergic licensed for hyperhidrosis. Oxybutynin hydrochloride is used off-label and oral preparations of glycopyrronium bromide (glycopyrrolate) are not licensed or available in the UK for treating hyperhidrosis – they must be either imported or prepared by 'specials' manufacturers.

There is only limited evidence from retrospective case series that oral glycopyrrolate reduces sweating in this population, while no (English language) studies on oral propantheline for hyperhidrosis were identified from a literature search. Oxybutynin in hyperhidrosis was effective compared to placebo in one small short-term RCT. It also appeared effective in several short-term prospective, nonrandomised, uncontrolled studies and one large retrospective study. Oxybutynin appears to be a reasonable alternative to glycopyrrolate considering the evidence base for oxybutynin is at least as good, and it offers savings on drug costs.

<u>Iontophoresis</u>
Clinical opinion and several small controlled trials and observational studies support tap water iontophoresis in palmoplantar disease. Clinical opinion also suggests iontophoresis for axillary disease may be effective in practice, despite a lack of compelling, published evidence. The evidence for adding glycopyrronium bromide solution is more limited

[1] Each hand or foot is placed in a small tray of water, with a weak electric current. It can also be used to treat armpits using wet contact pads.

(compared to tap-water iontophoresis), is associated with systemic adverse events and drug costs are high.

BTX-A

BTX-A is only licenced for hyperhidrosis of the axillae. Several large placebo-controlled RCTs have demonstrated the effectiveness of BTX-A for treating axillary disease. BTX-A for palmar and plantar hyperhidrosis is more painful and the evidence base is less robust (especially for plantar disease). Also, higher doses of BTX-A per hand or sole than per axillae are generally required and transient muscle weakness has been reported. There is only limited evidence for BTX-A for craniofacial hyperhidrosis.

Surgery

Endoscopic Thoracic Sympathectomy (ETS) – the most widely used surgical procedure for hyperhidrosis – is major surgery performed under a general anaesthetic and carries a significant risk of irreversible side effects and complications.

Will implementation of this new policy recommendation lead to additional expenditure?

Implementation of this policy recommendation is not anticipated to lead to significant additional expenditure. According to local experts, the majority of patients with hyperhidrosis currently receiving oral glycopyrrolate, would switch to BTX-A or iontophoresis given the option, due to tolerability issues associated with glycopyrrolate. BTX and iontophoresis provided as specified in the policy recommendation are likely to be less expensive options in most cases than oral glycopyrrolate[2].

Even if the number of patients suitable for BTX-A or iontophoresis is four times larger[3] than the number of patients currently receiving glycopyrrolate, implementation of this policy recommendation is likely to be associated with only small additional expenditure in North Kent and West Kent CCGs; implementation in East Kent is estimated to be associated with a small cost saving, even if the number of patients suitable for BTX-A or iontophoresis is four times larger than the number of patients currently receiving glycopyrrolate.

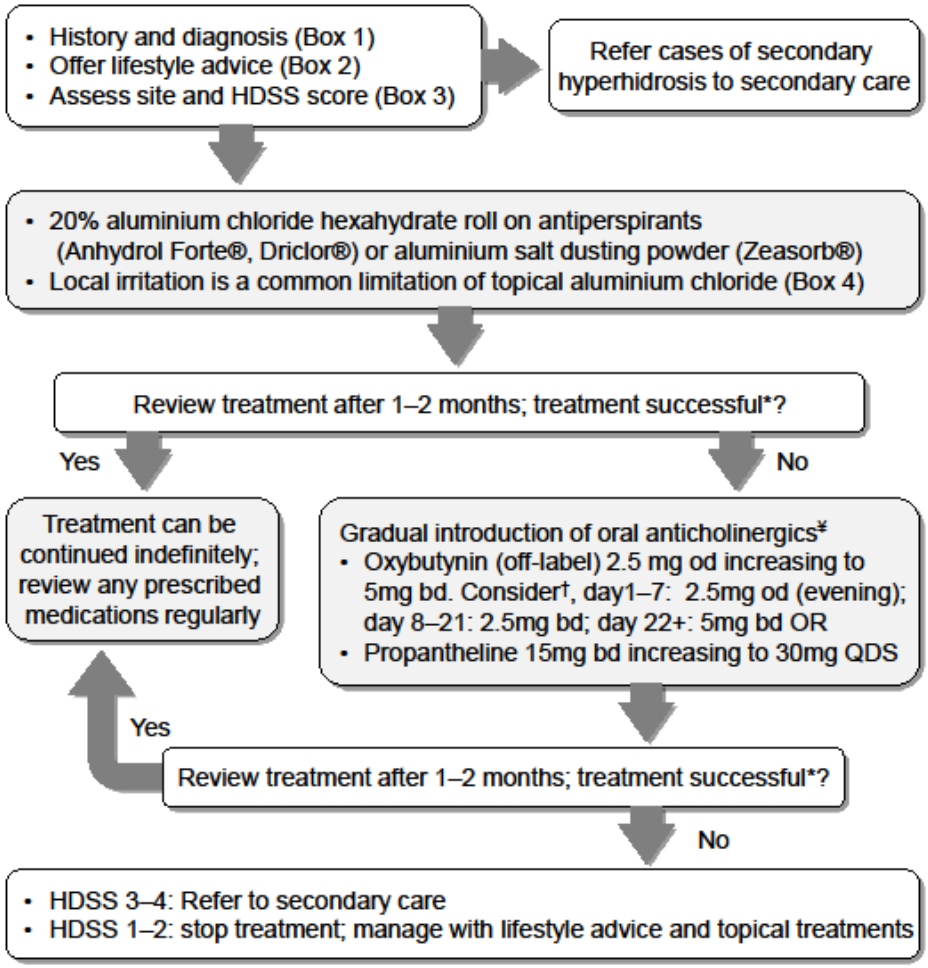
[2] Costs of oral glycopyrrolate vary widely according to what wholesalers charge pharmacies, since they must be either imported or prepared by 'specials' manufacturers; in primary care, costs of £500 per prescription are regularly reported locally, with occasional prescriptions over £1,000 (unclear whether 28, 56 or 84 day prescriptions).

[3] Considering that:

- if patients were aware that additional treatment options were available, greater numbers may present to primary care/ be referred to secondary care
- some patients who are not able to tolerate oral systemic anticholinergics may be suitable for BTX-A or iontophoresis

Appendix 1

Primary care

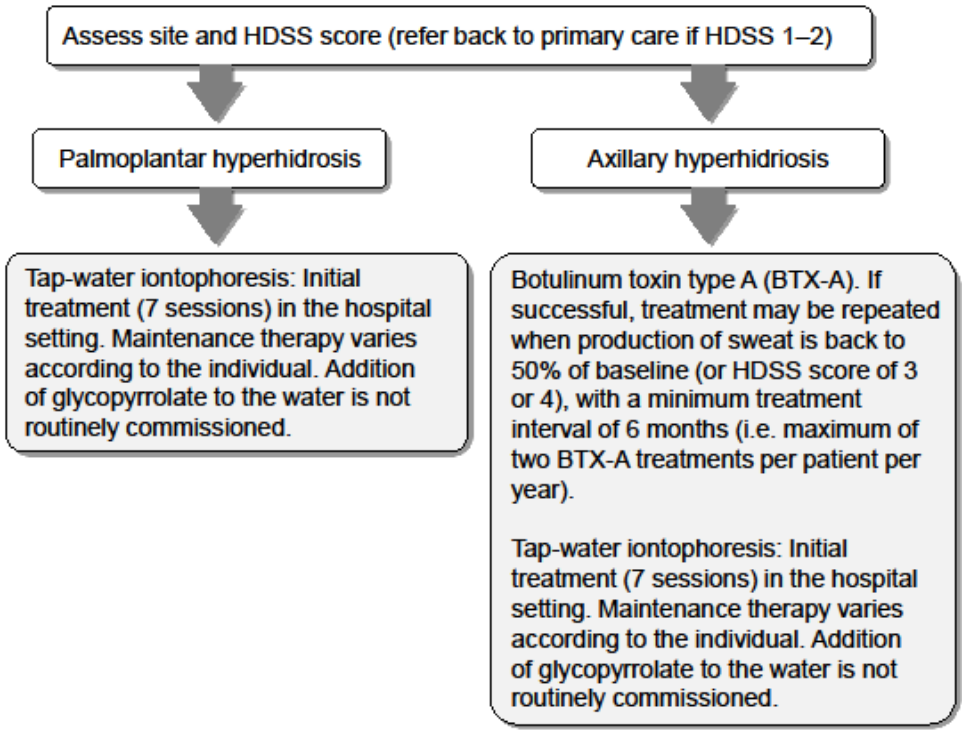


* Successful treatment: Reduction in HDSS score from 3–4 to 1–2. Treatment failure: no change in HDSS or lack of tolerability for treatment.

¥ Glycopyrrolate (unlicensed) is not routinely commissioned. Existing patients should be assessed and switched whenever possible.

† Wolosker N et al. *J Vasc Surg* 2012;55:1696–700.

Secondary care



Box 1 – Diagnosis of hyperhidrosis

Primary focal hyperhidrosis can be diagnosed when focal, visible, excessive sweating occurs in at least one of the following sites: axillae, palms, soles, or craniofacial region, and:

- has lasted at least 6 months, and
- has no apparent cause, and
- has at least two of the following characteristics:
  - bilateral and relatively symmetrical
  - impairs daily activities
  - frequency of at least one episode per week
  - onset before 25 years of age
  - positive family history
  - cessation of local sweating during sleep

If symptoms have lasted less than 6 months or onset is at 25 years of age or older, primary focal hyperhidrosis remains a likely diagnosis if other criteria are met, but extra care should be taken to exclude an underlying cause (see NICE CKS for more information).

If the presentation is characteristic, and there is no evidence of an underlying cause, no laboratory tests are needed.

For people with suspected secondary focal or generalised hyperhidrosis, the history, examination, and investigations should look for an underlying cause. Appropriate management will often include a referral to secondary care.

Box 2 – Lifestyle advice

Managing patient expectations is important. Give links to patients for further information: Hyperhidrosis Support Group (www.hyperhidrosisuk.org/). Patients should be advised:

- to avoid known triggers that make sweating worse, such as spicy foods, crowded rooms alcohol and caffeine
- to use antiperspirant spray frequently, rather than deodorants
- to avoid wearing tight, restrictive clothing and man-made fibres, such as nylon
- that wearing black or white clothing can help to minimise the signs of sweating
- that armpit shields can help to absorb excessive sweat and protect your clothes (these can be obtained via the internet or the Hyperhidrosis Support Group)
- to wear socks that absorb moisture, such as thick, soft socks that are made of natural fibres, or sports socks designed to absorb moisture. Avoid wearing socks that are made out of synthetic materials and change socks at least twice a day.
- to buy shoes that are made of leather, canvas or mesh, rather than synthetic material
- to avoid using soap-based cleansers, especially when using aluminium salts. Use emollient washes and moisturisers instead.

Box 3 – Hyperhidrosis Disease Severity Scale (HDSS) score

Measuring the impact on health-related quality of life may reflect the severity of hyperhidrosis more accurately than isolated quantitative measurements of sweat production, since the level of sweating which causes problems varies between individuals. The easy to use and validated Hyperhidrosis Disease Severity Scale (HDSS) should be used (http://www.sweathelp.org/pdf/HDSS.pdf):

How would you rate the severity of your hyperhidrosis?

1	My sweating is never noticeable and never interferes with my daily activities	Mild
2	My sweating is tolerable but sometimes interferes with my daily activities	Moderate
3	My sweating is barely tolerable and frequently interferes with my daily activities	Severe
4	My sweating is intolerable and always interferes with my daily activities	Severe

Box 4 – Application of topical treatments

- Anhydrol Forte®, Driclor® should be:
  - applied to dry skin of the axillae, feet, hands, or face (avoiding the eyes). Initially for a few hours, gradually increasing to overnight. Care should be taken to ensure that the area of application is completely dry and that the skin is not shaved for 24hrs before or after application.
  - always washed off at the first sign of significant sweating and in the morning
  - used every 1–2 days, as tolerated, until the condition improves and then as required, which may be up to every 6 weeks
- Consider soaking lotion pads for application to the face
- For plantar hyperhidrosis, Zeasorb® can be used
- Local irritation is a common limitation of topical aluminium chloride. It can be managed by the use of topical emollients and soap substitutes, a reduction in the frequency of application, or giving a short course of 1% hydrocortisone cream for up to 2 weeks.