This policy statement is approved by Halton, Knowsley, Liverpool, South Sefton, Southport and Formby, St Helens, and Warrington CCGs

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NHS
Pan Mersey
Area Prescribing Committee

BOTULINUM TOXIN TYPE A injection for severe axillary hyperhidrosis

The Pan Mersey Area Prescribing Committee recommends no more than TWO TREATMENT SESSIONS per YEAR of Botulinum Toxin Type A Injection by specialists for the treatment of severe axillary hyperhidrosis that has not responded to treatment with topical antiperspirants or other antihidrotic treatment, as a potential alternative to surgery.

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Botulinum toxin type A is recommended as a treatment option in patients with **severe** axillary hyperhidrosis that has not been adequately controlled by topical aluminium chloride or other extra-strength antiperspirants. It acts by inhibiting acetylcholine release from the sympathetic cholinergic nerve terminals that innervate sweat glands and the effects may last for 6-9 months[1]. Severe axillary hyperhidrosis is indicated by a baseline score of 3 or 4 on the Hyperhidrosis Disease Severity Scale (HDSS)[2].

The first line treatment for primary axillary hyperhidrosis is aluminium chloride hexahydrate 20% solution, the only licensed treatment that can be prescribed in primary care in the UK. Unlicensed or off label topical and oral treatments may be considered under specialist recommendation but there is weak evidence of their effectiveness. If primary care clinicians take prescribing and clinical responsibility for unlicensed or off label treatment options the GMC's Guidance Good Medical Practice should be taken into consideration.

For patients who proceed to treatment with botulinum toxin type A and who do not have a clinical response after one treatment session, consider alternative options for on-going management. **A clinical response is indicated by more than a 2-point improvement from baseline on the HDSS[2] scale or more than a 4-point improvement from baseline on the Dermatology Life Quality Index (DLQI) [3].**

There is limited evidence to support the use of botulinum toxin for the treatment of patients with severe axillary hyperhidrosis, but it is a potential alternative to surgery. Evidence suggests that botulinum toxin type A is more effective than placebo and topical aluminium chloride hexahydrate and possibly less effective than surgery. There are no good quality randomised controlled trials of the use of unlicensed and off label topical and oral treatments for hyperhidrosis.

Botulinum toxin type A should not be offered to treat hyperhidrosis in people with social anxiety disorder - NICE CG159 May 2013.[4]

The MHRA has warned healthcare professionals about the rare but serious risk of toxin spread when using all types of botulinum toxin.[5]

Note: Patients who are not eligible for treatment under this statement may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. In this situation, follow locally defined processes.

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Effectiveness

Botulinum toxin type A blocks the transmission of overactive nerve impulses to the targeted tissue by selectively preventing the release of the transmitter acetylcholine at the nerve ending, temporarily preventing transmission. Six medium sized randomised, placebo–controlled trials on the safety and efficacy of botulinum toxin type A treatment of primary axillary hyperhidrosis form the body of evidence. All trials showed a significant improvement in the primary outcome measures for treatment with botulinum toxin type A. A dose of 50 units per axilla was used in most of the trials. Three trials reported a mean duration of effect of botulinum toxin of over 200 days.[6-8]

Safety

Botulinum toxin type A is contraindicated in:

- Hypersensitivity to the active substance or any of the excipients.
- Infection at the proposed injection site(s).

The MHRA has issued a warning regarding the rare but serious risk of toxin spread with all botulinum toxin products.[5]

See Summary of Product Characteristics for Botox® for full details[9].

Cost[10,11]

Botulinum toxin type A drug cost per vial is £138. Tariffs per course of treatment are estimated to be £840 so the annual cost is £1,956.

Glycopyrronium (off label) 1mg to 8mg daily. Annual costs range from £2,769 to £12,203.

Oxybutynin MR tablets (off label) 5mg to 10mg daily. Annual cost is approximately £165.

Patient factors

- At each treatment session the injection is administered intradermally to each axilla, evenly distributed in multiple sites.
- Patients should be warned about the signs and symptoms of toxin spread, such as muscle weakness and breathing difficulties, and advised to seek medical attention if they experience such symptoms.

Adverse effects include compensatory sweating (5–10%) and injection-site pain or reactions (9–12%)[6].

Prescribing information

Where more than one botulinum toxin type A product is available, the least costly should be used, taking into account drug acquisition cost, anticipated administration costs, and licensed indications. Note different brands are not dose equivalent.

Only the licensed dose of botulinum toxin type A 50 Units injected intradermally per axilla is recommended, within its licensed indication, for severe axillary hyperhidrosis, in patients who have failed on topical antiperspirants and antihydrotics **and** who have a baseline HDSS score of ≥3.

Continuation criteria

- It should only be continued when there is a ≥ 2-point reduction in HDSS from baseline or more than a 4-point improvement from baseline on the DLQI at maximum efficacy.
- A maximum of two treatment sessions per year will be funded in patients who respond to treatment.

References

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11. NHS Business Services Authority. Drug Tariff. Accessed 13/10/20 Drug Tariff NHS BSA