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

Halton | Knowsley | Liverpool | Southport and Formby | South Sefton | St Helens | ~~Warrington~~ | ~~West Lancashire~~

PAN MERSEY APC

PAN MERSEY AREA PRESCRIBING COMMITTEE
PRESCRIBING POLICY STATEMENT
REF: PS145 FINAL
APC BOARD DATE: 29 JUL 2015

NHS
Pan Mersey
Area Prescribing Committee

BOTULINUM TOXIN TYPE A (Botox®) for Severe Axillary Hyperhidrosis

RED

The Pan Mersey Area Prescribing Committee recommends no more than TWO TREATMENT SESSIONS per YEAR of Botulinum Toxin Type A Injection (Botox®) 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.

- 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. Severe axillary hyperhidrosis is indicated by a baseline score of 3 or 4 on the Hyperhidrosis Disease Severity Scale (HDSS)[1].
- The first line treatment for primary axillary hyperhidrosis is aluminium chloride hexahydrate 20% solution, the only licensed non-surgical treatment currently available 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 practice in prescribing and managing medicines and medical devices, 2013 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[1] scale or more than a 4 point improvement from baseline on the Dermatology Life Quality Index (DLQI) [2].**
- 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.[3]
- The MHRA has warned healthcare professionals about the rare but serious risk of toxin spread when using all types of botulinum toxin.[4]

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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Review date: July 2017
(or earlier if there is significant new evidence relating to this recommendation)

BOTULINUM TOXIN TYPE A INJECTION (Botox®) for Severe Axillary Hyperhidrosis

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.

4 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 4 trials showed a significant improvement in the primary outcome measures for treatment with botulinum toxin A. A dose of 50 units per axilla was used in 3 of the trials. Two trials reported a mean duration of effect of botulinum toxin of over 200 days.[5]

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 issued a warning in 2007 regarding the rare but serious risk of toxin spread with all botulinum toxin products.[4]

See Summary of Product Characteristics for Botox® for full details.[6]

COST

- Drug cost (including VAT) for one, 100 unit vial is £166.
- Estimated tariffs (initial first appointment, skin therapy (JC14Z, JC15Z) and follow up appointment) £104, £536 and £68 respectively.[7]
- Estimated total cost per treatment session is £874.

Treatment	Cost £ per annum*	Comments
Botulinum toxin (2 treatment sessions)	1748	Includes estimated cost of hospital activity
Glycopyrronium 1mg to 8mg daily - oral solution	1,608 - 3,464	Unlicensed 'Special'
Glycopyrronium 1mg to 8mg daily - tablets	1296 - 6,624	Off label
Oxybutynin 5-10mg MR tablets daily	165 - 330	Off label

*Drug Tariff April 2015/BNF March 2015

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%)[5].

PRESCRIBING AND IMPLEMENTATION

- Only the licensed dose of Botox 50 Units injected intradermally per axilla is recommended.

Initiation criteria

- Botulinum toxin type A is only recommended within its licensed indication for severe axillary hyperhidrosis without prior funding approval by commissioners, in patients who have failed on topical antiperspirants and antihydrotics **and** who have a baseline HDSS score of ≥3.

Continuation criteria

- ≥ 2 point reduction in HDSS from baseline or more than a 4 point improvement from baseline on the Dermatology Life Quality Index (DLQI) at maximum efficacy.
- Maximum of two treatment sessions per year in patients who respond to treatment.

Exit criteria

- If, at maximum efficacy, a 2 point reduction in HDSS or more than a 4 point improvement from baseline on the Dermatology Life Quality Index (DLQI) is not achieved, funding of a repeat session must not be given without seeking funding approval via the patient's CCG process.
  If the criteria described above are not met, prior funding approval should be sought from the patient's CCG in line with their agreed process.

REFERENCES

1. Hyperhidrosis Disease Severity Scale, International Hyperhidrosis Society. Accessed 9 March 2015 http://www.sweathelp.org/pdf/HDSS.pdf
2. Dermatology Life Quality Index (DLQI). Accessed 9 March at http://www.dermatology.org.uk/quality/dlqi/quality-dlqi.html
3. Do not do recommendation: - Social anxiety disorder: recognition, assessment and treatment NICE Clinical Guideline CG159 May 2013. Accessed 9 March 2015 at: http://www.nice.org.uk/savingsAndProductivity/collection#/savingsAndProductivity/collection?page=1&pageSize=10&type=&published=&impact=&filter=botulinum
4. MHRA. Drug Safety Update October 2007. Accessed 9 March 2015 http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON079276
5. Anon. Treatments for excessive armpit sweating. Drug and Therapeutics Bulletin 2005; 43(10): 77-80
6. Allergan Ltd. Summary of product Characteristics for Botox®. Accessed 9 March 2015 http://www.medicines.org.uk/emc/medicine/112/SPC/BOTOX®®+100+Units/
7. National Tariff Payment System. Accessed 9 March 2015 at: https://www.gov.uk/government/publications/national-tariff-payment-system-2014-to-2015