NHS
Shropshire, Telford and Wrekin
Clinical Commissioning Group

Policy on the commissioning of treatments with Botulinum toxin type A and type B

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Document Amendment History

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Contents

1 Introduction

Botulinum toxin is a powerful neurotoxin which blocks cholinergic transmission at the neuromuscular junction. In simple terms it paralyses muscles. It has medical uses where abnormal or excessive muscle activity causes problems for patients i.e. dystonia and spasticity.

Where there are multiple licensed preparations for a given indication, treatment should normally be started with the drug with the lowest acquisition cost.

2 Purpose

- This policy will guide cost effective use of Botulinum Toxin in line with national and local recommendations
- To provide the basis for completion of a Blueteq new medicines request form based on access criteria in the above
- This Policy is the basis for clinical and financial audit

3 Responsibilities

The STWCCG Medicines Quality Team is responsible for maintaining up to date policies which guide appropriate and safe medicines use and sustainable management of NHS resources.

The Medicines Quality QIPP programme seeks to secure the best value for the NHS whenever medicines are used.

3.1 The Chief Executive

The Chief Executive has responsibility for ensuring local medicines policies are compliant with access criteria which are nationally mandated or locally agreed as a result of a rigorous critical appraisal of clinical trial data.

Decisions to include medicines in local pathways are made at The Area Prescribing Committee and adhere to NICE appraisals and guidelines; value based local decision making; Equality and Human Rights Commission guidelines and the principles of the NHS constitution.

3.2 Executive Directors, Community Health Services Managing Director and Deputy Directors

Liz Walker, Deputy Director, Medicines Management STWCCG

Zena Williams, Director of Quality, STWCCG

3.3 Specialist Staff

Initiation of botulinum toxin will be initiated by physicians experienced in its use who will be able to determine whether patients are continuing to respond well to treatment and stop treatment if patients don’t respond initially and/or who respond initially but fail to show continued improvement in symptom control

- Neurologists
- Urologists
- Specialist Nurses

NB GPs (and specialists not experienced in its use) **will not** be expected to initiate treatment with Botulinum Toxin or continue to prescribe when initiated under specialist supervision. A share care guideline will not be agreed for transfer of prescribing responsibility.

3.4 Line Managers

Divisional managers in the Trust will have responsibility for managing service delivery working closely with clinical directors. Specialist nurses will need to receive appropriate training and clinical supervision before they are expected to initiate or continue to prescribe Botulinum Toxin.

3.5 All Staff

Medical specialists: senior registrars, FY1s; specialist nurses; clinical pharmacists; physiotherapists; occupational therapists involved in Service Deliver will need to work as a team to ensure patients obtain optimal benefit from Botulinum Toxin.

3.6 The Board

The Governing Body of Shropshire, Telford and Wrekin CCG will provide clinical oversight of all clinical policies and support the Board in taking a lead on providing assurance of clinical policy implementation.

A representative from the CCG Governing Body will actively participate in the APC meetings and to support short life working groups to support local policy development.

3.7 Committees and Groups

The Area Prescribing Committee will be the decision making committee for new clinical policies and provide the main channel for communication with those specialties and specialist/specialised services affected by them.

3.7.1 Clinical Sponsorship

Policy development will start with a concerted effort to consult with the clinical specialties and a clinical sponsor will be sought to act as a subject matter expert at the APC and spokesperson on behalf of clinical peers.

It will be the responsibility of the clinical sponsor to communicate APC decisions in provider trust to Medical Director; Clinical Director; Divisional Manager; Service Manager; Senior Nursing Staff; Director of Pharmacy.

3.7.2 Critical Appraisal

Crucial to the agreement of access criteria in a clinical policy will be the rigorous review of clinical trials (evidence base) and relevant *real world* studies which position medicines on a treatment pathway. The licensing and cost impact of different options will be included in this review and the recommendations given to the APC.

So each policy will explicitly state a set of clinical criteria that need to be met before a medicine can be used.

Local access criteria will be subject to review when NICE publishes a Technology Appraisal or Clinical Guideline so that local clinical decisions align with national policy.

4 Procedures / Processes

The need for a clinical policy will be considered at the APC

4.1 Unmet Need

The need for a clinical policy arises when there is ambiguity about the positioning of a medicine in a treatment pathway, often due to its high cost, which could lead to unwarranted variation and inequity of access.

Important in the consideration of the need are population health factors; healthy inequality and opportunity cost. Also important is whether the current pathway is preventing higher acuity illness across 'at risk' groups.

Public Health expertise will be sought by the APC when there are population health factors to consider.

4.2 Cost

Local Decision Making will establish whether the new policy will have a significant cost impact and whether it is necessary for a business case to be submitted for consideration at Investment Panels which will be coordinated by the single strategic commissioner (shadow ICS for Shropshire System).

Medicines which have a direct impact on the cost of admissions or length of stay in hospital or which reduce the burden of care in primary care compared with current treatment options, will be prioritised.

(NICE determines the cost effectiveness of health care interventions determined by a threshold of affordability equivalent to £30k/QALY. NICE criteria will usually take precedence over local criteria.

The determination of this level of value for healthcare is determined after a detailed health economic assessment using expertise not available to support local decision making hence NICE decisions will take precedence.

The £30K/ QALY threshold is considered to be the outer limit of affordability (based on the affordability of renal dialysis) and most healthcare interventions for routine care will far well short of this.

4.2.1 Short Life Working Group

Time for detailed consideration of the evidence base and comparison with existing treatment options is not available at the APC because of the wide range of treatments considered at this committee. And the availability of expertise to reach a decision at the committee is limited for this reason also.

So in order for the business of the APC to be conducted in a timely manner Short Life Working Groups (SLWG) will be formed to co-opt the necessary

clinical expertise to consider the evidence carefully and recommendations brought back to the APC for ratification

SLWG will consider the need for a new medicine to be included and what constraints on use will be needed to make the NHS benefit in a proportionate way.

As well as determining which access criteria are needed, the SLWG will consider whether changes to referral pathways are needed, what category the medicine falls into (Red, Amber or Green) and whether a shared care guideline is needed and make this recommendations to the APC.

To be supported in this the SLWG will need access to a data analysis looking at hospital activity and prescribing costs in order to make a valid comparison. The SLWG will need to bring together different clinical disciplines (specialist and generalist); public health; hospital management; nursing and pharmacy (the latter to consider the practical aspects of service provision.

4.3 Decisions – access criteria

The access criteria for Botulinum Toxin are laid out clearly and determine where it adds value and by definition where it doesn't, in the management of spasticity.

The criteria are open to challenge as new evidence becomes available and the APC will specify a suitable review date.

Decisions about access to a medicine are important in the context of the Long Term Plan which seeks to reduce the number of outpatient appointments by 30% overall and so making decisions about medicines with such a wide scope covering a number of services has a system wide significance.

Appendix 1: Botulinum Policy

4.4 MHRA Warning

The Medicines and Healthcare Regulatory Authority (MHRA) as the UK licensing authority (alongside *Scottish Medicines Consortium* and *The All Wales Medicines Advisory Group*) has issued a warning letter from June 2007[i] made the following recommendations**:**

- Botulinum toxin products should only be administered by physicians with appropriate experience including use of the required equipment.
- Patients or caregivers should be informed about the risk of spread of toxins and be advised to seek immediate medical care if swallowing, speech or respiratory disorders arise.
- Botulinum toxin units are not interchangeable from one product to another.
- The recommended administration techniques and specific dosing guidance (including the recommendation to use the minimum effective dose and titrate according to individual requirements) should be followed.

All commissioned use of Botulinum toxin should be in accordance with the above recommendations.

As with other medicines the MHRA requires prescribers to report all adverse drug reactions by completing a yellow card form, this will inform safe use of medicines and give a clear picture of issues as they arise protecting patient safety.

https://yellowcard.mhra.gov.uk/_assets/files/Healthcare-Professional-Yellow-Card-Reporting-Form-(July-2019).pdf

5 STWCCG Formulary

All prescribing formulary decisions are publically available on the netFormulary site http://www.shropshireandtelfordformulary.nhs.uk/

6 Dissemination

This Botulinum for Spasticity Policy will be disseminated by the following methods:

- SATH Drug and Therapeutics Committee
- NHS Shropshire Telford and Wrekin CCG website

  https://www.shropshireccg.nhs.uk/ - professional resources – medicines management - policies
- Awareness raising by Clinical Directors; Neurology and Urology

7 Advice and Training

Each department is responsible for staff training including training in connection with use of new medicines. Training should include all staff who are involved in the management of patients with spasticity so that a holistic consideration of the outcome from Botulinum treatment can be considered.

The NHS Long Term Plan advocates the creation of multidisciplinary teams (MDTs) to guide clinical decision making including when to initiate and terminate treatment and when to allow access on a trial basis.

7.1 Clinical Audit

Clinical Audit should be the basis on which treatment value for the cohort of patients with Botulinum toxin is regularly reviewed. The Trust has a clinical audit team who can provide advice on how to conduct clinical audit:

Mrs Sally Allen
Manager,
Clinical Audit Team
Shrewsbury and Telford Hospitals
NSH Trust
Direct Line: 01743 261478
Email: sally.allen5@nhs.net

7.2 Sponsored Training

Training should be provided which supports and reinforces treatment decisions which align with this policy. Any training provider should provide training which is unbiased and free from commercial considerations.

Pharmaceutical manufacturers can provide useful training updates which are free from promotional material – this is governed by regulation of the Pharmaceutical Industry code of conduct known as the ABPI Code which has a specific clause about 'disguised promotion'.

Service managers wishing to take advantage of sponsored training opportunities but who are unsure about the ABPI Code, can contact the CCG medicines quality team for advice:

Liz Walker

Deputy Director, Medicines Management,

Email: Elizabeth Walker

8 Review and Compliance Monitoring

The date for review of policies is usually three years after they are agreed at the APC exceptions to this include:

- Publication of safety alerts by the MHRA
- Publication of new clinical studies that challenge the basis for the access criteria in the current policy i.e. which either lower or raise the threshold of use – these new studies are subject to appraisal and need to be 'sponsored' for review at the APC by a specialist with insight into the benefits shown in the study (usual declaration of interest applies)
- Publication of national guidance (NICE, NHSE/I Regional Medicines Optimisation Committee)

8.1.1 Blueteq

Requests to initiate botulinum toxin type A must be submitted via 'Blueteq' approval template.

The process for submission of Blueteq forms is well established and provides a means of regulating access and ensuring use of medicines remain within the agreed criteria.

The invoicing of The CCG by the Trust for medicines not included in the PBR Tariff is done using Blueteq there is no other way for medicines to be initiated.

Any use which isn't authorised will be included in a **challenge report** by the CCG and is unlikely to be funded and so any treatment which hasn't been approved will be a cost that is borne by the Trust alone.

Support for using Blueteq can be obtained from the Trust Pharmacy dept.

8.2 Compliance Monitoring

The APC will undertake periodic reviews of use based on Blueteq data and write to the Medical Director to raise awareness of prescribing which deviates from the access criteria in this policy.

The financial sustainability of the Shropshire system is reliant on following clinical policies as the cost assumptions are built in to financial forecasts and so deviation from these assumptions will threaten the viability of the whole system and have impacts on other services in the Trust and the system as a whole.

9 References

- Royal College of Physicians National guidelines: Spasticity in adults: management using botulinum 2018 https://www.google.com/search?q=nice+spasticity+guidelines&gws_rd=ssl#spf=1620647334602

- NICE Clinical Guideline: Spasticity in under 19s: management Clinical guideline [CG145] Published: 25 July 2012 Last updated: 29 November 2016 https://www.nice.org.uk/guidance/cg145

- NICE Chronic anal fissure: botulinum toxin type A injection Evidence summary [ESUOM14] Published: 25 June 2013 https://www.nice.org.uk/advice/esuom14/chapter/Key-points-from-the-evidence
- NICE Technology appraisal guidance [TA260] Published: 27 June 2012: Botulinum toxin type A for the prevention of headaches in adults with chronic migraine https://www.nice.org.uk/guidance/ta260

10 Glossary

Term / Abbreviation	Explanation / Definition
NICE	National Institute for Health and Care Excellence
RCP	

Appendix 1 – Botulinum Policy

Policy on the commissioning of treatments with Botulinum toxin type A and type B

Introduction

Botulinum toxin is a powerful neurotoxin which blocks cholinergic transmission at the neuromuscular junction. In simple terms it paralyses muscles. It has medical uses where abnormal or excessive muscle activity causes problems for patients i.e. dystonia and spasticity.

Where there are multiple licensed preparations for a given indication, treatment should normally be started with the drug with the lowest acquisition cost.

Commissioned Indications

The following clinical indications for Botulinum toxin type A and B will be routinely commissioned:

Indication	Licensed product
Cervical dystonia (spasmodic torticollis)	Botox®, Dysport®, Xeomin® Neurobloc®
Severe blepharospasm	Botox®, Dysport®, Xeomin®, Xeomin®
Hemifacial spasm	Botox®, Dysport®, Xeomin®
Management of severe hyperhidrosis of the axillae, which does not respond to topical treatment with antiperspirants or antihidrotics • **with the exception of** hyperhidrosis in people with social anxiety disorder (SAD) (this is because there is no good quality evidence).	Botox®, Dysport® NICE Social anxiety disorder: recognition, assessment and treatment section 1.6.5
Focal spasticity in upper and lower limb in adults (causes other than stroke) *NB – Focal spasticity in under 19s is NHS England commissioned*	Botox®, Dysport® (Xeomin® - upper limb only) NG119 Cerebral palsy in adults (January 2019)
Bladder wall injection to women with overactive bladder caused by detrusor overactivity that has not responded to non-surgical management, including pharmacological treatments after a local MDT review. Start treatment with botulinum toxin A only if the woman is willing, in the event of developing significant voiding dysfunction : • To perform clean intermittent catheterisation on a regular basis for as long as needed or • To accept a temporary indwelling catheter if she is unable to perform clean intermittent catheterisation. Where urodynamic investigation has not demonstrated detrusor overactivity, if the symptoms have not responded to non-surgical management and the woman does not wish to have other invasive treatments consider botulinum toxin type A.	Botox® NG123 (June 2019) :Urinary incontinence and pelvic organ prolapse in women: management
Prophylaxis of headaches in chronic migraine as directed by NICE TA260 (June 2012)	Botox® TA260 (June 2012): Botulinum toxin type A for the prevention of headaches in adults

	with chronic migraine
Bladder wall injection to adults, children and young people: • with spinal cord disease (for example, spinal cord injury or multiple sclerosis) **and** • in whom antimuscarinic drugs have proved to be ineffective or poorly tolerated **and** • with symptoms of an overactive bladder **or** with urodynamic investigations showing impaired bladder storage	Botox® CG148 (August 2012): Urinary incontinence in neurological disease: assessment and management
Chronic sialorrhoea caused by neurological disorders in adults as directed by NICE TA605 (Oct 2019)	Xeomin® TA605 (October 2019): Xeomin (botulinum neurotoxin type A) for treating chronic sialorrhoea
Dysphagia caused by achalasia	Unlicensed
Chronic Anal Fissures[ii,iii,iv] Botulinum toxin A will only be commissioned for treating chronic or recurrent anal fissures in adults where: • the condition has failed to heal spontaneously • chronic symptoms (pain and / or rectal bleeding) have persisted for more than 6 weeks • all other appropriate non-surgical, pharmacological (e.g. topical diltiazem, glyceryl trinitrate [GTN]) and dietary treatments have been tried and failed. One treatment with Botulinum toxin A will be commissioned - if the anal fissure fails to heal during the three-month period after injection, and chronic symptoms persist, surgical intervention may be indicated.	Unlicensed ESUOM14 (June 2013): Chronic anal fissure: botulinum toxin type A injection

[i] MHRA Drug Safety update Vol1 Issue 3 October 2007
[ii] NICE ESUOM14: Chronic anal fissure: botulinum toxin type A injection June 2013
[iii] DTB 2013 51: 102-104 Non-surgical treatments for anal fissures in adults
[iv] Cross et al. The Management of Anal Fissure: ACPGBI Position Statement (2008) The Association of Coloproctology of Great Britain and Ireland. Colorectal Disease, 10 (Suppl. 3), 1–7.