NHS Dorset Clinical Commissioning Group

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Botulinum Toxin Type A

Criteria Based Access Protocol



Supporting people in Dorset to lead healthier lives

NHS DORSET CLINICAL COMMISSIONING GROUP

BOTULINUM TOXIN TYPE A CRITERIA BASED ACCESS PROTOCOL

1. Introduction

1.1 This protocol describes the inclusion and exclusion criteria regarding the use of Botulinum Toxin Type A and will be applied in accordance with the Policy for Individual Patient Treatment.

1.2 NHS Dorset Clinical Commissioning Group will only support the use of Botulinum Toxin Type A in the case of clinical need, where the patient meets the access criteria incorporated in section 3.1.

2. Access Criteria

2.1 For the conditions specified below the use of Botulinum Toxin Type A is commissioned in the following pathways:

Adults

- Axillary Hyperhidrosis as a second line treatment in those patients who have initially been considered for iontophoresis (as per current pathway for The Management of Axillary Hyperhidrosis);
- Cervical dystonia;
- Focal spasticity due to Stroke, Multiple Sclerosis, or Traumatic Brain Injury;
- Blepharospasm and hemi facial spasm where there is recorded functional or visual impairment;
- Achalasia for patients who are deemed unfit for surgery or pneumatic dilatation; and
- Chronic Migraine as part of the locally agreed pathway in line with the NICE Technology Appraisal (TA260).

Children

- Focal spasticity of the upper and lower limb (in line with NICE CG145) if deemed appropriate by the relevant regional paediatric neuroscience centre and forms part of the NHS England specialised commissioned pathway(s) for children with spasticity. Botulinum Toxin Type A should be given with a clear treatment goal in mind and if the treatment goal is not achieved then the Botulinum Toxin Type A should not be continued.

2.2 There will be no requirement for prior approval for the use of Botulinum Toxin Type A in the pathways detailed in section 2.1. It is expected that Trusts will submit monthly audit data at patient level on the use within pathways which covers speciality, consultant, indication, dose, and patient outcomes.

3. Exclusions

Commissioners have decided that for all instances of use of Botulinum Toxin Type A in any pathways, other than the ones defined above in section 2.1 that funding its use will be a provider/clinician responsibility. For use of Botulinum Toxin Type A for Overactive Bladder please see the specific Criteria Based Access Protocol for that indication.

4. Cases for Individual Consideration

4.1 Should a patient not meet the criteria detailed within this protocol, the Policy for Individual Patient Treatments (which is available on the NHS Dorset Clinical Commissioning Group website or upon request), recognises that there will be occasions when patients who are not considered for funding may have good clinical reasons for being treated as exceptions. In such cases the requesting clinician must provide further information to support the case for being considered as an exception.

4.2 The fact that treatment is likely to be effective for a patient is not, in itself a basis for exceptional circumstances. In order for funding to be agreed there must be some unusual or unique clinical factor in respect of the patient that suggests that they are:

- significantly different to the general population of patients with the particular condition; and
- they are likely to gain significantly more benefits from the intervention than might be expected for the average patient with the condition

4.3 In these circumstances, please refer to www.dorsetccg.nhs.uk/aboutus/clinical-policies.htm which provides guidance on submitting individual patient treatment requests.

5. Consultation

5.1 Prior to approval from Dorset CCG's Clinical Commissioning Committee this Protocol was reviewed within the local NHS including input from commissioners, clinicians and other relevant stakeholders and agreed by the Dorset Medical Advisory Group.

5.2 An Equality Impact Assessment for this Criteria Based Access Protocol is available on request.

6. Recommendation and Approval Process

6.1 This access protocol has been reviewed and agreed by the Dorset Medicines Advisory Group and subsequently approved on behalf of the Clinical Commissioning Committee in line with processes agreed by the CCG's Governing Body.

7. Communication/Dissemination

7.1 Following approval of Criteria Based Access Protocols at Clinical Commissioning Committee each Protocol will be uploaded to the CCG's Intranet, Internet and added to the next GP Bulletin.

8. Implementation

8.1 There has been significant discussion with stakeholders in respect of the introduction and implementation of this new access protocol. It is therefore considered that there is no requirement for a formal implantation plan.

9. Document Review Frequency and Version Control

9.1 This Criteria Based Access Protocol requires a review every three years, or in the event of any changes to national guidance or when new guidance is issued.

FREQUENTLY ASKED QUESTIONS

GLOSSARY

A	DOCUMENT DETAILS
Procedural Document Number	To be completed by the Patient Safety and Risk team
Author (Name and Job Title)	Michael Cross, Senior Commissioner Individual Patients
Clinical Delivery Group (recommending group)	Dorset Medicines Advisory Group
Date of recommendation by CDG	12 September 2017
Date of approval by CCC	November 2017
Version	5.0
Review frequency	3 Years
Review date	November 2020

B	CONSULTATION PROCESS		
Version No	**Review Date**	**Author and Job Title**	**Level of Consultation**
5.0	September 2017		Dorset Medicines Advisory Group including clinical and patient and public representation.

C	VERSION CONTROL				
Date of recommendation	**Version No**	**Review date**	**Nature of change**	**Approval date**	**Approval Committee**
June 2014	2.0	August 2015	Transfer into new format.	June 2014	Clinical Commissioning Committee
July 2014	3.0	August 2015	Revision of access criteria in respect of children agreed at CCC	July 2014	Clinical Commissioning Committee
August 2015	4.0	August 2017	Remove 'interim' from document title. Cross refer	August 2015	Clinical Commissioning Committee

			Botulinum Toxin Type A and Botulinum Type A for Overactive Bladder Criteria Based Access Protocols.		
September 2017	5.0	November 2017	Inclusion of achalasia as an indication for which the provision of Botulinum Toxin Type A is supported in specific clinical circumstances	November 2020	Clinical Commissioning Committee

D	ASSOCIATED DOCUMENTS

- Policy for Individual Patient Treatment, NHS Dorset Clinical Commissioning Group
- Making sense of Local Access Based Protocols, NHS Dorset Clinical Commissioning Group

E	SUPPORTING DOCUMENTS/EVIDENCE BASED REFERENCES		
Evidence		**Hyperlink (if available)**	**Date**

G	DISTRIBUTION LIST		
Internal CCG Intranet	**CCG Internet Website**	**Communications Bulletin**	**External stakeholders**
✓	✓	✓	✓