# Botulinum Toxin Policy

| | |
|---|---|
| Version: | 2017-20 |
| Ratified by: | NHS Leeds West CCG Assurance Committee on; NHS Leeds North CCG Governance on Performance and Risk Committee on; NHS Leeds South and East CCG Governance and Risk Committee on |
| Name & Title of originator/author(s): | Dr Simon Stockill Medical Director, NHS Leeds West CCG<br>Dr Manjit Purewal, Medical Director NHS Leeds North CCG<br>Dr David Mitchell, Medical Director NHS Leeds South and East CCG<br>Dr Fiona Day, Consultant in Public Health Medicine, Leeds City Council |
| Name of responsible committee/individual: | Dr Simon Stockill Medical Director, NHS Leeds West CCG Governing Body<br>Dr Manjit Purewal, Medical Director NHS Leeds North CCG Governing Body<br>Dr David Mitchell, Medical Director NHS Leeds South and East CCG Governing Body |
| Date issued: | July 2017 |
| Review date: | September 2020 |
| Target audience: | Primary and secondary care clinicians, individual funding request panels, and the public |
| Document History: | Leeds CCGs Cosmetic Exceptions and Exclusions Policy Feb 2014<br>Botox Policy Dec 2016 |

**Produced on behalf of NHS Leeds West Clinical Commissioning Group, NHS Leeds North Clinical Commissioning Group and NHS Leeds South and East Clinical Commissioning Group**

## Executive Summary

This policy applies to all Individual Funding Requests (IFR) for people registered with General Practitioners in the following three Clinical Commissioning Groups (CCGs), where the CCG is the responsible commissioner for this treatment or service:

- NHS Leeds West CCG
- NHS Leeds North CCG
- NHS Leeds South and East CCG

This policy does not apply where any one of the Leeds CCGs is not the responsible commissioner. In a number of the circumstances below the specialties are currently (2017) commissioned by NHS England Specialist Commissioning team, whose commissioning policies will apply. However, some of these services are expected to transfer to CCGs within the period of this policy and so are included for completeness.

The policy updates all previous policies and must (where appropriate) be read in association with the other relevant Clinical Commissioning Groups in Leeds commissioning policies, which are to be applied across all three CCGs, including but not limited to policies on cosmetic exceptions and non-commissioned activity.

All IFR and associated policies will be publicly available on the internet for each CCG.

This policy relates specifically to **Botulinum Toxin use.**

**Contents**

## 1 Introduction

The Clinical Commissioning Groups (CCGs) (NHS Leeds West CCG, NHS Leeds North CCG and NHS Leeds South and East CCG) were established on 1 April 2013 under the Health and Social Care Act 2012 as the statutory bodies responsible for commissioning services for the patients for whom they are responsible in accordance with s3 National Health Service Act 2006.

As part of these duties, there is a need to commission services which are evidence based, cost effective, improve health outcomes, reduce health inequalities and represent value for money for the taxpayer. The CCGs in Leeds are accountable to their constituent populations and Member Practices for funding decisions.

In relation to decisions on Individual Funding Requests (IFR), the CCGs in Leeds have a clear and transparent process and policy for decision making. They have a clear CCG specific appeals process to allow patients and their clinicians to be reassured that due process has been followed in IFR decisions made by the Non Commissioned Activity Panel, Cosmetic Exclusions and Exceptions Panel, or Non NICE Non Tariff Drug Panel (the IFR panels).

Due consideration must be given to IFRs for services or treatments which do not form part of core commissioning arrangements, or need to be assessed as exceptions to Leeds CCGs Commissioning Policies. This process must be equitably applied to all IFRs.

All IFR and associated policies will be publically available on the internet for each CCG. Specialist services that are commissioned by NHS England or Public Health England are not included in this policy.

## 2 Purpose

The purpose of the IFR policy is to enable officers of the Leeds CCGs to exercise their responsibilities properly and transparently in relation to IFRs, and to provide advice to general practitioners, clinicians, patients and members of the public about IFRs. Implementing the policy ensures that commissioning decisions in relation to IFRs are consistent and not taken in an ad-hoc manner without due regard to equitable access and good governance arrangements. Decisions are based on best evidence but made within the funding allocation of the CCGs.

The policy outlines the process for decision making with regard to services/treatments which are not normally commissioned by the CCGs in Leeds, and is designed to ensure consistency in this decision making process.

The policy is underpinned by the following key principles:

- The decisions of the IFR panels outlined in the policy are fair, reasonable and lawful, and are open to external scrutiny.

- Funding decisions are based on clinical evidence and not solely on the budgetary constraints.
- Compliance with standing financial instructions / and statutory instruments in the commissioning of healthcare in relation to contractual arrangements with providers.

Whilst the majority of service provision is commissioned through established service agreements with providers, there are occasions when services are excluded or not routinely available within the National Health Service (NHS). This may be due to advances in medicine or the introduction of new treatments and therapies or a new cross-Leeds Clinical Commissioning Group statement. The IFR process therefore provides a mechanism to allow drugs/treatments that are not routinely commissioned by the Leeds CCGs to be considered for individuals in exceptional circumstances.

## 3 Scope

The CCGs in Leeds have established the processes outlined in this policy to consider and manage IFRs in relation to the following types of requests: **botulinum toxin use.** Leeds CCGs *do not routinely commission* aesthetic (cosmetic) surgery and other related procedures that are medically unnecessary.

Providing certain criteria are met, Leeds CCGs will commission aesthetic (cosmetic) surgery and other procedures to improve the functioning of a body part or where medically necessary even if the surgery or procedure also improves or changes the appearance of a portion of the body.

Please note that, whilst this policy addresses many common procedures, it does not address all procedures that might be considered to be cosmetic. Leeds CCGs reserve the right not to commission other procedures considered cosmetic and not medically necessary. This policy is to be used in conjunction with the Individual Funding Requests (IFR) Policy for Leeds CCGs and other related policies.

### Endpoints

Following completion of the agreed treatment, a proportionate follow up process will lead to a final review appointment with the clinician where both patient and clinician agree that a satisfactory end point has been reached. This should be at the discretion of the individual clinician and based on agreeing reasonable and acceptable clinical and/ or cosmetic outcomes.

Once the satisfactory end point has been agreed and achieved, the patient will be discharged from the service.

Requests for treatment for unacceptable outcomes post treatment will only be considered through the Individual Funding Request route. Such requests will only be considered where a) the patient was satisfied with the outcome at the time of discharge and b) becomes dissatisfied at a later date. In these circumstances the patient is not automatically entitled to further treatment. Any further treatment will therefore be at the relevant Leeds Clinical Commissioning Group's discretion, and will be considered on an exceptional basis in accordance with the IFR policy.

Leeds CCGs are committed to supporting patients to stop smoking in line with NICE guidance in order to improve short and long term patient outcomes and reduce

health inequalities. Referring GPs and secondary care clinicians are reminded to ensure the patient is supported to stop smoking at every step along the elective pathway and especially for flap based procedures (in line with plastic surgery literature: abdominoplasty, panniculectomy, breast reduction, other breast procedures).

## 4 Definitions

The CCGs in Leeds are not prescriptive in their definitions. Each IFR will be considered on its merits, applying this Policy.

**Routinely commissioned** – this means that this intervention is routinely commissioned as outlined in the relevant policy, or when a particular threshold is met. Prior approval may or may not be required, refer to the policy for more information.

**Exceptionality request** – this means that for a service which is not routinely commissioned, or a threshold is not met, the clinician may request funding on the 'grounds of exceptionality' through the individual funding request process. Decisions on exceptionality will be made using the framework defined in the overarching policy 'Individual Funding Requests (IFR) Policy for the Clinical Commissioning Groups in Leeds'.

## 5 Duties

Whilst this policy and associated decision making policies will be applied on a cross- Leeds basis for patients from all three CCGs in Leeds, each individual CCG will retain responsibility for the decision making for its own patients. To this end, each CCG will delegate its decision making in relation to IFRs to a CCG specific decision maker for patients from that specific CCG, in accordance with its own Constitution.

This decision maker will attend the relevant IFR panel and will also have responsibility for approving the triage process for patients from their own CCG population. The triage process is the process of screening requests to see whether the request meets the policy criteria and which referrals need to be considered by an IFR panel; see sections on IFR panels for more information. The decision maker for each CCG is responsible for decision making solely for patients within their own CCG registered population. This will normally be the Medical Director or their designate. This will be detailed in the CCG Constitution as an Appendix.

In exceptional circumstances, when a CCG is unable to send a delegated decision maker to the IFR panel, the panel may discuss the case in their absence and may make a recommendation. However, the decision maker for the specific CCG must make the final decision whether or not to approve the IFR.

## 6 Main Body of Policy

Exceptionality funding can be applied for in line with the overarching policy through the IFR process if you believe your patient is an exception to the commissioning position. Please refer to the overarching policy for more information.

### 6.1 NHS Leeds CCGs consider botulinum toxin medically necessary for the following conditions:

**a. Strabismus in children, including gaze palsies accompanying diseases, such as:**

i. Neuromyelitis optica;
ii. Schilder's disease.

Note: Strabismus repair is considered cosmetic in adults with uncorrected congenital strabismus and no binocular fusion.

**b**. **Blepharospasm,** characterized by intermittent or sustained closure of the eyelids caused by involuntary contractions of the orbicularis oculi muscle, with evidence of functional visual impairment. Maximum frequency of every 4 months.

**c**. **Post-facial (7th cranial) nerve palsy** synkinesis (hemifacial spasms), characterized by sudden, unilateral, synchronous contractions of muscles innervated by the facial nerve. Maximum frequency of every 4 months

**d**. **Adductor laryngeal dystonia**, when all the following criteria are met:.

i. diagnosed by a Consultant Otolaryngologist (and a more generalised dystonia has been ruled out by a Consultant Neurologist)
ii. Speech and language therapy has not adequately improved the voice quality
iii. The resulting communication difficulties are interfering significantly with daily living and adversely affecting the patient's quality of life.

**e**. **Cervical dystonia** (spasmodic torticollis) of moderate or greater severity when all of the following criteria are met:

i. There are clonic and/or tonic involuntary contractions of multiple neck muscles (e.g., sternocleidomastoid, splenius, trapezius and/or posterior cervical muscles); and
ii. There is sustained head torsion and/or tilt with limited range of motion in the neck; and
iii. The duration of the condition is greater than 6 months; and
iv. Alternative causes of the member's symptoms have been considered and ruled out, including chronic neuroleptic treatment, contractures, or other neuromuscular disorders.
v. Maximum frequency of 3 monthly

**f**. **Focal dystonias, including**

i. Focal dystonias in corticobasilar degeneration;
ii. Hand dystonia (i.e., organic writer's cramp);
iii. Jaw-closing oromandibular dystonia, characterized by dystonic movements involving the jaw, tongue, and lower facial muscles;

iv. Lingual dystonia;
v. Symptomatic torsion dystonia (but not lumbar torsion dystonia).

**g**. **Limb spasticity, including:**
i. Equinus varus deformity in children with cerebral palsy
ii. Hereditary spastic paraplegia;
iii. Limb spasticity due to multiple sclerosis;
iv. Limb spasticity due to other demyelinating diseases of the central nervous system (including adductor spasticity and pain control in children undergoing adductor-lengthening surgery as well as children with upper extremity spasticity);
v. Spastic hemiplegia, such as due to stroke or brain injury.
(see NICE CG145 for further information)

**h**. **Oesophageal achalasia, for individuals who fulfil any of the following criteria:**
i. Are at high risk of complications of pneumatic dilation or surgical myotomy; or
ii. Have failed conventional therapy; or
iii. Have failed a prior myotomy or dilation; or
iv. Have had a previous dilation-induced perforation; or
v. Have an epiphrenic diverticulum or hiatal hernia, both of which increase the risk of dilation-induced perforation.

**i**. **Chronic anal fissure, 3rd line,** if unresponsive to conservative therapeutic measures. Only a single treatment will be funded. Any subsequent treatments will require prior approval.
First line treatment (after dietary treatments) is glyceryl trinitrate 0.4% ointment twice daily for 6-8 weeks.
Second line is Diltiazem cream 2% (not ointment) twice daily for 2 months. If some improvement, can be continued for a further 2 months

**j**. **Ptyalism/sialorrhea** (excessive secretion of saliva, drooling) that is socially debilitating and refractory to pharmacotherapy (including anticholinergics).

**k**. **Facial myokymia and trismus** associated with post-radiation myokymia only.

**l**. **Hirschsprung's** disease with internal sphincter achalasia following endorectal pull-through.

**m**. **Medically refractory upper extremity tremor** that interferes with activities of daily living (ADLs). (Additional botulinum toxin injections are considered medically necessary if response to a trial of botulinum toxin enables ADLs or communication).

**n**. **Detrusor-sphincter dyssynergia** after spinal cord injury.

**o**. **Overactive bladder**. – for women in line with NICE CG171 / for men in line with CG97

**p**. **Migraines** – the Leeds CCGs will only commission the use of botulinum toxin for the treatment of migraines in line with NICE TA260.

### 6.2 Hyperhydrosis – use of botulinum toxin for axillary hyperhidrosis

**Status: not routinely commissioned - prior approval via IFR process only.**

IFR will only be considered if:

Intractable, disabling focal primary hyperhydrosis when all of the following are met:

i. Topical aluminium chloride or other extra-strength antiperspirants are ineffective or result in a severe rash.

AND

ii. Iontophoresis has been ineffective for axillary/ palmar/ plantar hyperhydrosis

AND

iii. unresponsive or unable to tolerate pharmacotherapy prescribed for excessive sweating (e.g., anticholinergics) if sweating is episodic;

AND

iv. Significant disruption of life has occurred because of excessive sweating

Do not offer botulinum toxin to treat hyperhidrosis in people with social anxiety disorder. – NICE CG159

**NOTE - the CCG will fund a maximum of 2 treatments per year per patient of botulinum toxin, not to be repeated more frequently than every 16 weeks.**

**Botulinum toxin is not a good option for hands as multiple injections to hands are not generally tolerated.**

## 7 Equality Impact Assessment (EIA)

This document has been assessed, using the EIA toolkit, to ensure consideration has been given to the actual or potential impacts on staff, certain communities or population groups, appropriate action has been taken to mitigate or eliminate the negative impacts and maximise the positive impacts and that the and that the implementation plans are appropriate and proportionate.

The full EIA is attached as Appendix A.

## 8 Implications and Associated Risks

This policy and supporting frameworks set evidence based boundaries to interventions available on the NHS. It may conflict with expectations of individual patients and clinicians.

## 9 Education and Training Requirements

Members of the panels will undergo training at least every three years, particularly in relation to the legal precedents around IFRs. Effective policy dissemination is required for local clinicians.

## 10 Monitoring Compliance and Effectiveness

Each IFR panel will maintain an accurate database of cases approved and rejected, to enable consideration of amendments to future commissioning intentions and to ensure consistency in the application of the CCGs in Leeds Commissioning Policies.

The financial impact of approvals outside of existing Service Level Agreements will be monitored to ensure the Leeds CCGs identify expenditure and ensure appropriate value for money. Member Practice clinicians need to be aware that all referrals will ultimately be a call on their own CCG budgets.

## 11 Associated Documentation

This policy must be read in conjunction with the underpinning Leeds CCGs decision making frameworks.

## 12 References


NICE (2013) CG159 Social anxiety disorder: recognition, assessment and treatment

NICE (2012) TA 260 Botulinum toxin type A for the prevention of headaches in adults with chronic migraine

NICE (2015) CG171 Urinary incontinence in women: management

NICE (2015) CG97 Lower urinary tract symptoms in men: management

NICE (2016) CG145 Spasticity in under 19s: management

## Appendices

## Appendix A: Equality Impact Assessment

| | | |
|---|---|---|
| **Title of policy** | Botulinum Toxin | |
| **Names and roles of people completing the assessment** | Fiona Day Consultant in Public Health Medicine, Helen Lewis, Head of Acute Provider Commissioning | |
| **Date assessment started/completed** | 25.3.17 | 30.3.17 |

| **1. Outline** | |
|---|---|
| **Give a brief summary of the policy** | The purpose of the commissioning policy is to enable officers of the Leeds CCGs to exercise their responsibilities properly and transparently in relation to commissioned treatments including individual funding requests, and to provide advice to general practitioners, clinicians, patients and members of the public about IFRs. Implementing the policy ensures that commissioning decisions are consistent and not taken in an ad-hoc manner without due regard to equitable access and good governance arrangements. Decisions are based on best evidence but made within the funding allocation of the CCGs. This policy relates to requests for botulinum toxin. |
| **What outcomes do you want to achieve** | We commission services equitably and only when medically necessary and in line with current evidence on cost effectiveness. |

| **2. Evidence, data or research** | |
|---|---|
| **Give details of evidence, data or research used to inform the analysis of impact** | See list of references |

| **3. Consultation, engagement** | |
|---|---|
| **Give details of all consultation and engagement activities used to inform the analysis of impact** | Discussion with clinicians and patient representatives on the principles of decision making. Based on NICE guidance or equivalent - NICE has extensive stakeholder engagement. |

| 4. Analysis of impact | | | |
|---|---|---|---|
| This is the core of the assessment, using the information above detail the actual or likely impact on protected groups, with consideration of the general duty to; eliminate unlawful discrimination; advance equality of opportunity; foster good relations | | | |
| | **Are there any likely impacts? Are any groups going to be affected differently? Please describe.** | **Are these negative or positive?** | **What action will be taken to address any negative impacts or enhance positive ones?** |
| **Age** | No | | |
| **Carers** | No | | |
| **Disability** | Where conditions relevant | positive | Ensures evidence based an equitable access based on clinical need |
| **Sex** | yes | Positive | For overactive bladder in both sexes in line with NICE guidance and clinical need |
| **Race** | No | | |
| **Religion or belief** | No | | |
| **Sexual orientation** | No | | |
| **Gender reassignment** | No | | |
| **Pregnancy and maternity** | No | | |
| **Marriage and civil partnership** | No | | |
| **Other relevant group** | | | |
| | | | |
| **If any negative/positive impacts were identified are they valid, legal and/or justifiable? Please detail.** | In line with NICE guidance | | |

| 5. Monitoring, Review and Publication | | | |
|---|---|---|---|
| **How will you review/monitor the impact and effectiveness of your actions** | IFR requests and complaints | | |
| **Lead Officer** | Helen Lewis | **Review date:** | annually |

| 6.Sign off | | | |
|---|---|---|---|
| **Lead Officer** | Helen Lewis | | |
| **Director** | Simon Stockill | **Date approved:** | 12 July 2017 |

## Appendix B: Policy Consultation

| | |
|---|---|
| **Title of document** | Botulinum Toxin policy |
| **Author** | Jo Alldred/Fiona Day |
| **New / Revised document** | Revised |
| Lists of persons involved in developing the policy<br>List of persons involved in the consultation process: | Jo Alldred<br><br>Consultant Dermatologists<br><br>Consultant Vascular Surgeon<br><br>NICE |