Equality Impact and Risk Assessments

Pan Merseyside Policies: Policy for Botulinum Toxin A&B

Midlands and Lancashire CSU

Current Status
Stage 2 Approved

Review Date
16/02/2017

Person Responsible
Harinder Kaur

Service
Policy for Botulinum Toxin A&B

Service Area
Individual Funding Request / Individual Patient Activity Procedure for Policies of Lower Clinical Priority

Project Lead

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Explanation

Botulinum toxin A is a powerful neurotoxin which is used medically to relax muscles and for certain conditions there are recognised clinical benefits to patients. It is commonly known as B-Tox. However, due to its mechanism of action botulinum toxin A can be used for medical conditions for which the clinical benefits have not been proven or are unclear and inconsistencies have arisen before this policy existed. Therefore this document summarises the commissioning status of Botulinum Toxin A for specified medical conditions. This policy has been identified as low clinical priority. The CCGs has a limited funding resource and therefore has to prioritise services that are commissioned. CCGs currently gives greater priority to life threatening and chronic ill health. The Policy Review Group are working to identify areas of impact through the changes they make balanced with the need to align eligibility for treatments with best clinical evidence and balancing health resources for the whole population. This policy is part of a suite of policies are being reviewed collaboratively across Merseyside CCG's with Warrington CCG. The CCG's that are part of this review are: NHS Halton Clinical Commissioning Group NHS Liverpool Clinical Commissioning Group NHS St Helens Clinical Commissioning Group NHS South Sefton Clinical Commissioning Group NHS Southport and Formby Clinical Commissioning Group NHS Warrington Clinical Commissioning Group The revised criteria has not changed. Criteria aligned with the Pan Mersey Area Prescribing Committee. This assessment has been carried out by Equality and Inclusion Business Partner at MLCSU – Jennifer Mulloy. This assessment was updated in April 2019.

Assessment

Equality Impact

1	**Does this issue plan to withdraw a service, activity or presence?**	✔
No: This policy reviews previous policies for use of Botulinum Toxin A and B with proposed revised criteria for adoption across CCG's in Merseyside and Warrington CCGs.		
2	**Does this issue plan to reduce a service, activity or presence?**	✔
No: The proposed criteria contains some changes which may potentially extend treatments to a greater cohort of patients. The proposed criteria now includes treatment for patients with severe axillary hyperhidrosis. Therefore there may be an increase in activity levels.		
3	**Does this issue plan to introduce or increase a charge for Service?**	✔
No: There is no plan to introduce charges. The policy outlines criteria for eligibility of treatment for Botulinum Toxin A and B. The criteria excludes treatment for cosmetic reasons. Patients wishing to seek the treatment for cosmetic reasons may seek this privately.		
4	**Does this issue plan to make a change to a commissioned service?**	✔
No: The treatment is still available but the criteria to access this have changed. This policy plans to routinely commission Botulinum Type A for the treatment of severe axillary hyperhidrosis that has not been controlled by topical aluminium chloride or other extra-strength antiperspirants (unless the patient has a social anxiety disorder). The previous policy did not routinely commission Botulinum Type A for hyperhidrosis of any severity. However, the revised policy brings the criteria in line with the Pan Mersey Area Prescribing Committee's recommendation (29.07.2015). This inclusion is aligned to NICE guidelines - CG159.		
5	**Does this issue plan to introduce, review or change a policy, strategy or procedure?**	✖

Yes: This policy is being reviewed by a Policy Review group to align policies across Merseyside CCG's and Warrington CCG. Criteria for this policy is now superceeded by the Plan Mersey area Prescribing Committee. The changes in criteria is aligned to NICE guidance.

6	**Does this issue plan to introduce a new service or activity?**	✔

No: See Q4

7	**Is this primarily about improving access to, or delivery of a service?**	✖

Yes: The change to widen criteria should improve access to this treatment. This policy is part of a Pan Merseyside and Warrington CCG policy review group. The work of the policy review group should help bring greater consistency in decision making for patients living in the Merseyside and Warrington area.

8	**Does this affect Employees or levels of training for those who will be delivering the service?**	✔

No: there should not be any significant impact on employees. This assessment does recognise that any staff making decisions on patients requiring this treatment will need to be aware of any policy change. The Policy Review group are engaging with G.P's as part of the engagement process.

9	**Does this issue affect Service users?**	✖

Yes: There are changes to the previous policy with more information and revised eligibility criteria / access to service. The treatment for Botulinum toxin type A for prophylaxis of migraine will be prescribed and administered within the Walton Centre NHS Foundation Trust. The following conditions that may be suitable for Botulinum A are those with chronic anal fissures and severe axillary hyperhidrosis. There are also other criteria contained such as patients with Anal Fissures, Migraine, Blepharospasm, hemifcial spasm, Multiple Scherosis, Focal Dystonia, Focas spasticity for patients with motor neurone syndrome, Idiopathic cervical dystonia. Further engagement should further highlight any impacts from the revised policy.

10	**Can you foresee a negative impact on any Protected Characteristic Group(s)?** *If YES please state what these could be.*	✔

No: The revised criteria increases eligibility for patients with severe hyperhidrosis. Further engagement work should help identify impacts of the policy. A stage 2 Assessment will be carried out to further detail potiential impacts. Initial scoping of impacts has highlighted that there may be underlying conditions that cause chronic anal fissures. Certain conditions such as Thyroid conditions and Diabetes can be underlying reasons for hyperhidrosis.

Equality Risk

11	**Have you got any general intelligence (research, consultation, etc.)?** *If YES please list any related documents.*	✔

Yes: there are a range of websites that provide information on conditions where this treatment is used. NICE guidance on conditions where this treatment is recommended. http://www.blepharospasm.org/botulinum-toxin-avsb.html http://www.panmerseyapc.nhs.uk/recommendations/documents/PS145.pdf?UNLID=89963070720171024181622

12	**Have you got any specific intelligence (research, consultation, etc.)?** *If YES please list any related documents.*	✔

Activity data across the CCG's show: 2013/14: 1198 2014/15: 1123 2015/16: 952 Local data from Individual Funding Request Panel for this treatment has been reviewed. Data for 2016/17 has been documented. The number of requests for Botox is relatively low with only 6 requests and 2 approved for 2016/17. Botox for rectal spasm - 4 requests and 2 approved. Botulinum Toxin Injections - 4 requests and 4 approved. Cranial Botox - 3 requests and 1 approved. In support of equality impact assessment work, local area demographic profiling has been undertaken. This has been shared with the Policy Review Group in order to provide contextual population information across the CCG's. This document is available upon request.

13	**Have you taken specialist advice? (Legal, E&I Team, etc).** *If YES please state.*	✔

Yes: The policy has been subject to clinical review by the IFR panel. Further engagement work has included clinical review. Equality advice and involvement within the policy review group is embedded.		
14	**Have you considered your Public Sector Equality Duty?** *Please provide a rationale.*	✔
Yes: This is an ongoing process. There are no equality concerns currently identified within the revised policy criteria. Further engagement work will further inform impact.		
15	**Do you plan to publish your information?** *Include any "Decision Reports"*	✔
Yes: Policy and any equality impact assessments will be made available to the public.		
16	**Can you minimise any negative effect?** *Please state how.*	✔
Yes: The policy has undertaken engagement work with Clinicians review. The criteria is superseded by Pan Merseyside Area Prescribing Committee. Further engagement work with the public is planned.		
17	**Do you have any supporting evidence?** *If YES please list the documents.*	✔
Yes - data sets on activity data added to question 12.		
18	**Have you/will you engage with affected staff and users on these proposals?**	✔
Yes: The policy group has undertaken review of changes within the revised policy. This has involved engagement with Clinician's and Service Providers. This policy will be shared with the public - to request feedback on the policy to help identify any impact - both negative and positive.		

Human Rights Impact

19	**Will the policy/decision or refusal to treat result in the death of a person?**	✔
No: the refusal to treat a person when following eligibility criteria should not result in the death of a person.		
20	**Will the policy/decision lead to degrading or inhuman treatment?**	✔
No: the policy should not lead to degrading or inhuman treatment.		
21	**Will the policy/decision limit a person's liberty?**	✔
No: the policy should not limit a persons liberty.		
22	**Will the policy/decision interfere with a person's right to respect for private and family life?**	✔
No: the policy should not interfere with a person's right to respect for private and family life.		
23	**Will the policy/decision result in unlawful discrimination?**	✔
No: The policy should lead to unlawful discrimination as it does not exclude any groups based on protected characteristics.		
24	**Will the policy/decision limit a person's right to security?**	✔
No: the policy should not limit a person's right to security.		
25	**Will the policy/decision breach the positive obligation to protect human rights?**	✔
No: the policy should not breach human rights.		
26	**Will the policy/decision limit a person's right to a fair trial (assessment, interview or investgation)?**	✔

No: this policy should not limit a person's right to a fair assessment.		
27	**Will the policy/decision interfere with a person's right to participate in life?**	✔
No: the policy should not interfere with a person's right to participate in life.		

Stage 2 Details

Equality Policies

EIRA ST2 BOTOX A B 31072019 QA.pdf (568909 bytes) - *Attached below*

Equality Other

No files uploaded

Human Rights

No files uploaded

Additional Files

No files uploaded

Comments

Assessment Comment

Update April 2019: due to delay with review work, this policy is now ready for public engagement - further insight will be added to a stage 2 assessment due to related impacts on patients with long term conditions, disabilities and changes to criteria regarding hyperhidrosis. A stage 2 assessment will be carried out.
09/04/2019
mulloy, jennifer

Approval Comment

A stage 2 assessment to be carried out. Further queries regarding age and first line treatments.
09/04/2019
mulloy, jennifer

Stage 2 Comment

Stage 2 assessment completed and shared with policy development group.
09/09/2019
mulloy, jennifer

Last Activation Comment

No comment saved

Last Deactivation Comment

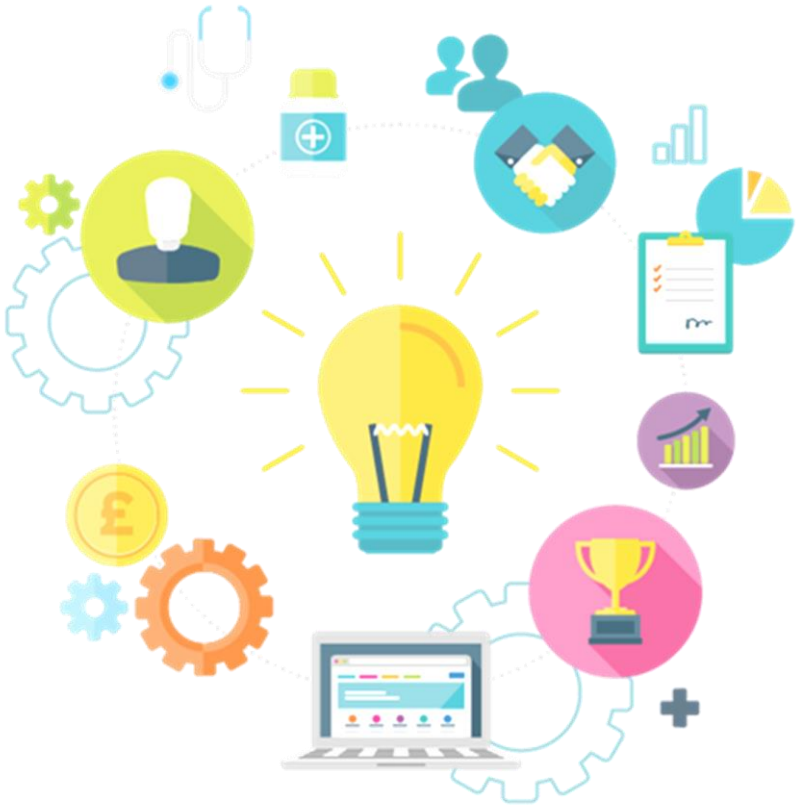
No comment saved

NHS
Midlands and Lancashire
Commissioning Support Unit

Equality Impact and Risk Assessment Stage 2 for Policies

Title of Policy / Strategy:

Policy for Botulinum Toxin A and B updated 31/7/19



Equality & Inclusion Team, Corporate Affairs
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Email: equality.inclusion@nhs.net

Midlands and Lancashire Commissioning Support Unit

EQUALITY IMPACT AND RISK ASSESSMENT STAGE 2 ALL SECTIONS MUST BE COMPLETED Guidance is provided in appendix 3 SECTION 1 – DETAILS OF POLICY			
Organisation: CCG's that are part of this review: NHS Halton Clinical Commissioning Group NHS Liverpool Clinical Commissioning Group NHS St Helens Clinical Commissioning Group NHS South Sefton Clinical Commissioning Group NHS Southport and Formby Clinical Commissioning Group NHS Warrington Clinical Commissioning Group			
Policy Assessment Lead and Contact Details: Michael O'Brien – Project Manager			
Directorate/Team: Commissioning			
Responsible Director / CCG Board Member for the assessment: Various as being ratified within each CCG			
Policy implementation Date: 2019			
Who is involved in undertaking this assessment? Jennifer Mulloy – Equality and Inclusion Business Partner MLCSU Clinical Policy Development and Implementation Group (CPDIG) Virtual Clinical Forum Communications and Engagement teams			
Date of commencing the assessment: 09/04/19			
Date for completing the assessment: 31/7/19			
EQUALITY IMPACT ASSESSMENT **Section 1**			
Please tick which group(s) this policy will or may	**Yes**	**No**	**Indirectly**

impact upon?			
Patients, Service Users	x		
Carers or Family			x
General Public		x	
Staff			x
Partner Organisations			x

How was the need for the policy identified? (is it part of a workstream / strategy?)

This policy is part of a suite of policies are being reviewed collaboratively across Merseyside CCG's and Warrington CCG as part of the Clinical Policy Development and Implementation Group (CPDIG). This policy has been identified as low clinical priority. The CCGs has a limited funding resource and therefore has to prioritise services that are commissioned. The CCG currently gives greater priority to life threatening and chronic ill health. The CPDIG are working to identify areas of impact through the changes they make balanced with the need to align eligibility for treatments with best clinical evidence and balancing health resources for the whole population.

The policy is for Botulinum Toxin A&B.

Botulinum Toxin A&B can be used to treat a number of disorders that cause excessive or abnormal muscle movement. It can also be used to treat excessive sweating – hyperhidrosis, Migraine, Anal fissures and excessive salivary drooling – Sialorhoea.

The use of Botulinum Toxin A&B can also be used for cosmetic reasons – to address unwanted wrinkles and pump out lips.

What are the aims and objectives of the policy?

To provide clinicians and the public with updated policies in line with clinical guidance. To provide consistency across the Merseyside and Warrington area.

To provide clear eligibility criteria across all policies of low clinical priority.

The current policy from 2014/15:

The use of botulinum toxin type A is commissioned in the following indications:

- Anal fissures only following a minimum of two months with standard treatment (lifestyle and topical pharmaceutical products) for chronic anal fissures that have not resulted in fissure healing; and only a maximum of 2 courses of injections.
- Blepharospasm and hemifacial spasm.
- Probable contracture of joint in multiple sclerosis, in conjunction with prolonged stretching modalities (i.e. in line with NICE Clinical Guideline 8). http://guidance.nice.org.uk/CG8
- Focal dystonia, where other measures are inappropriate or ineffective.

- Focal spasticity in patients with upper motor neurone syndrome, caused by cerebral palsy, stroke, acquired brain injury, multiple sclerosis, spinal cord injuries and neurodegenerative disease, where other measures are inappropriate or ineffective.
- Idiopathic cervical dystonia (spasmodic torticollis).
- Prophylaxis of headaches in adults with chronic migraine (defined as headaches on at least 15 days per month of which at least 8 days are with migraine) that has not responded to at least three prior pharmacological prophylaxis therapies, and whose condition is appropriately managed for medication overuse (i.e. in line with NICE Technology Appraisal 260). http://guidance.nice.org.uk/TA260
- Refractory detrusitor overactivity, only line with NICE Clinical Guideline 171 (women) http://guidance.nice.org.uk/CG171 and Clinical Guideline 97 (men) http://guidance.nice.org.uk/CG97 where conservative therapy and conventional drug treatment has failed to control symptoms.
- Sialorrhoea (excessive salivary drooling), when all other treatments have failed.

Botulinum toxin type A is not routinely commissioned in the following indications:

- Canthal lines (crow's feet) and glabellar (frown) lines.
- Hyperhidrosis.
- Any other indication that is not listed above

The use of Botulinum Type B is not routinely commissioned.

Where the use of botulinum toxin is used to treat an indication outside of the manufacturer's marketing authorisation, clinicians and patients should be aware of the particular governance requirements, including consent (which must be documented) for using drugs outside of their licensed indications.

For patients with conditions which are not routinely commissioned, as indicated above, requests will continue to be considered by Cheshire & Merseyside Clinical Commissioning Groups processes for individual funding requests, if there is evidence that the patient is considered to have clinically exceptional circumstances to any other patient experiencing the same condition within Cheshire & Merseyside. Requests to commission the use of botulinum toxin as an option to treat other indications, where a known cohort of patients can be identified, should be processed in accordance with the relevant CCG's defined processes.

If a subsequent CCG approved policy supersedes the information above, this section will be reviewed and updated.

The revised policy contains the proposed changes:

In summary: the revised policy contains greater information on criteria and additional criteria for treatment for Severe axillary hyperhidrosis. Revised policy as follows:

Botulinum Type B

The use of Botulinum toxin type B is not routinely commissioned.

Botulinum Type A

Botulinum toxin type A is not routinely commissioned in the following indications:

- Canthal lines (crow's feet) and glabellar (frown) lines.
- Any other indication that is not listed below.

The use of Botulinum type A is commissioned for the following indications and provided the eligibility criteria are met:

Anal fissures

- Botulinum toxin type A is recommended as a treatment option in patients with chronic anal fissure that has not healed despite at least 8 weeks of topical management.

It has a similar mechanism of action to topical products. The preferred first line topical product is 0.4% glyceryl trinitrate (GTN) ointment, the only licensed non-surgical option available in the UK. Unlicensed topical 2% diltiazem cream and unlicensed topical 0.2% GTN ointment are alternatives if there has been a partial response to topical 0.4% GTN but intolerance such as headache has necessitated discontinuation.

For patients who proceed to treatment with botulinum toxin type A and whose fissure has not healed after one course of injections, alternative options for on-going management should be considered. However, where the specialist determines there has been a partial response to the first course, a second course may be considered particularly for patients where surgery is less suitable.

To assist with healing prevention of recurrence of fissures, patients should be encouraged to eat a high fibre diet and use laxatives if necessary.

For the use of Botulinum toxin type A in treating Anal Fissures, refer also to the Pan Mersey Area Prescribing Committee Prescribing policy statement ***BOTULINUM TOXIN Type A injection for chronic anal fissure***:
https://www.panmerseyapc.nhs.uk/media/1568/botulinum_anal_201805_ps67_v0300.pdf

Hyperhidrosis

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).

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.

- 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 scale or more than a 4 point improvement from baseline on the Dermatology Life Quality Index (DLQI).

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

For the use of Botulinum toxin type, A in treating Hyperhydrosis, refer also to the Pan Mersey Area Prescribing Committee Prescribing policy statement ***BOTULINUM TOXIN TYPE A for Severe Axillary Hyperhidrosis***

https://www.panmerseyapc.nhs.uk/media/1067/botulinum_hidrosis_201507_ps145_v0101.pdf

BOTULINUM TOXIN TYPE A is not routinely commissioned for non-axillary Hyperhidrosis.

Migraine

Botulinum toxin type A is recommended as a treatment option for the prophylaxis of headaches in adults with migraine in accordance with NICE TA 260 (June 2012).

NICE recommend Botulinum toxin type A as an option for the prophylaxis of headaches in adults with chronic migraine (defined as headaches on at least 15 days per month of which at least 8 days are with migraine):

- that has not responded to at least three prior pharmacological prophylaxis therapies

AND

- whose condition is appropriately managed for medication overuse.

Treatment with botulinum toxin type A should be stopped in people whose condition:

- is not adequately responding to treatment (defined as less than a 30% reduction in headache days per month after two treatment cycles)

OR

- has changed to episodic migraine (defined as fewer than 15 headache days per month) for three consecutive months.

Botulinum toxin type A for the prophylaxis of migraine will be prescribed and administered under the supervision of a specialist designation neurological centre.

Botulinum Toxin A is also commissioned in the following indications:

Blepharospasm and hemifacial spasm

Probable contracture of joint in multiple sclerosis, in conjunction with prolonged stretching modalities where other measures are inappropriate or ineffective (i.e. in line with NICE Clinical Guideline 186).
https://www.nice.org.uk/guidance/cg186

Focal dystonia, where other measures are inappropriate or ineffective.

Focal spasticity in patients with upper motor neurone syndrome, caused by cerebral palsy, stroke, acquired brain injury, multiple sclerosis, spinal cord injuries and neurodegenerative disease, where other measures are inappropriate or ineffective.

Idiopathic cervical dystonia (spasmodic torticollis).

Refractory detrusitor overactivity, only line with NICE Clinical Guideline 171 (women) http://guidance.nice.org.uk/CG171 (updated November 2015) and Clinical Guideline 97 (men) http://guidance.nice.org.uk/CG97 (updated June 2015)where conservative therapy and conventional drug treatment has failed to control symptoms and the patient is able and willing to self-catheterise.

Sialorrhoea (excessive salivary drooling), when other treatments have failed.

What evidence have you considered as part of the Equality Impact Assessment?

- Demographic profile information on the areas
- https://research.cerebralpalsy.org.au/about-cerebral-palsy/interventions-and-

therapies/botulinum-toxin-a-injections-for-supporting-pain-and-comfort-in-children-with-cerebral-palsy/

- https://www.migrainetrust.org/living-with-migraine/treatments/botox/
- https://www.nhs.uk/conditions/anal-fissure/treatment/
- https://www.mstrust.org.uk/a-z/botulinum-toxin-botox
- https://www.nhs.uk/conditions/excessive-sweating-hyperhidrosis/ and https://hyperhidrosisuk.org/treatment-options/ and http://www.bad.org.uk/shared/get-file.ashx?id=93&itemtype=document

Clinical guidance:

- NICE guidance: https://www.nice.org.uk/guidance/cg159
- NICE guidance on migraines: https://www.nice.org.uk/guidance/ta260
- NICE guidance on treatment of Multiple Sclerosis in adults https://www.nice.org.uk/guidance/cg186
- http://www.panmerseyapc.nhs.uk/recommendations/documents/PS145.pdf?UNLID=899630709201710241816 22

Are there any identified health inequalities relating to this decision? If so, please summarise these:

No health inequalities identified specific to this policy.

SECTION 2

In this section you will need to consider:

What activities you currently do that help you to comply with the Public-Sector Equality Duty (three aims).

Will your policy affect your ability to meet the Public-Sector Equality Duty?

How you will mitigate any adverse impact?

- Eliminate, unlawful discrimination, harassment, victimisation and any other conduct prohibited by the Act;
- Advance equality of opportunity between people who share a protected characteristic and those who do not;
- Foster good relations between people who share a protected characteristic and those who do not.

Please answer 'Yes' or 'No' and explain your answer	Yes	No
Does the policy provide an opportunity to eliminate discrimination, harassment and victimisation? What do we mean? Unlawful discrimination takes place when people are treated 'less favourably' as a result of having a protected characteristic. Harassment is unwanted conduct (including a wide range of behaviours) because of or connected to a protected characteristic. Victimisation is where one-person subjects another to a detriment because they have acted to protect someone under the act. (e.g. bullied for reporting discrimination / harassment for a work colleague with a protected characteristic)	x	
Explanation: The CPDIG considers any impact of change on different patient groups (considering those in protected groups) The policy group are aligning policies to create improved consistency across decision making within the area A range of information has been used within this assessment and clinical engagement has been undertaken. The policy has been shared with the public for information purposes.		
Please answer 'Yes' or 'No' and explain your answer	**Yes**	**No**
Does the policy provide an opportunity to advance equality of opportunity between people who share a protected group and those who don't share it? What do we mean? Equality of opportunity is about making sure that people are treated fairly and given equal access to opportunities and resources. Promoting is about: • Encouraging people/services to make specific arrangements • Take action to widen participation • Marketing services effectively • Remove or minimise disadvantages • Take steps to meet different needs Securing special resources for those who may need them	x	

Explanation:

Equality of opportunity has been considered as part of the equality impact assessment process.

Due to some changes in the criteria of this policy, it has been shared with the public and any public comments were invited. This has been carried out in order to share the policy for information and identify any concerns.

The policy has undergone engagement with providers and clinicians to ensure that criteria is based on best clinical advice and guidance. The policy is aligned to the Pan Mersey Area Prescribing Committee and NICE 186.

Please answer 'Yes' or 'No' and explain your answer	Yes	No
Does the policy provide an opportunity to Foster Good Relations between people who share a protected characteristic and those who don't share it? What do we mean? Foster Good Relations between people: This is about bringing people from different backgrounds together by trying to create a cohesive and inclusive environment for all. This often includes tackling prejudice and promoting understanding of difference. • Tackle prejudice • Promote understanding • Could the policy create any issues for Community cohesion (will it impact certain communities compared to others and how this be managed?)	x	

Explanation:

The revised policy has been subject to wide engagement and the communication and communication plan has included sharing the policy with different parts of the community.

Please answer 'Yes' or 'No' and explain your answer	Yes	No
Has engagement/involvement or consultation been carried out with people who will be affected by the policy?	x	

Explanation:

Clinical engagement work has been carried out. The policy has been shared with the public via CCG information portals. No responses have been received by CCGs regarding the policy.

Please answer 'Yes' or 'No' and explain your answer	Yes	No
Has the engagement/involvement or consultation highlighted any inequalities?		x

Explanation:

No responses from the public were received regarding the criteria on this policy. The policy criteria is aligned to NICE and the Pan Mersey Area Prescribing Committee.

Ongoing engagement with clinicians helped identify early policy development.

Please answer 'Yes' or 'No' and explain your answer	Yes	No
Have you added an Equality Statement to the Policy? Example statement: Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have given regard to the need to • eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and • reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities • make reasonable adjustments when necessary	x	

Explanation:

The policy introduction section contains reference to equality legislation.

All the policy review meetings contain an 'equality and inclusion' agenda item where any issues can be raised and discussed.

Ongoing EIA content is shared and discussed with the CPDIG group.

SECTION 3

Does the 'policy' have the potential to:

- Have a positive impact (benefit) on any of the equality groups?
- Have a negative impact / exclude / discriminate against any person or equality groups?
- Have a neutral / potential indirect effect on any equality groups?
- Explain how this was identified? Evidence/Consultation?
- Who is most likely to be affected by the proposal and how (think about barriers, access, effects, outcomes etc.)

Guidance document available on Equality Groups and their issues. This document may help and support your thinking around barriers for the equality groups.

Equality Group / Protected Group	Positive effect	Negative effect	Neutral or indirect effect
Age	x		

Explanation:

The review of the policy has included excessive axillary hyperhidrosis – this can occur at any age. The British Association of Dermatologists note that the cause is not known and can begin in childhood or adolescence and may improve with age. The inclusion of this condition within the criteria should have a positive impact for all ages.

The criteria within the policy does not contain any age restrictions. Age restrictions on first line topical treatments were queried with Medicines Management team (using British National Formulary) during this assessment:

- anal fissures – can 0.4% glyceryl trinitrate (GTN) ointment is not licensed under the age of 18 so this first line treatment cannot be applied to under 18's. – advised policy author.
- Hyperhidrosis – can topical aluminium chloride / extra strength antiperspirants can be used. It is licensed for children and no age range has been specified.
- Migraine – criteria is option for migraine in adults – within groups under 18 - The Summary of Product Characteristics states that for migraine, safety and efficacy has not been established in children under 18. No data are available.

Policy published by CCGs – no responses made by the public.

Equality Group /	Positive effect	Negative effect	Neutral or indirect

Protected Group			effect
Disability	x		

Explanation:

The criteria contained within the revised policy remained unchanged in terms of using Botulinum Toxin A for conditions relating to the muscles going into spasm. This includes:

- Blepharospasm and hemifacial spasm
- Multiple sclerosis
- Focal dystonia
- Upper motor neurone syndrome caused by cerebral palsy, stroke, acquired brain injury, multiple sclerosis, spinal cord injuries and neurodegenerative disease, where other measures are inappropriate or ineffective.
- Migraine

The revised policy now includes criteria for excessive axillary hyperhidrosis. There may be other long term conditions which lead to hyperhidrosis. An example of this may be low blood sugar, over active thyroid gland, infections and certain medications. All the above conditions may constitute as a 'disability' or long term condition as defined within the Equality Act 2010.

The use of Botulinum toxin can help to reduce pain and decrease muscle spasm.

In relation to patients wishing to access Botulinum toxin for cosmetic reasons, this is excluded. This assessment notes that some of these patients may experience psychological distress due to a factor relating to the physical appearance.

In relation to Hyperhidrosis, the criteria does not include treatment where this is caused by anxiety. This decision is aligned to NICE guidance CG 159. This states in section 1.6.5: "Do not offer botulinum toxin to treat hyperhidrosis (excessive sweating) in people with social anxiety disorder. This is because there is no good-quality evidence showing benefit from botulinum toxin in the treatment of social anxiety disorder and it may be harmful".

Policy published by CCGs – no responses made by the public.

Equality Group / Protected Group	Positive effect	Negative effect	Neutral or indirect effect
Sexual Orientation			x

Explanation:

No impact has been found on this group. Policy published by CCGs – no responses made by the public.

Equality Group / Protected Group	Positive effect	Negative effect	Neutral or indirect effect
Gender Reassignment			x

Explanation:

Assessment work has highlighted that trans men can have problems with sweating as a side effect from hormone treatment. This information is limited however if a clinical diagnosis was given, they would not be excluded on the basis of the gender reassignment status. Source: https://www.ftmtopsurgery.ca/blog/testosterone-therapy/happens-first-year-testosterone/

No impact has been found on this group.

Policy published by CCGs – no responses made by the public.

Equality Group / Protected Group	Positive effect	Negative effect	Neutral or indirect effect
Sex (Gender)	x		

Explanation:

Revised criteria for excessive axillary hyperhidrosis may have a positive impact on women who may experience this condition due to the menopause.

There is little information on prevalence in relation to sex.

Criteria will apply to all sexes.

Policy published by CCGs – no responses made by the public.

Equality Group / Protected Group	Positive effect	Negative effect	Neutral or indirect effect
Race			x

Explanation:

No impact has been found on this group. Policy published by CCGs – no responses made by the public.

Equality Group / Protected Group	Positive effect	Negative effect	Neutral or indirect effect
Religion or Belief			x

Explanation:

No impact has been found on this group.

During this assessment clarification was requested if botulinum toxin a & b does it contain animal ingredients which may impact on patients from certain beliefs receiving the treatment on religious grounds. Medicines Management team have confirmed that all brands contain human albumin. None have bovine or porcine excipients.

Policy published by CCGs – no responses made by the public.

Equality Group / Protected Group	Positive effect	Negative effect	Neutral or indirect effect
Pregnancy and Maternity			x

Explanation:

No impact has been found on this group. Policy published by CCGs – no responses made by the public.

Equality Group / Protected Group	Positive effect	Negative effect	Neutral or indirect effect
Marriage and Civil Partnership			x

Explanation:

No impact has been found on this group. Policy published by CCGs – no responses made by the public.

This group are protected in relation to employment – not service provision.

Equality Group / Protected Group	Positive effect	Negative effect	Neutral or indirect effect
Carers			x

Explanation:

The revised criteria should not have any impact on this group. Policy published by CCGs – no responses made by the public.

Equality Group / Protected Group	Positive effect	Negative effect	Neutral or indirect effect
Deprived Communities			x

Explanation:

The revised criteria should not have any impact on this group.

This assessment notes that for patients wishing to receive Botulinum Toxin for cosmetic treatments, this group are less likely to be able to afford privately funded treatment for cosmetic treatment.

Policy published by CCGs – no responses made by the public.

Equality Group / Protected Group	Positive effect	Negative effect	Neutral or indirect effect
Vulnerable Groups e.g. Asylum Seekers, Homeless, Sex Workers, Military Veterans, Rural communities			x

Explanation:

The revised criteria should not have any impact on this group.

Policy published by CCGs – no responses made by the public.

SECTION 5: HUMAN RIGHTS ASSESSMENT

How does this policy affect the rights of patients set out in the NHS Constitution or their Human Rights?

No Human Rights concerns identified.

SECTION 6: RISK ASSESSMENT

See guidance and table of risks in appendix 3 section 6 for step by step guidance for this section

RISK MATRIX

	Risk level				
Consequence level	**RARE 1**	**UNLIKELY 2**	**POSSIBLE 3**	**LIKELY 4**	**VERY LIKELY 5**
1. Negligible	**1**	**2**	**3**	**4**	**5**
2. Minor	**2**	**4**	**6**	**8**	**10**
3. Moderate	**3**	**6**	**9**	**12**	**15**
4. Major	**4**	**8**	**12**	**16**	**20**
5. Catastrophic	**5**	**10**	**15**	**20**	**25**

Consequence Score: **Likelihood Score:** **Risk score = consequence x likelihood**	**4**
Any comments / records of different risk scores over time (e.g. reason for any change in scores over time):	**N/A**

Important: If you have a risk score of 9 and above you should escalate to the organisations risk management procedures.

EQUALITY IMPACT AND RISK ASSESSMENT AND ACTION PLAN

Risk identified	Actions required to reduce / eliminate the negative impact	Resources required *(see guidance below)	Who will lead on the action?	Target date
Age related potential disadvantage	Clarify age related queries for first line treatments		E&I team	May 2019
Potential disadvantage relating to religion and belief	Clarify ingredients of A&B for animal products		E&I team	May 2019

'Resources required' is asking for a summary of the costs that are needed to implement the changes to mitigate the negative impacts identified

SECTION 7 – EQUALITY DELIVERY SYSTEM 2 (EDS2)
Please go to Appendix 1 of the EIRA and tick the box appropriate EDS2 outcome(s) which this policy relates to. This will support your organisation with evidence for the Equality and Inclusion annual equality progress plan and provide supporting evidence for the annual Equality Delivery System 2 Grading
SECTION 8 – ONGOING MONITORING AND REVIEW OF EQUALITY IMPACT RISK ASSESSMENT AND ACTION PLAN
Please describe briefly, how the equality action plans will be monitored through internal governance processes? CPDIG processes and regular meetings to ensure equality related information has been shared and informs decision making. Internal governance processes within each CCG will oversee the implementation of the revised policy. **Date of the next review of the Equality Impact Risk Assessment section and action plan?** Review dates to be decided by individual CCG as part of their governance processes.
SECTION 9 **FINAL SECTION**
Date completed: 09/04/2019
Date received for quality check: 31/7/19
Signature of person completing the assessment: *Jennifer Mulloy*
Date reviewed by Equality and Inclusion Team: 31/7/19
Signature and Date quality check completed by Equality and Inclusion Team: *31/7/*19
Date signed off by CCG / CSU Committee: TBA

Appendix 1: Equality Delivery System 2:

APPENDIX 1: The Goals and Outcomes of the Equality Delivery System			Tick box(s) below
Objective	**Narrative**	**Outcome**	
1. Better health outcomes	The NHS should achieve improvements in patient health, public health and patient safety for all, based on comprehensive evidence of needs and results	**1.1** Services are commissioned, procured, designed and delivered to meet the health needs of local communities	**x**
		1.2 Individual people's health needs are assessed and met in appropriate and effective ways	**x**
		1.3 Transitions from one service to another, for people on care pathways, are made smoothly with everyone well-informed	
		1.4 When people use NHS services their safety is prioritised and they are free from mistakes, mistreatment and abuse	**x**
		1.5 Screening, vaccination and other health promotion services reach and benefit all local communities	
2. Improved patient access and experience	The NHS should improve accessibility and information, and deliver the right services that are targeted, useful, useable and used in order to improve patient experience	**2.1** People, carers and communities can readily access hospital, community health or primary care services and should not be denied access on unreasonable grounds	**x**
		2.2 People are informed and supported to be as involved as they wish to be in decisions about their care	**x**
		2.3 People report positive experiences of the NHS	
		2.4 People's complaints about services are handled respectfully and efficiently	
3. A representative	The NHS should increase the diversity	**3.1** Fair NHS recruitment and selection processes lead to a more representative workforce at all levels	

and supported workforce	and quality of the working lives of the paid and non-paid workforce, supporting all staff to better respond to patients' and communities' needs	**3.2** The NHS is committed to equal pay for work of equal value and expects employers to use equal pay audits to help fulfil their legal obligations	
		3.3 Training and development opportunities are taken up and positively evaluated by all staff	
		3.4 When at work, staff are free from abuse, harassment, bullying and violence from any source	
		3.5 Flexible working options are available to all staff consistent with the needs of the service and the way people lead their lives	
		3.6 Staff report positive experiences of their membership of the workforce	
4. Inclusive leadership	NHS organisations should ensure that equality is everyone's business, and everyone is expected to take an active part, supported by the work of specialist equality leaders and champions	**4.1** Boards and senior leaders routinely demonstrate their commitment to promoting equality within and beyond their organisations	**x**
		4.2 Papers that come before the Board and other major Committees identify equality-related impacts including risks, and say how these risks are managed	**x**
		4.3 Middle managers and other line managers support their staff to work in culturally competent ways within a work environment free from discrimination	