**Procedure for participation of non-medical ophthalmology staff in administering Botulinum Toxin for Hemifacial and Blepharospasm**

<table>
<thead>
<tr>
<th>Division/Directorate</th>
<th>Surgery</th>
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</thead>
<tbody>
<tr>
<td>Department</td>
<td>Ophthalmology</td>
</tr>
<tr>
<td>Year</td>
<td>2018</td>
</tr>
<tr>
<td>Version Number</td>
<td>1</td>
</tr>
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<td>Central Index Number</td>
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<tr>
<td>Ratifying Committee</td>
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<td>Date Ratified</td>
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<td>Approval Committee</td>
<td>Ophthalmology Clinical Governance</td>
</tr>
<tr>
<td>Date Approved</td>
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</tr>
<tr>
<td>Author Name and Job Title</td>
<td></td>
</tr>
<tr>
<td>Date Published on Document Library</td>
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</tr>
<tr>
<td>Review Date</td>
<td></td>
</tr>
</tbody>
</table>

**Target Audience**

All non-medical staff involved in administering Botulinum Toxin for hemifacial and blepharospasm on the Hinchingbrooke site.

Where there is a corresponding site specific procedural document include the Central Index Number /Name of Document
<table>
<thead>
<tr>
<th>Year and Version Number</th>
<th>Author</th>
<th>Date Published on Document Library</th>
<th>Revisions from previous issue</th>
<th>Ratifying Committee</th>
<th>Date of Ratification</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>TC CR</td>
<td></td>
<td>New Trust format &amp; changes of staff names</td>
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Summary of key points in this document:

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- 

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## Contents

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<td>Scope</td>
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<td>4</td>
<td>Process (Note: the author can give this section any appropriate name and can follow it with as other sections as required.)</td>
</tr>
</tbody>
</table>

**Appendices**

A - Quality Assurance Checklist

*(Other appendices can be added as required.)*

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The latest version of this document is on The Document Library.

Any printed copies must be checked against the Document Library version to ensure that the latest version is being used.

Note: The author can use the automated Microsoft Word contents page for this section if preferred but this is not obligatory. If the automated contents is used then by using Heading1, Heading2 etc. as styles for headings the contents list can be automatically generated and updated. This avoids having to manually update the contents list each time a new section is added or a paragraph takes a section over a page break.
1. Introduction

1.1 Blefarospasm and hemifacial spasm are focal dystonias. Blefarospasm is an idiopathic involuntary closure of the eyelids, usually but not always bilateral, and the severity ranges from frequent blinking to uncontrollable complete lid closure. Hemifacial spasm causes involuntary muscle contractions of one side of the face and also involuntary blinking of closure of the eyelids on that side. Although it may be idiopathic, it can be caused by vascular anomalies or more rarely other space occupying lesions irritating the facial nerve as it exits the brainstem, which need to be excluded by imaging investigations (MRI, MRA). The aim of therapy is to inject small doses of botulinum toxin subcutaneously at a number of separate sites around the eye to induce temporary weakness of the orbicularis oculi muscle, allowing the patient to regain control of eyelid opening.

1.2 Botulinum toxin is an exotoxin produced by the bacteria Clostridium botulinum. Its pharmacological mechanism is the inhibition of the release of acetylcholine at the neuromuscular junction, which in turn reduces excessive muscular contraction and helps normalize muscle activity (Wabbles et al 2011). The block of release is permanent and recovery takes several months as the neuromuscular junctions remodel. Botulinum toxin has become the treatment of choice for a number of movement disorders and is now commonly used to treat blepharospasm and hemifacial spasm. Current use of this locally requires the CCG to approve the use for named patients before treatment can begin.

1.3 Ophthalmic trained nurses, optometrists and orthoptists who have satisfied the Trust management structures of their competence may expand their sphere of practice with ophthalmic patients and administer botulinum toxin for blepharospasm and hemifacial spasm.

1.4 This document applies to patients over the age of sixteen.

1.5 The expansion in nursing, optometric and orthoptic practice is supported by Mr Cornelius Rene, consultant ophthalmologist and Maxine Drake, Ophthalmology Assistant General Manager.

2. Purpose

2.1 This policy provides details of minimum qualifications and training in order to administer botulinum toxin. It sets out consent, prescribing and documentation required. This policy also sets out the required procedural steps including equipment required and the management of complications. The contraindications to this procedure are also outlined.

3. Scope

3.1 This policy covers the administration of prescribed doses of botulinum toxin by named ophthalmic nurses, optometrists and orthoptists in the management of blepharospasm and hemifacial spasm in the Eye Clinic at Hinchingbrooke Hospital.
4. Clinic procedures

A list of all the equipment required in this clinic is available in Appendix A.

4.1 Approval

Prior to injecting, all patients must have had approval from the CCG to receive botulinum treatment. Approval is sought using the Group Prior Approval form (Appendix B) with the patient’s verbal consent provided to share medical details with the CCG. The form is completed when the decision is made by the ophthalmologist and the patient that treatment should be started and will be sent via the ophthalmic secretary to the CCG who will send a formal letter to both the hospital and the patient as to whether the treatment is approved or denied. As approval is usually rapid, once a decision to treat is made the patient can be booked into the next botulinum clinic in anticipation of the decision.

4.2 Patient inclusion

Patients with blepharospasm:

- will be referred to an ophthalmic consultant
- will attend the outpatient clinic where the ophthalmic consultant or appropriately trained non-consultant ophthalmic surgeon will confirm the diagnosis and discuss the planned procedure, deciding the site, number of injections and dose of botulinum toxin.
- The ophthalmologist will check the patient’s medical history, current medication, and carry out any clinical investigations if necessary.
- The ophthalmologist will undertake the initial consenting discussion and will ask patient to sign a consent form (Appendix C). Further consent updates can be undertaken by the orthoptist, optometrist or nurse practitioner in the toxin clinic.
- The ophthalmologist will also give the patient a Group Prior Approval (GPA) patient information leaflet (Appendix D)

4.3 Patient exclusion

Patients excluded from treatment -

Definite exclusions:

- pregnant or considering becoming pregnant, or breast feeding
- signs of inflammation or infection at injection site
- known allergy to toxin

Relative contraindications (extra caution, discuss risks and make individual patient decision)

- significant weakness or wasting of muscles which are to be injected e.g. myasthenia gravis
- significant bleeding disorder or anticoagulant drugs such as warfarin

4.4 Consent Information

All patients undergoing botulinum toxin therapy will need to give their consent prior to the procedure, following trust consent policy. Within the consenting procedure, the following needs to be discussed:

- How the treatment is given and what to expect.
- Benefits: effective method of controlling symptoms in the majority of patients. Its effect is only temporary and it is not a cure. Onset of effect not immediate, within 2-3 days, building up over 2 weeks and lasting 3-6 months. For continued relief of symptoms, it should be repeated every three months or so.
- Risks: Commonly soreness, swelling and bruising at the injection site, injection area itching, occasional ptosis (1:20 risk).
- Less common side effects are double vision, ectropion, entropion, mild facial weakness, reduced blinking, dry eye.

NB: Nearly all side-effects are temporary. Very rarely there can be permanent lid or facial weakness.

Serious systemic side-effects such as anaphylaxis are extremely rare.

4.5 **Patient Specific Direction**

A Patient Specific Direction (PSD) is completed by the consultant (Appendix E) to provide written confirmation of their agreement for the non-medical healthcare professional to administer the dose of Botox, and this is placed in the patient notes. The non-medical healthcare professional must sign and complete the form whenever doses of Botox are administered to that patient. The PSD is specific to the patient, and thus every patient undergoing administration of Botox by a non-healthcare professional must have the proforma completed and retained in the notes.

4.6 **Preparation of equipment**

Botulinum Toxin “Botox” 50 units (rarely use 100 units) Powder for solution, for injection 0.9% Sodium Chloride - for injection vials.

1ml and 2 or 5 ml syringes

Needles: white or green needle to reconstitute drug, grey or yellow needle to inject

Tissues

Local anaesthetic eye drops eg. Proxymetacaine or Oxybuprocaine hydrochloride 0.4%

Alcohol wipes

Cardboard disposable trays

Non sterile gloves

Toxin history sheet pro formas

Toxin GP letters

Toxin administration form

4.7 **Reconstitution of botulinum toxin (Botox®)**

For normal concentration toxin: 2ml of sodium chloride solution is added to a 50 Unit vial of Botox® (Botulinum toxin type A). This yields a solution which contains 2.5 units per ml of botulinum toxin.

A 2 or 5 ml syringe with a green or white needle attached should be used to draw up 2 ml of the saline solution, tilting the container while drawing up the solution and ensuring all air bubbles are expelled by firmly ‘flicking’ the syringe with thumb and middle finger.

Puncture the top of the vial, with the tip of the needle and gently press into the bottle. Push the top of the syringe gently to ensure the solution is expelled into the bottle.

Gently swirl the bottle a couple of times to ensure the mixture is dissolved in the saline solution. Do not shake hard as this denatures the protein. Remove the syringe, ensuring the needle remains in the glass bottle.

For double strength concentration, 1 ml of sodium chloride is added to a 50U vial yielding a solution with 5 units per ml. For double strength, a 1 or 2 ml syringe should be used to draw up 1 ml of the saline and otherwise the same procedure as for normal strength should be used.
4.8 Drawing up

Insert a 1ml syringe into the top of the needle situated inside the vial. Ensure the needle tip is kept within the solution at all times; the vial may need to be tilted.

Draw up the required dosage of botulinum toxin, tilting the ampule if necessary. Normal strength is 0.1 ml = 2.5 units or 0.2ml = 5 units. Double strength is 0.1 ml = 5 units or 0.2ml = 10 units, 0.4ml = 20 units. If air bubbles are drawn, then gently flick the syringe with thumb and middle finger.

Remove the syringe from the green needle and place a yellow or grey needle in its sheath at the end of the syringe. The injection is then ready.

Check the dosage complies with that agreed by the consultant and recorded in the notes.

Inject the prescribed amount of botulinum toxin subcutaneously at the sites indicated by the consultant.

4.9 Technique and procedure

Check patient’s identity, check side (one side or both sides, if one side which side) and consent has been signed within 1 year. Verbally confirm consent and no change in medical condition or medications. If consent more than 1 year old, reconfirm and re-sign consent form 3.

Explain the procedure to the patient.

Check patient’s notes for required dose of botulinum toxin to be drawn up

Instil oxybuprocaine or proxymetacaine eye drops, after warning patient about initial stinging.

Clean patients skin with an alcohol swab.

Identify the sites for injection, check this against hospital notes.

Stretch the skin with a finger then insert the needle into the skin with the needle nearly tangential to the skin. Ensure the whole opening at the tip of the needle is under the skin.

Slowly press the plunger and administer the injection to raise a small "bleb" at the injection site.

Avoid injecting into the angular vein at the medial lower lid.

At the end of the injection, withdraw needle and apply pressure to injection site with a tissue.

Dispose of the syringe and the needle (into the appropriate sharps box), as soon as the injection has been undertaken.

4.10 Post Procedure

Check injection sites for bleeding & apply pressure to stop bleeding if necessary.

Ensure patient records are completed correctly recording the site, volume and dose of each injection on the toxin proforma (Appendix F).

Remind patient the toxin can take three days to be effective

Normal activities can be resumed straight away.

Over the counter painkillers can be taken if any discomfort.

An outpatient appointment at the toxin clinic is given for three months (longer at patient’s request).

Advise patient to contact clinic if any post treatment problems.

Record the name, diagnosis and overall dosage to toxin on the toxin administration record form.

Complete a toxin GP letter and clip to the front of the notes for the secretary (Appendix G).

4.11 Procedure to follow for safe disposal of unused vial of botox

This should be discarded into the sharps container.
4.12  **Record keeping**
A record should be kept of the exact dosage of botulinum toxin injected, and the specific sites of injection.

The batch number and expiry date of Botox® should also be recorded.

Any side effects or concerns expressed by the patient should always be documented.

Documentation of the above will be directly into the patients hospital case notes using the Botox proforma (See Appendix F).

4.13  **Pharmacy Log**
Following each clinic, a copy of the Administration Record for Botox must be sent to Pharmacy Stores at the main hospital pharmacy (See Appendix H)

4.14  **Emergency and Resuscitation Drugs**
The following drugs MUST be present and readily accessible during botulinum toxin administration.

- Adrenaline 1 in 1000 (1mg/ml) IM
- Hydrocortisone 100mg powder (plus diluent) IV
- Chlorphenamine (Chlorpheniramine) 10mg/ml IV

5.  **Professional accountability**

5.1 On registration, nurses are subject to the code of professional conduct (Nursing and Midwifery Council, 2015) and are accountable for their own practice.

5.2 On registration, orthoptists are also subject to professional codes of conduct. These are set out by the Health and Care Professions Council (HCPC), and all orthoptists must act within these codes of conduct.

5.3 On registration, Optometrists are also subject to professional codes of conduct. These are set out by the General Optical Council (GOC), and all optometrists must act within this code of conduct.

6.  **Qualifications and training**

6.1 Ophthalmic nurses, optometrists and orthoptists undertaking this procedure must possess the following qualifications or equivalent:

- Nurses: Registered nurse with a minimum of 2 years experience in an ophthalmic unit, and with appropriate post qualification training certificate (e.g. ENB 346/348 / N76 or equivalent)
- Orthoptists: Registered orthoptist, listed on the HCPC register, holding a degree in orthoptics (BSc Hons or BMedSci) or diploma in Orthoptics (DBO) with a minimum of 2 years post qualification experience.
- Optometrists: Registered Optometrist, listed in GOC register, holding a degree in optometry (BSc Hons) or overseas equivalent within a minimum 2 years post qualification experience.

6.2 Non-medical practitioners must be competent to consent for the procedure. Orthoptists are trained at degree level to consent. Nurses and optometrists must undergo generic consent training. All non-medical practitioners in the toxin clinic must undergo a training session with the ophthalmic consultant on the administration, risks and benefits of toxin for ophthalmic use, and must observe the ophthalmologist consenting and be observed consenting.
themselves and signed off as competent by the consultant ophthalmologist (see Appendix I for the competency checklist).

6.3 Non medical practitioners involved in injecting will be trained by the consultant ophthalmology to inject: firstly by observing, then by administering injections observed and then by injecting unobserved for some cases during the consultant led toxin clinics and the consultant ophthalmologist must be satisfied with their injection technique and the practitioner signed off as competent before they are allowed to administer the treatment without supervision.

7. Responsibilities

7.1 Director of Nursing
The Director of Nursing has executive responsibility for the management of Pharmacy.

7.2 Medical Staff
7.2.1 Medical staff have a responsibility to ensure that they are fully aware of Trust policies and service-specific protocols and procedures appropriate to their area of practice.
7.2.2 They have professional responsibilities for ensuring their awareness, knowledge and role in the management of medicines.
7.2.3 They are accountable for the implementation and monitoring the implementation of the Botulinum Toxin Policy by non medical Staff.
7.2.4 They are responsible for ensuring that all staff working within the toxin clinics are aware of the existence and content of this policy and are able to implement it fully.
7.2.5 They are accountable for ensuring that incidents and near misses involving botulinum toxin are reported, in accordance with the Trust incident reporting policy.
7.2.6 They should ensure that any difficulties with the implementation of the policy are brought to the attention of the Drugs and Therapeutics and Medicines Management Committee.

7.3 Chief Pharmacist
The Chief Pharmacist is responsible for advising managers on procedure and requirements as necessary for the safe and secure management of medicines.
The Chief Pharmacist has operational responsibility for Pharmacy.

7.4 Pharmacy Staff
The Pharmacy department provides an advisory service for all staff involved in the process of medicines management and provides the botulinum toxin.

7.5 Nursing Department Manager
It is the responsibility of the nurse department manager to ensure that all registered nurses involved in injecting are assessed as competent in the administration of medications against the agreed competency frameworks.

7.6 Head Orthoptist
It is the responsibility of the Head Orthoptist to ensure that all registered orthoptists involved in injecting are assessed as competent in the administration of medications against the agreed competency frameworks.

7.7 Head Optometrist
It is the responsibility of the Head Optometrist to ensure that all registered optometrists involved in injecting are assessed as competent in the administration of medications against the agreed competency frameworks.
7.8 **All Clinical and Non-clinical staff**  
All staff that have any involvement with botulinum toxin are responsible for ensuring that they are fully aware of their roles and responsibilities. They are responsible for identifying any training and competence issues, and raising these with their line manager.

7.9 **Drugs and Therapeutics and Medicines Management Committee**  
The Drugs and Therapeutics and Medicines Management committee is responsible for ensuring the policy is reviewed and updated every 4 years or sooner if there are changes to clinical indications treated and the procedures used.

8. **Licensing**

8.1 Botulinum toxin is licenced by the MHRA for use in blepharospasm and hemifacial spasm for adults. Botulinum is also used in medical clinics for the treatment of other ocular conditions for which there is no alternative and for which there is much published medical evidence of safety and efficacy.

<table>
<thead>
<tr>
<th>Clinical use</th>
<th>Botox</th>
<th>Dysport</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Blepharospasm</strong></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Hemifacial spasm</strong></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Squint</strong></td>
<td>✓</td>
<td>X</td>
</tr>
<tr>
<td><strong>Protective ptosis</strong></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td><strong>Nystagmus</strong></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td><strong>Entropion</strong></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td><strong>VII nerve aberrant regeneration (including gustatory lacrimation)</strong></td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

9. **References**


Persaud et al 2013


Wabbels et al 2011

10. Related Policies and Procedures

Consent to examination or treatment procedure
Administration of medicines procedure
Procedure for the management of sharps injuries or blood splashes
Management tool for medication incidents
Improving medication error incident reporting and learning alert
Hand hygiene procedure
Ordering and storage of medicines procedure
Appendix A

Equipment List

Botulinum Toxin “Botox” 50 units (rarely use 100 units) Powder for solution, for injection
0.9% Sodium Chloride - for injection vials.
1ml and 2 or 5 ml syringes
Needles: white or green needle to reconstitute drug, grey or yellow needle to inject
Tissues
Local anaesthetic eye drops eg. Proxymetacaine or Oxybuprocaine hydrochloride 0.4%
Alcohol wipes
Cardboard disposable trays
Non sterile gloves
Toxin history sheet proformas
Toxin GP letters
Toxin administration forms
Appendix B

Group Prior Approval – Funding Application

Botulinum toxin for torsion dystonias and other involuntary movements – Local Policy

Please ensure you complete the patient consent section below and share the patient leaflet with your patient. We will return this form if the patient consent section is not complete – this may delay the decision making process.

<table>
<thead>
<tr>
<th>Patient Consent</th>
<th>Delete as appropriate</th>
<th>Mark as appropriate</th>
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</thead>
<tbody>
<tr>
<td>Is the patient aware of this referral and the contents of this form and supporting documents?</td>
<td>YES/NO</td>
<td></td>
</tr>
<tr>
<td>I confirm that the patient consents to the CCG Exceptional Cases Team accessing personal clinical information about them that is held by clinical staff involved with their care to enable full consideration of this GPA.</td>
<td>YES/NO</td>
<td></td>
</tr>
</tbody>
</table>

By submitting this GPA you are confirming that you have fully explained to the patient the proposed treatment and they have consented to you raising this GPA on their behalf. It is NHS Cambridgeshire and Peterborough CCG’s policy to let the patient know of the outcome of the funding application unless it is not clinically appropriate to do so.

I confirm that it is clinically appropriate for the patient to be copied into all correspondence.

I confirm that it is not clinically appropriate for the patient to be copied into all correspondence.

Please confirm that you have brought the CCG patient leaflet on the collection and use of patient data for the funding application process to the patient’s attention: ‘Why we need to collect your personal confidential information and your rights’. The leaflet is available on the following web page:  [http://www.cambsphn.nhs.uk/CCPF/ExcptnalandIFR.aspx](http://www.cambsphn.nhs.uk/CCPF/ExcptnalandIFR.aspx)
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<tr>
<th>GPA Request - PROVIDER COMMISSIONING TO COMPLETE</th>
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<tbody>
<tr>
<td><strong>Patient NHS No:</strong></td>
</tr>
<tr>
<td><strong>Patient DoB:</strong></td>
</tr>
<tr>
<td><strong>Patient Name and Address:</strong></td>
</tr>
<tr>
<td><strong>Confirm patient status:</strong> (*select 1 option)</td>
</tr>
<tr>
<td><strong>GP Practice code:</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Please indicate whether patient meets the following NICE criteria</th>
<th>Please mark as appropriate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>The contraindications to botulinum toxin therapy can be found in its Summary of Product Characteristics via <a href="http://www.emc.medicines.org.uk">www.emc.medicines.org.uk</a></strong></td>
<td></td>
</tr>
<tr>
<td>1. Please confirm the treatment is being instigated and monitored by a consultant</td>
<td>☐ Yes ☐ No</td>
</tr>
<tr>
<td>2. I can confirm that treatment will only be continued in accordance with NICE guidance.</td>
<td>☐ Yes ☐ No</td>
</tr>
<tr>
<td>3. The patient is being treated for one of the following:</td>
<td>☐ Yes ☐ No</td>
</tr>
<tr>
<td>- Focal spasticity</td>
<td>☐ Yes ☐ No</td>
</tr>
<tr>
<td>- Wrist and hand disability due to upper limb spasticity associated with stroke</td>
<td>☐ Yes ☐ No</td>
</tr>
<tr>
<td>- Symptomatic relief of blepharospasm</td>
<td>☐ Yes ☐ No</td>
</tr>
<tr>
<td>- Symptomatic relief of hemifacial spasm</td>
<td>☐ Yes ☐ No</td>
</tr>
<tr>
<td>- Symptomatic relief of severe spasmodic torticollis (Cervical Dystonia)</td>
<td>☐ Yes ☐ No</td>
</tr>
<tr>
<td>- Ankle disability due to lower limb spasticity associated with stroke in adults</td>
<td>☐ Yes ☐ No</td>
</tr>
</tbody>
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Please forward this form to us via your internal processing team.

Or via Bluteq®
Appendix C

Consent form 3

Consent Form 1

Patient agreement to investigation or treatment

Patient details (or pre-printed label)

Patient’s surname/family name__________________________________________
Patient’s first names__________________________________________________
Date of birth_________________________________________________________
Responsible health professional_________________________________________
Job title______________________________________________________________
NHS number (or other identifier)_________________________________________

☐ Male ☐ Female

Special requirements__________________________________________________
(eg other language/other communication method)

To be retained in patient’s notes

NOTE TO PATIENTS:
You should read this form thoroughly together with the information sheets you have been given. When ready, you should sign on page 9 only (marked with ☒) and bring the signed form with you when you come for your treatment.
Name of proposed procedure or course of treatment

BOTULINUM TOXIN INJECTION TO CORRECT BLEPHAROSPASM OR HEMIFACIAL SPASM

Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)
I have explained the procedure to the patient. In particular, I have explained:

The intended benefits: TO REDUCE LID AND FACIAL SPASM/TIC AND/OR TO REDUCE UNWANTED CLOSURE OF EYELIDS.

Serious or frequently occurring risks:
Nearly all side effects are temporary and include:
- Bruising, swelling, discomfort
- Drooping/shut eyelid
- Double vision/eye misalignment
- Out-turning eyelid
- Weakness mouth difficulty biting or chewing
- Dry eye

Rarely: Permanent eyelid or facial paralysis or weakness, extremely rarely serious infection or bleeding

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

The following leaflet has been provided: Botulinum toxin treatment for eye conditions

This procedure will involve: ☑ local anaesthesia

Signed_______________________________________Date________________________________________

Name (PRINT) ________________________________Job title________________________________

Contact details (if patient wishes to discuss options later) 01480 416416 extn 8794

Statement of interpreter (where appropriate)
I have interpreted the information above to the patient to the best of my ability and in a way in which I believe s/he can understand.

Signed_______________________________________Date________________________________________

Name (PRINT) _______________________________________________________________________

Top copy accepted by patient: yes/no (please ring)

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Name of proposed procedure or course of treatment

BOTULINUM TOXIN INJECTION TO CORRECT BLEPHAROSPASM OR HEMIFACIAL SPASM

Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)
I have explained the procedure to the patient. In particular, I have explained:

The intended benefits: TO REDUCE LID AND FACIAL SPASM/TIC AND/OR TO REDUCE UNWANTED CLOSURE OF EYELIDS.

Serious or frequently occurring risks:

Nearly all side effects are temporary and include:

- Bruising, swelling, discomfort
- Drooping/shut eyelid
- Double vision/eye misalignment
- Out-turning eyelid
- Weakness mouth difficulty biting or chewing
- Dry eye

Rarely: Permanent eyelid or facial paralysis or weakness, extremely rarely serious infection or bleeding

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

The following leaflet has been provided: Botulinum toxin treatment for eye conditions

This procedure will involve: ☑ local anaesthesia

Signed________________________________ Date________________________________

Name (PRINT) ________________________________ Job title________________________

Contact details (if patient wishes to discuss options later) 01480 416416 extn 8794

Statement of interpreter (where appropriate)
I have interpreted the information above to the patient to the best of my ability and in a way in which I believe s/he can understand.

Signed________________________________ Date________________________________

Name (PRINT)______________________________________________________________

Document title: Botox procedure Version 1 Year 2018 Page 19 of 27

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Statement of patient

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of page 8 which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure or course of treatment described on this form.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

☐ Patient’s signature_________________________ Date__________

Name (PRINT)__________________________________________

A witness should sign below if the patient is unable to sign but has indicated his or her consent. Young people/children may also like a parent to sign here (see notes).

Signed__________________________ Date____________________

Name (PRINT) __________________________________________

Confirmation of consent (to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance). On behalf of the team treating the patient, I have confirmed with the patient that s/he has no further questions and wishes the procedure to go ahead.

Signed__________________________ Date____________________

Name (PRINT) ___________________ Job title ________________________

Important notes: (tick if applicable)
☐ See also advance directive/living will (eg Jehovah’s Witness form)
☐ Patient has withdrawn consent (ask patient to sign/date here)
Appendix D

Group Prior Approval, and Exceptional and Individual Funding Requests Patient Information sheet

Group Prior Approval (GPA), and Exceptional and Individual Funding Requests

Why we need to Collect Your Personal Confidential Data and Your Rights

The GP or the hospital clinician making a funding request for you has provided you with this patient leaflet and Clinical Commissioning Group (CCG) clinical policy, as appropriate, so that you are aware of why we need to collect personal confidential data about you and what we do with the information.
| **Why does a funding request form need to be completed?** | Where the CCG does not have arrangements in place for a particular treatment or procedure to be provided by the local hospital in the form of a contract with them, your GP or hospital clinician will need to make a special request for your treatment for you. We call this ‘non-commissioned care’ and requests for treatment are called Exceptional or Individual Funding Requests (E/IFRs). For example, we do not routinely pay for cosmetic surgery unless a patient meets pre-set criteria for a procedure or requires cosmetic surgery as the result of an accident or illness. (See over page for details of where you can access the CCG clinical policies and this patient leaflet.)
To make this special request for treatment for you your GP or hospital clinician will complete an Exceptional and Individual Funding Request Form.
If a hospital clinician prescribes a high cost drug for you that has been NICE (National Institute for Health and Care Excellence) or locally approved, and you meet the criteria applicable for that drug, the clinician will complete a Group Prior Approval (GPA) form - GPA forms are required to check that criteria for treatment are fulfilled and to enable the CCG to monitor use of and charges for high cost drugs.
When a clinician completes a request for you they will complete a patient consent section to confirm that the request has been discussed with you and that you agree to the sharing of your personal information. |
| **Why do you need my personal confidential data?** | When the CCG Exceptional Cases Panel discuss your E/IFR request they need to have all the relevant information to allow them to fully consider the request. We need to know your name and address so that we can correspond with you as well as your GP or hospital clinician.
In the case of GPA forms, the team who administer high cost drug requests review applications and confirm the decision to approve or decline the request with you and your hospital clinician. |
<p>| <strong>What data do</strong> | For either the E/IFR or GPA form, we need basic details such as name, |</p>
<table>
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<th>you collect?</th>
<th>address, date of birth and NHS number. For the E/IFR form, information about your health and well being that is relevant to your application is required. This may include clinic letters, medication details and test results.</th>
</tr>
</thead>
</table>
| Is my personal confidential data shared with anyone else? | Your GP or hospital clinician initially shares your personal data with the CCG Exceptional Cases Team by completing the funding request form or GPA. We may then request additional information from clinical staff involved with your care.  
In the case of an E/IFR request it will be discussed by the Funding Panel. They receive details of your medical history - patient identifiable information is removed – this is referred to as a case file by the EC Team. The full case file (electronic file) containing your personal confidential information is made available to the Chair of the Panel for verifying information about you – the Chair of the Panel is a GP. |
| **Is my personal confidential data shared with anyone else? cont’d?** | We have a form you can complete if you wish to authorise us to communicate with your next of kin about your case.  
If you wish to correspond with the Exceptional Cases Team by email we will request that you confirm this in writing to us – email will do – otherwise we have a form for this as well.  
*NHS accounts are encrypted to protect data. You should be aware that personal home email accounts may not be encrypted.  
All staff working for the NHS have a duty to ensure that your information is secure and confidential and is only shared when there is a legitimate reason to do so. |
| **Do you need to keep my personal confidential data?** | We keep some funding request data for the purposes of payments/invoicing and because we need to monitor and assess future funding requests – some funding requests are approved subject to conditions or may relate to a particular high cost drug where an increase in dose or change of drug may be requested. We might also need to carry out an audit of requests at some point. |
| **Your Rights.** | • You have the right to know how we will use the information about you.  
• You have a right to access your medical record (Subject Access Right).  
• You have the right to object to us making use of your information.  
• You have the right to restrict the way we use your information and we are obliged to agree if it is possible to do so.  
• You have the right to correct information if what we are holding is incorrect. |
| **What You Can Do To Help.** | • Tell us if any of your details change, for example a new address.  
• Tell us if any of the information in your records is wrong.  
• Allow us to share information; we need to ensure that you receive the best care possible. |
Who do I contact if I want to raise a particular concern or objection, or access the information held about me?

You can contact the Exceptional Cases Team as follows:

- If your enquiry relates to a non-drug related funding request please contact:
  Peterborough Office: 01733 776182
  Cambridge Office: 01223 725423
- If your enquiry relates to a drug related funding request please contact:
  Peterborough office: 01733 776181

* If you wish to email the Exceptional Cases Team the nhsnet email address is: cpccge-ifr@nhs.net

Our address is: Exceptional Cases Team
NHS Cambridgeshire and Peterborough CCG
Lockton House
Clarendon Road
Cambridge CB2 8FH

Where can I access CCG Clinical Policies and Exceptional Cases Information?

Our clinical policy information is available on the following web page:
http://www.cambsphn.nhs.uk/CCPF/PHPolicies.aspx

Our Exceptional Cases Procedure Policy is available on the following web page:
http://www.cambsphn.nhs.uk/CCPF/ExcptnalandIFR.aspx

If you would like to receive a printed copy of a policy you can:

Write: to the above address marking the envelope for the attention of the Secretary of the Clinical Policies Forum.

Telephone: the Secretary of the Cambridgeshire and Peterborough CCG Clinical Policies Forum on 01733 776180.

Email: CAPCCG.clinpolicies@nhs.net

Note:

If you are not resident in Cambridgeshire or Peterborough and you have been given this leaflet by your hospital clinician please contact your local CCG for further information.
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<tr>
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<th>Quality Assurance Checklist - Version Number: Appendix A</th>
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<tbody>
<tr>
<td>1</td>
<td>Title of document</td>
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<tr>
<td>2</td>
<td>Type of document (e.g. policy, guidance)</td>
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<tr>
<td>3</td>
<td>Introduction</td>
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<tr>
<td>4</td>
<td>Content</td>
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<td>5</td>
<td>Evidence Base</td>
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<td>6</td>
<td>Approval Route</td>
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<td>7</td>
<td>Process to Monitor Compliance and Effectiveness (policies only)</td>
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<td>8</td>
<td>Review Date</td>
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<tr>
<td>9</td>
<td>Equality and Diversity (policies only)</td>
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</tbody>
</table>

|   | Y/N/n/a | COMMENTS (to author for any amendments) |

1. Title of document
2. Type of document (e.g. policy, guidance)
   - Is it clear whether the document is a policy, guideline, procedure?
3. Introduction
   - Are reasons for the development of the document clearly stated?
4. Content
   - Is there a standard front cover?
   - Are the key points identified? (Policies only)
   - Is the document in the correct format?
   - Is the purpose of the document clear?
   - Is the scope clearly stated?
   - Are the definitions clearly explained?
   - Are the roles and responsibilities clearly explained? (policies only)
   - Have recommendations from Counter Fraud/Internal Audit been included?
   - *Does this policy concern the handling, moving or storage of personal identifiable or commercially sensitive information?*
   - *If yes, has a Summary Privacy Impact Assessment been completed?*
5. Evidence Base
   - Is the type of evidence to support the document explicitly identified?
   - Are key references cited?
   - Are associated documents referenced?
6. Approval Route
   - Does the document identify which committee/group will approve it?
7. Process to Monitor Compliance and Effectiveness (policies only)
   - Are there measureable standards or KPIs to support the monitoring of compliance with the effectiveness of the document? (has Appendix D Compliance Monitoring been completed)
8. Review Date
   - Is the review date identified?
9. Equality and Diversity (policies only)
   - Is a completed Equality Impact Assessment attached?
**Compliance Team:**

1. Date of Compliance Team approval
2. Date Comments returned to author by Compliance Lead
3. Name of Compliance Lead

**Approval Committee:**

If the committee/group is happy to approve this document would the chair please sign below and send the document and the minutes from the approval committee to the author. To aid distribution all documentation should be sent electronically wherever possible.

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**Ratifying Committee:**

If the committee/group is happy to ratify this document would the chair please sign below and send the document and the minutes from the ratifying committee to the author. To aid distribution all documentation should be sent electronically wherever possible.

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If answers to any of the above questions is 'no', then this document is not ready for ratification, it needs further review.