## Administration
## PATIENT GROUP DIRECTION (PGD) FOR

# BOTULINUM TOXIN TYPE A INJECTION

YOU MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE YOU ATTEMPT TO WORK ACCORDING TO IT

| **Clinical Condition** | |
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| **Indication** | Local injection to give symptomatic relief from muscle spasm. |
| **Inclusion criteria** | Aged 18 years and over with a high degree of muscular tone which is specific to a small number of muscles and resulting from a neurological insult affecting upper and or lower limbs. As determined by a full initial assessment (within the previous 16 weeks) from a trust employed consultant neurosurgeon.<br>*Its use in lower limb spasticity in patients with neurological conditions is considered within best clinical practice, despite being outside the terms of the marketing authorisation*<br>Patients may be considered for treatment by specialist neuro-rehabilitation physiotherapists under this PGD if they<br>- are medically stable<br>- have received at least one botulinum treatment from the consultant without complication<br>- are deemed to have predictable requirements for ongoing anti-spasticity management with botulinum<br>- are thought to be suitable for treatment under the PGD and this has been recorded in the case notes by the consultant.<br>- do not fulfil any of the exclusion criteria listed below |
| **Exclusion criteria**<br>If any of the following apply the PGD CANNOT be used and the patient must be referred to a prescriber | Under 18 years of age<br>Pregnant or breast feeding.<br>Hypersensitive to the injection components eg human albumin, blood products, latex, botulinum toxin<br>Local infection at the proposed site of injection<br>Generalised muscle disorders including myasthenia gravis and Lambert Eaton Syndrome<br>Concurrent aminoglycoside antibiotic use<br>Bleeding disorders including patients on anticoagulants eg warfarin, dabigatran, rivaroxaban, apixaban or heparin.<br>Severe neuromuscular dysphagia with suspicion of chronic aspiration<br>Botulinum Toxin administered in the last 12 weeks<br>Patients who do not wish to be seen by the physiotherapists |
| **Cautions - Seek further advice from doctor before proceeding and document advice** | Patients with swallowing difficulties, chronic respiratory disorders, are at increased risk of serious side effects in the possible event of toxin spreading from the injection site. |
| **Further information** | There is a potential risk of muscle weakness and/or visual disturbance which could impair driving or operating machinery. |

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| **Action if patient declines or is excluded** | Referred back to consultant neurologist for continued care |
| **Drug Details** | |
| **Name, form & strength of medicine** | Botulinum toxin type A Botox®<br>Botulinum toxin type A Dysport®<br>Botulinum toxin type A Xeomin® |
| **Legal status** | Prescription Only Medicine (POM) |
| **Route/Method** | Intra-muscular.<br>The specific muscles or groups of muscles to be injected will be indicated by the consultant at first assessment and recorded in the notes. The precise muscles to be injected in a group of muscles may be varied at the physiotherapist's discretion if indicated by the supervising consultant. |
| **Dosage** | Dose as prescribed by consultant at initial consultation.<br>Dose range will be between 10 to 1000 units per treatment (see quantity to administer below) diluted with sodium chloride 0.9%.<br>Actual dose to be given will be indicated by consultant at first assessment and when patient is signed over to treatment under the PGD.<br>Dose may be increased or decreased by up to 50% by the physiotherapist depending on response at subsequent visits to a maximum dosage. See below under Quantity to administer for product specific dosage information. |
| **Frequency** | Not more than once every 12 weeks |
| **Quantity to administer** | The total dose administered for **Botox** should not exceed 400 units divided among selected muscles at any treatment session and the maximum single total dose per injection site should not exceed 50 units.<br>The total dose administered for **Dysport** should not exceed 1,000 units divided among selected muscles at any treatment session and the maximum total dose per injection site should not exceed 200 units.<br>The total dose administered for **Xeomin** should not exceed 500 units divided among selected muscles at any treatment session and the maximum single total dose per injection site should not exceed 50 units. |
| **Side effects** | 1) Side effects related to the spread of toxin distant from the site of administration have been reported, such as exaggerated muscle weakness, dysphagia, aspiration/aspiration pneumonia, with fatal outcome in some very rare cases.<br>2) Flu -like symptoms: advise patient these may occur and that they can be treated by paracetamol or ibuprofen |

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| | 3) Undue weakness: if in the muscle groups treated to be reviewed by the physiotherapy team. If more generalised weakness for urgent review by the neurology team on call or even the Regional Centre at QE if necessary<br>4) Bleeding/bruising: at the time of injection, press on injection site firmly until bleeding stops. Advise patient that bruising may occur afterwards.<br>5) Urinary bladder dysfunction (in lower limb proximal injections): advise patient of risk and arrange urgent neurology review if patient reports difficulty of micturition 1-2 weeks post injection.<br>6) Complete and post yellow card bound within BNF or report on the website www.yellowcard.gov.uk |
| **Storage & destruction** | To be stored in a locked fridge or cupboard (depending on product). Running stock levels to be maintained to account for all vials. Unused part contents of vials and syringes to be disposed of by denaturing before disposal (consult SPC) into suitable sharps bins. |
| **Advice to patient/carer** | All patients should be provided with a patient information leaflet relating to this injection and their attention drawn to the listed potential side-effects.<br>Discuss the side effects most relevant to the site of injection used. |
| **Follow up** | Inform GP of treatment course<br>Physiotherapists working under this direction should seek further advice in the following situations:<br>• Development of serious possible adverse events: i.e. dysphagia, generalised weakness, bladder dysfunction, severe<br>• Local injection site reaction suspected or confirmed anaphylaxis, possible allergic reaction to toxin e.g. rash, severe flu-like symptoms.<br>• Apparent failure of toxin to produce functional benefit on two or more occasions<br>• Patient complaint or dissatisfaction with treatment<br>• Worsening symptoms of spasticity (despite effective response to botulinum) which may require pharmacological treatment or identification and treatment of specific triggers |

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| Staff Characteristics | |
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| **Professional qualifications** | Chartered physiotherapists. Registered practitioner with the Health and Care Professions Council (HCPC) |
| **Specialist competencies or qualifications** | Successful completion of the Masters module in Injection therapy. With a minimum of 10 years experience in neuro-rehabilitation and extensive knowledge of the treatment of spasticity.<br>Specifically trained on safe use of Botulinum toxin Type A to include reconstitution, storage, administration and disposal.<br>Has undertaken appropriate training for working under PGDs for the administration of medicines, and in the management of anaphylaxis. |
| **Continuing education & training** | The practitioner should be aware of any change to the recommendations for the medicine listed. It is the responsibility of the individual to keep up-to-date with clinical developments as part of their continued professional development |

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| Referral Arrangements and Audit Trail | |
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| **Records/audit trail** | Patient's name, address, date of birth and GP details.<br>Diagnosis, and patient consent to treatment<br>Time and site of injections with dose administered at each site and total dose for the session.<br>Batch details and expiry date<br>Advice given to patient (including side effects).<br>Signature/name of staff who administered the treatment.<br>Details of any adverse drug reaction and actions taken including documentation in the patient's medical record.<br>Referral arrangements (including self-care). |
| **References/Resources and comments** | Current versions of Summary of Product Characteristics, BNF, A clinical guideline for the use of injection therapy by physiotherapists. RCP National Guidance on the Treatment of spasticity in adults with botulinum toxin. |

| Clinical Authorisation | |
|---|---|
| **Lead Doctor** | Dr John Devapriam, Medical Director<br>Signature: Date: 17/7/18 |
| **Lead Pharmacist** | Dr Alex Johnson, Prescribing Support Pharmacist<br>Signature: Date: 25/7/18 |
| **Snr Physiotherapist** | Tracey Vacher, Senior Physiotherapist<br>Signature: Date: 6/7/18 |
| **Organisational Authorisation** | |
| **On behalf of Worcestershire Health & Care NHS Trust** | Michelle Clarke, Director of Nursing & Quality<br>Signature: Date: 23/7/18 |

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## Individual Authorisation

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY.

**It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct.**

Note to Authorising Managers: authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation. Authorising managers should be sure that staff signed up to use the PGD have the necessary competence, training and knowledge to apply it.

I have read and understood the Patient Group Direction and agree to supply/administer this medicine only in accordance with this PGD. I confirm that I have the necessary competence, training and knowledge to apply it.

| Name of Professional | Signature | Authorising Manager | Date |
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