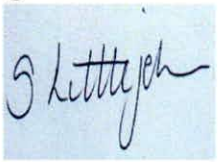
Patient Group Direction For The Administration Of Xeomin® By Intramuscular Injection By Approved Physiotherapists Working Within NHS Grampian

Lead Author: Operational Lead Physiotherapist for Specialist Rehabilitation, NHSG	**Consultation Group**: See relevant page in the PGD	**Approver:** Medicines Guidelines and Policies Group **Authorisation:** NHS Grampian

Signature: 		**Signature:** 

NHSG Identifier: MGPG/PGD/Xeomin/1476	**Review Date:** February 2026 **Expiry Date:** February 2027	**Date Approved:** February 2024

NHS Grampian have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 1

Revision History:

PGD that has been superseded	N/A - New PGD	
Date of change	**Summary of Changes**	**Section heading**
01/12/23	New PGD development from MGPG template.	

NHGS Identifier: MGPG/PGD/Xeomin/1476

Keyword(s): PGD Patient Group Direction Xeomin Physiotherapist

Policy Statement: It is the responsibility of the individual healthcare professionals and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Document:	Drafted:	7th November 2023
	Completed:	9th January 2024
	Approved:	29th February 2024 (published April 2024)
	Amended and re-authorised:	

Organisational Authorisations

This PGD is not legally valid until it has had the relevant organisational authorisation.

PGD Developed/Reviewed by;

Medical practitioner	**Name:** Dr Angela Gall **Title:** Consultant in Rehabilitation Medicine **Contact email:** angela.gall@nhs.scot **Signature:** ..... **Date:** 14/03/2024
Senior representative of the professional group who will provide care under the direction	**Name:** Fiona Douglas **Title:** AHP Consultant **Contact email:** fiona.douglas2@nhs.scot **Signature:** ..... **Date:** 14/03/2024
Lead author	**Name:** Shiona Littlejohn **Title :** Operational Lead Physiotherapist for Specialist Rehabilitation, NHSG **Contact email:** shiona.littlejohn@nhs.scot **Signature:** ..... **Date:** 13/03/2024
Pharmacist	**Name:** Morag Smart **Title :** Specialist Pharmacist (Neurosciences and Stroke) **Contact email:** morag.smart2@nhs.scot **Signature:** ..... **Date:** 21/03/2024

Approved and authorised for use within NHSG by;

Medicines Guidelines and Policies Group Chair	Signature	Date Signed
Lesley Coyle		01/05/2024

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and is best practice to have a representative of the professional group who will provide care under the direction.

Name:	Title:
Shiona Littlejohn	**Lead Author:** Operational Lead Physiotherapist for Specialist Rehabilitation, NHSG
Morag Smart	**Pharmacist:** Specialist Pharmacist (Neurosciences and Stroke) NHSG
Dr Angela Gall	**Medical Practitioner:** Consultant, rehabilitation medicine NHSG
Fiona Douglas	**Senior Representative:** AHP consultant NHSG (Physiotherapist)
Martin Cossar	Advanced Nurse Practitioner (Posture and Movement Clinic) NHSG
Lesley Stables	Operational Lead Physiotherapist for Specialist Rehabilitation, NHSG

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Clinical indication to which this PGD applies

Definition of situation/ Condition	This Patient Group Direction (PGD) will authorise approved physiotherapists to administer Xeomin® by Intramuscular Injection to individuals who have spasticity due to a neurological condition. Injection therapy with botulinum toxin would be considered as first line treatment for individuals presenting with spasticity secondary to a neurological condition, in conjunction with physiotherapy treatment/advice. Physiotherapists are ideally placed to carry out this treatment to facilitate the individuals continued rehabilitation without the need for referral to a Doctor/specialist clinic. The PGD will authorise approved qualified physiotherapists to undertake these injections leading to reduced workload for hospital consultants. This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF) and the individual Summary of Product Characteristics (SmPC).
Inclusion criteria	Individuals, aged 18 years or over who present with focal spasticity of the upper limb or focal spasticity of the lower limb affecting the ankle joint. **Note:** Diagnosis and treatment must be made by a senior physiotherapist with post graduate training and experience in the management of spasticity. The final diagnosis and decision to inject must be made by the individual physiotherapist. The physiotherapist trained to undertake the injection therapy must fully assess the individual's condition and determine that injection therapy is the most appropriate management. Prior to the administration of the medicine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current NHSG consent policy.

Exclusion criteria	Individuals may be administered botulinum toxin under this PGD unless: • Pregnant • Breast feeding • Known hypersensitivity to Botulinum Toxin (BTX) or human albumin or any of the other ingredients of Xeomin® • Previous allergic reaction to Botulinum Toxin • Myasthenia Gravis • Lambert-Eaton Syndrome • Infection, inflammation, bruising or local tissue damage at proposed injection site • Current acute febrile illness • INR over 3 • Known bleeding disorder • Has received botulinum toxin injection in the last 2 months • Patients with a secondary unstable medical condition • Individuals for whom no valid consent has been received.
Precautions and special warnings	On initial assessment, patients on anticoagulants should have their treatment plan agreed with the patient's consultant/GP. Individuals on anticoagulants should be warned that there is an increased risk of bruising/bleeding from the injection site and are to be carefully observed for signs of bleeding. Too frequent doses may increase the risk of antibody formation, which can result in treatment failure. The potential for antibody formation may be minimised by injecting with the lowest effective dose at the longest intervals between injections as clinically indicated. Xeomin® contains Human Albumin and therefore Jehovah witnesses should be informed of this as part of the consent process.
Action if excluded from treatment	Medical advice must be sought – refer to relevant medical practitioner. Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.
Action if treatment is declined	Inform/refer to the patients consultant if individual declines treatment. Document that the administration was declined, the reason and advice given in appropriate clinical records.

Description of treatment available under the PGD

Name form and strength of medicine	Xeomin® powder for solution for injection. Xeomin® 200 units powder for solution for injection: One vial contains 200 units of Clostridium Botulinum neurotoxin type A (150 kD), free from complexing proteins*. Xeomin® 100 units powder for solution for injection: One vial contains 100 units of Clostridium Botulinum neurotoxin type A (150 kD), free from complexing proteins*. Xeomin® 50 units powder for solution for injection: One vial contains 50 units of Clostridium Botulinum neurotoxin type A (150 kD), free from complexing proteins*. * Botulinum neurotoxin type A, purified from cultures of Clostridium Botulinum (Hall strain)
Legal status	Xeomin® is a Prescription-only Medicine (POM)
Is the use out with the SmPC?	Under this PGD, Xeomin® can be used 'off label' for any skeletal muscle which has been assessed to have increased spasticity. This is outside the terms of the marketing authorisation and constitutes an off-label use of the medicine. The individual should be informed prior to the administration that the use is off-label.
Dosage/Maximum total dose	The maximum total dose for the treatment of upper limb spasticity should not exceed 500 units per treatment session, and no more than 250 units should be administered to the shoulder muscles. The maximum total dose for the treatment of lower limb spasticity should not exceed 400 units per treatment session. If treatment is required in the upper and lower limbs during the same treatment session, the dose of Xeomin® should not exceed a maximum total dose of 500 units for the first treatment session. Following the first treatment session, if well tolerated, the maximum total dose for the combined treatment of the upper and lower limbs in subsequent treatment sessions can be increased to 600 units.

<table>
<tr><td></td><td>The exact dose and number of injection sites per muscle should be tailored to the individual patient based on the size, number and location of involved muscles, the severity of spasticity, and the presence of local muscle weakness.</td></tr>
<tr><td>Frequency of dose/Duration of treatment</td><td>See below.</td></tr>
<tr><td>Maximum or minimum treatment period</td><td>Individual intervals should be determined on the actual clinical need of the patient. However, these should be no more frequent than every 12 weeks. If deemed necessary for the patient to receive Xeomin® more frequently, the patient should be referred back to their consultant physician.</td></tr>
<tr><td>Route/Method of administration</td><td>Xeomin® should be administered by intramuscular injection.

Xeomin® should be reconstituted with sterile unpreserved normal saline (0.9% sodium chloride for injection). Reconstitution and dilution should be performed in accordance with good clinical practice guidelines, particularly with respect to asepsis.

Reconstituted Xeomin® is a clear, colourless solution.

Xeomin® must not be used if the reconstituted solution has a cloudy appearance or contains floccular or particulate matter.

Concentrations for Xeomin® 50, 100, and 200 units are indicated in the following table (taken from SmPC):

<table>
<tr><td rowspan="2">Resulting dose (in units per 0.1 ml)</td><td colspan="3">Solvent added (sodium chloride 9 mg/ml (0.9 %) solution for injection)</td></tr>
<tr><td>Vial with 50 units</td><td>Vial with 100 units</td><td>Vial with 200 units</td></tr>
<tr><td>20 units</td><td>0.25 ml</td><td>0.5 ml</td><td>1 ml</td></tr>
<tr><td>10 units</td><td>0.5 ml</td><td>1 ml</td><td>2 ml</td></tr>
<tr><td>8 units</td><td>0.625 ml</td><td>1.25 ml</td><td>2.5 ml</td></tr>
<tr><td>5 units</td><td>1 ml</td><td>2 ml</td><td>4 ml</td></tr>
<tr><td>4 units</td><td>1.25 ml</td><td>2.5 ml</td><td>5 ml</td></tr>
<tr><td>2.5 units</td><td>2 ml</td><td>4 ml</td><td>Not applicable</td></tr>
<tr><td>2 units</td><td>2.5 ml</td><td>5 ml</td><td>Not applicable</td></tr>
<tr><td>1.25 units</td><td>4 ml</td><td>Not applicable</td><td>Not applicable</td></tr>
</table>

The therapist must maintain a clean working environment, ensure safe injection technique and minimise infection risk as appropriate to that procedure.</td></tr>
</table>

Quantity to be administered	Please see dose section.
Storage requirements	Xeomin® must not be stored in temperatures above 25°C. Once reconstituted the product should be used immediately.
Additional Information	None.
Follow-up (if applicable)	Individuals should not leave the clinical area within 10 minutes. If they are feeling unwell they should speak to the healthcare professional who administered the medicine. If necessary a doctor or the individuals GP should be contacted for advice. Follow up with the injecting physiotherapist should be arranged within 4 -6 weeks to assess the results of the injections and discussion about future treatment, if applicable.
Advice (Verbal)	• Advise individual/carer what to expect and of the possible side effects and their management. • Individuals should be safe to drive unless they have a hypersensitivity reaction to the injection or feel light headed in which case they must be advised against driving. • Patients can continue with any rehabilitation programme they have been prescribed. • If serious adverse or persistent effects occur, the individual/parent/carer should be advised to contact their GP/Accident and Emergency department/NHS24. • Individuals/carers should be advised to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme.
Advice (Written)	The Patient Information Leaflet (PIL) contained in the medicine(s) should be made available to the individual/carer. Where this is unavailable, or unsuitable, sufficient information should be given in a language/format that they can understand.
Identifying and managing possible adverse reactions	**Application related undesirable effects** Localised pain, inflammation, paraesthesia, hypoaesthesia, tenderness, swelling, oedema, erythema, itching, localised infection, haematoma, bleeding and/or bruising may be associated with the injection.

	Needle related pain and/or anxiety may result in vasovagal responses, including transient symptomatic hypotension, nausea, tinnitus, and syncope. **Toxin spread** Undesirable effects, such as an unintentional new weakness, related to spread of toxin distant from the site of administration have been reported very rarely to produce symptoms consistent with Botulinum toxin type A effects. **Hypersensitivity reactions** Serious and/or immediate hypersensitivity reactions including anaphylaxis, serum sickness, urticaria, soft tissue oedema, and dyspnoea have been rarely reported. Swallowing problems/headaches/nausea/dry mouth and cough are all noted as uncommon adverse reactions to the injection. **This list is not exhaustive. Please also refer to current BNF and manufacturers SmPC for details of all potential adverse reactions.** **BNF**: BNF British National Formulary - NICE **SmPC/PIL/Risk Minimisation Material:** Home - electronic medicines compendium (emc) MHRA Products | Home RMM Directory - (emc) If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible. Document in accordance with locally agreed procedures in the individual's record. Report any suspected adverse reactions using the Yellow Card System. Yellow Card Scheme - MHRA
Facilities and supplies required	The following are to be available at sites where the medicine is to be administered: • Appropriate storage facilities • An acceptable level of privacy to respect individual's right to confidentiality and safety • Basic airway resuscitation equipment (e.g. bag valve mask)

	• Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection • Access to a working telephone • Another competent adult, who can summon urgent emergency support if required should ideally be present • Access to medical support (this may be via the telephone) • Approved equipment for the disposal of used materials – appropriate sharps bin • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • A copy of this current PGD in print or electronically.

Characteristics of staff authorised to administer medicine(s) under PGD

Professional qualifications	Registered Physiotherapists as recognised by the Health and Care Professions Council (HCPC).
Specialist competencies	**Approved by the organisation as:** • Competent to assess the individual's capacity to understand the nature and purpose of the medicine administration in order to give or refuse consent • Aware of current treatment recommendations and be competent to discuss issues about the medicine with the individual • Having undertaken appropriate training to carry out clinical assessment of individuals identifying that treatment is required according to the indications listed in the PGD • Competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions • Competent to undertake administration of the medicine • Have completed training requirements set out in the CSP Expectations of educational programmes in Injection Therapy for physiotherapists Feb 2021 • Competent to work under this PGD and authorised by name as an approved person to work under the terms of the PGD.
Ongoing training and competency	**All professionals working under this PGD must:** • Have undertaken NoS PGD module training on TURAS Learn • Have attended basic life support training either face to face or online and updated in-line with Board requirements • Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis in-line with Board requirements

	• Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct. **Note:** All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of the medicine. If any training needs are identified these should be discussed with those responsible for authorisation to act under the PGD • Have knowledge and familiarity of the following; ○ SmPC for the medicine(s) to be administered in accordance with this PGD.
Responsibilities of professional manager(s)	**Professional manager(s) will be responsible for;** Ensuring that the current PGD is available to all staff providing care under this direction. Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above. Maintain up to date record of all staff authorised to administer the medicine(s) specified in this direction.

Documentation

Authorisation of administration	Physiotherapists working within NHS Grampian can be authorised to administer the medicine(s) specified in this PGD by their Consultant in rehabilitation medicine. All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1). A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed locally.
Record of administration	An electronic or paper record must be completed to allow audit of practice. An electronic/HEPMA record of the screening and subsequent administration, or not of the medicine(s) specified in this PGD should be made in accordance with individual Health Board electronic/HEPMA recording processes. If a paper record is used for recording the screening of individuals and the subsequent administration, or not of the medicine(s) specified in this PGD. This should include as a minimum:

	• Date and time of administration • Individuals name and CHI • Exclusion criteria, record why the medicine was not administered (if applicable) • Record that valid consent to treatment under this PGD was obtained • The name, dose, form, route, batch number, expiry date and anatomical site of injection of the medicine(s) administered • Advice given, including advice given if excluded or declined treatment under this PGD • Signature and name in capital letters of the healthcare professional who administered the medicine, and who undertook the assessment of the individual's clinical suitability for the administration/supply of the medicine • Record of any adverse effects and the actions taken (advise individuals' GP/relevant medical practitioner). Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically, in one (or more) of the following systems, as appropriate: • Individual's GP records if appropriate • Secondary Care Medical Notes • Individual service specific systems. Local policy should be followed with respect to sharing information with the individual's General Practitioner. All records should be clear, legible and contemporaneous and in an easily retrievable format.
Audit	All records of the medicine(s) specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD.
References	Electronic Medicines Compendium http://www.medicines.org.uk Xeomin® – Date of revision of text 14/06/23, accessed 20/07/23. British National Formulary https://www.bnf.org/products/bnf-online/ accessed 20/07/23.

	CSP, PD071_InjectionTherapyExpecs_Feb2021[1].pdf (csp.org.uk) CSP expectations of educational programmes in Injection Therapy for physiotherapists (3rd Edition) / accessed 20/07/23 CSP, PD003_InjectionTherapy_2023.pdf (csp.org.uk), accessed 20/07/23 H. I.S. SIGN (2016). *National clinical guidelines for stroke for the UK and Ireland*. [Online]. SIGN guidelines. Last Updated: 2023. Available at: https://scottish.sharepoint.com/sites/LethamWardQualityMeetings/_layouts/15/viewer.aspx?sourcedoc={1 [Accessed 30 November 2023]. RCP (2018). *Revised Guidelines: Spaticity in adults: management using botulinum Toxin.* Available at : https://www.rcplondon.ac.uk/guidelines-policy/spasticity-adults-management-using-botulinum-toxin

Appendix 1

Healthcare Professional Agreement to Administer Medicine(s) Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer the medicine(s) contained within the following Patient Group Direction:

Patient Group Direction For The Administration Of Xeomin® By Intramuscular Injection By Approved Physiotherapists Working Within NHS Grampian – Version 1

I have completed the appropriate training to my professional standards enabling me to administer the medicine(s) under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN: _____

Appendix 2

Healthcare Professionals Authorisation to Administer Medicine(s) Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to administer the medicine(s) under this PGD is responsible for ensuring that they are competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to administer the medicine(s) under this PGD is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to their individual code of professional practice and conduct.
Patient Group Direction For The Administration Of Xeomin® By Intramuscular Injection By Approved Physiotherapists Working Within NHS Grampian – Version 1
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

Patient Group Direction For The Administration Of Xeomin® By Intramuscular Injection By Approved Physiotherapists Working Within NHS Grampian – Version 1					
Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**