Torbay and South Devon NHS
NHS Foundation Trust

Patient Group Direction 2243 version 1.0
Administration of Alprostadil (MUSE, Caverject or Viridal) by Registered Practitioners employed by Torbay and South Devon NHS Foundation Trust

Date of Introduction: June 2019
Review Date: May 2021

Developed By	Name	Signature	Date
Physician	Consultant Urologist		
Pharmacist	Pharmacist		
Lead Professional	Urology Oncology Nurse		

Note: The Lead Professional is responsible for ensuring the co-ordination, composition, consultation, revision and distribution of the PGD to practitioners who will be using the PGD as well as ensuring that the PGD is no longer used if becomes out of date and once it has expired.

The Clinical Effectiveness Department will write to the Lead Professional approximately 4 months before the review date as a reminder that a review is required.

Ratified on behalf of: TORBAY AND SOUTH DEVON NHS FOUNDATION TRUST	
Medicines Management Committee Chair	
Signed:	
Name:	Paul Foster, Clinical Director – Pharmacy and Prescribing
Date:	
Lead Officer	
Signed:	
Name:	Dr Rob Dyer, Medical Director
Date:	

Patient Group Direction 2243 version 1.0
Administration of Aloprostadil (MUSE, Caverject or Viridal) by Registered Practitioners employed by Torbay and South Devon NHS Foundation Trust

Objective	Treatment of erectile dysfunction in a nurse led clinic

1. Clinical Condition

Definition of condition/situation	Erectile dysfunction according to local protocol
Facilities required	▪ **MUSE** (Alprostadil) intraurethral pellets dosages 250mcg, 500mcg, 1000mcg ▪ **CAVERJECT** (Alprostadil) intracavernosal injections 2.5mcg in titrating doses, maximum dosage 40mcg. ▪ **VIRIDAL** (Alprosatdil) intracavernosal injections 10mcg titrating dosage to 40mcg maximum dosage
Criteria for inclusion	▪ Patients referred to the ED clinic in Urology having undergone assessment by the competent Urology ED nurse following full patient informed consent ▪ Patients with no contraindications to the above medications unless previous documented authorisation from referring/prescribing consultant.
Criteria for exclusion	Hypersensitivity to the active substances or ▪ Alprostadil should not be used in patients who have a known hypersensitivity to alprostadil or to any of the excipients listed in manufactures summary of product characteristics ▪ Patients who have conditions that might predispose them to priapism, such as sickle cell anaemia or trait, multiple myeloma, or leukaemia; ▪ Patients with anatomical deformation of the penis, such as angulation, cavernosal fibrosis, or Peyronie's disease. ▪ Patients with penile implants should not be treated with alprostadil. ▪ Uretheral application is contraindicated in balanitis, sever curvature, severe hypospadia, urethral stricture, urethritis ▪ Alprostadil should not be used in men for whom sexual activity is inadvisable or contraindicated. ▪ Patients already on medications for erectile dysfunction
Action if excluded	Refer to medical practitioner (or non-medical prescriber if appropriate) or alternative action as indicated by related protocol and document in patient's records
Action if patient refuses medication	▪ Document informed refusal in patient's records and action taken: a) Referral to protocol b) Referral to appropriate medical practitioner

2. Characteristics of Staff

Qualifications required	Registered Urology Nurse Specialists

Additional requirements	▪ Working knowledge of relevant Organisation Policies, including Medicines Policy and associated Standard Operating Procedures, Anaphylaxis Policy, Consent Policy and Injectable Medicines Policy and associated risk assessments where appropriate. ▪ Working knowledge of relevant Organisation protocols ▪ Evidence of continuing professional development, (and any training and competence relevant to this PGD) ▪ Working knowledge of the NMC Standards for Medicines Management 2007, (updated 2010) www.nmc-uk.org and other relevant codes of professional practice.

3. Description of Treatment

Name of Medicine Administered	**MUSE (Aloprostadil)**
Legal Class	POM (Prescription Only Medicine)
Storage	Lockable cabinet - intracavernosal injection Controlled temperature fridge – Intra urethral pellet
Dose to be used	250 mcg, 500 mcg, 1000 mcg
Method or route of administration	Intraurethral
Total dose and number of times drug to be given. Details of supply (if supply made)	One pellet as required in clinic setting. Test doses given in clinic to obtain therapeutic dosing Directions for administration ▪ By urethral application ▪ Adult ▪ Initially 250 micrograms, adjusted according to response; usual dose 0.125–1 mg; maximum 2 doses per day; maximum 7 doses per week. ▪ With urethral use: During initiation of treatment the urethral application should be used under medical supervision; self-administration may only be undertaken after proper training ▪ When therapeutic dose established then to be continued via the G.P practice.
Contra-indications	▪ See criteria for exclusion ▪ Refer to medical practitioner (or non-medical prescriber if appropriate) or alternative action as indicated by related protocol and document in patient's records
Cautions	▪ Anatomical deformations of penis ▪ Priapism (patients should be instructed to report any erection lasting 4 hours or longer)
Interactions	If patient is taking any other medications consult BNF Appendix 1 for any potential interactions.

Potential side-effects and adverse reactions	***Side-effects common or very common*** Headache, dizziness Symptomatic hypotension, haematoma Nausea Urticaria Muscle spasms Urethral burning Minor urethral bleeding Penile pain Erection increased, Peyronie's disease, penis disorder, vaginal burning/itching (in partners) ***Side-effects uncommon*** Common cold Syncope, pre-syncope, hypoaesthesia, hyperaesthesia Vein disorder, peripheral vascular disorder, vasodilatation Nausea Swelling of the leg veins, erythema, hyperhidrosis, rash, pruritus, scrotal erythema Leg pain Dysuria, pollakiuria, micturition urgency, urethral haemorrhage Perineal pain, erectile dysfunction, ejaculation disorder, balanitis, painful erection, phimosis, priapism, testicular pain, scrotal disorder, scrotal erythema, scrotal pain, spermatocele, scrotal oedema, testicular disorder, testicular swelling, testicular oedema, testicular mass, pelvic pain ***Side-effects rare*** Penile fibrosis Urinary tract infection Urticaria
Management of potential side-effects and adverse reactions	Unusual or life threatening reactions require immediate medical attention. Priapism associated with alprostadil, initial management with aspiration and lavage of corpora. If unsuccessful then intracavernosal injection of adrenaline: 10–20 micrograms every 5–10 minutes, using a 20 microgram/mL solution. ***Important:*** if suitable strength of adrenaline not available may be specially prepared by diluting 0.1 mL of the adrenaline 1 in 1000 (1 mg/mL) injection to 5 mL with sodium chloride 0.9%, continuously monitor blood pressure and pulse; maximum 100 micrograms per course.
Advice and information to patient/carer including follow-up	▪ Unusual or life threatening reactions require immediate medical attention. ▪ Patients should be instructed to report to a physician any erection lasting for a prolonged time period, such as 4 hours or longer.
Specify method of recording supply /administration including audit trail	The following will be recorded in the patient's records: ▪ The diagnosis and treatment ▪ The dose administered ▪ Batch number and expiry date if appropriate ▪ The route of administration and site of administration where appropriate ▪ The frequency of administration and duration of treatment ▪ The time and date of administration ▪ The signature and name of the person administering the medication Document allergies and other adverse drug reactions clearly in patient records and inform the GP and other relevant practitioners/patient/carer for further reporting and action if required. Report any adverse drug reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) through the yellow card reporting system (www.mhra.gov.uk).

3. Description of Treatment

Name of Medicine Administered	**Caverject (Aloprostadil)**
Legal Class	POM (Prescription Only Medicine)
Storage	Lockable cabinet - intracavernosal injection Controlled temperature fridge – Intra urethral pellet
Dose to be used	2.5mcg titrating dose to maximum dose 60mcg
Method or route of administration	Intracavernously
Total dose and number of times drug to be given. Details of supply (if supply made)	One injection as required in clinic setting. Test doses given in clinic to obtain therapeutic dosing ▪ Erectile dysfunction ▪ By intracavernosal injection ▪ Adult ▪ Initially 2.5 micrograms for 1 dose (first dose), followed by 5 micrograms for 1 dose (second dose), to be given if some response to first dose, alternatively 7.5 micrograms for 1 dose (second dose), to be given if no response to first dose, then increased in steps of 5–10 micrograms, to obtain a dose suitable for producing erection lasting not more than 1 hour; if no response to dose then next higher dose can be given within 1 hour, if there is a response the next dose should not be given for at least 24 hours; usual dose 5–20 micrograms (max. per dose 60 micrograms), maximum frequency of injection not more than 3 times per week with at least 24 hour interval between injections. With intracavernosal use: ▪ The first dose of the intracavernosal injection must be given by medically trained personnel; self-administration may only be undertaken after proper training.
Contra-indications	▪ See criteria for exclusion ▪ Refer to medical practitioner (or non-medical prescriber if appropriate) or alternative action as indicated by related protocol and document in patient's records
Cautions	▪ Anatomical deformations of penis ▪ priapism (patients should be instructed to report any erection lasting 4 hours or longer)
Interactions	If patient is taking any other medications consult BNF Appendix 1 for any potential interactions.

Potential side-effects and adverse reactions	***Side-effects common or very common*** Muscle spasms, Injection site haematoma, Haematoma, Ecchymosis Peyronie's disease, Penis disorder, Erection increased ***Side-effects uncommon*** Fungal infection, Common cold Presyncope, Hypoaesthesia, Hyperaesthesia Mydriasis Supraventricular extrasystoles Venous haemorrhage, Hypotension, Vasodilatation, Peripheral vascular disorder, Vein disorder Nausea, Dry mouth Erythema, Rash, Hyperhidrosis, Pruritus Urethral haemorrhage, Haematuria, Dysuria, Pollakiuria, Micturition urgency Priapism, Pelvic pain, Testicular mass, Spermatocele, Testicular swelling, Testicular oedema, Testicular disorder, Scrotal pain, Scrotal erythema, Scrotal oedema, Testicular pain, Scrotal disorder, Painful erection, Balanitis, Phimosis, Erectile dysfunction, Ejaculation disorder Haemorrhage, Injection site haemorrhage, Inflammation, Injection site inflammation, Injection site warmth, Injection site oedema, Injection site swelling, Injection site pain, Injection site irritation, Asthenia, Injection site anaesthesia, Oedema, Oedema peripheral, Injection site pruritus Blood creatinine increased, Blood pressure decreased, Heart rate increased ***Side-effects frequency unknown*** ▪ anaphylaxis ▪ Myocardial ischaemia
Management of potential side-effects and adverse reactions	Unusual or life threatening reactions require immediate medical attention. Priapism associated with alprostadil, initial management with aspiration and lavage of corpora. If unsuccessful then intracavernosal injection of adrenaline: 10–20 micrograms every 5–10 minutes, using a 20 microgram/mL solution ***Important:*** if suitable strength of adrenaline not available may be specially prepared by diluting 0.1 mL of the adrenaline 1 in 1000 (1 mg/mL) injection to 5 mL with sodium chloride 0.9%, continuously monitor blood pressure and pulse; maximum 100 micrograms per course.
Advice and information to patient/carer including follow-up	Unusual or life threatening reactions require immediate medical attention. Patients should be instructed to report to a physician any erection lasting for a prolonged time period, such as 4 hours or longer.
Specify method of recording supply /administration including audit trail	The following will be recorded in the patient's records: ▪ The diagnosis and treatment ▪ The dose administered ▪ Batch number and expiry date if appropriate ▪ The route of administration and site of administration where appropriate ▪ The frequency of administration and duration of treatment ▪ The time and date of administration ▪ The signature and name of the person administering the medication Document allergies and other adverse drug reactions clearly in patient records and inform the GP and other relevant practitioners/patient/carer for further reporting and action if required. Report any adverse drug reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) through the yellow card reporting system (www.mhra.gov.uk).

3. Description of Treatment

Name of Medicine Administered	**Viridal**
Legal Class	POM (Prescription Only Medicine)
Storage	Lockable cabinet - intracavernosal injection Controlled temperature fridge – Intra urethral pellet
Dose to be used	2.5mcg titrating dose to maximum dose 40mcg
Method or route of administration	Intracavernously
Total dose and number of times drug to be given. Details of supply (if supply made)	One injection as required in clinic setting. Test doses given in clinic to obtain therapeutic dosing ▪ Erectile dysfunction ▪ By intracavernosal injection ▪ Adult ▪ Initially 2.5 micrograms, increased in steps of 2.5–5 micrograms, to obtain dose suitable for producing erection not lasting more than 1 hour; usual dose 10–20 micrograms (max. per dose 40 micrograms), maximum frequency of injection not more than 3 times per week with at least 24 hour interval between injections; reduce dose if erection lasts longer than 2 hours. With intracavernosal use: ▪ The first dose of the intracavernosal injection must be given by medically trained personnel; self-administration may only be undertaken after proper training.
Contra-indications	▪ See criteria for exclusion ▪ Refer to medical practitioner (or non-medical prescriber if appropriate) or alternative action as indicated by related protocol and document in patient's records
Cautions	▪ Anatomical deformations of penis ▪ priapism (patients should be instructed to report any erection lasting 4 hours or longer)
Interactions	If patient is taking any other medications consult BNF Appendix 1 for any potential interactions.

Potential side-effects and adverse reactions	***Side-effects frequency unknown*** Amnesia, cerebro-vascular accident, Myocardial ischemia, myocardial infarction, Penile oedema ***Side-effects common or very common*** Haematoma Muscle spasms Dysuria, haematuria, pollakiuria, micturition urgency, urethral heamorrhage Penile pain Erection increased, Peyronie's disease, penis disorder, fibrotic alterations (e.g. fibrotic nodules, plaques at the site of injection or in the corpus cavernosum) can occur during long term treatment Haematoma, ecchymosis, injection site haematoma, burning sensation during injection and after the injection, pain of mostly mild intensity at the site of injection. ***Side-effects uncommon*** Fungal infection, common cold Headache. hypoaesthesia , hyperaesthesia, presyncope Mydriasis Supraventricular extrasystoles Vein disorder, hypotension, vasodilation, peripheral vascular disorder Nausea, dry mouth Rash, pruritis, scrotal erythema, erythema, hyperhidrosis Dysuria, haematuria, pollakiuria, micturition urgency, urethral heamorrhage Fibrotic alterations associated with slight penile axis deviations, erectile dysfunction, balanitis, priapism (mainly seen during dose titration), phimosis, painful erection, ejaculation disorder, testicular pain, scrotal disorder, scrotal erythema, scrotal pain, pelvic pain, testicular swelling, testicular oedema, scrotal oedema, spermatocele, testicular disorder, testicular mass Spot-like haemorrhage / spot-like bruises at the site of puncture, haemosiderin deposits, inflammation, oedema peripheral, oedema, injection site haemorrhage, injection site mass, injection site inflammation, injection site pruritis, injection site swelling and reddening, injection site oedema, injection site irritation, injection site anaesthesia, injections site pain, injection site warmth, asthenia, haemorrhage Blood pressure decreased, heart rate increased, blood creatinine increased ***Side-effects rare/very rare*** Isolated cases of thrombocytopenia Hypersensitivity ranging from dermatitis allergic urticaria to anaphylactic / anaphylactoid reactions Vertigo, dizziness Circulatory effects such as short periods of hypotension Urticaria Fibrotic changes of the cavernous body during a long term treatment lasting up to 4 years.
Management of potential side-effects and adverse reactions	Unusual or life threatening reactions require immediate medical attention. Priapism associated with alprostadil, initial management with aspiration and lavage of corpora. If unsuccessful then intracavernosal injection of adrenaline: 10–20 micrograms every 5–10 minutes, using a 20 microgram/mL solution ***Important:*** if suitable strength of adrenaline not available may be specially prepared by diluting 0.1 mL of the adrenaline 1 in 1000 (1 mg/mL) injection to 5 mL with sodium chloride 0.9%, continuously monitor blood pressure and pulse; maximum 100 micrograms per course.
Advice and information to patient/carer including follow-up	Unusual or life threatening reactions require immediate medical attention. Patients should be instructed to report to a physician any erection lasting for a prolonged time period, such as 4 hours or longer.

Specify method of recording supply /administration including audit trail	The following will be recorded in the patient's records: ▪ The diagnosis and treatment ▪ The dose administered ▪ Batch number and expiry date if appropriate ▪ The route of administration and site of administration where appropriate ▪ The frequency of administration and duration of treatment ▪ The time and date of administration ▪ The signature and name of the person administering the medication Document allergies and other adverse drug reactions clearly in patient records and inform the GP and other relevant practitioners/patient/carer for further reporting and action if required. Report any adverse drug reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) through the yellow card reporting system (www.mhra.gov.uk).

4. Other Information

Follow up treatment:	Patients will continue to be followed up via the Erectile Dysfunction clinic nurse. When a therapeutic dose is achieved discharge of the patient to the GP/referring clinician is to be arranged. Continuation of the medication is advised to the referring clinician if applicable.
Arrangements for medicine supply:	Not applicable
Arrangements for medical referral:	Refer back to the GP of referring consultant.
Lines of accountability:	**Medical** – Lead Clinician Urology **Nursing** – Lead Urology Nurse

5. Appendices

References used in the development of this PGD:	▪ NICE guidance ▪ National Institute for Health and Care Excellence, 2013, NICE medicines practice guidelines [MPG2] Patient Group Directions | Guidance and guidelines | NICE ▪ BNF ▪ MIMMS ▪ Current SPCs: - MUSE 125mcg urethral stick –Mylan, last updated on emc 9.1.14 - Caverject 10mcg powder for solution for injection – Pfizer 19.6.17 - Viridal DUO 10mcg/ml powder and solvent for solution for injection – UCB, last updated 21.5.19. ▪ Department of Health Information ▪ Trust Protocols and Documents ▪ Local Formularies
Audit details	In the nurse led clinics there will be an audit of administration of Caverject, Viridal and MUSE post implementation of the PGD, measuring numbers given and safety data.
Training	**Competency assessment:** ▪ Competent in administering and monitoring for side effects. ▪ Competent in assessing for contra indications. ▪ Urology Specialist Nurse competent with delivering ED services / treatments only to administer. (Signed accountability log) ▪ Evidence of Annual update ▪ SOP Guidance

Please refer to the summary of product characteristics for full information

This Patient Group Direction is operational from the start of June 2019 and expires end of May 2021

Version History

Version	Date	Brief Summary of Change	Owner's Name
v 1.0	May 2019	Development of new PGD for nurse led urology clinics	Torbay and South Devon NHS Foundation Trust

For more information on the status of this document, contact:	Medicines Governance Team Administrator Pharmacy Department Torbay Hospital tsdft.medicinesgovernance@nhs.net
Date of Issue	**June 2019**
Reference	PGD 2243 v 1.0 Aloprostadil
Path	V:/medicines governance/PGDs/Urology/PGD 2243 v 1.0 Alprostadil (MUSE, Caverject or Viridal) Jun19-May21

Patient Group Direction 2243 version 1.0
Administration of Aloprostadil (MUSE or Caverject) by Registered Practitioners employed by Torbay and South Devon NHS Foundation Trust

Objective: Treatment of erectile dysfunction in a nurse led clinic

The individual practitioners named below are authorised to operate within the above PGD, being employees of Torbay and South Devon NHS Foundation Trust

CLINICAL AREA	LOCATION / DEPARTMENT

The following list must be kept with a copy of the PGD in each clinical area using that PGD. Each practitioner will receive and sign for an individual copy of the PGD. Only fully competent, qualified and trained professionals may operate within PGDs.

I agree to administer/supply the above preparation in accordance with this Patient Group Direction and I have received an up to date copy of the ratified PGD:

NAME *(please print)*	PROFESSIONAL TITLE	SIGNATURE	AUTHORISING MANAGER *(please print)*	MANAGER'S SIGNATURE	DATE

Document Control Information

This is a controlled document and should not be altered in any way without the express permission of the author or their representative.

Please note this document is only valid from the date approved below, and checks should be made that it is the most up to date version available.

If printed, this document is only valid for the day of printing.

This guidance has been registered with the Trust. The interpretation and application of guidance will remain the responsibility of the individual clinician. If in doubt contact a senior colleague or expert. Caution is advised when using clinical guidance after the review date, or outside of the Trust.

Ref No:	2243		
Document title:	Alprostadil (MUSE or Caverject / Viridal, Administration of		
Purpose of document:			
Date of issue:	19 July 2019	**Next review date:**	31 May 2021
Version:	1	**Last review date:**	
Author:	Consultant Urologist Pharmacist Urology Oncology Nurse		
Directorate:	Pharmacy		
Equality Impact:	The guidance contained in this document is intended to be inclusive for all patients within the clinical group specified, regardless of age, disability, gender, gender identity, sexual orientation, race and ethnicity & religion or belief		
Committee(s) approving the document:	Medical Director Chair, Trust Medicines Management Committee		
Date approved:	8 July 2019		
Links or overlaps with other policies:			

Have you identified any issues on the Rapid (E)quality Impact Assessment. If so please detail on Rapid (E)QIA form.	Yes ☐	
	Please select *Yes*	*No*
Does this document have implications regarding the Care Act? *If yes please state:*	☐	☐
Does this document have training implications? *If yes please state:*	☐	☐
Does this document have financial implications? *If yes please state:*	☐	☐

Is this document a direct replacement for another? *If yes please state which documents are being replaced:*	☐	☐

Document Amendment History

Date	Version no.	Amendment summary	Ratified by:
19 July 2019	1	New	Medical Director Chair, Trust Medicines Management Committee

The Mental Capacity Act 2005

The Mental Capacity Act provides a statutory framework for people who lack capacity to make decisions for themselves, or who have capacity and want to make preparations for a time when they lack capacity in the future. It sets out who can take decisions, in which situations, and how they should go about this. It covers a wide range of decision making from health and welfare decisions to finance and property decisions

Enshrined in the Mental Capacity Act is the principle that people must be assumed to have capacity unless it is established that they do not. This is an important aspect of law that all health and social care practitioners must implement when proposing to undertake any act in connection with care and treatment that requires consent. In circumstances where there is an element of doubt about a person's ability to make a decision due to 'an impairment of or disturbance in the functioning of the mind or brain' the practitioner must implement the Mental Capacity Act.

The legal framework provided by the Mental Capacity Act 2005 is supported by a Code of Practice, which provides guidance and information about how the Act works in practice. The Code of Practice has statutory force which means that health and social care practitioners have a legal duty to have regard to it when working with or caring for adults who may lack capacity to make decisions for themselves.

"The Act is intended to assist and support people who may lack capacity and to discourage anyone who is involved in caring for someone who lacks capacity from being overly restrictive or controlling. It aims to balance an individual's right to make decisions for themselves with their right to be protected from harm if they lack the capacity to make decisions to protect themselves". (3)

All Trust workers can access the Code of Practice, Mental Capacity Act 2005 Policy, Mental Capacity Act 2005 Practice Guidance, information booklets and all assessment, checklists and Independent Mental Capacity Advocate referral forms on iCare

http://icare/Operations/mental_capacity_act/Pages/default.aspx

Infection Control

All staff will have access to Infection Control Policies and comply with the standards within them in the work place. All staff will attend Infection Control Training annually as part of their mandatory training programme.

Clinical and Non-Clinical Policies – Data Protection

Torbay and South Devon NHS Foundation Trust (TSDFT) has a commitment to ensure that all policies and procedures developed act in accordance with all relevant data protection regulations and guidance. This policy has been designed with the EU General Data Protection Regulation (GDPR) and Data Protection Act 2018 (DPA 18) in mind, and therefore provides the reader with assurance of effective information governance practice.

The UK data protection regime intends to strengthen and unify data protection for all persons; consequently, the rights of individuals have changed. It is assured that these rights have been considered throughout the development of this policy. Furthermore, data protection legislation requires that the Trust is open and transparent with its personal identifiable processing activities and this has a considerable effect on the way TSDFT holds, uses, and shares personal identifiable data.

Does this policy impact on how personal data is used, stored, shared or processed in your department? Yes ☐ No ☐

If yes has been ticked above it is assured that you must complete a data mapping exercise and possibly a Data Protection Impact Assessment (DPIA). You can find more information on our GDPR page on ICON (intranet)

For more information:

- Contact the Data Access and Disclosure Office on dataprotection.tsdft@nhs.net,
- See TSDFT's Data Protection & Access Policy,
- Visit our Data Protection site on the public internet.