This patient group direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction (PGD)

For the administration of

Tranexamic Acid

By registered health care professionals for

For the treatment of severe haemorrhage

Throughout the Manx Care and those contracted by the Manx Care where appropriate within practice

PGD NUMBER 157

1. Change history

Version number	Change details	Date
1	Original PGD ratified	March 2022

2. Medicines practice guideline 2: *Patient group directions*

Refer to the relevant sections of NICE medicines practice guideline 2: *Patient group directions* as stated in the blank template notes. For further information about PGD signatories, see the NHS and Manx Care PGD website FAQs

3. PGD development

Refer to the NICE PGD competency framework for people developing PGDs

Job Title & organisation	Name	Signature	Date
Author of the PGD			
Member of the PGD working group			

4. PGD authorisation

Refer to the NICE PGD competency framework for people authorising PGDs

Job Title	Name	Signature	Date
Medical Director			
Chief Pharmacist/ Pharmaceutical Adviser			
Senior Paramedic			
Director of Nursing			
GP Adviser			
Senior Microbiologist (if PGD contains antimicrobials)			

5. PGD adoption by the provider

Refer to the NICE PGD competency framework for people authorising PGDs

Job title and organisation	Signature	Date	Applicable or not applicable to area

6. Training and competency of registered healthcare professionals, employed or contracted by the Manx Care, GP practice or Hospice

Refer to the NICE PGD competency framework for health professionals using PGDs

	Requirements of registered Healthcare professionals working under the PGD
Qualifications and professional registration	• Registered healthcare professionals, working within or contracted by the Manx Care, GP practice or Hospice who are permitted staff groups outlined within the current PGD policy • Pharmacists must be practising in Manx Care authorised premises i.e. contracted pharmacy premises
Initial training	• Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria • Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD • Local training in the use of PGDs
Competency assessment	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGDs
Ongoing training and competency	The registered health care professionals should make sure they are aware of any changes to the recommendations for this medication; it is the responsibility of the registered health care professionals to keep up to date with continuing professional development. PGD updates will be held every two years

7. Clinical Conditions

Clinical condition or situation to which this PGD applies	Patients with signs of actual or suspected severe haemorrhage in the following clinical scenarios: • Injured patients triggering local network major trauma criteria • Patients with a time critical injury, including pregnant women, where significant internal or external haemorrhage is known or suspected • Head injury patients, age 18 and over with a Glasgow Coma Score (GCS) of 12 or less • Post-partum haemorrhage after the administration of an uterotonic drug. N.B. A post-partum haemorrhage may start within 4 but up to 24 hours after delivery
Inclusion criteria *(continued)*	**Trauma** Treatment of known or suspected severe traumatic internal or external haemorrhage as soon as clinically possible and within 3 hours of bleeding starting in adults and children, including pregnant women, who are considered to be at risk of significant haemorrhage related to severe trauma. This may be demonstrated by one or more of: • Systolic blood pressure < 90mmHg or absent radial pulse or heart rate > 110 bpm believed to be due to bleeding in adults. In children this may be demonstrated by changes in the normal physiological parameters for age (see JRCALC page for age) • Any patient where haemostatic gauze, arterial tourniquet/s, chest dressing/s or pressure dressing/s have been applied • Patient who has suffered a traumatic cardiac arrest Women who are breastfeeding should have tranexamic acid administered in life-threatening circumstances. **Head Injury** Patients age 18 and over who have a known or suspected head injury where the following criteria is met: • The GCS is 12 or less • The injury has occurred within the last 3 hours **Post-Partum Haemorrhage (PPH)** Any of the following criteria: • PPH (bleeding from the genital tract >500ml) which usually occurs within 4 hours (but up to 24 hours) after delivery. This can be associated with haemodynamic instability. Rranexamic Acid should be given <u>after</u> the administration of an uterotonic drug

Inclusion criteria *(continued)*	• Woman with a post-partum haemorrhage when uterine trauma (rupture) is suspected. Bleeding may be intra-abdominal • Woman for whom uterotonic drugs are contraindicated (rare)
Exclusion criteria	• Known hypersensitivity to the active ingredient or to any component of the product • Bleeding started more than 3 hours ago. Note that a PPH occurs within 4 hours (but up to 24 hours) **after delivery** but actual bleeding should not have started more than 3 hours ago • Obvious resolution of haemorrhage • Critical interventions required (must only be given after critical interventions have been performed: i.e. airway managed; control or splinting of major haemorrhage etc and if does not delay transfer noting it may be administered en route)
Cautions (including any relevant action to be taken)	**Where a caution is present the practitioner should be aware of the possible effects of administration but should continue to administer where the benefit outweighs risk. Contact the local senior on call clinician for advice on the below if required.** • Patients with a known history of convulsions or convulsions from any cause during the incident. High dose regimes have been associated with convulsions; however, in the low dose regime recommended here, the benefit from giving tranexamic acid for severe haemorrhage outweighs the risk of convulsions. An increase in convulsion rate may be due to the antagonistic effect of tranexamic acid on GABA receptors. Treat convulsions which may be caused by treatment with tranexamic acid as per JRCALC guidance (management not covered under this PGD) • Patients with a known history of acute venous or arterial thrombosis. In the low dose regime recommended here, the benefit from giving tranexamic acid for severe haemorrhage outweighs the risk of thrombotic events. This information should be passed to the receiving hospital • Patients with known severe renal impairment (eGFR <30ml/min 1.73m^2). There is a risk of accumulation of tranexamic acid. In the low dose regime recommended here, the benefit from giving tranexamic acid for severe haemorrhage outweighs the risk of accumulation. This information should be passed to the receiving hospital. • Rapid injection may cause hypotension and loss of consciousness • Do not administer through the same line as blood products or penicillin antibiotics (including co-amoxiclav)
Arrangements for referral for medical advice	Patient should be referred to a more experienced clinical practitioner for further assessment
Action to be taken if patient excluded	Patient should be referred to a more experienced clinical practitioner for further assessment

Action to be taken if patient declines treatment	• A verbal explanation should be given to the patient on: the need for the medication and any possible effects or potential risks which may occur as a result of refusing treatment • This information must be documented in the patients' health records • Any patient who declines care must have demonstrated capacity to do so • Where appropriate care should be escalated

8. Details of the medicine

Name, form and strength of medicine	Tranexamic acid 100mg/ml solution for injection available as 5ml and 10ml ampoules
Legal category	Prescription Only Medicine (POM)
Indicate any <u>off-label use</u> (if relevant)	The use of tranexamic acid in: • severe haemorrhage following trauma and in head injury is off label. However its use is supported by national JRCALC guidelines • children under 1 year of age is off label. However its use is supported by national JRCALC guidelines Intraosseous and intramuscular routes are supported by JRCALC guidance.
Route/method of administration	Intravenous injection (IV)/Intraosseous (IO)/Intramuscular injection (IM). The IV/IO dose should be administered by slow injection over 10 minutes – can be given in 10 aliquots 1 minute apart. Rapid injection may cause hypotension and loss of consciousness. Where IV access is not achievable promptly, and the IO route is not appropriate, the IM route can be considered into a large muscle.
Dose and frequency *(continued)*	**Traumatic Haemorrhage**

Age	Dose	Volume (100mg/ml)
Adults and children aged 12 years and over	1000mg	10ml
11 years	500mg	5ml
10 years	500mg	5ml
9 years	450mg	4.5ml
8 years	400mg	4ml
7 years	350mg	3.5ml
6 years	300mg	3ml
5 years	300mg	3ml
4 years	250mg	2.5ml
3 years	200mg	2ml
2 years	200mg	2ml
18 months	150mg	1.5ml

<table>
<tr><td>Dose and frequency
(continued)</td><td>
<table>
<tr><td>12 months</td><td>150mg</td><td>1.5ml</td></tr>
<tr><td>9 months</td><td>150mg</td><td>1.5ml</td></tr>
<tr><td>6 months</td><td>100mg</td><td>1ml</td></tr>
<tr><td>3 months</td><td>100mg</td><td>1ml</td></tr>
<tr><td>1 month</td><td>50mg</td><td>0.5ml</td></tr>
<tr><td>Birth</td><td>50mg</td><td>0.5ml</td></tr>
</table>
Head injury (GCS 12 or less)
<table>
<tr><th>Age</th><th>Dose</th><th>Volume (100mg/ml)</th></tr>
<tr><td>Adults (18 years and over)</td><td>1000mg</td><td>10ml</td></tr>
</table>
Post-partum haemorrhage

1000 mg (10ml) administered by slow IV/IO injection over 10 minutes.
</td></tr>
<tr><td>Quantity to be administered</td><td>As per dosage table</td></tr>
<tr><td>Maximum or minimum treatment period</td><td><u>Traumatic</u> haemorrhage and head injury

Single dose permitted under this PGD.

Post-partum haemorrhage

A second dose can be administered under this PGD if bleeding continues after 30 minutes of the first dose being administered and there is delay in reaching the destination hospital. A maximum of two doses may be administered in 24 hours.</td></tr>
<tr><td>Storage</td><td>Room temperature</td></tr>
<tr><td>Adverse effects</td><td>Common side effects (more than 1 in 100 but less than 1 in 10)L:
Nausea
Vomiting
Diarrhoea
Serious adverse effects (unknown rate of incidence):
Hypersensitivity reactions including anaphylaxis have been reported
Rapid injection may cause hypotension and loss of consciousness
Arterial or venous embolism at any site</td></tr>
<tr><td>Records to be kept</td><td>The administration of any medication given under a PGD must be recorded within the patient’s medical records</td></tr>
</table>

9. Patient information

Verbal/Written information to be given to patient or carer	• Verbal information must be given to patients and or carers for all medication being administered under a PGD • Where medication is being supplied under a PGD, written patient information leaflet must also be supplied • A patient information leaflet is available on request
Follow-up advice to be given to patient or carer	If symptoms do not improve or worsen or you become unwell, seek medical advice immediately

10. Appendix A

References
1. British National Formulary (BNF) available online: https://bnf.nice.org.uk 2. Nursing and Midwifery "The code" available online: https://www.nmc.org.uk 3. Current Health Care Professions Council standards of practice 4. Joint Royal Colleges Ambulance Liaison Committee (JRCALC) Clinical Practice Guidelines 5. General Pharmaceutical Council standards 6. The General Optical Council 7. Electronic medicines compendium available online: https://www.medicines.org.uk

11. Appendix B

Health professionals agreed to practice
• Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor • A mentor is defined within the Manx Care policy as any ward/area managers, sisters, senior nurses, GPs, pharmacists or senior paramedics who has completed the PGD training themselves