



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 only

Alteplase variable weight based dose

By registered health care professionals for

Acute Ischaemic stroke for patients assessed for the delivery of alteplase via remote consultation at Noble's Hospital and agreed to meet the inclusion criteria by the remote consultant

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

PGD NUMBER 115

1. Change history

Version number	Change details	Date
1	Reviewed and place into new template from original version in 2018. Updated information regarding age and contraindications	May 2020
2	Reviewed and placed onto new template from second version in 2020. Updated information with regards to new stroke thrombolysis parameters	June 2024

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](#)

Pre Signatures			
Job Title	Name	Signature	Date
Chief Pharmacist			
Head of Ambulance Services			
GP Adviser			
Senior Microbiologist (if PGD contains antimicrobials)	N/A	N/A	N/A
Final signatures			
Medical Director			
Director of Nursing			

5. 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	<ul style="list-style-type: none"> Registered healthcare professionals, working as a part of the stroke thrombolysis delivery team and holding up to date stroke thrombolysis competencies.
Initial training	<ul style="list-style-type: none"> Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria. Stroke Thrombolysis competencies 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 PGD's
Competency assessment	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGD's
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.

6. Clinical Conditions

Clinical condition or situation to which this PGD applies	<ul style="list-style-type: none"> Acute Ischaemic stroke for patients assessed for the delivery of alteplase via remote consultation at Noble's Hospital and agreed to meet the inclusion criteria by the remote consultant
Inclusion criteria	<ul style="list-style-type: none"> Can only be used after 5pm – 9am Monday to Friday and Bank holidays and weekends over a 24 hour period. Patients aged over 16 years of age Acute ischaemic stroke: <ul style="list-style-type: none"> Within preceding 4.5 hours no age limit Within 4.5hrs and 9hrs if delivery is support by CTP imaging Within 9hrs on mid-point of sleep if delivery is supported by CTP imaging No absolute contraindications present All Relative Contraindications assessed and justified by remote consultant Assessed by stroke thrombolysis nurse and stroke thrombolysis trained physician remotely and deemed appropriate for IV thrombolysis

<p>Exclusion criteria</p> <p><i>(continued ...)</i></p>	<p>Absolute Exclusion Criteria:</p> <ul style="list-style-type: none"> • Under 16 years of age • Patient refuses treatment • Last seen well >9hrs ago • Awoke with symptoms and >9hrs post midpoint of sleep • Haemorrhagic diathesis: <ul style="list-style-type: none"> ○ Inherited ○ Acquired including chronic liver disease ○ Platelets <100000/mm³ ○ APTT >1.2 ○ INR >1.7 or PT>15s • Active bleeding • Arterial puncture at a non-compressible site, or lumbar puncture, within the last 7 days • Head injury, intracranial surgery or stroke within the last 3 months • Any history of intracranial haemorrhage, brain tumor, intracranial AVM or aneurysm • CT head showing major multilobar infarction (hypodensity >1/3 cerebral hemisphere) / Intracerebral haemorrhage / Subarachnoid haemorrhage • GI Malignancy / GI Bleed in the last 21 days • Infective endocarditis • Suspected aortic dissection • Persistent elevated BP: systolic >185mmHG or diastolic >110mmHG (having received more than 2 doses of labetalol) <p>Relative Exclusion criteria:</p> <ul style="list-style-type: none"> • Coma: <ul style="list-style-type: none"> ○ GCS <8 ○ NIHSS question 1a=3 • NIHSS >25 of stroke symptoms over 3hours • Minor deficit or rapidly improving symptoms <ul style="list-style-type: none"> ○ Proceed if potentially disabling symptoms <ul style="list-style-type: none"> ▪ Aphasia ▪ Dysphasia ▪ Significant visual deficit ▪ Gait disturbance • Anticoagulation <ul style="list-style-type: none"> ○ Warfarin <ul style="list-style-type: none"> ▪ Safe to proceed in INR ≤1.7 ○ Unfractionated heparin <ul style="list-style-type: none"> ▪ Safe to proceed if APTT ≤1.2 ○ Prophylactic LMWH <ul style="list-style-type: none"> ▪ Safe to proceed in doses ≤5000units ○ Therapeutic LMWH <ul style="list-style-type: none"> ▪ CONTRAINDICATED in doses >5000units
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<p>Exclusion criteria</p> <p>(... continued)</p>	<ul style="list-style-type: none"> ○ DOACs including (but not limited to): <ul style="list-style-type: none"> ▪ Dabigatran ▪ Rivaroxaban ▪ Apixaban ▪ Edoxaban <p>All DOACs CONTRAINDICATED if taken in past 48hours:</p> <ul style="list-style-type: none"> ● History of GU or GI bleed ● Malignancy which may increase bleeding risk ● Seizure at onset ● Hypoglycaemia (<2.8) or hyperglycaemia (>22.2) mmol/L <ul style="list-style-type: none"> ○ Correct first then reassess suitability ● Myocardial infarction in past 3 months ● Pregnancy ● Major surgery/serious trauma within last 14days
<p>Cautions (including any relevant action to be taken)</p>	<ul style="list-style-type: none"> ● Patient should report and nursing team monitor for: <ul style="list-style-type: none"> ○ Bleeding ○ Significant bruising ○ Headache ○ Worsening of stroke symptoms ○ angioedema ● Avoid invasive procedures for 24 hours post administration including but not limited to: <ul style="list-style-type: none"> ○ PVCs ○ Central lines ○ Blood sampling ○ Catheterisation ○ Nasogastric tube insertion <p>A detailed list of cautions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF https://bnf.nice.org.uk</p>
<p>Arrangements for referral for medical advice</p>	<p>Patient should be referred to a more experienced clinical practitioner for further assessment</p>
<p>Action to be taken if patient excluded</p>	<ul style="list-style-type: none"> ● Document findings within consent section of stroke thrombolysis policy. ● Continue with acute stroke management. ● Refer to medical team if not a stroke
<p>Action to be taken if patient declines treatment</p>	<ul style="list-style-type: none"> ● 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 (see the Manx Care Policy for Capacity, Best Interests Decisions and Deprivation of Liberty). ● Where appropriate care should be escalated.

7. Details of the medicine

Name, form and strength of medicine	<ul style="list-style-type: none"> Alteplase 10mg powder for IV injection Alteplase 20mg powder for IV injection Alteplase 50mg powder for IV injection 		
Legal category	Prescription Only Medicine (POM)		
Indicate any <u>off-label use</u> (if relevant)	<p>Up to 4.5 hour: no off label use</p> <p>4.5 – 9hours: off label and responsibility lies with the person using the PGD</p> <p>Wake-up and 9hours from mid-point of sleep: off label and responsibility lies with the person using the PGD</p>		
Route/method of administration	Intravenous Injection (IV) bolus and infusion		
Dose and frequency	<p>Administration:</p> <ul style="list-style-type: none"> ONE single dose at time of event Total dose split into 10% of dose given as an IV bolus over 2-3minutes followed by 90% of the total dose infused IV over 1 hour <p>Dose:</p> <ul style="list-style-type: none"> Dose as per weight 0.9mg per kg max dose 90mg <p>Frequency:</p> <ul style="list-style-type: none"> Once per 3 months <p>To support traceability of biological medicines the batch number of the administered product should be clearly recorded in patient's record / drug chart</p>		
Quantity to be administered	Dose as per weight 0.9mg per kg max dose 90mg		
Maximum or minimum treatment period	<p>Acute ischaemic stroke</p> <ul style="list-style-type: none"> Within preceding 4.5 hours no age limit Within 4.5hrs and 9hrs if delivery is support by CTPimaging Within 9hrs of mid-point of sleep if delivery is supported by CTP imaging 		
Storage	<ul style="list-style-type: none"> Below 25°C In original package protected from sunlight 		
Adverse effects	<table border="0"> <tr> <td> <ul style="list-style-type: none"> Anaphylaxis Angioedema Angina pectoris Bleeding Cardiac arrest Cardiogenic shock Chills Ecchmysois </td> <td> <ul style="list-style-type: none"> Fever Heart failure Hypotension Nausea Pericarditis Pulmonary oedema Significant bruising Vomiting </td> </tr> </table> <p>A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF https://bnf.nice.org.uk</p>	<ul style="list-style-type: none"> Anaphylaxis Angioedema Angina pectoris Bleeding Cardiac arrest Cardiogenic shock Chills Ecchmysois 	<ul style="list-style-type: none"> Fever Heart failure Hypotension Nausea Pericarditis Pulmonary oedema Significant bruising Vomiting
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Records to be kept	<ul style="list-style-type: none"> • The administration of any medication given under a PGD must be recorded within the patient’s medical records. • Specifically the Stroke Thrombolysis pathway.
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8. Patient information

Verbal/Written information to be given to patient or carer	<ul style="list-style-type: none"> • 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

9. Appendix A

References	
1.	British National Formulary (BNF) available online: https://bnf.nice.org.uk . Accessed 12/06/24
2.	Nursing and Midwifery “The code” available online: https://www.nmc.org.uk
3.	Current Health Care Professions Council standards of practice
4.	General Pharmaceutical Council standards
5.	Electronic medicines compendium available online: https://www.medicines.org.uk . Accessed 12/06/24
6.	Manx Care Policy for Capacity, Best Interests Decisions and Deprivation of Liberty http://edrmgi/sites/hospital/Clinical%20Policies%20and%20Procedures/Policy%20for%20Capacity,%20Best%20Interests%20Decisions%20and%20Deprivation%20of%20Liberty.pdf#search=deprivation
7.	National Clinical Guideline for stroke for the UK + Ireland 2023 www.strokeguideline.org . Accessed 13/06/24

10. Appendix B

Health professionals agreed to practice
<ul style="list-style-type: none"> • 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

11. Appendix C

Dosage calculation chart for alteplase in acute ischaemic stroke thrombolysis

Weight (kg)	Total Dose rtPA (mg)	Bolus Dose (mg) over 1 min	IV infusion (mg) over 1 hour	1mg / ml dilution		2mg / ml dilution	
				10% bolus ml	90% infusion ml	10% bolus ml	90% infusion ml
55	50	5	45	5ml	45ml	2.5ml	22.5ml
56	51	6	45	6ml	45ml	3ml	22.5ml
57	51	6	45	6ml	45ml	3ml	22.5ml
58	52	6	46	6ml	46ml	3ml	23ml
58	52	6	46	6ml	46ml	3ml	23ml
59	53	6	47	6ml	47ml	3ml	23.5ml
60	54	6	48	6ml	48ml	3ml	24ml
61	55	6	49	6ml	49ml	3ml	24.5ml
62	56	6	50	6ml	50ml	3ml	25ml
63	57	6	51	6ml	51ml	3ml	25.5ml
64	58	6	52	6ml	52ml	3ml	26ml
65	59	6	53	6ml	53ml	3ml	26.5ml
66	59	6	53	6ml	53ml	3ml	26.5ml
67	60	6	54	6ml	54ml	3ml	27ml
68	61	6	55	6ml	55ml	3ml	27.5ml
68	61	6	55	6ml	55ml	3ml	27.5ml
69	62	6	56	6ml	56ml	3ml	28ml
70	63	6	57	6ml	57ml	3ml	28.5ml
71	64	6	58	6ml	58ml	3ml	29ml
72	65	7	58	7ml	58ml	3.5ml	29ml
73	66	7	59	7ml	59ml	3.5ml	29.5ml
74	67	7	60	7ml	60ml	3.5ml	30ml
75	68	7	61	7ml	61ml	3.5ml	30.5ml
76	68	7	61	7ml	61ml	3.5ml	30.5ml
77	69	7	62	7ml	62ml	3.5ml	31ml
78	70	7	63	7ml	63ml	3.5ml	31.5ml
78	70	7	63	7ml	63ml	3.5ml	31.5ml
79	71	7	64	7ml	64ml	3.5ml	32ml
80	72	7	65	7ml	65ml	3.5ml	32.5ml
81	73	7	66	7ml	66ml	3.5ml	33ml
82	74	7	67	7ml	67ml	3.5ml	33.5ml
83	75	8	67	8ml	67ml	4ml	33.5ml
84	76	8	68	8ml	68ml	4ml	34ml
85	77	8	69	8ml	69ml	4ml	34.5ml
86	77	8	69	8ml	69ml	4ml	34.5ml
87	78	8	70	8ml	70ml	4ml	35ml
87	78	8	70	8ml	70ml	4ml	35ml
88	79	8	71	8ml	71ml	4ml	35.5ml
89	80	8	72	8ml	72ml	4ml	36ml
90	81	8	73	8ml	73ml	4ml	36.5ml
91	82	8	74	8ml	74ml	4ml	37ml
92	83	8	75	8ml	75ml	4ml	37.5ml
93	84	8	76	8ml	76ml	4ml	38ml
94	85	9	76	9ml	76ml	4.5ml	38ml
95	86	9	77	9ml	77ml	4.5ml	38.5ml
96	86	9	77	9ml	77ml	4.5ml	38.5ml
97	87	9	78	9ml	78ml	4.5ml	39ml
98	88	9	79	9ml	79ml	4.5ml	39.5ml
99	89	9	80	9ml	80ml	4.5ml	40ml
100	90	9	81	9ml	80ml	4.5ml	40.5ml

12. Appendix D

Audit of patient records for Medicines supplied under a PGD

This audit has been devised to demonstrate compliance with PGD legislation and their utilisation within the organisation. This audit must be completed prior to revalidation of a PGD. It can be utilised to demonstrate compliance with NICE guidelines and also the Manx Care PGD policy 2019.

Evidence of Audit must be supplied to the PGD working group prior to revalidation of a PGD, failure to submit this will result in a delay to the revalidation of the individual PGD and therefore render it unusable.

The information collected must relate to the PGD being used on 4 different dates, a minimum of 10 records should be checked. Due to the PGDs being utilised in different areas each area must complete their own Audit prior to review.

Medicines supplied or administered under PGD										
PGD number : 115	PGD name : Alteplase					Review date: 6 th March 2024				
Audit date:	Completed by: GHorsey									
Criteria	Patient record number									
	1	2	3	4	5	6	7	8	9	10
Was the medication clearly documented, has been given under a PGD										
Was patient informed they were having medication under a PGD recorded										
Was the medication given in accordance with the inclusion criteria										
If the patient was excluded from using a PGD was the reason and follow up action recorded clearly										
Was there a record of information being given to the patient or the carer?										
Has the practitioner signed the entry in the patients notes										
Was the date of supply / administration recorded by the practitioner										
Where details of medication given recorded e.g. name, dose, strength, time, frequency and route?										

Annual PGD audit

This audit is to be completed annually by a nominated service lead.

This audit must be completed for each PGD in practice on an annual basis to ensure compliance with NICE guidelines and DHSC policy, it is relevant to each area of the DHSC and is the responsibility of the nominated service lead to undertake and submit findings to the PGD Working group.

Medicines supplied or administered under PGD		
PGD number :115	PGD name : Alteplase for acute ischaemic stroke	Review date:
Audit date:	Completed by:	Area:

Criteria	Completed or incomplete
Is there a clear list of authorised registered healthcare professionals for this PGD?	
How many registered healthcare professionals within this area currently working under this PGD?	
How many authorised registered healthcare professionals have signed the PGD in agreement of its use? (Target 100%)	
How many practitioners have left the organisation but still remain listed to practice under this PGD? (Target 0)	
Is there evidence that all staff listed as authorised users of PGDs received up to date and appropriate training? (Target 100%)	