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 or supply of

Ametop Gel 4%

By registered health care professionals for

Percutaneous local anaesthetic to produce anaesthesia of the skin prior to venepuncture or venous cannulation

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

PGD NUMBER 4

1. Change history

Version number	Change details	Date
1	Original PGD ratified	June 2021
2	Minor changes and amendments only	February 2023

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	• 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
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

6. Clinical Conditions

Clinical condition or situation to which this PGD applies	Percutaneous local anaesthetic to produce anaesthesia of the skin prior to venepuncture or venous cannulation
Inclusion criteria	Adults and children from 1 month of age
Exclusion criteria	• Premature babies • Full term infants less than 1 month of age • Known hypersensitivity to any of the ingredients or to local anaesthetic of the ester type • Breast feeding mothers • Do not apply Ametop Gel 4% to broken skin, mucous membranes or to the eyes or ears
Cautions (including any relevant action to be taken)	• Caution in patients with epilepsy • Maximum cumulative dose in a 24 hour period should not exceed 7 tubes for adults and 2 tubes for children 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

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 (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	• Ametop Gel 4%, each gram containing 40mg of tetracaine base • 1.5g single use tube
Legal category	Pharmacy (P)
Indicate any <u>off-label use</u> (if relevant)	None
Route/method of administration	For application to intact, normal skin
Dose and frequency	**Children over 1 month of age and under 5 years:** • No more than 1 tube should be applied **Adults (including the elderly), Children over 5 years:** • Maximum 5 tubes (5 grams) can be applied • Apply 30 minutes before venepuncture and 45 minutes prior to venous cannulation • Doses can be repeated after a minimum of 5 hours if necessary • Maximum cumulative dose in a 24 hour period should not exceed 7 tubes for adults and 2 tubes for children
Quantity to be administered and/or supplied	1.5g single use tube
Maximum or minimum treatment period	One episode of care
Storage	• Store at 2 - 8°C. Do not freeze • Protect from heat
Adverse effects	• Slight oedema or itching at the site. Rarely severe • Blistering of the skin at the application site 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
Records to be kept	The administration of any medication given under a PGD must be recorded within the patient's medical records

8. 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 your symptoms 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
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
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

10. 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