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

Benzydamine Hydrochloride 0.15% oral rinse/spray

By registered health care professionals for

Painful inflammatory conditions of oropharynx

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

PGD NUMBER 121

1. Change history

Version number	Change details	Date
1	Original PGD ratified	June 2021

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	Painful inflammatory conditions of oropharynx
Inclusion criteria	Sore throat and painful mouth ulcers
Exclusion criteria	• Known allergy to Benzydamine or any of its excipients • Pregnant or lactating females
Cautions (including any relevant action to be taken)	• Avoid contact with eyes • Do not swallow solution • Rinse/spray may be diluted with water if irritation occurs • Benzydamine use is not advisable in patients with hypersensitivity to acetylsalicylic acid or other NSAIDs • Bronchospasm may be precipitated in patients suffering from or with a previous history of bronchial asthma. Caution should be exercised in these patients • If the condition is aggravated or not improved use should cease • Oroeze Spray/Benzydamine 0.15% w/v Oromucosal Spray contains methyl parahydroxybenzoate which may cause allergic reactions (possibly delayed). It also contains propylene glycol which may cause skin irritation. It also contains 1126mg of alcohol (ethanol) in each 15ml dose – this is equivalent to less than 30ml beer or 12ml wine. The small amount of alcohol in this medicine will not have any noticeable effects. • Oroeze Spray/Benzydamine 0.15% w/v Oromucosal Spray contains small amounts of ethanol (alcohol), less than 100 mg per dose
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	Benzydamine Hydrochloride 0.15%
Legal category	Pharmacy only
Indicate any <u>off-label use</u> (if relevant)	None
Route/method of administration	Oral
Dose and frequency	**Adults and Elderly:** • Spray: 4 to 8 sprays, 1½ - 3 hourly. Because of the small amount of drug applied, elderly patients can receive the same dose as adults • Oral rinse: Rinse or gargle with 15ml every 1.5 to 3 hours as required for pain relief **Children (6-12):** • Spray: 4 sprays, 1½ - 3 hourly • Oral rinse: Not suitable for children aged 12 years and under **Children Under 6:** • Spray: One spray to be administered per 4 kg body weight, up to a maximum of 4 sprays, 1½ - 3 hourly • Oral rinse: Not suitable for children aged 12 years and under
Quantity to be administered and/or supplied	Spray: • Administration: See 'dose section' of number of sprays • Supply: 1 bottle Oral rinse: • Administration: 15ml • Supply: 1 bottle
Maximum or minimum treatment period	Maximum treatment period: Four consecutive days
Storage	• Room temperature • Use within 6 months of opening
Adverse effects	• Numbness or stinging • Rarely hypersensitivity reactions and anaphylactic reactions • Laryngospasm or bronchospasm • Pruritis, urticaria, photosensitivity reaction and rash • Angioedema
Records to be kept	The administration of any medication given under a PGD must be recorded within the patient's medical records

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 (2018) "The code" available online: https://www.nmc.org.uk 3. Current Health Care Professions Council standards of practice 4. General Pharmaceutical Council standards 5. The General Optical Council 6. 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