

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

**Codeine Phosphate tablets 30mg**

By registered health care professionals for

**Acute, moderate to severe pain**

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

**PGD NUMBER 108**

### 1. Change history

Version number	Change details	Date
1	Original PGD ratified	June 2021
2	Minor word changes to ensure clarify of PGD and links added to Cautions and Adverse Effects, and reference to Manx Care Policy for Capacity added. Plus: <ul style="list-style-type: none"> <li>• Cautions updated</li> <li>• Amendments make to Exclusion criteria</li> <li>• CD schedule 5 added to Legal Category</li> </ul>	Nov 2023 & May 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](#)

	<b>Requirements of registered Healthcare professionals working under the PGD</b>
<b>Qualifications and professional registration</b>	<ul style="list-style-type: none"> <li>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</li> <li>Pharmacists must be practising in Manx Care authorised premises i.e. contracted pharmacy premises</li> </ul>
<b>Initial training</b>	<ul style="list-style-type: none"> <li>Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria</li> <li>Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD</li> <li>Local training in the use of PGDs</li> </ul>
<b>Competency assessment</b>	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGDs
<b>Ongoing training and competency</b>	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**

<b>Clinical condition or situation to which this PGD applies</b>	Acute, moderate to severe pain
<b>Inclusion criteria</b>	<ul style="list-style-type: none"> <li>Patients 12 years and over</li> <li>Acute moderate to severe pain</li> </ul>
<b>Exclusion criteria</b>	<ul style="list-style-type: none"> <li>Children under age 12</li> <li>Acute respiratory depression</li> <li>Acute asthma/COPD</li> <li>Acute colitis</li> <li>Allergy and hypersensitivity to Codeine</li> <li>Antibiotic associated colitis</li> <li>Breastfeeding</li> <li>Conditions where abdominal distension develops</li> <li>Conditions where peristalsis may be impaired Head injury/raised ICP</li> <li>Hypothyroidism</li> <li>Hypotension (systolic &lt;100mmHg)</li> <li>Inflammatory or obstructive bowel disorders</li> <li>Risk of paralytic ileus</li> <li>Third trimester of pregnancy</li> <li>When using other opiate based medicines</li> </ul>

<b>Cautions (including any relevant action to be taken)</b>	<ul style="list-style-type: none"> <li>• Patients who are pregnant</li> <li>• Asthma/COPD</li> <li>• Biliary tract disease</li> <li>• Cardiac arrhythmias</li> <li>• Chronic malnutrition or dehydration</li> <li>• Convulsive disorders</li> <li>• Hepatocellular insufficiency</li> <li>• History of alcohol dependence, or chronic alcoholism</li> <li>• History of drug addiction or those currently prescribed Naltrexone</li> <li>• Inflammatory bowel disorders, and obstructive bowel disorders</li> <li>• Marked increase in morphine toxicity in patients who are ultra-rapid codeine metabolisers (CYP2D6 Ultra Rapid Metabolisers)</li> <li>• Myasthenia gravis</li> <li>• Prostatic hypertrophy</li> <li>• Reduced therapeutic effect in poor codeine metabolisers</li> <li>• Shock</li> <li>• Urethral stenosis</li> </ul> <p><b>MHRA advice:</b> Caution should be taken as to prescribing opioid analgesics in patients prescribed benzodiazepines</p> <p>A detailed list of cautions is available in the SPC, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> and BNF <a href="https://bnf.nice.org.uk">https://bnf.nice.org.uk</a></p>
<b>Arrangements for referral for medical advice</b>	Patient should be referred to a more experienced clinical practitioner for further assessment
<b>Action to be taken if patient excluded</b>	Patient should be referred to a more experienced clinical practitioner for further assessment
<b>Action to be taken if patient declines treatment</b>	<ul style="list-style-type: none"> <li>• 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</li> <li>• This information must be documented in the patients' health records</li> <li>• 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)</li> <li>• Where appropriate care should be escalated</li> </ul>

## 7. Details of the medicine

<b>Name, form and strength of medicine</b>	Codeine Phosphate 30mg tablets
<b>Legal category</b>	<ul style="list-style-type: none"> <li>• Prescription Only Medicine (POM)</li> <li>• CD schedule 5</li> </ul>
<b>Indicate any <u>off-label use</u> (if relevant)</b>	None

<b>Route/method of administration</b>	Oral
<b>Dose and frequency</b>	<b>12 years and over:</b> 30 – 60mg every 6 hours if required (4-6 hourly)
<b>Quantity to be administered and/or supplied</b>	<b>Administered:</b> One by stated dose <b>Supplied:</b> One original pack
<b>Maximum or minimum treatment period</b>	<b>12 years and over:</b> maximum 240mg per day for maximum of 3 days
<b>Storage</b>	Room temperature
<b>Adverse effects</b>	<ul style="list-style-type: none"> <li>• Arrhythmias</li> <li>• Confusion</li> <li>• Constipation</li> <li>• Dizziness</li> <li>• Drowsiness</li> <li>• Dry mouth</li> <li>• Euphoric mood</li> <li>• Flushing</li> <li>• Hallucination</li> <li>• Headache</li> <li>• Hyperhidrosis</li> <li>• Hypotension (with high doses)</li> <li>• Miosis</li> <li>• Nausea (more common on initiation)</li> <li>• Palpitations</li> <li>• Respiratory depression (with high doses)</li> <li>• Skin reactions</li> <li>• Urinary retention</li> <li>• Vertigo</li> <li>• Visual impairment</li> <li>• Vomiting (more common on initiation)</li> <li>• Withdrawal syndrome</li> </ul> <p>A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> and BNF <a href="https://bnf.nice.org.uk">https://bnf.nice.org.uk</a></p>
<b>Records to be kept</b>	The administration of any medication given under a PGD must be recorded within the patient's medical records

## 8. Patient information

<b>Verbal/Written information to be given to patient or carer</b>	<ul style="list-style-type: none"> <li>• Verbal information must be given to patients and or carers for all medication being administered under a PGD</li> <li>• Where medication is being supplied under a PGD, written patient information leaflet must also be supplied</li> <li>• A patient information leaflet is available on request</li> <li>• Patients should be advised to avoid driving and or operating heavy machinery should this medication cause drowsiness</li> </ul>
<b>Follow-up advice to be given to patient or carer</b>	If symptoms do not improve or worsen or you become unwell, seek medical advice immediately

## 9. Appendix A

References
<ol style="list-style-type: none"><li>1. British National Formulary (BNF) available online: <a href="https://bnf.nice.org.uk">https://bnf.nice.org.uk</a></li><li>2. Nursing and Midwifery “The code” available online: <a href="https://www.nmc.org.uk">https://www.nmc.org.uk</a></li><li>3. Current Health Care Professions Council standards of practice</li><li>4. General Pharmaceutical Council standards</li><li>5. Electronic medicines compendium available online: <a href="https://www.medicines.org.uk">https://www.medicines.org.uk</a></li><li>6. Manx Care Policy for Capacity, Best Interests Decisions and Deprivation of Liberty <a href="http://edrmgi/sites/hospital/Clinical%20Policies%20and%20Procedures/Policy%20for%20Capacity,%20Best%20Interests%20Decisions%20and%20Deprivation%20of%20Liberty.pdf#search=deprivation">http://edrmgi/sites/hospital/Clinical%20Policies%20and%20Procedures/Policy%20for%20Capacity,%20Best%20Interests%20Decisions%20and%20Deprivation%20of%20Liberty.pdf#search=deprivation</a></li></ol>

## 10. Appendix B

Health professionals agreed to practice
<ul style="list-style-type: none"><li>• Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor</li><li>• 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</li></ul>