



Bronllys Hospital, Bronllys, Brecon, Powys, LD3 0LU

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. Health professionals should always access the PGD via the PTHB internet to ensure that they are always working to the most up to date version

Patient Group Direction

for the supply and/or administration of

Codeine Phosphate 15 mg Tablets

by registered health professionals

for

acute mild to moderate pain

to

Adults and Children over 16 years old

in

Powys Teaching Health Board

Version number: **PGD0047-D**

Bwrdd Iechyd Addysgu Powys yw enw gweithredol Bwrdd Iechyd Lleol Addysgu Powys Powys Teaching Health Board is the operational name of Powys Teaching Health Board

Change history

Version number	Change details	Date
PGD0047	Initial issue	01/12/2010
PGD0047-A	Review issue: changes to NICE guidance and new drug driving rules (March 2015)	15/09/2017
PGD0047-B	Review issue, amendment to exclude children under 16 years old, removal of references to ibuprofen and paracetamol PGDs and use of new PTHB template	22/03/2021
PGD0047-C	Review issue, links to updated Protocol: MPr002 - P/GSL Ibuprofen and/or Paracetamol (MIU); adding MPr002 into advice section when patient declines treatment or/and is excluded	05/05/2021
PGD 0047D	Review version to include management of PTHB inpatients following a fall with possible injury. Formatting and wording changes, updated as per current references, amended recommended dose, as per references. Appendix A updated. Amended link to updated protocols MPr 004, MPr 005 and MPr 009.	17/04/2024


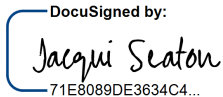


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PGD authorisation

Name	Job title and organisation	Signature	Date
Senior Doctor Dr Kate Wright	Lead Doctor for PTHB	 DocuSigned by: Kate Wright 1F267952823F473...	4/23/2024
Chief Pharmacist Jacqui Seaton	Chief Pharmacist for PTHB	 DocuSigned by: Jacqui Seaton 71E8089DE3634C4...	4/16/2024
Senior Representative of Professional Group using the PGD Claire Roche	Executive Director of Nursing and Midwifery for PTHB	 DocuSigned by: Claire Roche F07413E114E04B1...	4/23/2024
Clinical Governance Lead Amanda Edwards	Clinical Governance Lead for PTHB – Assistant Director for Innovation and Improvement	 DocuSigned by: Amanda Edwards 74A4E51A42E9473...	4/25/2024

[Appendix A](#) provides a practitioner accreditation sheet. Individual practitioners must be authorised by name to work to this PGD.

Those using this PGD must ensure that it is organisationally authorised and signed by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)¹. **The PGD is not legal or valid without signed authorisation in accordance with [HMR2012 Schedule 16 Part 2](#).**

The final authorised copy of this PGD should be kept by PTHB for 25 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for 25 years after the PGD expires.

¹ This includes any relevant amendments to legislation

Training and competency of registered health professionals

<p>Qualifications and professional registration</p>	<p>Practitioners must only work under this PGD where they are competent to do so.</p> <p>Practitioners working under this Patient Group Direction (PGD) must also be a registered professional with one of the following bodies:</p> <ul style="list-style-type: none"> • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) (Note: This PGD is not relevant to privately provided community pharmacy services) • paramedics and physiotherapists currently registered with the Health and Care Professions Council (HCPC) <p>Practitioners must also fulfil the additional requirements listed below.</p> <p>Check Appendix A – Staff Accredited to use this Patient Group Direction to confirm whether all the registered practitioners listed above have organisational authorisation to work under this PGD.</p>
<p>Initial training</p>	<p>The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training in:</p> <ul style="list-style-type: none"> • The competencies to undertake clinical assessment of patients ensuring safe provision of the medicine listed in accordance with local policy. • The administration and/or supply of Codeine phosphate 15mg tablets and knowledge of its uses, contraindications and adverse effects. <p>Additionally, practitioners:</p> <ul style="list-style-type: none"> • must be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines. Recommended training eLfh PGD elearning programme. PTHB staff to access via ESR. • must be competent in the use of PGDs (see NICE Competency framework for health professionals using patient group directions)

	<ul style="list-style-type: none"> • must have completed locally required training (including updates) in safeguarding children and vulnerable adults or a minimum of level 3 safeguarding or the equivalent, as relevant to the role. • must be familiar with codeine phosphate tablets and alert to changes in the BNF and Summary of Product Characteristics • must have undertaken training appropriate to this PGD as required by local policy • must have received training and be competent in the recognition, management of, and reporting of recognised adverse reactions, including anaphylaxis. • must be competent in the administration of adrenaline and have up to date Intermediate Life Support (ILS) skills. • must have access to the Patient Group Direction and associated online resources <p>THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.</p>
<p>Competency assessment</p>	<ul style="list-style-type: none"> • Evidence of ongoing/refresher PGD training to be submitted to Line Manager annually- this should include an annual completion certificate of PGD e-learning or a dated screenshot of the PGD e-learning assessment results as proof of completion. • Practitioners must be competent, recognise their own limitations and personal accountability and act accordingly. • Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions. • Practitioners operating under this PGD must be assessed as competent (see Appendix A). The individual must complete a self-declaration of competency in their Personal Appraisal and Development Review (PADR)- the personal development plan (yellow) section of the PADR booklet should be used to record completion of Statutory and Mandatory training, including annual PGD e-learning. • Evidence of training in life support, anaphylaxis and safeguarding.

<p>Ongoing training and competency</p>	<ul style="list-style-type: none"> • Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be addressed and further training provided as required. • Updating at least every 2 years, or earlier in response to new local/national guidance, or other sources of medicines information, on the use of PGDs and codeine phosphate 15mg tablets. • Practitioners must ensure they are up to date with relevant issues and clinical skills and management of anaphylaxis, ILS, with evidence of appropriate Continued Professional Development (CPD), which must be retained and made available on request. • Compliance with all mandatory NHS training including safeguarding at the level relevant to the role (if relevant). • Evidence of ongoing / refresher PGD training to be submitted to line manager annually. <p>It is the responsibility of the healthcare professional to maintain their own competency to practice within this PGD. The decision to administer/supply any medication rests with the individual registered healthcare professional who must abide by the PGD and any associated organisational policies.</p>
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Clinical condition

<p>Clinical condition or situation to which this PGD applies</p>	<ul style="list-style-type: none"> • Short-term treatment of acute mild to moderate pain: <ul style="list-style-type: none"> ○ For individuals who are not PTHB inpatients, use in conjunction with paracetamol and/or ibuprofen, if appropriate (Refer to MMPr004 - P/GSL Ibuprofen and/or MMPr 005 – P/GSL Paracetamol). Codeine should only be used to relieve acute mild to moderate pain if the patient has an inadequate response to paracetamol and/or a nonsteroidal anti-inflammatory drug. Refer to NICE CKS for information on the choice of analgesic and combining analgesics. ○ For inpatients following a fall with possible injury when no prescriber is available within a reasonable timeframe, if paracetamol alone doesn't provide sufficient pain relief, in line with NICE CG124. Refer to MMP009 - Discretionary Homely Medicines Policy, if appropriate. <p>If in doubt, seek medical advice.</p>
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	<p>It is the responsibility of the administering/ supplying healthcare professional to ensure that the patient is within the inclusion criteria, and that there are no reasons for exclusion before proceeding with the treatment. If there is any reason for concern, seek medical advice.</p>
<p>Inclusion criteria</p>	<ul style="list-style-type: none"> • Adult or child over 16 years old • Short-term treatment of acute mild to moderate pain which has not resolved following the use of other analgesics such as paracetamol and/or a nonsteroidal anti-inflammatory drug (such as ibuprofen). NB. Codeine should only be used to relieve acute moderate pain in children • Medical and drug history taken, no reason for exclusion • Informed consent from the individual or a person legally able to act on their behalf, must be obtained for administration and recorded appropriately. The patient information leaflet should be available to inform consent. NB Refer to PTHB Consent to Treatment and Examination Policy. The individual should be informed they are being treated using a PGD. • Patient is alert, with adequate respiratory function and oxygenation • In addition, the following criteria must be met for PTHB inpatients: <ul style="list-style-type: none"> ○ Patient has fallen ○ Adult over 18 years of age ○ Patient has evidence of new pain post fall ○ no prescriber is available within a reasonable timeframe <p>In case of any doubt, contact medical team or emergency services.</p>
<p>Exclusion Criteria (Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required)</p>	<ul style="list-style-type: none"> • Conditions outside of the clinical situations criteria • No valid consent- Refer to section 'action to be taken if the patient / carer declines treatment' • Children under 16 years old • Pregnancy or breastfeeding • NEWS score of 3 or more in a medically unwell patient or AVPU score of V P or U • Known or suspected renal impairment • Liver disease or known or suspected hepatic impairment • Acute alcoholism or history of alcohol abuse or dependency, and/or patients taking nalmefene or naltrexone

- Acute respiratory depression (respiratory rate less than 12 per minute)
- Acute diarrhoeal conditions, e.g.
 - acute ulcerative colitis
 - antibiotic-associated colitis
 - diarrhoea caused by poisoning
- Where there is a risk of paralytic ileus
- Raised intracranial pressure or head injury
- Patients with COPD or obstructive airways disease
- Patients with acute asthma attack
- Pheochromocytoma
- Biliary tract disease
- Known allergy or hypersensitivity to codeine or other opioid analgesics or to any of the excipients listed in the SPC -see www.medicines.org.uk
- Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency/total lactase deficiency or glucose-galactose malabsorption should not take certain brands of this medicine as they may contain lactose- check [individual SPC](#).
- Conditions where abdominal distension develops
- Conditions where inhibition of peristalsis should be avoided
- Children aged 16-18 years who have breathing problems or whose breathing may be compromised, eg. neuromuscular disorders, severe cardiac or respiratory conditions, upper respiratory or lung infections, multiple trauma or extensive surgical procedures
- Children aged 16-18 years with obstructive sleep apnoea who undergo removal of tonsils or adenoids
- Comatose patients
- Patients who are unable to swallow tablets
- Concomitant use of benzodiazepines and benzodiazepine-like drugs (risk of sedation and respiratory depression, coma and death)
- Patients taking a monoamine oxidase inhibitor (MAOI) within the last 14 days e.g. phenelzine, isocarboxazid, tranylcypromine, Moclobemide (reversible MAOI)
- Concomitant use of ozanimod
- Active suicidal ideation, previous reported/documentated opiate dependency and /or overdose
- Individuals who are known ultra-rapid codeine metabolisers (CYP2D6 ultra-rapid metabolisers)
- Concomitant use of other codeine or opioid containing analgesics
- Total daily dose of codeine phosphate already taken
- Contraindications listed in [SPC](#) and [BNF](#)

NB. If in doubt, discuss with medical staff.

	Refer to section ' action to be taken if the patient is excluded '
	<p>Seek medical advice:</p> <ul style="list-style-type: none"> • Patients with complex multiple allergies, poly-pharmacy, or any medical condition or medication of which the healthcare professional is unsure or uncertain. • A reduced dose is recommended in elderly or debilitated patients- see dosage section • There can be a variation in the ability to metabolise codeine which can either lead to reduced therapeutic effect or marked increase in side effects • Patients with hypotension- consider reduced dose • Asthmatics or impaired respiratory function/ decreased respiratory reserve- consider reduced dose (NB: acute asthma attack is an exclusion) • Patients with central sleep apnoea NB refer also to exclusions. • Hypothyroidism- consider reduced dose • Adrenocortical insufficiency- consider reduced dose • Check for any other medications that the patient is taking, including topical or inhaled products, food supplements and herbal or homeopathic products. See Drug interactions section and refer to BNF/ Summary of drug Characteristics for full list. • Medications that can cause drowsiness/sedation – refer to Drug Interaction section and BNF/ Summary of drug Characteristics • Any signs of clinical shock (regardless of cause) • NEWS score of 3 or more in patients attending with injuries– also see exclusions • Patients with gallstones • Urethral stenosis • Use with caution/ consider reduced dose in the following: <ul style="list-style-type: none"> ○ Urethral stricture ○ Prostatic hypertrophy ○ Convulsive disorders ○ Inflammatory or obstructive bowel disorders ○ Myasthenia gravis • Current or history of mental health disorder • Current or history of substance use disorder • Acute abdomen • Cardiac arrhythmias

<p>Cautions /reasons for seeking further advice from a prescriber</p>	<ul style="list-style-type: none"> • Constipation is a common adverse effect of all weak opioids. If possible, avoid weak opioids in people with chronic constipation. • Patients who have recently consumed alcohol – see interactions • Patients who need to drive- refer to 2015 legislation regarding driving whilst taking medicines and "Drug Driving: guidance for healthcare professionals". Also see information to be given to patient/ carer section. <p>NB. Refer to BNF/SPC for full list. Call medical cover for advice and document advice given.</p> <p>Under Section 128 and 130 of the Social Services and Wellbeing (Wales) Act 2014, staff have a duty to inform the Local Authority if they have reasonable cause to suspect that an adult or child is at risk. Any vulnerable adult or child protection concerns should be referred to Safeguarding and PTHB safeguarding policies followed. Consider discussing with GP. Any safeguarding concerns need to be directed to Safeguarding Hub:</p> <ul style="list-style-type: none"> • To generic email address: PowysTHB.Safeguarding@wales.nhs.uk <p>And</p> <ul style="list-style-type: none"> • Central Safeguarding number: 01686 252806 • Out of hours: 0345 0544847 <p>Advice can also be sought from local Safeguarding leads</p>
<p>Arrangements for referral for medical advice</p>	<p>Contact GP for advice or refer to DGH if applicable. Document advice given.</p>
<p>Action to be taken if patient excluded</p>	<p>Offer alternative analgesic if appropriate.</p> <p>Refer to Protocol MPr004 Administration of pharmacy (P) and general sales list (GSL) classified ibuprofen preparations by registered nurses and/or Protocol MPr005 Administration of pharmacy (P) and general sales list (GSL) classified paracetamol preparations by registered nurses in MIU and outpatient departments, if appropriate.</p> <p>For inpatients, refer to MMP009 - Discretionary Homely Medicines Policy, if appropriate.</p> <p>Explain reason to patient / carer. Record reason and seek medical advice.</p>

<p>Action to be taken if patient / carer declines treatment</p>	<p>Explain consequences of refusing treatment. Make patient or their representative aware of alternative sources of treatment (DGH or GP as appropriate).</p> <p>Offer alternative management if appropriate.</p> <p>Refer to Protocol MPr004 Administration of pharmacy (P) and general sales list (GSL) classified ibuprofen preparations by registered nurses and/or Protocol MPr005 Administration of pharmacy (P) and general sales list (GSL) classified paracetamol preparations by registered nurses in MIU and outpatient departments, if appropriate.</p> <p>For inpatients, refer to MMP009 - Discretionary Homely Medicines Policy, if appropriate.</p> <p>Document refusal and any advice given. Complete a Discharge Against Advice Form if appropriate.</p> <p>Inform or refer to GP/follow local procedures as appropriate.</p> <p>Where appropriate, complete the letter on the WPAS system and send to the GP.</p>
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Details of the medicine

<p>Name, form and strength of medicine</p>	<p>Codeine Phosphate 15 mg tablets</p>
<p>Legal category</p>	<p>POM (controlled drug schedule 5)</p>
<p>Off-label use</p>	<p>NICE CKS: analgesia recommends a 15mg dose of codeine phosphate for the management of mild to moderate pain in specified patients (see dosage section). This is lower than the recommended dose of codeine phosphate to treat mild to moderate pain in the SPCs.</p> <p>Medicines should be stored according to the conditions detailed in the storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where medicines have been assessed by Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label supply under this PGD. The responsibility for the</p>

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	decision to release the affected medicines for use lies with pharmacy/Medicines Management.
Route/method of administration	Oral
Dose and frequency	<p>For PTHB inpatients following a fall with possible injury:</p> <ul style="list-style-type: none"> ○ 30mg (two 15mg tablets) (consider reducing the dose to one 15mg tablet in the elderly and/ or debilitated, patients with hypothyroidism or adrenocorticoid insufficiency) ○ To be taken up to four times a day, with a minimum of 6 hours between doses ○ Maximum of 120mg in 24 hours (two 15mg tablets four times a day) ○ Codeine should be used at the lowest effective dose for the shortest period of time <p>For all other patients: (including those treated in MIU)</p> <ul style="list-style-type: none"> ○ 30mg to 60mg (two to four 15mg tablets), unless a reduced dose is advised: <ul style="list-style-type: none"> ○ a reduced dose (for example codeine phosphate 15mg (one 15mg tablet) in the elderly and/or debilitated) ○ The recommended codeine dose for children aged 16 years to 18 years should be 30-60mg (two to four 15mg tablets). The dose is based on body weight (0.5-1mg/kg (to a maximum dose of 60mg)). All children aged between 16 and 18 years must be weighed. ○ a reduced dose in patients with: hypotension, asthma or impaired respiratory function/ decreased respiratory reserve, urethral stricture, prostatic hypertrophy, convulsive disorders, inflammatory or obstructive bowel disorders, myasthenia gravis ○ a reduced dose (for example codeine phosphate 15mg) in patients with: hypothyroidism or adrenocorticoid insufficiency. ○ To be taken up to four times a day, with a minimum of 6 hours between doses. ○ Codeine should be used at the lowest effective dose for the shortest period of time. ○ Maximum of 240mg in 24 hours (four 15mg tablets four times a day).

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<p>Quantity to be administered and/or supplied</p>	<p>For PTHB inpatients, two tablets of codeine 15mg to be administered, up to four times a day, with a minimum of 6 hours between doses (consider reducing the dose to one 15mg tablet in the elderly and/ or debilitated, patients with hypothyroidism or adrenocorticoid insufficiency). Administration of each dose must be recorded on the stat. section of the inpatient medication record. The patient must be re-assessed using the PGD (by a registered health professional who is authorised to work to the PGD) before each dose is administered, to confirm that the medication continues to be appropriate for the patient. For PTHB inpatients, ensure prescriber is aware of the administration of codeine phosphate 15 mg tablets via PGD.</p> <p>For all other patients (including those treated in MIU):</p> <ul style="list-style-type: none"> ○ A single dose (see Dose and frequency- above) may be administered in the MIU. ○ A pre-labelled MIU pack of not more than 28 x 15mg tablets may be supplied to take away, the patient must be advised as stated in this patient group direction.
<p>Maximum or minimum treatment period</p>	<p>For all patients the duration of treatment should be limited to 3 days Advise patient to seek further medical advice if the problem persists for more than three days.</p>
<p>Storage</p>	<p>Do not store above 25°C. Store in the original container.</p>
<p>Drug interactions</p>	<p>All concomitant medications should be checked for interactions.</p> <p>Also refer to the medicines listed in the exclusion criteria of this PGD (Benzodiazepines and benzodiazepine-like drugs, nalmefene, naltrexone, ozanimod and MAOIs).</p> <p>Alcohol: the hypotensive, sedative and respiratory depressive effects of alcohol may be enhanced.</p> <p>Anaesthetics: concomitant administration may cause increased CNS depression and/or respiratory depression and/or hypotension.</p> <p>Anti-arrhythmics: codeine delays the absorption of mexiletine.</p>

	<p>Quinidine: The analgesic activity of codeine is likely to be significantly impaired.</p> <p>Antidepressants: The depressant effects of opioid analgesics may be enhanced by tricyclic antidepressants.</p> <p>Antihistamines: concomitant administration of antihistamines with sedative properties may cause increased CNS depression and/or respiratory depression and/or hypotension.</p> <p>Antipsychotics: enhanced sedative and hypotensive effect.</p> <p>Clozapine can cause constipation, as can Codeine; concurrent use might increase the risk of developing intestinal obstruction. Both Codeine and Clozapine can cause sedation, which might affect the ability to perform skilled tasks.</p> <p>Anxiolytics and hypnotics: enhanced sedative effect.</p> <p>Domperidone and metoclopramide: codeine antagonises the effect of cisapride, metoclopramide and domperidone on gastrointestinal activity.</p> <p>Sodium oxybate: concomitant administration of codeine and sodium oxybate may cause increased CNS depression and/or respiratory depression and/or hypotension.</p> <p>Ulcer-healing drugs: Cimetidine may inhibit the metabolism of codeine resulting in increased plasma concentrations.</p> <p>Interference with laboratory tests: Opioids may interfere with gastric emptying studies.</p> <p>NB This list is not exhaustive -a detailed list of drug interactions is available in the BNF/SPC (http://www.medicines.org.uk) for full details.</p> <p>Refer to a prescriber if any concern of a clinically significant drug interaction.</p>
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Identification, management of, and reporting of adverse effects

Common:

- constipation, nausea, vomiting, drowsiness, hyperhidrosis (sweating).
- Respiratory depression may commonly occur with high doses.

This list is not exhaustive- a detailed list of adverse reactions is available in the BNF <https://bnf.nice.org.uk> or SPC www.medicines.org.uk.

Regular prolonged use of codeine is known to lead to addiction and tolerance. Symptoms of restlessness and irritability may result when treatment is then stopped.

Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: <http://yellowcard.mhra.gov.uk> or search for MHRA Yellow Card in the Google Play or Apple App Store. For established medicines, serious adverse events in adults or all suspected adverse reactions in children that may be attributable to the medication should be reported. Guidance on the yellow card system is available at the back of the BNF, or using the above link.

Record all adverse drug reactions (ADRs) in the patient's medical record and the individual's GP should be informed. Report any suspected adverse reactions to a doctor.

In case of an acute anaphylactic reaction occurring, adequate treatment provision must be available for immediate use: Anaphylaxis and resuscitation equipment including adrenaline (1 in 1000) injection and a working telephone.

In case of anaphylaxis:

- Refer to [adrenaline \(epinephrine\) PGD 0017](#) and [anaphylaxis policy](#)
- Request medical assistance urgently. If the GP is not immediately available dial 999 to transfer to A&E
- Ensure reaction is fully documented in patient notes
- Ensure all patient records are marked **ALLERGIC TO CODEINE PHOSPHATE**
- The patient may be advised to wear a MedicAlert or similar device to alert other healthcare providers

All significant adverse drug reactions should be reported via the [Once for Wales Reporting System](#).

<p>Records to be kept</p>	<p>Record consultation details as required by local procedures. In addition, record:</p> <ul style="list-style-type: none"> • Name, address and date of birth of patient • Name and address of GP with whom the individual is registered (or record where an individual is not registered with a GP) • Medical and drug history taken, including any allergies and previous adverse events and nature of reaction. Measure and record weight of child where appropriate. • Any reasons for exclusion or referral, including actions taken and referral arrangements made. • Any advice received from medical cover and advice given to patient / carer. • If the patient has refused treatment, and any advice given in this circumstance. • That valid informed patient consent to treatment was obtained. Record name of representative who gave consent if appropriate. • That the drug is being supplied/administered in accordance with a PGD- record PGD title, number and version. • Record any advice given about the medication including side effects, benefits, and action to take if any concerns. <p>For <u>administration</u>, record:</p> <ul style="list-style-type: none"> • Date and time of administration. • Name, form, strength and dose of drug administered. • Route of administration. • Expiry date(s). • Details of any adverse reactions and actions taken. <p>NB: for PTHB inpatients, there MUST be a record of each administration of the medication on the stat. section of the inpatient medication administration record</p> <p>For <u>supply</u>, record</p> <ul style="list-style-type: none"> • Date and time of supply. • Name, form, strength, dose, frequency and quantity of medication supplied. • Expiry date of medicine supplied. <p>The record must include the date, printed name and signature (or a password controlled e-records) of the healthcare professional responsible for administration/supply.</p> <p>All records should be clear, legible and contemporaneous.</p>
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	A record of all individuals receiving treatment under this PGD should be kept for audit purposes in accordance with local policy.
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Patient information

<p>Written and verbal information to be given to patient or carer</p>	<ul style="list-style-type: none"> • Provide patient information leaflet. • If providing labelled medication to take home: <ul style="list-style-type: none"> ○ draw patient's (or representative's) attention to the label and advise on the dosage to be taken - see dosage section. ○ If a dose has been given in MIU, the patient/carers should be advised that the next dose should not be taken for at least 6 hours, and that only 3 further doses may be taken within the following 24 hours. ○ The risks of developing tolerance should be explained to the patient. Overuse or misuse may result in overdose and/or death. It is important that patients only use medicines that are prescribed for them at the dose they have been prescribed and do not give this medicine to anyone else. ○ Advise patient to use the lowest effective dose for up to a maximum of 3 days. ○ All medication must be kept out of the reach of children. ○ Patient/carers to advise any healthcare professional that treats them that they are taking codeine. ○ Advise to stop taking if side effects occur and seek medical advice. • Give appropriate advice if medication is used off-label. • Explain indications, contraindications and cautions, possible side effects and their management. • Codeine may cause drowsiness and may also cause changes in vision, including blurred or double vision. Patients should be advised not to drive or operate tools or machinery if affected, or if patient feels dizzy or unable to concentrate. Driving at the start of therapy with opioid analgesics, should be avoided. • Give appropriate advice according to "Drug Driving: guidance for healthcare professionals". Stress the following: <ul style="list-style-type: none"> ○ this medicine is likely to affect a patient's ability to drive ○ do not drive until you know how the medicine affects you
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	<ul style="list-style-type: none"> ○ it is an offence to drive while under the influence of this medicine, unless it is taken according to the instructions provided, to treat a medical or dental problem, and the patient knows it does NOT affect their ability to drive safely. ● Avoid alcohol and/or other sedative medication whilst taking codeine- see interactions section. ● Advise to seek medical assistance if symptoms are worsening or not improving within 3 days. ● No other products containing codeine, dihydrocodeine, morphine or other opioid containing medicines should be taken at the same time. Be particularly careful if buying medicines over the counter. ● Advise parent/ carer how to recognise the signs and symptoms of morphine toxicity and to stop treatment and seek medical advice if symptoms of toxicity occur (including reduced consciousness, confusion, lack of appetite, somnolence, constipation, respiratory depression, "pin-point" pupils, nausea, vomiting). ● Seek medical advice immediately if overdose occurs. ● Advise if constipation occurs, patient should reduce or stop the medication, drink plenty of clear fluids, increase dietary fibre and consult a pharmacist. A regular laxative is not usually needed for short-term use of weak opioids.
<p>Follow-up advice to be given to patient or carer</p>	<p>All patients:</p> <ul style="list-style-type: none"> ○ Explain why the treatment is necessary. ○ Inform individual of possible side effects and their management. ○ For individuals with conditions listed in the Cautions section, provide the additional recommended advice. ○ Advise them to seek medical advice immediately if they have any unexpected reaction or other cause for concern. Outpatients should contact GP via surgery or emergency on call service; PTHB inpatients should inform the staff caring for them. <p>In addition, outpatients should be advised to seek medical advice if the problem worsens or persists for more than 3 days, or if adverse effects are seen.</p>

Key references

1. BNF/BNF for children online: <https://bnf.nice.org.uk> accessed on 22/01/2024
2. Summary of Product Characteristics: Codeine phosphate 15mg tablets Wockhardt UK Ltd; last revised 5/3/2020; accessed via www.medicines.org.uk
3. Patient information Leaflet: Codeine phosphate 15mg tablets, Wockhardt UK Ltd 11/2022, accessed via www.medicines.org.uk
4. Summary of Product Characteristics: Codeine phosphate 15mg tablets Aurobindo Pharma-Milpharm Ltd; last revised 15/12/2022
5. Patient information Leaflet: Codeine phosphate 15mg tablets. Milpharm Ltd, last revised 03/2022, accessed via www.medicines.org.uk
6. [NICE Clinical Knowledge Summary: Analgesia - Mild-to-moderate pain](#), Last revised in November 2021
7. NICE CG124: Hip fracture management, last updated 06/01/2023 [Overview | Hip fracture: management | Guidance | NICE](#)
8. NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions updated 27 March 2017 <https://www.nice.org.uk/guidance/mpg2>
9. MHRA/CHM advice: Benzodiazepines and opioids: reminder of risk of potentially fatal respiratory depression (March 2020)

Competency check list for manager or senior team lead to use as part of the authorising process for health professionals to work to a Patient Group Direction (PGD). Review of authorisation will take place on each PGD update and at the individual's annual PADR.

Name: Role:		Sign / Initial	Further training identified (Y/N) Specify in " comment s"	Comments
1	The PGD sign off is for the following PGD:(document the exact title and PGD number)			
2	We have discussed the expiry of the PGD and are using a version accessed electronically			
3	The member of staff has the appropriate qualifications and professional registration as outlined in the PGD			
4	The Patient Group Direction has been read in full by the staff member			
5	The identified training has been completed as specified in the PGD and is in date			
6	We have discussed some examples of inclusion criteria and exclusion criteria			
7	The staff member is confident in the administration method and doses			

Staff member print & sign name		Date
Manager or senior team lead to print & sign name		Date

Please send a copy of this completed form to individual's line manager, and to the staff member, in conjunction with the PGD Appendix A authorisation sheet. A copy of this form should also be kept by service lead in the training file.