

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**

for the administration of

Clopidogrel by registered nurses working on the Cardiac Care Unit, Royal Sussex County Hospital  
for

**Patients with suspected ST segment elevation myocardial infarction (STEMI) as part of the  
primary angioplasty pathway (see Appendix 2)**

Version number: 6

**Change history**

Version number	Change details	Date
6	Transferred to new template. Additional exclusion criteria with anti-retrovirals	March 21

## PGD development

Name	Job title and organisation	Signature	Date
Lead author	Sarah Young Nurse Consultant Cardiology	Via email	March 2021
Lead Doctor	Dr Lucy Blows, Cardiology Consultant	Via email	March 2021
Lead pharmacist	Sarah Connop, Lead Cardiology Pharmacist	Via email	March 2021
Lead Clinician for area	Dr Vicky Parish, Lead Cardiology Consultant	Via email	March 2021
Representative of other professional group using PGD (User review)	Delores Glover, Cardiology educator	Via email	March 2021

## Organisational authorisations

UHSussex authorises this PGD for use by the services or providers listed below:
Registered nurses working on the Cardiac Care Unit at the Royal Sussex County Hospital.
Limitations to authorisation
Who have achieved the necessary training and assessed as competent. For use as part of the primary angioplasty pathway.

Name	Signature & Name	Date
<b>Chair of PGD Group</b>	J. Pendlebury (email approval)	April 2021
<b>Chief Pharmacist</b>	M.Cross (email approval)	May 2021
<b>Medicines Governance Group chair</b>	M.Okorie (email approval)	May 2021

Local enquiries regarding the use of this PGD may be directed to [uhsussex.pgdgroup@nhs.net](mailto:uhsussex.pgdgroup@nhs.net) or PGD group chair.

Appendix 1 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD.

### Training and competency of registered health professionals

	<b>Requirements of registered health professionals working under the PGD</b>
<b>Qualifications and professional registration</b>	<p>Registered Nurses within the Cardiac Care Unit (CCU)</p> <p>Registered Nurse live on the register of the NMC</p> <p>The Nurse must have at least 6 months post registration experience in an acute cardiac ward.</p> <p>Up to date certificate in Adult Resuscitation Skills</p> <p>Have support of the clinical manager</p> <p>Is authorised by name, under the current version of this PGD</p> <p>PGD users will be responsible for collecting data and continuing to audit their practice</p>
<b>Additional requirements</b>	<p><b>THE INDIVIDUAL PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.</b></p> <p><b>The individual practitioner is required to have a working knowledge of adverse reactions to the medication used with the PGD and how to identify drug interactions.</b></p>
<b>Initial training</b>	<p>The nurse has undertaken appropriate training to undertake the clinical assessment of patients leading to diagnosis that requires treatment according to the indication listed in this PGD.</p> <p>Has undertaken appropriate training for working under patient group directions for the supply and administration of medicines.</p> <p>Has undertaken training appropriate to recognise and manage allergic/anaphylactic reactions.</p> <p>Has undertaken appropriate Trust resuscitation training.</p> <p>Authors of PGD needs to</p> <ul style="list-style-type: none"> <li>• Register and complete PGD training module (certificate can be printed out as evidence) <a href="https://portal.e-lfh.org.uk/">https://portal.e-lfh.org.uk/</a> (3 yearly)</li> </ul>
<b>Competency assessment</b>	<p>The nurse will demonstrate clinical and professional competency using the local clopidogrel assessment tool. Assessment by the</p>

	Nurse Consultant Cardiology
<b>Continued training requirements</b>	Complete NICE Competency PGD Framework Practitioners will have an annual practice review in the first year and thereafter bi-annually Up to date with mandatory training Maintain knowledge and skills within specialist area

**Clinical condition**

<b>Clinical condition or situation to which this PGD applies</b>	This PGD allows Registered Nurses to administer Clopidogrel in the treatment of patients with suspected ST segment elevation myocardial infarction (see attached primary angioplasty pathway)
<b>Inclusion criteria</b>	All Adults aged $\geq 18$ years  <b>Suspected ST segment elevation acute myocardial infarction (STEMI)</b> <ul style="list-style-type: none"> <li>• in combination with Aspirin in patients eligible for Primary Percutaneous Coronary Intervention (pPCI). Aspirin is administered by the ambulance crew prior to hospital arrival for patients with suspected ST segment elevation acute myocardial infarction</li> </ul>
<b>Exclusion criteria</b>	<ul style="list-style-type: none"> <li>• Any patient who does not meet the inclusion criteria</li> <li>• Patients without ST segment elevation</li> <li>• Any patient who is unable to swallow</li> <li>• Patients where the nurse feels it is inappropriate to use the PGD due to patient understanding</li> <li>• Verbal consent is unobtainable for any reason</li> </ul> <b>Contraindications</b> <ul style="list-style-type: none"> <li>• Hypersensitivity to clopidogrel and / or its excipients</li> <li>• Patients taking prasugrel or have already received loading dose of prasugrel in last 24 hours</li> <li>• Patients taking ticagrelor or have already received loading dose of ticagrelor in last 24 hours</li> <li>• Known severe liver impairment</li> <li>• Known bleeding disorder (e.g. Haemophilia)</li> <li>• Active internal bleeding (except for normal menstrual loss)</li> <li>• Suspected intracranial haemorrhage</li> <li>• Pregnancy</li> </ul>

	<ul style="list-style-type: none"> <li>• Breastfeeding</li> <li>• Patients on anticoagulation therapy e.g. Warfarin, Rivaroxaban, Dabigatran, Apixaban or Edoxaban</li> <li>• Patients who have been thrombolysed in past 24 hours</li> <li>• Acute ischaemic stroke in last 7 days</li> <li>• Patients on antiretrovirals for HIV</li> </ul>
<b>Cautions (including any relevant action to be taken)</b>	A full blood count (FBC) should be taken on admission to obtain a baseline but should not delay administration of Clopidogrel. Daily FBC to monitor Haemoglobin and Platelets for 48 hours then review ongoing frequency.
<b>Arrangements for referral for medical advice</b>	Referral to be made to the cardiology registrar or cardiology consultant. If immediate help is required a MET call can be made. Document actions in the notes.
<b>Action to be taken if patient excluded</b>	Referral to be made to the cardiology registrar or cardiology consultant. If immediate help is required a MET call can be made. Document actions in the notes.
<b>Action to be taken if patient declines treatment</b>	Referral to be made to the cardiology registrar or cardiology consultant. If immediate help is required a MET call can be made. Document actions in the notes.

### Details of the medicine

<b>Name, form and strength of medicine</b> <i>Include ▼ for <a href="#">black triangle medicines</a></i>	Clopidogrel 75mg film-coated tablets
<b>Legal category</b>	Prescription only medication
<b>Indicate any <a href="#">off-label use</a> (if relevant)</b>	<p>This is an unlicensed dose but is recommended as by an option by the European Society of Cardiology and is accepted practice for the management of patients undergoing primary angioplasty.</p> <p>For off label use in temperature extremes see storage below.</p>
<b>Route/method of administration</b>	oral
<b>Dose and frequency</b>	<p><b>Likely STEMI Treated with pPCI</b></p> <ul style="list-style-type: none"> <li>• All patients will receive a single loading dose of 600mg.</li> <li>• If they have already had a loading dose of 300mg given either pre-hospital or during this hospital stay the patient would receive an additional 300mg clopidogrel only.</li> </ul>

- If the patient has received 300mg clopidogrel in the last 24 hours the patient would receive an additional clopidogrel 300mg only.

The ambulance sheet must be checked before the administration of clopidogrel to review pre-hospital drug administration of clopidogrel or ticagrelor or prasugrel

<b>Quantity to be administered and/or supplied</b>	Single dose only. (See dosage)  BNF March 2021 <a href="https://www.medicinescomplete.com/mc/bnf/current/">https://www.medicinescomplete.com/mc/bnf/current/</a> EMC 2020 <a href="https://www.medicines.org.uk/emc/product/5207/smpc#gref">https://www.medicines.org.uk/emc/product/5207/smpc#gref</a>
<b>Maximum or minimum treatment period</b>	Prior to potential primary angioplasty. Single episode of care.
<b>Adverse effects</b>	<p><b>Common</b></p> <ul style="list-style-type: none"> <li>• Purpura</li> <li>• Bruising</li> <li>• Epistaxis</li> <li>• Diarrhoea</li> <li>• Abdominal pain</li> <li>• Dyspepsia</li> <li>• Skin reactions</li> </ul> <p><b><u>Serious/ rare</u></b></p> <ul style="list-style-type: none"> <li>• Haematoma</li> <li>• Haematuria</li> <li>• Intracranial bleeding</li> <li>• Thrombocytopenia</li> <li>• Paraesthesia</li> <li>• Leucopenia</li> <li>• Hallucinations</li> </ul> <p>Please refer to current BNF or SPC for full details.</p> <p>A detailed list of adverse reactions is available in the SPC for each medicine, which are available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a>.</p> <p>BNF/C also has information on adverse effects.</p>
<b>Drug interactions</b>	<p>A detailed list of drug interactions is available in the SPC (summary of product which are available from the electronic Medicines Compendium website: <a href="http://www.medicines.org.uk">www.medicines.org.uk</a>)</p> <p>BNF/C also has drug interaction information</p>
<b>Supplies</b>	Order from pharmacy
<b>Storage</b>	Drug Cupboard Drugs should be stored according to the conditions detailed in

the Storage section in this table. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where drugs have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected drugs for use lies with pharmacy/Medicines Management.

Where a drug is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence.



<p><b>Reporting procedure of adverse reactions</b></p>	<p>Healthcare professionals and individuals/parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: <a href="http://yellowcard.mhra.gov.uk">http://yellowcard.mhra.gov.uk</a></p> <p>For Black triangle any suspected adverse reactions should be reported via the Yellow Card Scheme.</p>
<p><b>Special considerations / additional information</b></p>	<p>None</p>
<p><b>Records to be kept</b></p>	<p>Record:</p> <p>that valid informed consent was given;</p> <p>name of individual, address, date of birth and GP with whom the individual is registered</p> <p>Drug history for patient including medical history</p> <p>name of HCP</p> <p>name of medication</p> <p>date of administration</p> <p>dose, form and route of administration</p> <p>quantity administered</p> <p>batch number and expiry date (if required)</p> <p>advice given,</p> <p>details of any adverse drug reactions and actions taken</p> <p>supplied via PGD</p> <p><b>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy. OR the patients should be identifiable in a timely manner for audit purposes.</b></p>
<p><b>Written information to be given to patient or carer</b></p>	<p>Patient information leaflet (PIL)</p> <p><a href="https://www.nhs.uk/medicines/">https://www.nhs.uk/medicines/</a></p>
<p><b>Follow-up advice to be given to patient or carer</b></p>	<p>Explain treatment and course of action</p> <p>Patients must be told about increased bleeding risks due to combination therapy with Aspirin and Heparin.</p> <p>Patients should inform the nurse if they have any black stools, blood in their urine or any other unusual bleeding or bruising</p>

## Audit

<b>Plan for audit</b> , It is essential for PGD renewal that audits have occurred.	Trust PGD audit to be completed
<b>Frequency</b>	Every 2 years
<b>Nominated lead to manage audit</b>	<i>Sarah Young</i> . Nurse Consultant Cardiology

## Key references

<b>Key references</b>	<p>BNF March 2021 <a href="https://www.medicinescomplete.com/mc/bnf/current/">https://www.medicinescomplete.com/mc/bnf/current/</a></p> <p>EMC 2020 <a href="https://www.medicines.org.uk/emc/product/5207/smpc#gref">https://www.medicines.org.uk/emc/product/5207/smpc#gref</a></p> <p>2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines – ScienceDirect</p> <p><a href="#">Journal of the American College of Cardiology</a>  <a href="#">Volume 61, Issue 4</a>, 29 January 2013, Pages e78-e140</p> <p>2017 ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation  <a href="#">European Heart Journal</a>, <a href="#">Volume 39, Issue 21</a>, 1 June 2018, <a href="#">Pages 1991</a>, <a href="https://doi.org/10.1093/eurheartj/ehx637">https://doi.org/10.1093/eurheartj/ehx637</a></p>
-----------------------	--

**Appendix 1 Health professionals' agreement to practise**

**PGD Title administration of Clopidogrel by registered nurses working on the Cardiac Care Unit, Royal Sussex County Hospital for Patients with suspected ST segment elevation myocardial infarction (STEMI) as part of the primary angioplasty pathway**

**Practitioner**, by signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct

Name of health professional	Role	Signature	Date

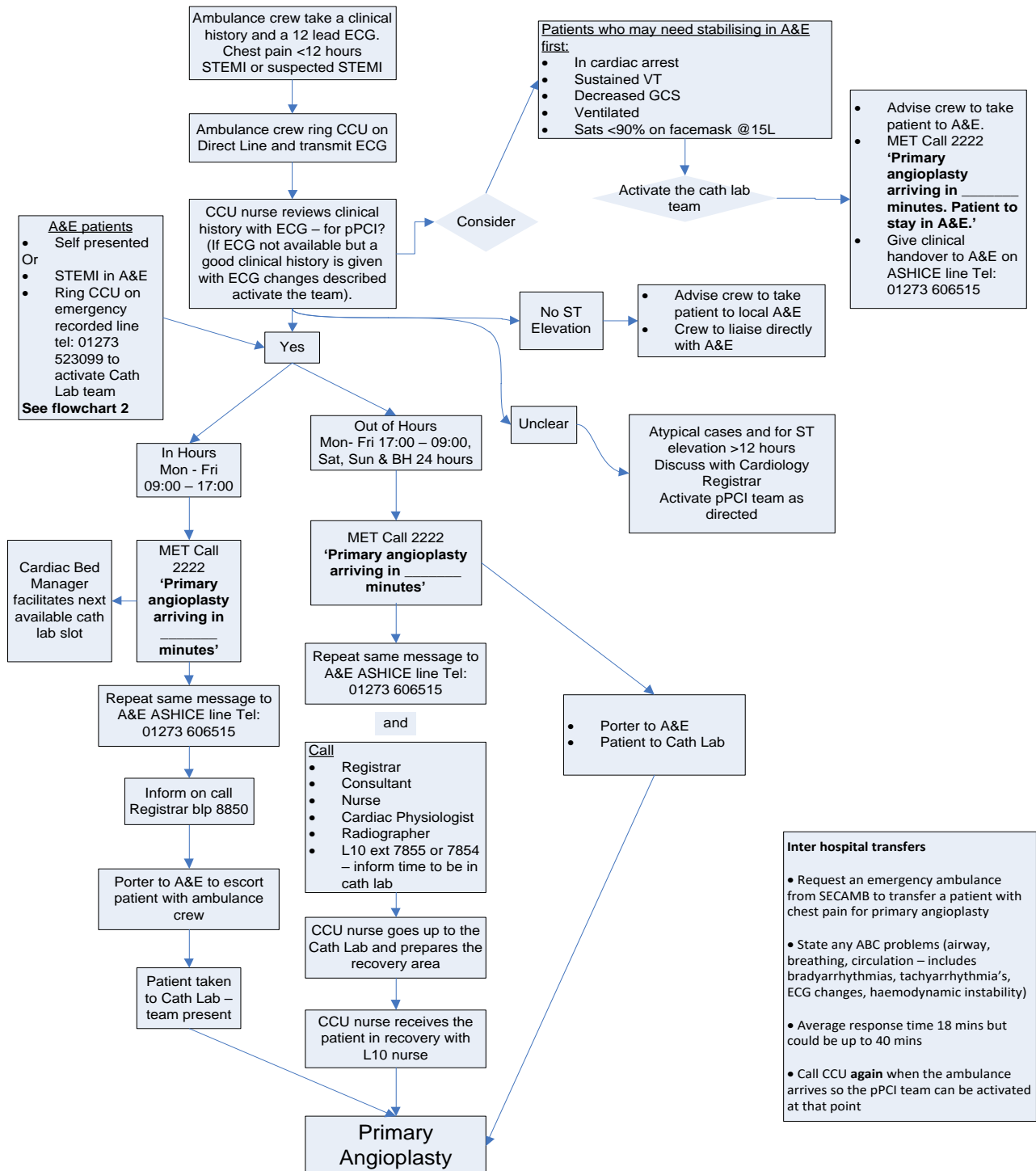
**Authorising manager**

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of UHSussex for the above named health care professionals who have signed the PGD to work under it.

Name	Role	Signature	Date

Appendix 2

**Primary Angioplasty: Direct Entry into the Cardiac Cath Lab**



**Bed Issues:**

- If Level 6A full, CCU nurse to have identified 1 male patient and 1 female patient who can move off Level 6A at anytime. Record on Handover Sheet.
- An empty bed is required in CCU out of hours – from 4pm Mon-Fri, and all day weekends and bank holidays.