

## PATIENT GROUP DIRECTION (PGD)

**Administration of Amiodarone Injection**  
**By Registered UHDB Staff providing advanced life support within**  
**Adult UHDB services**

### Documentation details

Reference no:	UHDB178
Version no:	1
Valid from:	15/06/2022
Review date:	15/12/2024
Expiry date:	14/06/2025

### Change history

Version number	Change details	Date
1	Transferred 2019 version to UHDB format and expand practitioner audience to include other sections trained in ALS and operating in the absence of prescribers (no clinical review/change required as 2021 RCUK guidelines are unchanged)	15/02/2022

### Glossary

Abbreviation	Definition

## 1. PGD template development (PGD Working Group)

**PGD Working Group Membership (minimum requirement of consultant, pharmacist and a registered professional who can work under a PGD (or manages the staff who do). If this is a review of existing PGD, replace previous names with the individuals involved for this version**

Name	Designation
James Hooley	Medicines Safety Officer (Pharmacist) – 2022
David Jones	Resuscitation & Clinical Skills Manager, UHDB – 2021 consulted on practitioner scope
Peter Cull	Consultant, ED & Clinical Tutor for Simulation – 2019 Clinical input – note no further clinical changes required for this version as UKRC unchanged

Where an antimicrobial is included, confirm the name, designation and date of the antimicrobial pharmacist who has reviewed this version

Name of antimicrobial pharmacist	Designation	Date Reviewed
N/A	-	-

## 2. Organisational authorisations

The PGD is not legally valid until it has had the relevant organisational authorisation.

**University Hospitals of Derby & Burton NHS Foundation Trust** authorises this PGD for use by the services or providers listed below:

<b>Authorised for use by the following organisation and/or services</b>
<p>All UHDB staff who are trained to provide advanced life support</p> <p>This is a core PGD and <u>can</u> be implemented in all adult services where training and resources have been allocated by senior staff to do so (see policy and limitations below if in doubt).</p>
<b>Limitations to authorisation</b>
<p>See section 3 qualifications.</p>

<b>Organisational Authorisation (legal requirement).</b>			
Role	Name	Sign	Date
<i>Chief Pharmacist / Deputy</i>	D Moore	<b>Signed copy held in Pharmacy</b>	<b>15/06/2022</b>

<b>Additional signatories (required as per legislation and locally agreed policy)</b>			
<b>Role</b>	<b>Name</b>	<b>Sign</b>	<b>Date</b>
Medicines Safety Officer (pharmacist)  <i>Clinical Pharmacist from PGD working group</i>	<b>James Hooley</b>	<b>Signed copy held in Pharmacy</b>	<b>06/06/2022</b>
Interim Medical Director / Deputy  <i>Doctor</i>	<b>Dr James Crampton</b>	<b>Signed copy held in Pharmacy</b>	<b>25/05/2022</b>
Chief Nurse / Deputy  <i>Registered Professional representing users of the PGD</i>	<b>Phil Bolton</b>	<b>Signed copy held in Pharmacy</b>	<b>16/05/2022</b>

Local enquiries regarding the use of this PGD may be directed to [UHDB.PGDgovernance@nhs.net](mailto:UHDB.PGDgovernance@nhs.net)

Section 7 provides a registered health professional authorisation sheet. Individual professionals must be authorised by name to work to this PGD.

### 3. Characteristics of staff

<b>Qualifications and professional registration</b>	<p>RCUK Advanced Life Support Provider or Instructor (in-date certification)</p> <p>All Divisions, Adult Areas, registered professional with current professional registration operating within their usual scope of practice. Must be a profession permitted by current legislation to practice under a patient group direction.</p>
<b>Initial training</b>	<ul style="list-style-type: none"> <li>- RCUK Advanced Life Support Provider or Instructor</li> <li>- Completion of all Essential-to-role training as outlined in the UHDB PGD policy.</li> <li>- Individual has read and understood full content of this PGD and signed authorisation (section 7)</li> <li>- Completion of Medicines Management Drug Assessment</li> <li>- Trust IV competency</li> </ul>
<b>Competency assessment</b>	<p>Staff operating under this PGD are encouraged to review their competency using the <a href="#">NICE Competency Framework for health professionals using patient group directions</a></p> <p>Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with either the authorising manager (section 7) or the manager within the PGD working group (section 1) so that further training can be provided as required.</p>
<b>Ongoing training and competency</b>	<p>RCUK Advanced Life Support Provider or Instructor</p> <p>Annual Medicines Safety Training (essential to role)</p> <p>Review/repeat initial training above when this PGD is revised</p> <p>Aseptic non-touch Technique (ANTT)</p>
<p><b><i>The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.</i></b></p>	

#### 4. Clinical condition or situation to which this PGD applies

<b>Clinical condition or situation to which this PGD applies</b>	Shock refractory Ventricular Fibrillation (VF) or pulseless Ventricular Tachycardia (VT)
<b>Criteria for inclusion</b>	<ul style="list-style-type: none"> <li>• Cardiac arrest in patients over 16 years with a clinical presentation as above</li> <li>• Absence of breathing and a pulse and CPR in progress</li> <li>• Where no prescriber/medic is immediately available to direct medication use</li> </ul>
<b>Criteria for exclusion</b>	<ul style="list-style-type: none"> <li>• Previous sensitivity or intolerance to the drug or any ingredient</li> <li>• patients under 16 years old</li> <li>• patients already on IV amiodarone</li> <li>• patients with an active Recommended Summary Plan for Emergency Care and Treatment (ReSPECT) form, where CPR is not recommended</li> </ul>
<b>Cautions including any relevant action to be taken</b>	<ul style="list-style-type: none"> <li>• Other antiarrhythmics being given e.g. lidocaine</li> </ul>
<b>Action to be taken if the patient is excluded</b>	<ul style="list-style-type: none"> <li>• Record reasons for exclusion in patient notes</li> <li>• Advise patient on alternative treatment</li> <li>• Refer to medical staff or prescriber for review and prescribing of alternative agent if appropriate.</li> </ul>
<b>Action to be taken if the patient or carer declines treatment</b>	<ul style="list-style-type: none"> <li>• Not applicable in this situation.</li> </ul>
<b>Arrangements for referral for medical advice</b>	<p>For anaphylaxis/cardiac arrest, follow your local medical emergency procedures (e.g. 2222 / 3333 / 999 procedures)</p> <p>In other situations, contact the patient's medical team, the on-call team or refer to agreed medical contacts in your core service (e.g. CCOT to intensivists etc).</p>

#### 5. Description of treatment

<b>Name, strength &amp; formulation of drug</b>	Amiodarone 300mg in 10ml pre-filled syringe or equivalent presentation as ampoules 2x 150mg/3ml
<b>Legal category</b>	POM
<b>Route / method of administration</b>	Intravenous or Intraosseous over at least 30 seconds
<b>Indicate any off-label use (if relevant)</b>	n/a

<b>Dose and frequency of administration</b>	300mg in 10mls presented as a pre-filled syringe or drawn up from ampoules over 30 seconds.
<b>Duration of treatment</b>	Initial stat dose only under PGD. Further dose may be given at discretion of doctor e.g. medical registrar leading resuscitation team.
<b>Quantity to be supplied (leave blank if PGD is administration ONLY)</b>	n/a
<b>Storage</b>	<p>Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below:</p> <ul style="list-style-type: none"> <li>Do not store above 25°C.</li> <li>Do not refrigerate or freeze. Storage at low temperature may cause the formation of precipitate. Do not use unless solution is clear.</li> <li>Store in the original container.</li> </ul>
<b>Drug interactions</b>	<p>The following interactions have been identified and should be considered where it is known a patient is on the following medicines:</p> <ul style="list-style-type: none"> <li>Patients on Digoxin or Warfarin refer to consultant afterwards to consider reducing dose of that medication</li> </ul> <p>A detailed list of drug interactions 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></p>
<b>Identification &amp; management of adverse reactions</b>	<p>May cause photosensitivity (&gt;50% patients), skin rash, headache, tremor, sleep disturbance, insomnia and nightmares. Also blurred vision, nausea or constipation</p> <p>Extravasation/ tissue damage risk. Bradycardia, sensitivity, rash, pneumonitis and very rarely bronchospasm.</p> <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></p>
<b>Management of and reporting procedure for adverse reactions</b>	<ul style="list-style-type: none"> <li>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: <a href="https://yellowcard.mhra.gov.uk">https://yellowcard.mhra.gov.uk</a></li> <li>Record all adverse drug reactions (ADRs) in the patient's medical record.</li> </ul> <p>Serious adverse reactions (moderate harm or above as per NRLS definition) should be reported via trust incident management system (e.g. Datix) to ensure duty of candour and learning from harm during clinical use.</p>
<b>Written information to be given to patient or carer</b>	None routinely given. If patient has questions, consider providing marketing authorisation holder's patient information leaflet (PIL) provided with the product or obtained via <a href="http://www.medicines.org.uk">www.medicines.org.uk</a> .
<b>Patient advice / follow up treatment</b>	Monitor for sensitivity reactions (refer to common side effects above also)

<b>Records</b>	<p>For inpatients, the record of administration must be documented in the ePMA system or medicines chart used in your area.</p> <p>For other areas, an ePMA system should be used if in-use in your area as this will ensure all legal criteria are fulfilled and auditable.</p> <p>Otherwise, records can be made in the medical notes or within the patient pathway (e.g. in daycase or triage where a pathway booklet is in use) but must include the legal requirements below.</p> <p>Either the system holding the record, or the healthcare practitioner working under the PGD, must capture/document all of the following:</p> <ul style="list-style-type: none"> <li>• name of individual, address, date of birth and GP with whom the individual is registered (if relevant)</li> <li>• name of registered health professional</li> <li>• name of medication supplied/administered</li> <li>• date of supply/administration</li> <li>• dose, form and route of supply/administration</li> <li>• quantity supplied/administered</li> <li>• batch number and expiry date (if applicable e.g. injections and implants)</li> <li>• advice given, including advice given if excluded or declines treatment</li> <li>• details of any adverse drug reactions and actions taken</li> <li>• Confirm whether <u>supplied and/or administered</u> via Patient Group Direction (PGD)</li> </ul> <p>Records should be signed and dated (or a password controlled e-records).</p> <p>All records should be clear, legible and contemporaneous.</p> <p>If you are not recording in ePMA (or other electronic system which has ability to generate audit reports) then a record of all individuals receiving treatment under this PGD should also be in the clinical area for audit purposes as per UHDB PGD policy.</p>
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## 6. Key references

<b>Key references</b>	<ul style="list-style-type: none"> <li>• <i>Electronic Medicines Compendium</i> <a href="http://www.medicines.org.uk/">http://www.medicines.org.uk/</a></li> <li>• <i>Electronic BNF</i> <a href="https://bnf.nice.org.uk/">https://bnf.nice.org.uk/</a></li> <li>• <i>NICE Medicines practice guideline "Patient Group Directions"</i> <a href="https://www.nice.org.uk/guidance/mpg2">https://www.nice.org.uk/guidance/mpg2</a></li> <li>• <a href="https://medusa.wales.nhs.uk">https://medusa.wales.nhs.uk</a></li> <li>• <i>RCUK. Adult advanced life support guidelines. May 2021. Accessed 15/02/2022</i> <a href="#">Adult advanced life support Guidelines   Resuscitation Council UK</a></li> </ul>
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## 7. Registered health professional authorisation sheet

**PGD Name [version]: Amiodarone Injection for ALS [v1.0]**  
**PGD ref: UHDB178**

**Valid from: 15/06/2022**

**Expiry date: 14/06/2025**

Before signing check that the document you have read is published on Koha or is an in-date hard-copy with all necessary authorisations signed in section 2. The Name/Version/Ref of the document you have read MUST match this authorisation form.

### Registered health professional

By signing this patient group direction you are indicating that

- a) You agree to and understand all content and commit to only work within this framework.
- b) You have completed any core PGD e-Learning or training records on My Learning Passport or within your department.
- c) You meet the staff characteristics and have completed any additional learning/competency outlined in Section 3 of this PGD.

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	Designation	Signature	Date

### Authorising manager / Assessor

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of University Hospitals of Derby & Burton NHS Foundation Trust for the above named health care professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

### Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet must be retained by a manager in the clinical department where the PGD is in-use to serve as a record of those registered health professionals authorised to work under this PGD.