Policy for the Supply and Administration of Medicines Under Patient Group Directions
Policy Title: Policy for the Supply and Administration of Medicines under Patient Group Directions (PGDs)

Executive Summary: This policy provides guidance to all staff in East Cheshire NHS Trust regarding all aspects of the development and use of PGDs.

Supersedes: Version 7

Description of Amendment(s): PGDs will be reviewed every 3 years not 2 years
Addition of podiatrists in section 2.1
Addition of statement “Commitment to maintaining professional competence in line with PDP as evidenced in annual appraisal” in section 2.3
Addition of PGD audit proforma in Appendix 3
Reference to Service Lines changed to Directorates

This policy will impact on: All health professionals involved in the supply and / or administration of medicines under a PGD

Financial Implications: Positive financial impact of releasing medical staff time from prescribing duties. Financial impact of staff time to develop PGD, address training needs and working under PGDs.

<table>
<thead>
<tr>
<th>Policy Area:</th>
<th>Medicines Management</th>
<th>Document Reference:</th>
<th>ECT002905</th>
</tr>
</thead>
<tbody>
<tr>
<td>Version Number:</td>
<td>8</td>
<td>Effective Date:</td>
<td>December 2017</td>
</tr>
<tr>
<td>Issued By:</td>
<td>Chair of Medicines Management Group</td>
<td>Review Date:</td>
<td>November 2020</td>
</tr>
<tr>
<td>Author:</td>
<td>Medicines Management Pharmacist</td>
<td>Impact Assessment Date:</td>
<td>November 2014</td>
</tr>
</tbody>
</table>

APPROVAL RECORD

<table>
<thead>
<tr>
<th>Committees / Group</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultation: Management – Medicines Management Group (for information)</td>
<td>February 2018</td>
</tr>
<tr>
<td>TCC</td>
<td></td>
</tr>
<tr>
<td>Specialist Advice (if required)</td>
<td></td>
</tr>
<tr>
<td>Other (please specify) PGD subgroup of the Medicines Management Group</td>
<td>December 2017</td>
</tr>
<tr>
<td>Approved by Director: Medical Director</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Director of Nursing and Patient Care Standards</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
CONTENTS PAGE

1 INTRODUCTION

1.1 Policy Statement
1.2 Definitions
1.3 Organisational Responsibilities
1.4 Planning and Implementation
1.5 Measuring Performance
1.6 Legislation
1.7 Audit
1.8 Review
1.9 Training
1.10 Dignity, Equality and Diversity

2 LEGAL REQUIREMENTS

3 DEVELOPMENT OF A PGD

4 THE PGD PROFORMA

5 REVIEW OF THE PGD

6 COMPETANCY OF THE PRACTITIONER SUPPLYING MEDICINES UNDER A PGD

7 MONITORING AND REVIEW

8 APPENDICES

APPENDIX 1 PGD PROFORMA

APPENDIX 2 GUIDANCE ON COMPLETION OF A PGD PROFORMA

APPENDIX 3 PGDs - POTENTIAL AREAS FOR AUDIT

APPENDIX 4 COMPETENCY ASSESSMENT TEMPLATE

APPENDIX 5 EQUALITY ANALYSIS STATEMENT

1 INTRODUCTION

1.1 Policy Statement

Policy for the Supply and Administration of Medicines under Patient Group Directions, version 8
Medicines Management Pharmacist, December 2017
The majority of clinical care, in this trust, should be provided on an individual, patient-specific basis. The supply and administration of medicines under patient group directions (PGD) should be reserved for those limited situations where this offers an advantage for patient care (without compromising patient safety), and where it is consistent with appropriate professional relationships and accountability as per NICE guidance on Patient Group Directions published on 02.08.13 and updated on March 2017.

This policy outlines the roles and responsibilities of staff in developing, implementing and working under a PGD.

1.2 Definitions
A patient Group Direction (PGD) is a specific written instruction for the supply or administration of named medicines in an identified clinical situation. It is drawn up locally by doctors, pharmacists and other appropriate professionals, and approved by the employing organisation, advised by the relevant professional advisory committees. It applies to groups of patients or other service users who may not be individually identified before presentation for treatment.

1.3 Organisational Responsibilities

1.3.1 Chief Executive
Has ultimate responsibility for the implementation and monitoring of the policies in use in the Trust. This responsibility may be delegated to an appropriate colleague.

1.3.2 Medical Director
Has Trust Board responsibility for all aspects of medicines management. The Medical Director is responsible for reporting any medicines management issues identified to the Trust Board.

1.3.3 Chair of Medicines Management Group
The Chair of the Medicines Management Group has responsibility for co-ordinating the activities of the Medicines Management Group to ensure that good practice relating to medicines becomes embedded in to everyday working practice across the Trust. The PGD subgroup reports directly to the Medicines Management Group. The Chair will raise any medicines management issues at the SQS Committee.

1.3.4 Chair of the PGD Subgroup
The subgroup is comprised of nurse and pharmacist representation. The Chair of the PGD Subgroup will co-ordinate the activities of the group to ensure this policy is followed, and PGDs are developed and implemented in an appropriate manner.

1.3.5 Chief Pharmacist
The Chief Pharmacist, or suitable deputy, will act as chair of the PGD subgroup and raise any issues relating to PGDs at the Medicines Management Group.

1.3.6 Directorate
It is the responsibility of the Clinical Directors (acting as clinical governance leads) and Heads of Service to ensure that PGDs are used in appropriate situations and that all staff are trained to carry out the tasks required of them in working under PGDs.

1.3.7 Ward / Department Managers and Senior Healthcare Professionals.
Responsibility for the operational implementation of PGDs, including ensuring staff within their ward / department attend appropriate training.

1.3.8 All staff using PGD’s
Are responsible for attending training relevant to the PGD and following guidance set out in this Policy.

Policy for the Supply and Administration of Medicines under Patient Group Directions, version 8
Medicines Management Pharmacist, December 2017
1.4 Planning and Implementation
- This policy has been circulated to the members of the Medicines Management Group and PGD Subgroup for comment
- The policy will be approved by the Medicines Management Group (MMG).
- The policy will be uploaded onto the Trust intranet and an email containing a link to the policy will be sent to all staff.
- It is the responsibility of the ward and department managers to inform their staff of the changes in the policy.

1.5 Measuring Performance
The Trust may be measured for compliance with NHSLA standard C4d, and by the Care Quality Commission

1.6 Legislation
This policy complies with all relevant legislation and guidelines that are considered to be good practice which relate to the supply and / or administration of medicines under PGDs.

1.7 Audit
East Cheshire NHS Trust recognises its responsibility to check practice in adherence to all trust policies. It is the responsibility of the Directorates to ensure that practice relating to the use of PGDs is audited appropriately. Audit results should be discussed by the PGD Subgroup to identify areas of good and poor practice, and to highlight training needs.

1.8 Review
It is the responsibility of the PGD Subgroup to review and amend this policy. This policy will be reviewed and up-dated every 3 years.

1.9 Training
All staff groups involved in working with PGDs should receive appropriate training. The training should be tailored to the requirements of the staff group involved. When PGDs are reviewed the PGD subgroup will be ask for assurance that training programmes and any educational materials used, are appropriate. Aspects of training might include training related to:
- the application of PGDs
- the clinical condition of patients to be treated under a PGD
- the medicines to be supplied / administered under a PGD

1.10 Competency Assessment
A Competency Assessment Framework will be requested when PGDs are due for review. A generic competency assessment template is included in appendix 4.

1.11 Dignity, Equality and Diversity
This policy has been impact assessed with regards to dignity, equality and diversity and there are no areas in the policy that contravene equality and diversity guidance – see appendix 5.

2 LEGAL REQUIREMENTS
2.1 The qualified health professionals who may supply or administer medicines under a
PGD are; nurses, midwives, podiatrists, optometrists, pharmacists, chiropodists, radiographers, orthoptists, physiotherapists, paramedics, dieticians, occupational therapists, speech and language therapists, prosthetists, orthotists, dental hygienists and dental therapists (information accessed from MHRA website 14.11.17). **They can only do so as named individuals. Prior training relating to the medicine in question is a pre-requisite (refer to section 6 below).**

2.2 The staff from the multidisciplinary group involved in developing the PGD must be listed, with designation and signature. This must include a senior doctor (or, if appropriate, a dentist) and a senior pharmacist.

2.3 The PGD must be approved and signed by the lead clinician for the area the PGD will apply. The PGD must then be authorised by the PGD subgroup of the Medicines Management Group and signed by the PGD Subgroup Chair.

2.4 The legislation specifies that each PGD must contain the following information. HSC 2000/026 provides the detail supporting the list below:

- The name of the business to which the direction applies;
- The date the direction comes into force and the date it expires;
- A description of the medicine(s) to which the direction applies;
- Class of health professional who may supply or administer the medicine;
- Signature of a doctor or dentist, as appropriate, and a pharmacist;
- Signature by an appropriate health organisation;
- The clinical condition or situation to which the direction applies;
- A description of those patients excluded from treatment under the direction;
- A description of the circumstances in which further advice should be sought from a doctor (or dentist, as appropriate) and arrangements for referral;
- Details of appropriate dosage and maximum total dosage, quantity, pharmaceutical form and strength, route and frequency of administration, and minimum or maximum period over which the medicine should be administered;
- Relevant warnings, including potential adverse reactions;
- Details of any necessary follow-up action and the circumstances;
- A statement of the records to be kept for audit purposes.

2.5 **Drugs requiring special consideration**

Certain medicines will require special consideration before inclusion in a PGD and some are restricted by legislation.

- **Controlled drugs (CDs)**
  There is limited scope within the legislation to allow the inclusion of controlled drugs in a PGD.
  - Morphine and diamorphine may be supplied by registered nurses and pharmacists under PGDs in any setting for the immediate necessary treatment of a sick or injured person (except for treatment of addiction).
  - Schedule 4 (Part 1) and schedule 5 CDs, midazolam (schedule 3) can be included. Those wanting to develop PGDs which include CDs must refer to current CD legislation and regulations.

- **Unlicensed medicines (medicines without marketing authority) and those used outside the terms of their Summary of Product Characteristic, SPC (off-license/off-label use)**
  Unlicensed medicines cannot be supplied and/or administered under a PGD. PGDs can be used to supply and/or administer medicines outside the terms of their SPC (off-license/off-label) provided that such use is supported by evidence and best clinical practice.
• Newly licensed drugs subject to special reporting arrangements (Black Triangle Drugs) should also only be considered in exceptional circumstances. Treatment guidelines must be followed and the PGD must clearly state the status of the product.

• Antimicrobials
Department of Health guidance suggests that particular caution should be used when deciding whether to use a PGD for an antimicrobial medicine. Antimicrobial resistance is a major public health concern. Inclusion in a PGD should only be considered where absolutely necessary and where measures to combat resistance will not be compromised. Use should be in line with Trust antibiotic guidelines and a local microbiologist should be involved in the drawing up of the PGD and the PGD should be regularly audited.

• Administration of repeat prescriptions
A PGD should not be used when it is reasonable to expect that a prescription (FP10 or a record signed by the GP, which is specific to the individual patient) could be written in advance.

• Flexible Dose - a flexible dose range can be included in a PGD so the healthcare professional can select the most appropriate dose for the individual patient.

• Abortifacients
The Abortion Act 1967, as amended, requires that a pregnancy may only be terminated by a registered medical practitioner (i.e. a doctor). Therefore, a PGD cannot be used to supply and/or administer abortifacients.

• Labelling and leaflets for medicines supplied under a PGD
Single dose medicines which are not injectables and which are supplied by a healthcare professional under PGD and then immediately self-administered by another person, such as a carer or healthcare worker, in the same room or clinic do not require labeling. This also applies to injectable medicines supplied and administered under a PGD by a healthcare professional.

Medicines supplied and taken away by the patient for self-administration or administration by a carer/another healthcare worker at a later time must be labeled.

A patient information leaflet must be supplied in every case whether or not the medicine has to be labelled separately.

3 DEVELOPMENT OR REVIEW OF A PGD

3.1 East Cheshire NHS Trust has a system in place that meets the requirements of the law. The Medicines Management Pharmacist maintains a database of approved PGDs within ECT on behalf of the PGD Subgroup. The medicines management pharmacist should check this database to ensure that a PGD does not already exist for the same indication.

3.1.1 The Process (see – Procedures for implementing Patient Group Directions)
  i) The need for each PGD is identified by local staff with agreement from the lead clinician for the relevant clinical speciality.
  ii) The author should seek approval from the relevant Directorate SQS to proceed with development of the PGD (if a new PGD) or to renew the PGD (if review of an existing PGD).
iii) Once approval from SQS has been obtained, the author should contact the Medicines Management Pharmacist, who will support the development or review of the PGD. The Medicines Management Pharmacist can check the database of approved PGD's, which is maintained by the PGD subgroup, for similar PGD's already approved.

iv) A senior healthcare professional and specialist clinician within the speciality draws up the PGD, in consultation with a pharmacist and any other relevant staff.

v) The draft PGD should be submitted to the Medicines Management Pharmacist for final review before submission to the PGD subgroup.

vi) Once ready for Trust approval it is sent to the PGD Subgroup of the Trust’s Medicines Management Group via the Medicines Management Pharmacist for discussion and approval. The PGD Subgroup meets every 6 weeks. When approved, the PGD should be signed by the Chair of the PGD subgroup.

vii) If a PGD is not approved, an appeal may be made to the Chair of the PGD Subgroup within 1 month of the decision.

viii) The author is responsible for obtaining the signature of the Clinical Director (acting as Clinical Governance Lead) for the Directorate Line. **This should be done within 2 weeks from the date of approval at the PGD subgroup.**

ix) The original copy of the PGD, with signatures, is kept by the pharmacy department. Photocopies of the PGD, with signatures, are kept by the author.

x) The PGD is entered on to the PGD database – maintained by the PGD subgroup.

xi) The manager of the area where the PGD is to be used ensures all staff who are to work under the PGD undertake appropriate training and signs the PGD proforma.

xii) Four months prior to expiry, the author will be notified by email, by the PGD Subgroup, of the need to review the PGD.
Process for PGD Approval or Review

1. Need identified by local staff and agreed by lead clinician

2. Written confirmation from the Directorate SQS for initial approval to proceed

3. Contact Medicines Management Pharmacist for support in development or review

4. PGD written or reviewed by AHP/Nurse/Pharmacist/Clinician

5. Send draft PGD to Medicines Management Pharmacist for final review and submission to the PGD Subgroup for approval

6. PGD signed by Chair of PGD Subgroup and Clinical Director for the Directorate. Original PGD retained by pharmacy and photocopies kept by author

7. Local consultation including senior doctor and pharmacist

8. Ensure legal requirements are met and assessment of wider implications. PGD may be approved or returned for amendment
4.0 THE PGD PROFORMA

4.1 The format follows the guidance contained in HSC 2000/026. An electronic version of the form can be obtained from the medicines management pharmacist. A sample is enclosed with this policy – see Appendix 1 and Appendix 2.

4.2 The proforma must be used in its entirety and may not be altered. Every section must be completed.

4.3 When completing the proforma the author should:
   - be as clear as possible; avoid abbreviations unless a glossary is provided
   - not include practitioners by a generic term eg RN.
   - Ensure each individual who may supply or administer medicines under a PGD is named on the form. These names must be updated on a 3 yearly basis as the policy is updated. It is the responsibility of the manager to ensure that this update occurs.

4.4 Where Patient Group Directions are co-authored with another Trust or Health Authority/Primary Care Trust, then each organisation must ensure signatures are obtained from within its own governing body.

5 REVIEW OF THE PGD

5.1 A Patient Group Direction must be reviewed every 3 years, after which date the PGD is no longer valid.

5.2 To facilitate such regular review, all Patient Group Directions are maintained on a database held by the PGD subgroup of the MMG. An e-mail will be sent out four months in advance, advising the lead practitioner named on the form that a review is due.

6 Monitoring and review

Policy for the Supply and Administration of Medicines under Patient Group Directions, version 8
Medicines Management Pharmacist, December 2017
6.1 It is the responsibility of the medicines management pharmacist upon consultation with the PGD subgroup to review and amend this policy. This policy will be reviewed and updated every three years. The use of each PGD should also be audited, see table below for responsibilities.

<table>
<thead>
<tr>
<th>Standard/process/issue required to be monitored</th>
<th>Monitoring and audit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Process for monitoring e.g. audit</td>
</tr>
<tr>
<td>It is the responsibility of the Specialities to ensure that practice relating to the use of PGDs is audited appropriately. Audit results should be discussed at the PGD Subgroup to identify areas of good and poor practice, and to highlight training needs. Appendix 3 highlights potential areas for audit.</td>
<td>Upon review of a PGD</td>
</tr>
</tbody>
</table>

7 Appendices

1. PGD proforma template
2. Guidance on completion of a PGD proforma
3. Audit Form for Renewal of PGD
4. Template for Competency Assessment
5. Equality analysis

************************************************************************** End of Policy **************************************************************************
PATIENT GROUP DIRECTIONS*

The Supply and/or Administration [delete as appropriate] of [insert name of medicine/medical device inc brand name where appropriate]

for [insert indication]

by

[insert healthcare professional(s) and clinical dept/service applicable to]

Version

Date of Introduction :

(It is intended that this document will be updated in 3 years subject to no amendments in the interim period)

Review Date :

*HSC 2000/026 Patient Group Directions (England Only)
<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Author</th>
<th>Status</th>
<th>Comment</th>
</tr>
</thead>
</table>

*HSC 2000/026 Patient Group Directions (England Only)*

Policy for the Supply and Administration of Medicines under Patient Group Directions, version 8
Medicines Management Pharmacist, December 2017
1. Clinical Condition

<table>
<thead>
<tr>
<th>1.1</th>
<th>Define situation/condition</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>[Provide details of patient group eligible for management under this PGD. For example: age, sex, presenting symptoms, diagnoses]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1.2</th>
<th>Criteria for inclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>[Provide details of those criteria which would exclude a patient from management under this PGD. For example: hypersensitivity/allergy to the treatment or any of it’s excipients, age, contraindications to treatment, symptoms, underlying medical conditions, interacting drugs, pregnancy, breastfeeding, recent course of treatment]</td>
</tr>
</tbody>
</table>

   A confirmed anaphylactic reaction to previous dose of vaccine containing the same antigens.
   A confirmed anaphylactic reaction to another component contained in the relevant vaccine.
   Patient refuses treatment by [insert healthcare professional(s)] under this PGD

<table>
<thead>
<tr>
<th>1.3</th>
<th>Criteria for exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>[Provide details of those criteria which would exclude a patient from management under this PGD. For example: hypersensitivity/allergy to the treatment or any of it’s excipients, age, contraindications to treatment, symptoms, underlying medical conditions, interacting drugs, pregnancy, breastfeeding, recent course of treatment]</td>
</tr>
</tbody>
</table>

   A confirmed anaphylactic reaction to previous dose of vaccine containing the same antigens.
   A confirmed anaphylactic reaction to another component contained in the relevant vaccine.
   Patient refuses treatment by [insert healthcare professional(s)] under this PGD

<table>
<thead>
<tr>
<th>1.4</th>
<th>Cautions/additional information</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>[Provide detail on the most relevant cautions and additional information]</td>
</tr>
</tbody>
</table>

For up-to-date detailed drug information consult BNF/Summary of Product Characteristics (SPC) [http://emc.medicines.org.uk/](http://emc.medicines.org.uk/)

<table>
<thead>
<tr>
<th>1.5</th>
<th>Action if patient excluded</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Record reason for exclusion in the patient’s clinical record. Refer to [insert healthcare professional e.g. GP, Consultant] for further advice/management</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1.6</th>
<th>Action if patient declines</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Record decision in the patient’s clinical record. Refer to [insert healthcare professional e.g. GP, Consultant] for further advice/management</td>
</tr>
</tbody>
</table>

2. Characteristics of staff

<table>
<thead>
<tr>
<th>2.1</th>
<th>Class of Health Professional for whom PGD is applicable (professional qualification and training)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>[Insert class of healthcare professional and their relevant professional body e.g. Registered General Nurse with full and valid membership of the NMC]</td>
</tr>
</tbody>
</table>
## 2.2 Additional requirements
- Competent to work under Patient Group Directions (PGD), including satisfactory completion of training to administer/supply in accordance with this PGD.
- Is authorised by name under the current version of the PGD.
- Is familiar with the East Cheshire NHS Trust Policy for the supply and administration of medicines under Patient Group Directions.

## 2.3 Continued training requirements
- Commitment to maintaining professional competence in line with PDP as evidenced in annual appraisal.
- Completion of mandatory and statutory training requirements as required by the organization.

## 3. Description of Treatment

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1</td>
<td>Generic name of medicine and form</td>
</tr>
<tr>
<td>3.2</td>
<td>Legal status</td>
</tr>
<tr>
<td>3.3</td>
<td>Storage</td>
</tr>
<tr>
<td>3.4</td>
<td>Licensed or unlicensed</td>
</tr>
<tr>
<td>3.5</td>
<td>Dose(s)</td>
</tr>
<tr>
<td>3.6</td>
<td>Route/Method of Administration</td>
</tr>
<tr>
<td>3.7</td>
<td>Frequency of administration</td>
</tr>
<tr>
<td>3.8</td>
<td>Total dose and number of times treatment can be administered over what time</td>
</tr>
</tbody>
</table>
| 3.9 | Side effects of drugs (including potential Adverse Drug Reaction)  
[Detail those side effects/ adverse drug reactions you believe the healthcare professional working under this PGD need to be most aware of]  
- Refer to SPC and BNF for full details. |
| 3.10 | Advice/management of adverse reactions/events  
- Seek advice from ……. [insert relevant clinician here] |
3.11 Procedure for reporting Adverse Drug Reactions (ADR’s)

- Report serious suspected adverse drug reactions (or all suspected ADRs if the medicine is black triangle) to the Medicines Health and Regulatory Agency using either the yellow cards or via [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk)
- Record serious ADR’s on DATIX
- Record any adverse drug reaction in the patient’s clinical record.
- Notify patient’s GP or …… [insert other clinician if appropriate]

3.12 Information on follow up treatment


3.14 Specify method of recording supply/administration, names of health professional, patient identifiers, sufficient to enable audit trail.

### 4. Development of the PGD

**Multidisciplinary Group:**

The group who have been involved in the development of this PGD included the following people:

<table>
<thead>
<tr>
<th>Name</th>
<th>Designation</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
5. References (for example)

- SPC for contraindications and cautions ([http://emc.medicines.org.uk/](http://emc.medicines.org.uk/))
- Current BNF
- NICE guidance
- Local guidelines

Responsible Organisations:

Responsibilities of each Organisation:

Each organisation is required to:

1. Approve the contents of this documentation (in the knowledge that it has been prepared by a multidisciplinary group as above).

2. Ensure that every PGD is approved and signed by a nominated Senior Pharmacist and Senior Doctor.

3. Ensure that the PGD is approved and signed by a senior member of staff, representative of the staff to whom the PGD relates eg. nurses, chiropodists etc.

4. Ensure that the PGD is approved and signed by the Clinical Governance Lead for the Organisation.

5. Ensure that individual health professionals working under the direction sign appropriate documentation.
Organisation (s)  

| Patient Group Direction – sub group chair |  
| Name |  
| Position |  
| Signature |  
| Date |  

| Clinical Governance Lead |  
| Name |  
| Position |  
| Signature |  
| Date |  

Record of Authorised staff

*Names must not be added to this list without the consent of the Doctor/Lead Health Professional whose signature appears below who is taking responsibility for the delivery of services under this PGD at the nominated location. I,......................................………., give authorisation for the named Health Care Professionals who have signed this protocol, to work within this Patient Group Direction

*Signed...........................................  Date..........................................................*

The undersigned nurses / health professionals
- Have read and understood the PGD
- Fulfil the required staff characteristics
- Are willing to accept delegated responsibility
- Will be professionally accountable (e.g. for nurses under the NMC Scope of Professional Practice)
- Have attended all training sessions and fulfilled all training requirements as required to operate under this PGD

<table>
<thead>
<tr>
<th>Staff Name</th>
<th>Signature of staff member</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
CRITERIA FOR PGDs

PGDs for the supply or administration of medicines should in all cases ensure that patient safety is not compromised or put at risk. Such PGDs should also take account of patient choice and patient convenience. They should specify clear arrangements for professional responsibility and accountability, and contribute to the effective use of resources. In all cases they should be consistent with the Summary of Product Characteristics which is part of the marketing authorisation granted for the product. The following should not normally be included in PGDs:-

- new drugs under intensive monitoring and subject to special adverse reaction reporting requirements (the Black Triangle scheme);
- unlicensed medicines, medicines used outside their licensed indications;
- medicines being used in clinical trials. There may be exceptions to this, and clarity is available in HSC 2000/026.

THE CONTENT OF A PGD

Each PGD should state the clinical need which it is intended to address, and the objectives of care which it will provide. Reference should be made to relevant national guidance, where it exists. PGDs should include clear statements on all the following.

1. **Clinical condition or situation to which the PGD applies**
   (i) **Define the situation/condition:** a clear and unambiguous definition of the clinical condition/situation, including the criteria for confirmation of the condition/situation.
   (ii) **Criteria for inclusion:** description of the clinical criteria under which a patient will be eligible for inclusion in the PGD.
   (iii) **Criteria for exclusion:** description of the criteria for excluding a patient from treatment under the PGD (e.g. complex medical needs, inappropriate age group).
   (iv) **Action if excluded:** details of the action to be followed for patients who are excluded from treatment under the PGD.
   (v) **Action if patient declines:** details of action to be followed for patients who do not wish to receive, or do not adhere to, care under the PGD.
   (vi) **Precautions:** warnings/alerts to be taken into account

2. **Characteristics of staff authorised to take responsibility for the supply or administration of medicines under a PGD.**
   (i) details of professional qualification required. It is suggested that all individuals should be fully qualified health professionals, normally registered with a recognised regulatory body.
   (ii) Specialist qualifications, training, experience and competence considered necessary and relevant to the clinical condition to be treated: all individuals should receive appropriate training.
   (iii) Specialist qualifications, training, experience and competence considered relevant to the medicines used in the PGD: all individuals should receive appropriate training (see competency record attached to this document)
   (iv) Requirements for continued training or education for staff supplying or administering under the PGD.

3. **Description of treatment available under a PGD**
   (i) names of all medicines to be supplied under the PGD
   (ii) names of all medicines to be administered under the PGD
   (iii) the legal status (i.e. POM, P, or GSL) of all the medicines available under the PGD.
(iv) dose(s) of medicines which can be supplied or administered, including, where a range of doses is permissible, the criteria for deciding on a dose
(v) method or route by which the medicine is to be administered.
(vi) if more than one dose is required, the frequency of administration permitted.
(vii) the total dosage and number of times treatment can be administered, and over what period of time.
(viii) information about any follow-up treatment which may be required.
(ix) The advice (including any written advice) to be given to the patient or carer before or after treatment; product information should be given to the patient or carer using the authorised Patient Information Leaflet, if one is available.
(x) Instructions on identifying and managing any possible adverse outcomes.
(xi) Arrangements for referral to medical advice
(xii) Facilities and supplies which should be available at sites where care by PGDs is provided.
(xiii) Details of treatment records required, to include a clear audit trail
(xiv) Special consideration should be given to any patients who are receiving concurrent medication.

4 Management and monitoring of Patient Group Directions

(i) the names of the professionals drawing up the PGDs should be stated.
(ii) The professional advisory groups which have approved the PGD should be named, these should include the local Medicines Management Group
(iii) The manager who has authorised the use of the PGD should be named (normally the Lead Clinician).
(iv) The PGD should include a clear audit trail, so that the name of the health professional providing treatment, patient identifiers, and the medicine being provided are recorded.
(v) PGDs should include instructions for nurses and other health care professionals involved in patient care to report any suspected adverse drug reactions to the doctor or dentist.
(vi) The PGD should be dated.
(vii) A review date should be stated which should be no longer than 3 years; after this date the PGD is no longer valid and should be retained for a period of 8 years or 25 years if the medicines is supplied or administered to children under the PGD.
## Audit Form for Renewal of Patient Group Directions

This form should be completed and forwarded to the Patient Group Direction Subgroup with the PGD that is being renewed.

Form completed by…………………………………………Date……………………

<table>
<thead>
<tr>
<th>Name of PGD</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of expiry of current PGD</td>
<td></td>
</tr>
<tr>
<td>Date last used (please tick)</td>
<td>Within 0-1 months</td>
</tr>
<tr>
<td>Number of times used within last 2 years (please tick)</td>
<td>&lt;5</td>
</tr>
<tr>
<td>Approval at SQS prior to renewal at PGD Subgroup?</td>
<td>Yes / No</td>
</tr>
<tr>
<td>Is there a training programme in place for users of the PGD?</td>
<td>Yes / No</td>
</tr>
<tr>
<td>How often is the training delivered? Are educational materials used?</td>
<td></td>
</tr>
<tr>
<td>How is the competency measured of the member of staff using the PGD? Is a competency assessment used? If so please attach.</td>
<td></td>
</tr>
</tbody>
</table>
Are patient labelled packs available for supply if appropriate?  Yes/ No

The audit form for renewal of PGD should be submitted along with the reviewed PGD to the PGD subgroup.

Other potential areas to audit:

1. Number of patients treated under the PGD
2. Documentation of difficulties in using the approved PGD
3. Numbers of patients excluded/refusing treatment under the PGD.
4. Number of referrals back to the medical team
5. Record of the incidence of ADR’s and actions taken
6. Evidence of ongoing education by practitioner
7. Record of training sessions delivered and practitioner attendance at training sessions
### APPENDIX 4 – COMPETENCY ASSESSMENT TEMPLATE

<table>
<thead>
<tr>
<th>Competency:</th>
<th>Evidence against the Trust KSF dimensions:</th>
<th>Document competency stage (1-5) and sign</th>
</tr>
</thead>
<tbody>
<tr>
<td>Relevant Knowledge/Training/Qualifications:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benner's Stages:</td>
<td>Self-Assessment</td>
<td>1st Assessment Stage</td>
</tr>
<tr>
<td>Stage 1 – Novice</td>
<td>Date/initial</td>
<td>Date/initial</td>
</tr>
<tr>
<td>Stage 2 – Advanced Beginning</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage 3 – Competent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage 4 – Proficient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage 5 – Expert</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Performance Indicator:</td>
<td>STAGE</td>
<td></td>
</tr>
</tbody>
</table>
### Annual Review

<table>
<thead>
<tr>
<th>Year</th>
<th>Year</th>
<th>Year</th>
<th>Year</th>
<th>Year</th>
<th>Year</th>
<th>Year</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Variance: (list competencies &amp; complete variance form)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Staff signature</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assessor signature</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Evidence of competency maybe demonstrated using the methods below – a minimum of x2 is required,

<table>
<thead>
<tr>
<th>Written evidence</th>
<th>Observation</th>
<th>Testimonial</th>
<th>Discussion/Questioning</th>
<th>Reflection</th>
<th>Simulation/questioning</th>
</tr>
</thead>
<tbody>
<tr>
<td>WE</td>
<td>O</td>
<td>T</td>
<td>QD</td>
<td>R</td>
<td>S</td>
</tr>
</tbody>
</table>

Policy for the Supply and Administration of Medicines under Patient Group Directions, version 8

Medicines Management Pharmacist, December 2017
# Equality Analysis (Impact assessment)

Please START this assessment BEFORE writing your policy, procedure, proposal, strategy or service so that you can identify any adverse impacts and include action to mitigate these in your finished policy, procedure, proposal, strategy or service. Use it to help you develop fair and equal services.

Eg. If there is an impact on Deaf people, then include in the policy how Deaf people will have equal access.

## 1. What is being assessed?

<table>
<thead>
<tr>
<th>Policy for the Supply and Administration of Medicines Under Patient Group Directions</th>
</tr>
</thead>
</table>

### Details of person responsible for completing the assessment:

- **Name**: Aarti Littlewood
- **Position**: Medicines Management Pharmacist
- **Team/service**: Pharmacy

### State main purpose or aim of the policy, procedure, proposal, strategy or service:

*(usually the first paragraph of what you are writing. Also include details of legislation, guidance, regulations etc which have shaped or informed the document)*

This policy outlines the roles and responsibilities of staff in developing, implementing and working under a patient group direction.

## 2. Consideration of Data and Research

To carry out the equality analysis you will need to consider information about the people who use the service and the staff that provide it. Think about the information below – how does this apply to your policy, procedure, proposal, strategy or service

### 2.1 Give details of RELEVANT information available that gives you an understanding of who will be affected by this document

Cheshire East (CE) covers Eastern Cheshire CCG and South Cheshire CCG. Cheshire West & Chester (CWAC) covers Vale Royal CCG and Cheshire West CCG. In 2011, 370,100 people resided in CE and 329,608 people resided in CWAC.

**Age:** East Cheshire and South Cheshire CCG’s serve a predominantly older population than the national average, with 19.3% aged over 65 (71,400 people) and 2.6% aged over 85 (9,700 people).

Vale Royal CCGs registered population in general has a younger age profile compared to the CWAC average, with 14% aged over 65 (14,561 people) and 2% aged over 85 (2,111 people).

Since the 2001 census the number of over 65s has increased by 26% compared with 20% nationally. The number of over 85s has increased by 35% compared with 24% nationally.

**Race:**

- In 2011, 93.6% of CE residents, and 94.7% of CWAC residents were White British
- 5.1% of CE residents, and 4.9% of CWAC residents were born outside the UK – Poland and India being the most common
- 3% of CE households have members for whom English is not the main language (11,103 people) and 1.2% of CWAC households have no people for whom English is their main language.
Gender: In 2011, c. 49% of the population in both CE and CWAC were male and 51% female. For CE, the assumption from national figures is that 20 per 100,000 are likely to be transgender and for CWAC 1,500 transgender people will be living in the CWAC area.

Disability:
- In 2011, 7.9% of the population in CE and 8.7% in CWAC had a long term health problem or disability
- In CE, there are c.4500 people aged 65+ with dementia, and c.1430 aged 65+ with dementia in CWAC. 1 in 20 people over 65 has a form of dementia
- Over 10 million (c. 1 in 6) people in the UK have a degree of hearing impairment or deafness.
- C. 2 million people in the UK have visual impairment, of these around 365,000 are registered as blind or partially sighted.
- In CE, it is estimated that around 7000 people have learning disabilities and 6500 people in CWAC.
- Mental health – 1 in 4 will have mental health problems at some time in their lives.

Sexual Orientation:
- CE - In 2011, the lesbian, gay, bisexual and transgender (LGBT) population in CE was estimated at 18,700, based on assumptions that 5-7% of the population are likely to be lesbian, gay or bisexual and 20 per 100,000 are likely to be transgender (The Lesbian & Gay Foundation).
- CWAC - In 2011, the LGBT population in CWAC is unknown, but in 2010 there were c. 20,000 LGB people in the area and as many as 1,500 transgender people residing in CWAC.

Religion/Belief:
The proportion of CE people classing themselves as Christian has fallen from 80.3% in 2001 to 68.9% in 2011 and in CWAC a similar picture from 80.7% to 70.1%, the proportion saying they had no religion doubled in both areas from around 11%-22%.
- Christian: 68.9% of Cheshire East and 70.1% of Cheshire West & Chester
- Sikh: 0.07% of Cheshire East and 0.1% of Cheshire West & Chester
- Buddhist: 0.24% of Cheshire East and 0.2% of Cheshire West & Chester
- Hindu: 0.36% of Cheshire East and 0.2% of Cheshire West & Chester
- Jewish: 0.16% of Cheshire East and 0.1% of Cheshire West & Chester
- Muslim: 0.66% of Cheshire East and 0.5% of Cheshire West & Chester
- Other: 0.29% of Cheshire East and 0.3% of Cheshire West & Chester
- None: 22.69% of Cheshire East and 22.0% of Cheshire West & Chester
- Not stated: 6.66% of Cheshire East and 6.5% of Cheshire West & Chester

Carers: In 2011, nearly 11% (40,000) of the population in CE are unpaid carers and just over 11% (37,000) of the population in CWAC.

2.1
This document affects all staff and patients who use and are treated under a patient group direction

2.2 Evidence of complaints on grounds of discrimination: (Are there any complaints or concerns raised either from patients or staff (grievance) relating to the policy, procedure, proposal, strategy or service or its effects on different groups?)
No, this policy provides staff with fixed standards of clinical practice and guidelines for the development, implementation and working under a patient group direction and does not discriminate any patient group.

2.3 Does the information gathered from 2.1 – 2.3 indicate any negative impact as a result of this document?
3. Assessment of Impact

Now that you have looked at the purpose, etc. of the policy, procedure, proposal, strategy or service (part 1) and looked at the data and research you have (part 2), this section asks you to assess the impact of the policy, procedure, proposal, strategy or service on each of the strands listed below.

**RACE:**
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, racial groups differently?  Yes  No

*Explain your response:* When assessing and explaining information to patients whose first language is not English, interpretation facilities must be used to ensure they understand what is being said to them. If written information is provided, this can be translated following the trust’s interpretation and translation policy.

**GENDER (INCLUDING TRANSGENDER):**
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, different gender groups differently?  Yes  No

*Explain your response:* Treatment and care would be the same regardless of gender, although note would need to be taken of a patient undergoing gender reassignment and the drugs they may regularly take to ensure there is no interaction with any of the drugs prescribed under this guideline.

**DISABILITY**
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, disabled people differently?  Yes  No

*Explain your response:* If a patient is deaf then a British sign language interpreter could be used to ensure they understand the information. Written information can also be used to reinforce the information. If a patient has visual impairment or is blind, information can be provided in other formats such as audio, large print, Braille. If a patient has learning disabilities, the picture communications book can be used to aid understanding and written information can be adapted into easy read versions.

**AGE:**
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, age groups differently?  Yes  No

*Explain your response:* Older people are more likely to experience mobility problems and possibly sensory disabilities, therefore see also section above.

**LESBIAN, GAY, BISEXUAL:**

*From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, lesbian, gay or bisexual groups differently?  Yes  No*
Explain your response: Treatment and care would be the same regardless of sexuality. Staff have access to equality and diversity training.

RELIGION/BELIEF:
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, religious belief groups differently? Yes ☑ No ❏
Explain your response: Certain medications included within a patient group direction may include ingredients which may not be suitable for certain religious groups. Staff using the patient group direction should be aware of this and be able to offer advice in this situation.

CARERS:
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, carers differently? Yes ☑ No ❏
Explain your response: The guideline does not affect carers disproportionately, and they should be involved in discussions around care and treatment so as to support the patient, particularly those with disabilities.

OTHER:
From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect any other groups differently? Yes ☑ No ❏
Explain your response: If a woman is pregnant or is breastfeeding then the advice listed in the patient group direction should be followed.

4. Safeguarding Assessment - CHILDREN
a. Is there a direct or indirect impact upon children? Yes ☑ No ❏

b. If yes please describe the nature and level of the impact (consideration to be given to all children; children in a specific group or area, or individual children. As well as consideration of impact now or in the future; competing / conflicting impact between different groups of children and young people): Patient group directions may include children – the appropriateness of any medication prescribed would be reviewed by the patient group direction subgroup prior to the patient group direction being approved.

c. If no please describe why there is considered to be no impact / significant impact on children

5. Relevant consultation
Having identified key groups, how have you consulted with them to find out their views and that the policy, procedure, proposal, strategy or service will affect them in the way that you intend? Have you spoken to staff groups, charities, national organisations etc?

Consultation has taken place with the following groups – patient group direction sub group, medicines management committee.

6. Date completed: December 2017 Review Date: November 2020

7. Any actions identified: Have you identified any work which you will need to do in the future to ensure that the document has no adverse impact?

Policy for the Supply and Administration of Medicines under Patient Group Directions, version 8
Medicines Management Pharmacist, December 2017
<table>
<thead>
<tr>
<th>Action</th>
<th>Lead</th>
<th>Date to be Achieved</th>
</tr>
</thead>
</table>

8. Approval  – At this point, you should forward the template to the Trust Equality and Diversity Lead lynbailey@nhs.net

Approved by Trust Equality and Diversity Lead: 

Date: 10.11.14