

Patient group directions

Medicines practice guideline

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www.nice.org.uk/guidance/mpg2

Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

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Overview

This guideline covers good practice for developing, authorising, using and updating patient group directions. It also offers advice on deciding whether a patient group direction is needed.

Patient group directions allow healthcare professionals to supply and administer specified medicines to pre-defined groups of patients, without a prescription. This guideline aims to ensure that patient group directions are used in line with legislation, so that patients have safe and speedy access to the medicines they need.

Who is it for?

People and organisations who are considering the need for, developing, authorising, using and updating patient group directions in the NHS. This includes independent organisations and contractors who are commissioned to provide NHS services.

Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in [your care](#).

[Making decisions using NICE guidelines](#) explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

1.1 Considering the need for a patient group direction

- 1.1.1 Provide the majority of clinical care involving supplying and/or administering medicines on an individual, patient-specific basis. Reserve [patient group directions \(PGDs\)](#) for limited situations in which this offers an advantage for patient care, without compromising patient safety, and where there are clear governance arrangements and accountability.
- 1.1.2 Explore all the available options for supplying and/or administering medicines in a specific clinical situation. Consider whether 1 option or a range of options is appropriate.
- 1.1.3 Use the [NHS Specialist Pharmacy Service PGD resources](#) to consider whether a PGD is necessary. Do not use PGDs for medicines when exemptions in legislation allow their supply and/or administration without the need for a PGD.
- 1.1.4 Consider investing in the training of additional non-medical prescribers to enable redesign of services if necessary, as part of a wider development or review of local medicines policy.
- 1.1.5 PGDs must be used only by named and authorised registered health professionals who can legally supply and/or administer medicines using a PGD (see [recommendation 1.4.9](#)) in line with the [Human Medicines Regulations 2012](#).
- 1.1.6 PGDs must only include medicines with a UK marketing authorisation, in line with the [Human Medicines Regulations 2012](#).

- 1.1.7 Ensure that off-label use of a licensed medicine is included in a PGD only when clearly justified by best clinical practice. Clearly state that the medicine is being used outside the terms of the marketing authorisation on the PGD. Consider informing the patient or their carer that the use is off-label, in line with General Medical Council guidance on prescribing unlicensed medicines.
- 1.1.8 Ensure that a black triangle medicine is included in a PGD only when clearly justified by best clinical practice. Clearly indicate the black triangle status on the PGD.
- 1.1.9 Ensure that a controlled drug is included in a PGD only when legally permitted and clearly justified by best clinical practice.
- 1.1.10 Do not jeopardise local and national strategies to combat antimicrobial resistance and healthcare-associated infections. Ensure that an antimicrobial is included in a PGD only when:
- clinically essential and clearly justified by best practice guidance
 - a local specialist in microbiology has agreed that a PGD is needed and this is clearly documented (see recommendation 1.3.2)
 - use of the PGD is monitored and reviewed regularly (see recommendations 1.6.4 and 1.8.5).
- 1.1.11 Do not include a medicine needing frequent dosage adjustments or frequent or complex monitoring in a PGD (for example, anticoagulants or insulin).
- 1.1.12 Do not make dose adjustments to a medicine supplied under a PGD when the medicine is already in the patient's possession.
- 1.1.13 Carefully consider the risks and benefits of including more than 1 medicine in a PGD on a case-by-case basis. Ensure all legal requirements are met for each medicine in line with the Human Medicines Regulations 2012.
- 1.1.14 Do not use PGDs for managing long-term conditions, such as hypertension or diabetes, or when uncertainty remains about the differential diagnosis.

1.2 Obtaining agreement to develop a patient group

direction

- 1.2.1 Establish a robust and transparent process for obtaining the agreement of the authorising body before proceeding to develop a PGD. Ensure that relevant information is clear and easily accessible.
- 1.2.2 Ensure that a multidisciplinary PGD approval group, with a locally defined mix of members, reviews proposals to develop PGDs. Define the roles and responsibilities of members and consider their training and competency needs.
- 1.2.3 Ensure that governance arrangements for the PGD approval group are firmly established, with clear lines of accountability and the delegated authority of the authorising body. This should include:
- agreeing and documenting terms of reference
 - declaring any conflicts of interests
 - setting the agenda of meetings and taking minutes or notes
 - prioritising PGD proposals
 - establishing reporting arrangements
 - engaging stakeholders, such as clinical groups and patients and the public
 - liaising with commissioning and finance.
- 1.2.4 Ensure that the following information is included in proposal documentation for seeking agreement to develop a PGD:
- the title of the PGD
 - details of the proposer and other individual people who would be involved in developing and authorising the PGD
 - details of the organisation delivering the service (if this organisation is not the authorising body)
 - the setting where the PGD would be used
 - the condition to be treated, considering patient inclusion and/or exclusion criteria

- benefits to patient care
- potential risks to patient safety
- details of medicine(s) to be supplied and/or administered, including dosage, quantity, formulation and strength, route and frequency of administration, duration of treatment and whether it is included in the local formulary
- health professional groups who would work under the PGD, including training and competency needs
- current and/or future service provisions for supplying and/or administering the medicine(s), including its position within the care pathway
- evidence to support the proposal
- resources needed to deliver the service
- a timescale for developing the PGD.

1.2.5 Establish a robust and transparent decision-making process that clearly defines standard criteria for reviewing proposals to develop a PGD. Ensure that:

- all legal requirements have been met
- robust local processes and clear governance arrangements are in place
- the risks and benefits of all options for supplying and/or administering the medicine(s) have been explored
- the PGD will deliver effective patient care that is appropriate in a pre-defined clinical situation, without compromising patient safety
- the views of stakeholders, such as clinical groups, patients and the public, and the provider or commissioning organisation have been considered
- appropriate registered health professionals are available to use the PGD, and training and competency needs are addressed
- people who are developing, authorising, monitoring, reviewing and updating the PGD are identified, and training and competency needs are addressed
- the need for appropriately labelled packs and safe storage can be met

- adequate resources, such as finance, training, medicines procurement and diagnostic equipment are available for service delivery
- adequate resources are available to ensure that processes are followed within any locally agreed timeframe
- decisions are aligned with local clinical commissioning frameworks.

1.2.6 Record decisions to accept or reject the proposal, including the rationale for the decision. Communicate the decision by writing to the person who submitted the proposal, within a locally agreed timeframe. Ensure that the decision is communicated to other appropriate stakeholders.

1.2.7 Establish and publish a robust and transparent process for appeals of decisions made by the PGD approval group. Clearly define the acceptable grounds and timescale for appeals.

1.3 Developing patient group directions

1.3.1 Ensure that a named lead author has responsibility for developing a PGD, supported by a locally determined multidisciplinary PGD working group. Include a doctor (or dentist), pharmacist and representative of any other professional group(s) using the PGD. Define their roles and responsibilities, and consider their training and competency needs.

1.3.2 Liaise with a local specialist in microbiology when developing a PGD that includes an antimicrobial (see recommendation 1.1.10).

1.3.3 Seek views on draft PGDs and agree final draft PGDs with relevant stakeholders, including clinicians and local medicines decision-making groups.

1.3.4 All legally required information must be included in a PGD in line with the Human Medicines Regulations 2012. Use a standard template to ensure that the format is consistent across the organisation.

1.3.5 Ensure PGDs are consistent with the relevant summary of product characteristics, unless the medicine is being used off-label or relevant national guidance is being followed (see recommendation 1.1.7).

- 1.3.6 Use the best available evidence, such as NICE guidance and other sources of high-quality information when developing PGDs. Include key references in an appendix to the PGD.

1.4 Authorising patient group directions

- 1.4.1 PGDs must be authorised only by an appropriate authorising body in line with the Human Medicines Regulations 2012.
- 1.4.2 Address barriers that may delay authorising PGDs, such as lack of clear leadership, ownership and understanding of legislation and governance arrangements.
- 1.4.3 At an early stage, identify the appropriate senior doctor (or dentist) and senior pharmacist who will sign the PGD, in line with the Human Medicines Regulations 2012. Define the roles and responsibilities of these people and consider their training and competency needs.
- 1.4.4 When acting as a doctor, dentist or pharmacist signatory, establish that the clinical and pharmaceutical content is accurate and supported by the best available evidence.
- 1.4.5 At an early stage, identify the appropriate person who will sign the PGD as a representative of any professional group(s) practising under the PGD. Consider their training and competency needs.
- 1.4.6 At an early stage, identify the appropriate person, such as the clinical governance or patient safety lead, who has designated responsibility for signing PGDs on behalf of the authorising body, in line with the Human Medicines Regulations 2012. Define the roles and responsibilities of this person and consider their training and competency needs.
- 1.4.7 When signing a PGD on behalf of an authorising body, establish that:
- local processes and governance arrangements have been followed
 - all legal requirements have been met.
- 1.4.8 Assess local needs and develop a communications plan to support the

dissemination of PGDs. Identify an appropriate person who is responsible for ensuring that this occurs.

1.4.9 For each PGD, the provider organisation should:

- identify a senior, responsible person from within the service^[1] to authorise named, registered health professionals to practise under the PGD (see recommendation 1.1.5)
- ensure that authorised health professionals have signed the appropriate documentation (see recommendation 1.5.2).

1.4.10 Publish final signed versions of PGDs on an intranet.

1.4.11 When a PGD is developed and authorised by a commissioning organisation for use across multiple provider organisations, ensure that it is adopted for use within each provider organisation.

1.5 Using patient group directions

1.5.1 When supplying and/or administering a medicine under a PGD, health professionals should follow local organisational policies and act within their code(s) of professional conduct and local governance arrangements (see recommendations 1.8.1 and 1.8.2).

1.5.2 Before practising under a PGD, health professionals should ensure that they:

- have undertaken the necessary initial training and continuing professional development
- have been assessed as competent and authorised to practise by the provider organisation (see recommendation 1.4.9)
- have signed the appropriate documentation (see recommendation 1.4.9)
- are using a copy of the most recent and in date final signed version of the PGD (see recommendation 1.4.10)
- have read and understand the context and content of the PGD.

1.5.3 When practising under a PGD, health professionals should:

- not delegate their responsibility
- ensure that they can determine that the patient meets the inclusion criteria as set out in the PGD
- ensure that they can determine that no exclusion criteria apply
- discuss alternative options for treating the patient's condition, when appropriate
- assess each individual patient's circumstances and preferences
- recognise when signposting or referral to another health professional or service is needed, as specified in the PGD
- understand relevant information about the medicine(s) included in the PGD, such as:
 - how to administer the medicine
 - how the medicine acts within the body
 - dosage calculations
 - potential adverse effects and how to manage them
 - drug interactions, precautions and contraindications
 - storage requirements, including maintenance of the 'cold chain'
 - follow-up arrangements
- be able to advise the patient or their carer about the medicine(s), as appropriate.

1.5.4 When supplying a medicine(s), provide an appropriately labelled pack. Health professionals (other than pharmacists or dispensing doctors) should not split packs.

1.5.5 Ensure that the patient receives a manufacturer's patient information leaflet with each medicine.

1.5.6 Identify whether patients supplied with a medicine(s) under a PGD are exempt from NHS prescription charges. The appropriate prescription charge(s) must be collected from patients who are not exempt, in line with the National Health Service (Charges for Drugs and Appliances) Amendment (No. 2) Regulations

2000.

1.5.7 Document the following information about the clinical assessment and supply and/or administration of the medicine(s):

- date and time of supply and/or administration
- patient details, such as name, date of birth, allergies, previous adverse events and how the patient met the criteria of the PGD
- details of medicine, such as name, strength, dose, frequency, quantity, route and site (if by injection) of administration (record the batch number and expiry date for vaccines, blood-derived products and other medicines if recommended by relevant national guidance)
- a statement that supply or administration is by using a PGD
- name and signature (which may be an electronic signature) of the health professional supplying or administering the medicine
- relevant information that was provided to the patient or their carer
- whether patient consent to treatment was obtained, in line with the [Department of Health's advice on consent](#) (2009).

1.6 Reviewing and updating patient group directions

1.6.1 Establish and manage a structured work programme for reviewing, updating and reauthorising PGDs. Ensure that sufficient resources are available to deliver the work programme.

1.6.2 Ensure that a named lead author has responsibility for reviewing and updating the PGD, supported by a locally determined multidisciplinary [PGD working group](#). Include a doctor (or dentist), pharmacist and representative of any other professional group(s) using the PGD. Define their roles and responsibilities and consider their training and competency needs (see [recommendation 1.3.1](#)).

1.6.3 When reviewing the PGD, conduct an appropriate literature search to identify new evidence. Ensure that this evidence is evaluated to assess its relevance and validity.

- 1.6.4 When reviewing the PGD, determine whether the PGD remains the most appropriate option to deliver the service. This should be informed by local monitoring and evaluations, frequency of use of the PGD, views of health professionals working under the PGD and views of relevant stakeholders, such as patients or their carers.
- 1.6.5 Determine the expiry date for an individual PGD on a case-by-case basis, with patient safety paramount. Ensure that this date does not exceed 3 years from the date the PGD was authorised.
- 1.6.6 Ensure that an updated PGD is reauthorised, in line with the [Human Medicines Regulations 2012](#) (see [recommendations 1.4.3 to 1.4.7](#)).
- 1.6.7 When a PGD is updated, ensure all relevant documentation is also updated, including the record and signatures of health professionals authorised to practise under the PGD (see [recommendation 1.8.6](#)).
- 1.6.8 Ensure that an updated PGD is communicated and disseminated effectively to all relevant stakeholders (see [recommendations 1.4.8 and 1.4.10](#)).
- 1.6.9 Establish a robust and transparent process for the unscheduled review and updating of a PGD, when the need for this has been identified. This should include responding to:
- changes in legislation
 - important new evidence or guidance that changes the PGD, such as new NICE guidance
 - new information on drug safety
 - changes in the summary of product characteristics
 - changes to the local formulary.

1.7 Training and competency

- 1.7.1 Identify the senior person in each profession who is responsible for ensuring that only fully competent, qualified and trained health professionals use PGDs.

- 1.7.2 Identify gaps in competency and establish a comprehensive and appropriate training programme for all people involved in considering the need for, developing, authorising, using and updating PGDs.
- 1.7.3 Ensure that adequate educational materials are available to enable individual people and organisations to deliver safe and effective services in which PGDs are used.
- 1.7.4 Consider collaborating with other organisations and sharing existing educational materials to ensure a comprehensive approach.
- 1.7.5 Ensure that training and re-training of health professionals using PGDs incorporates a post-training assessment of competency.

1.8 Organisational governance

- 1.8.1 For each PGD, the commissioning and provider organisation(s) should collaborate to firmly establish local governance arrangements with clear lines of responsibility and accountability.
- 1.8.2 Develop or review the organisational PGD policy and associated procedures to ensure that robust and transparent processes are documented. Ensure that the PGD policy is publicly available.
- 1.8.3 Ensure that a designated person has overall organisational responsibility for PGDs.
- 1.8.4 Ensure that patient safety incidents relating to PGD use are reported, collated and reviewed by the appropriate organisations in a planned programme, in line with national patient safety reporting systems.
- 1.8.5 Agree and undertake a planned programme of monitoring and evaluation of PGD use within the service.
- 1.8.6 Ensure that appropriate organisational records are maintained, stored securely and archived, in line with relevant legislation and the Department of Health's code of practice on records management. These records should include:

- patient safety incidents, such as medication errors, near misses and suspected adverse events
- terms of reference and minutes or notes of the [PGD approval group](#)
- a list of all PGDs in use within the organisation, including their review date and expiry date
- master authorised copies of PGDs
- expired versions of PGDs
- members of the [PGD working group](#)
- signatures of people signing a PGD
- a list of named, registered health professionals authorised to practise under each PGD used within the service
- training records
- results of monitoring and evaluation.

Terms used in the guideline

Appropriately labelled pack

In most cases, the pack to be issued under a PGD will need to be labelled to reflect the dose exactly as authorised in the PGD, as if it were being dispensed against a prescription. Separate requirements exist for prescription-only medicines (POMs) and for pharmacy (P) and general sales list (GSL) medicines. In practice, medicines supplied for use under a PGD are often in packs that are pre-labelled by a licensed manufacturing unit. These labels include all the standard labelling requirements, leaving a space on the pack for the patient's name, date of dispensing and address of the supplying service to be added at the time of supply. This is sometimes known as over-labelling.

Authorising body

An organisation listed in the [Human Medicines Regulations 2012](#) (and subsequent amendments) that is legally able to authorise a PGD. The commissioning and/or provider organisation may be an authorising body.

In the NHS in England, these organisations are:

- clinical commissioning groups (CCGs)
- local authorities
- NHS trusts or NHS foundation trusts
- NHS England
- Public Health England.

Black triangle medicine

Black triangle medicines are licensed medicines that are intensively monitored and subject to special reporting arrangements for adverse events.

Commissioning organisation/commissioner

The organisation with which a contract or agreement for the provision of a service that may require the prescribing, supply or administration of medicines has been made.

Off-label use

Using a UK licensed medicine outside the terms of its marketing authorisation, such as outside defined indications, doses or routes of administration. For example, when amitriptyline, licensed for the treatment of depression, is used for neuropathic pain.

Organisations

Unless stated otherwise, use of the term 'organisation' includes authorising bodies and any other organisations (both NHS and non-NHS) who are considering the need for, developing, authorising, using and updating PGDs to provide public-funded services.

Patient group direction (PGD)

Defined in [Health Service Circular \(HSC 2000/026\)](#) as 'Written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment'.

Patient safety incident

Any unintended or unexpected incident that could have or did lead to harm for 1 or more patients

receiving healthcare. This includes clinical errors, medication errors, adverse events and near misses.

PGD approval group

A locally determined multidisciplinary group that considers proposals to develop a PGD to deliver a service. This group may also be involved at other stages of the process, depending on local arrangements. For example, the group may approve a final draft of the PGD before it is submitted for authorisation. The term 'PGD approval group' is used for the purpose of this guidance, but other names for the group may be used locally. The group may be an existing local medicines decision-making group, such as the drug and therapeutics committee, or subgroup.

PGD working group

A locally determined multidisciplinary group established for each individual PGD. The PGD working group is responsible for developing the PGD and its subsequent review and updating. The term 'PGD working group' is used for the purpose of this guideline, but other names for the group may be used locally.

Provider organisation/provider

The organisation responsible for providing the commissioned service, which may require the prescribing, supply or administration of medicines. This may be an NHS organisation or a non-NHS organisation providing public-funded service.

Public-funded service

A service commissioned by the NHS or local authority that may be provided by an NHS organisation or a non-NHS organisation, such as:

- independent organisations, for example, independent hospitals
- independent contractors, for example, community pharmacies
- voluntary and charitable agencies, for example, hospices.

^[1] If the provider is not the authorising body, this responsibility would require a formal agreement between the commissioner and provider.

Context

This guideline provides good practice recommendations for the systems and processes used when commissioners and providers of public-funded services are considering the need for, developing, authorising, using and updating patient group directions (PGDs). It also covers governance arrangements to ensure that patients receive safe and appropriate care, and timely access to medicines, in line with legislation.

The guideline incorporates medicines legislation and takes into account the range of organisations providing public-funded services. This includes NHS organisations, local authorities (in England), and any public-funded services provided by non-NHS organisations, such as:

- independent organisations (for example, independent hospitals)
- independent contractors (for example, community pharmacies)
- voluntary and charitable agencies (for example, hospices).

Legislation establishing PGDs was introduced in 2000, and the [Health Service Circular \(HSC 2000/026\)](#) provided additional guidance. The current legislation for PGDs is included in [The Human Medicines Regulations 2012](#), which came into force in August 2012. This legislation was amended in April 2013 to reflect changes to NHS organisational structures in England, as a result of the [Health and Social Care Act 2012](#) (see [The National Treatment Agency \[Abolition\] and the Health and Social Care Act 2012 \[Consequential, Transitional and Saving Provisions\] Order 2013](#)).

PGDs provide a legal framework that allows the supply and/or administration of a specified medicine(s), by named, authorised, registered health professionals, to a pre-defined group of patients needing prophylaxis or treatment for a condition described in the PGD, without the need for a prescription or an instruction from a prescriber.

A PGD is defined in Health Service Circular (HSC 2000/026) as: 'Written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment.' This definition should not be interpreted as indicating that the patient should not be identified. Patients may or may not be known to the service provider.

The Health Service Circular (HSC 2000/026) states that 'the majority of clinical care should be provided on an individual, patient-specific basis'. Supplying and/or administering medicines under PGDs should be reserved for situations in which this offers an advantage for patient care without

compromising patient safety, and there are clear governance arrangements and accountability. Using a PGD is not a form of prescribing.

More information

You can also see this guideline in the NICE pathway on [patient group directions](#).

To find out what NICE has said on topics related to this guideline, see our web page on [medicines management](#).

See also the guideline committee's discussion and the evidence reviews (in the [full guideline](#)), and information about [how the guideline was developed](#), including details of the committee.

Update information

March 2017: The format of this guideline has been updated and the numbering of the recommendations has changed. Changes have also been made to 3 recommendations, and some definitions and hyperlinks have been updated.

Recommendation 2.8.4 in the 2013 version of the guideline has been removed because it is out of date. The recommendation advised on complying with the Care Quality Commission's essential standards of quality and safety. However, the essential standards have been replaced by fundamental standards, which do not refer specifically to medicines.

Changes were also made to recommendation 1.5.4 (2.5.4 in the 2013 version) to clarify changes in interpretation of the legislation. The recommendation is now clear that pharmacists and dispensing doctors may split original packs to supply a medicine against a PGD, as they would when supplying a medicine in accordance with a prescription.

In recommendation 1.1.10 (2.1.10 in the 2013 version) reference to Public Health England guidance has been removed. NICE is developing a guideline on managing common infections for all care settings.

February 2014: From February 2014, good practice guidance became known as medicines practice guidelines. This is to bring the guideline naming in line with other NICE products. This is purely a name change – the guideline recommendations and everything else remains the same.

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Accreditation

