



Pharmacy Independent Prescribing Service: Common Ailments and Contraception

Service Specification for a National Directed Service

Authors

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Key dates

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Version history

| Version | Changes from previous version | Date |
|---------|--|-------------|
| 1 | First approved version | 21 Feb 2022 |
| 1.3 | Clarification that the service is not considered 'available' until the point that a pharmacist independent prescriber is employed or engaged at the pharmacy and is able to provide consultations and issue prescriptions, if appropriate – see paragraph 6.20. Clarification to clause 5.10.3 that transfer of information from external clinical records is permitted to support the safe and effective provision of direct care to patients presenting for this service | 23 Nov 2022 |
| 1.5 | Updates to Appendix 1 for clarity around included conditions | 11 Oct 2023 |

1. INTERPRETATION

- 1.1. The definitions set out in The Pharmaceutical Services (Clinical Services) (Wales) Directions 2022 (or subsequent iterations of this document) apply to this specification.
- 1.2. "CCPS" means the Clinical Community Pharmacy Service, or one of the component services included within it.
- 1.3. "Local Health Board" (LHB) means the Local Health Board that the pharmacy in which the service is being provided is located.
- 1.4. "Patient" means any person in receipt of the service.
- 1.5. "Pharmacist" means a person registered in Part 1 of the GPhC register or in the register maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976.
- 1.6. "Pharmacy" means any premises included on a health board pharmaceutical list where a pharmacist provides drugs or services as part of pharmaceutical services.
- 1.7. "Pharmacy Contractor" (or "Contractor") means a person lawfully conducting a retail pharmacy business.

2. SCOPE

- 2.1. This service specification relates to provision of the Pharmacy Independent Prescribing Service (PIPS) for treatment of common ailments or contraception. Included conditions and clinical circumstances are set out in Appendix 1.

- 2.2. A Local Health Board may extend the scope of this service, to respond to a local need, by issuing a supplementary service specification that defines the extended scope and the nature of the extended Pharmacy Independent Prescribing Service to be delivered.

3. AIMS

- 3.1. To provide patients presenting in the community pharmacy access to effective advice and treatment, relevant to their clinical needs, provided by a community pharmacist independent prescriber.
- 3.2. To deliver prudent healthcare using a 'community pharmacy first' model of care, through diverting demand from patients who can be appropriately managed in the community pharmacy setting, away from GP practices or other primary health services providers.
- 3.3. To appropriately refer service users to other health and social care services and to act as a gateway to other services, in line with local care pathways, and support development of stronger clinical relationships between community pharmacy and other healthcare providers.

4. OUTCOMES

- 4.1. Provide timely access to advice and appropriate prescribed medication for assessment, advice and treatment relevant to the presenting circumstances
- 4.2. Appropriately reduce demand on consultations relating to relevant patient needs in General Practice and other health care service providers;
- 4.3. To improve access to advice and treatment in primary care, and provide onward referral when necessary, for people who may require further clinical assessment and treatment for conditions outside the scope of this service.

5. SERVICE OUTLINE

- 5.1. All care shall be as part of NHS Wales and shall be made at no cost to patients

Patient Eligibility

The service is available to:

- 5.2. Patients resident (including temporarily), or registered with a GP practice, in Wales.
- 5.3. Patients presenting with conditions and requests for care that:

- 5.3.1. are within the scope of practice of the Pharmacist Independent Prescriber; **and**
 - 5.3.2. can be appropriately managed in a community pharmacy setting; **and**
 - 5.3.3. is within the scope of clinical conditions or circumstances listed in Appendix 1 of this document;¹ **and**
 - 5.3.4. self-care (including the sale of over-the-counter medication or CCPS consultation²) is not immediately identifiable as the most appropriate response; **or**
 - 5.3.5. an examination of the patient is required in order to determine the most appropriate treatment or course of action.
- 5.4. The pharmacy will offer a user-friendly, non-judgmental, patient-centred, and confidential service.
 - 5.5. The pharmacy will provide advice on how to prevent recurrence or worsening of the condition and any associated conditions (e.g. sexually transmitted infections).
 - 5.6. Where presenting symptoms or circumstances indicate a problem that is outside of the scope of this service, the pharmacist will refer patients to an appropriate service provider that is able to meet their needs.
 - 5.7. The pharmacist/contractor will have relationships with other appropriate service providers such that patients with ongoing needs can be referred effectively.
 - 5.8. All care provided to patient who are less than 16 years of age shall be offered in accordance with Fraser Guidelines and any other relevant guidance issued by the Welsh Government.

Clinical information

- 5.9. The service will only be provided when the Pharmacist Independent Prescriber is satisfied that they have sufficient clinical information to make a professional

¹ The Pharmacy Independent Prescribing Service can only be provided for clinical circumstances and conditions that fall outside of the scope of this specification with prior explicit agreement of the relevant Local Health Board and, unless related to common ailments or contraception, would be covered by a supplementary service specification that defines the scope of such an extension and details how such a service will be delivered. See also paragraph 5.21.

² Where the pharmacist independent prescriber has conducted a PIPS consultation for a condition listed within the All Wales Common Ailments Formulary it would normally be expected that only those medicines listed in the formulary would be prescribed/supplied – where a prescriber chooses to deviate from this formulary, clear reasons why a product from this evidence based formulary is not considered appropriate for the patient MUST be documented in the clinical record for the consultation

judgement regarding the patient request and, in the Pharmacist Independent Prescribers professional opinion, it is in the patient's best interest to provide the service.

- 5.10. Where an external clinical record is available and relevant to the provision of this service:
 - 5.10.1. The Pharmacist Independent Prescriber will only access external clinical record systems where the patient has provided informed consent before the record is accessed.
 - 5.10.2. The patient will be provided with sufficient information to allow them to understand the implications of providing or withholding consent.
 - 5.10.3. The Pharmacist Independent Prescriber will not download, print, or in any other way reproduce or retain any part of an externally held clinical record for any purpose other than to support the safe and effective provision of direct clinical care to a patient who has presented under this service.
 - 5.10.4. The Pharmacist Independent Prescriber will share, with patient consent, relevant information with other health care professionals and agencies, in line with locally agreed care pathways.

Consultations

- 5.11. Consultations will be undertaken by the Pharmacist Independent Prescriber in a designated consultation area meeting the criteria set out in paragraph 6.3.
- 5.12. A physical examination of patients will be undertaken where the Pharmacist Independent Prescriber considers it necessary to determine the most appropriate treatment or course of action.
- 5.13. When conducting consultations or examinations, patients must be offered a chaperone in line with the pharmacy contractor's Chaperone Policy (see 6.17).
- 5.14. Before any physical examination takes place, the Pharmacist Independent Prescriber will explain the reason for the examination and gain explicit consent of the Patient (or accompanying adult in the case of children and young people under 15 years of age).
- 5.15. Where the Pharmacist Independent Prescriber requires support to determine the most appropriate course of action, they will contact an appropriate health care provider for such support. The Pharmacist Independent Prescriber will be aware of organisations or individuals from which clinical support can be obtained if needed and how they may be contacted. This may include a local or out-of-hours

general practitioner, NHS 111 clinical support, sexual health service, optometrist etc. Any advice given should be documented in the clinical notes as appropriate.

Treatment & management

- 5.16. Where treatment is offered, the Pharmacist Independent Prescriber will provide the patient with details of the available options and their comparative strengths and limitations to facilitate shared decision making.
- 5.17. Where diagnosis is a feature of the consultation, the Pharmacist Independent Prescriber will provide the patient with details of their diagnostic impression, rationale for this, and a detailed action plan for management of their condition
- 5.18. Where appropriate, the Pharmacist Independent Prescriber will provide recommendations for further care, or follow up, that may be necessary to complete treatment, including how and when to access this. Such recommendations will include safety netting advice to support the patient to access timely follow-on care where necessary.
- 5.19. Having assessed the patient, the Pharmacist Independent Prescriber will consider clinical and cost effectiveness of possible treatments and offer the most appropriate course of action which may include:
 - 5.19.1. advice and reassurance only; **or**
 - 5.19.2. advice and medicine(s), relevant to the presenting circumstances; **or**
 - 5.19.3. referral to another healthcare provider.
- 5.20. Where a supply of medicine is considered appropriate, the Pharmacist Independent Prescriber will select the most appropriate of:
 - 5.20.1. Advise the patient on the purchase of a suitable GSL or P medicine; **or**
 - 5.20.2. Prescribe a medicine that is listed in the LHB formulary for primary care use, and is in line with relevant national and local prescribing guidance.
- 5.21. In exceptional circumstances the Pharmacist Independent Prescriber may prescribe a medicine outside the scope of the service. Such an action should be undertaken following consultation with clinical colleagues (where possible) and, in all cases:
 - 5.21.1. the prescribing must be within the Pharmacist Independent Prescriber's clinical and professional competence; **and**
 - 5.21.2. the action taken must be the most practical option available to meet a clear clinical need of the patient and must be in their best interests; **and**

- 5.21.3. the nature of the exceptional circumstances, including any discussions with clinical colleagues, must be clearly described in the clinical record.

Prescribing & dispensing

- 5.22. All prescribing will fall within extant national, regional, or local clinical and prescribing guidance relevant to the condition or circumstances being managed;
- 5.23. All antimicrobial prescribing will be in line with current LHB infection treatment guidelines;
- 5.24. Prescribing will be within the relevant LHB formulary at all times, this lists all medicines approved for use by all prescribers and is defined by each Local Health Board;
- 5.25. Prescriptions will normally be written for the most cost effective preparations (based on drug tariff price, or otherwise advised by the Local Health Board). Where an alternative preparation is prescribed, the rationale for a more expensive preparation will be included in the clinical notes.
- 5.26. At the end of the consultation, any prescription issued will be handed to the patient and they should be advised that they may present this at the pharmacy counter, or take it to another pharmacy for dispensing.
- 5.27. The pharmacy contractor will have in place robust governance procedures to safely separate the processes of prescribing and dispensing, in line with current regulatory guidance.
- 5.28. Dispensing will be undertaken in line with extant legal and professional frameworks for supply against a prescription, including labelling requirements and the requirements of the current pharmacy contract.

Record of the consultation

- 5.29. During or **immediately** following the consultation, the Pharmacist Independent Prescriber will record relevant information in the patient's clinical record using an approved clinical record system, and ensure that a detailed record of the consultation record is sent to the patient's GP (unless consent for sharing is withheld by the patient) as soon as possible. The consultation record will include (as a minimum)³:

- 5.29.1. Patient consent;

³ The specific content and structure of the clinical record will depend on the circumstances and the approach of the prescriber. All records should be complete and reflect best practice standards as relevant to the nature of the consultation.

5.29.2. Nature of relevant presenting circumstances;

5.29.3. Examination / history;

5.29.4. Diagnostic impression (where appropriate);

5.29.5. Agreed treatment / management plan;

5.29.6. Any follow up / referral recommended.

5.30. All clinical records must be maintained in an approved system,⁴ in which records must be clearly linked to the patient who received the service, stored in a secure format that only allows access by authorised individuals, and be retrievable to allow clinical follow up or audit if necessary.

Follow Up & Referral

5.31. Where the patient is likely to benefit from a follow-up, the Pharmacist Independent Prescriber will provide sufficient information to support the patient in deciding if or when to return to the pharmacy or visit another service provider.

5.32. The Pharmacist Independent Prescriber will ensure that they are aware of, and have contact details for, organisations to which they may need to refer. Where possible, they will agree in advance such referral pathways that would expedite the process for patients (e.g. through allocation of appointments without the need for additional triage).

5.33. Where referral to an alternative service provider is considered necessary, the Pharmacist Independent Prescriber will provide sufficient information to support the patient in accessing the alternative provider within an appropriate timescale.

5.34. Where an urgent referral is indicated, this will be clearly communicated to the patient and the Pharmacist Independent Prescriber will facilitate the urgent referral as much as is possible (this may include liaising directly with the appropriate alternative service provider) to ensure effective handover of care.

6. PROVIDER RESPONSIBILITIES

Contractors

6.1. Contractors wishing to provide this service will indicate this through submission of a Premises Listing Form to the NHS Wales Shared Services Partnership

⁴ Approval will either be national, via the National Extended Services Management Board, or by the relevant Local Health Board

- 6.2. The Contractor will ensure that the service is provided only by Pharmacist Independent Prescribers who are listed in the NHS Wales Approved List of Pharmacist Independent Prescribers.
- 6.3. Other than with the prior agreement of the LHB,⁵ when provided within the pharmacy premises, the Contractor will ensure that the service is only provided from a consultation area which:⁶
- 6.3.1. is a clearly designated area for confidential discussion which is distinct from the general public areas of the pharmacy; **and**
 - 6.3.2. allows both the patient receiving the service and the Pharmacist Independent Prescriber to sit down together and talk at normal speaking volumes without being overheard by other visitors to the pharmacy or by any other person, including pharmacy staff; **and**
 - 6.3.3. ensures the dignity and privacy of the patient is maintained; **and**
 - 6.3.4. is of an appropriate size and layout to allow a Pharmacist Independent Prescriber undertaking appropriate patient examinations in accordance with accepted standards of safe practice; **and**
 - 6.3.5. has handwashing facilities with hot and cold running water; **and**
 - 6.3.6. contains suitable work surfaces to enable safe and effective delivery of consultations; **and**
 - 6.3.7. has wipable and non-porous surfaces (work surfaces, chairs, and floors) to facilitate appropriate infection control; **and**
 - 6.3.8. has a suitable receptacle for the safe disposal of clinical waste.
- 6.4. Remote and off-site provision is permitted for this service subject to the following:
- 6.4.1. Off-site and remote consultations will only be provided where the patient has expressed a wish for the consultation to take place in this manner

⁵ Where a contractor has a consultation area that does not yet meet these standards, but there is a defined plan for its refurbishment within a reasonable timescale, the LHB would normally provide agreement for the service to be provided from this consultation area until such time as the refurbishment takes place – agreement is obtained by submission of a Specification Variation Form

⁶ Note: the nature of the consultation area available may limit the range of conditions that can appropriately be provided from that pharmacy and the pharmacist providing the service will consider the appropriateness of the facilities available before embarking on, or continuing with, any consultation with a patient.

- 6.4.2. When providing off-site and remote consultations, the Contractor / Pharmacist Independent Prescriber must ensure that the conversation cannot be overheard by anyone other than those the patient has consented to inclusion in the consultation (e.g. a carer);
- 6.4.3. Where consultations are provided by telephone or video call, the Pharmacist Independent Prescriber must do this from the pharmacy premises
- 6.4.4. Where consultations are provided off-site, this must have been consented to by the Local Health Board.
- 6.5. The contractor must ensure that appropriate infection prevention and control policies are in place, including handling of any samples, and cleaning between patients.
- 6.6. To maximise effective use of the service locally, the contractor will ensure that it is clear to the Local Health Board, other local healthcare providers,⁷ and patients who may wish to access the service what clinical conditions and circumstances are in the scope of practice for the pharmacist providing services on a given day. As part of this, the contractor will engage with any communications campaign run by the Local Health Board to promote the availability of the service
- 6.7. The Contractor will liaise with other members of their primary care cluster (and neighbouring clusters where appropriate) to ensure that the availability of the service, including the conditions that are in scope, is clear to those who may be in a position to refer patients in to the service and local care pathways can be effectively developed.
- 6.8. The Contractor will communicate in advance, details of service availability to relevant services and the Local Health Board. Other than in exceptional circumstances, the contractor will provide this information for a minimum of 14 days forward from any given date. Planned leave of absence for the Pharmacist Independent Prescriber that cannot be covered by a locum will be communicated as part of the above.
- 6.9. The Contractor will, as soon as is possible, notify the relevant Local Health Board and relevant primary care services, of circumstances which result in the service being temporary unavailable for any period for which it has previously been notified as available.
- 6.10. All support staff will be fully informed and suitably trained in relation to their involvement in the service, which may include the provision of any part of the service provided on behalf of a Pharmacist Independent Prescriber, where they

⁷ For example, local GP practices, NHS 111/GPOOH, sexual health services, local community pharmacies, etc.

are competent and it is legal for them to do so. In this context, 'staff' will include any person or persons employed or engaged by the contractor, to provide any part of the service.

- 6.11. The contractor will have processes in place to confirm the initial and ongoing competence of any Pharmacist Independent Prescriber who is providing the service on their premises, and the Superintendent will be required to provide details of the processes to the relevant Local Health Board on request.
- 6.12. The Contractor will not offer, or provide to, any person employed or engaged by them any inducements or targets relating to the provision of the service.
- 6.13. The Contractor will ensure that the premises are commissioned to provide the Clinical Community Pharmacy Service and that the necessary facilities are available to the pharmacist to be able to offer the service to patients.
- 6.14. The contractor will ensure that the following equipment and associated consumables are available for use by a Pharmacist Independent Prescriber providing this service (as a minimum):
 - 6.14.1. Weighing scales
 - 6.14.2. Height measurement equipment
 - 6.14.3. Thermometer
 - 6.14.4. Blood pressure monitor
 - 6.14.5. Blood glucose monitor
 - 6.14.6. Stethoscope
 - 6.14.7. Pulse oximeter
 - 6.14.8. Otoscope
 - 6.14.9. Appropriate point of care testing equipment relevant to the care being offered (e.g. urinalysis testing strips)
- 6.15. The Contractor will ensure that all diagnostic equipment or point of care tests used in connection with this service are designed for multi-patient use, are CE marked, or otherwise validated for the specific task for which they are being used for. Further, the contractor will be responsible for ensuring that any such equipment is calibrated and maintained according to the standards set by the manufacturer/validating body.

- 6.16. The Contractor will ensure that their procurement and use of any Point of Care Tests (POCTs) is in line with relevant local and national policies and guidance, including MHRA medical devices guidance, the Wales POCT Policy, and any policies required by the Local Health Board relating to POCT.
- 6.17. The Contractor will ensure that the pharmacy has a chaperone policy, which all staff involved in delivering the service are aware of, and that this is available to be viewed upon request by the Local Health Board.
- 6.18. Contractors will ensure that adequate indemnity insurance is in place that covers all aspects of the provision of the service and that it covers all age groups that will be seen under the service.
- 6.19. Contractors will engage in meetings with representatives of the Local Health Board (and facilitate attendance by relevant Pharmacist Independent Prescribers) to discuss prescribing in general and resolve any concerns regarding potentially inappropriate prescribing (on cost or clinical effectiveness grounds) by one or more pharmacist independent prescribers employed or engaged by that contractor and will take such steps as are necessary to address any sub-optimal prescribing as is identified through this, or internal governance processes.⁸
- 6.20. The contractor will only make claims for the availability of this service where a PIP has been employed or engaged at the pharmacy premises at which the service is provided for the period to which the claim relates **and** has had access to an NHS Wales prescription pad (or single sheets) with valid J number issued by NWSSP that is linked to that pharmacy.

Pharmacist Independent Prescribers

- 6.21. Before agreeing to provide this service, Pharmacist Independent Prescribers will ensure that they are listed on the NHS Wales approved list of Pharmacist Independent Prescribers.
- 6.22. The Pharmacist Independent Prescriber is responsible for ensuring that they provide all aspects of this service within their own professional competence.
- 6.23. The Pharmacist Independent Prescriber will, as appropriate, report adverse drug events that are identified in their practice to the Medicines and Healthcare Products Regulatory Agency via the Yellow Card Scheme.

⁸ Failure to adequately address such issues or concerns would be dealt with through the dispute resolution processes set out in The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020, or subsequent regulations.

- 6.24. The Pharmacist Independent Prescriber will ensure that they are aware of national, regional, and local guidance relevant to their area of practice
- 6.25. In line with their professional standards, Pharmacist Independent Prescribers providing the service will ensure that appropriate indemnity insurance covering the provision of the service is in place and that it covers all age groups that they will see under the service.
- 6.26. Pharmacist Independent Prescribers providing the service will ensure that any prescriptions issued to them are stored securely and are only accessible to the prescriber.
- 6.27. Pharmacist Independent Prescribers providing the service are responsible for deciding what diagnostic equipment, or point of care tests, they use in assessing a patient and for ensuring that they are familiar with the use of these and how to interpret the results obtained. Any testing undertaken should be in line with current evidence based guidance.
- 6.28. Pharmacist Independent Prescribers providing this service will engage in meetings with representatives of the Local Health Board to discuss prescribing in general and any concerns regarding potentially inappropriate prescribing (on cost or clinical effectiveness grounds) by them and take such steps as are necessary to address any sub-optimal prescribing as is identified through this.

Appendix 1 – Clinical conditions & circumstances that are in scope

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| Ear: <ul style="list-style-type: none"> • Otitis Externa / superficial infections of the external auditory canal • Impacted or excessive cerumen • Otitis Media | Respiratory tract <ul style="list-style-type: none"> • Sinusitis • Allergic rhinitis • Sore throat / tonsillitis • Oral thrush • Other acute respiratory tract conditions |
| Skin: <ul style="list-style-type: none"> • Fungal and candida infections (excluding fungal nail infections) • Acne & rosacea (topical treatments only) • Inflammatory skin disorders and psoriasis (topical treatments only) • Dry Skin • Herpes Zoster • Skin infections (e.g. Impetigo, cellulitis) & paronychia • Skin reactions (urticaria, hives, bites/stings, etc) | Other: <ul style="list-style-type: none"> • Viral infection • Pyrexia • Bacterial conjunctivitis • Gout exacerbation • Constipation • Migraine⁹ • Other conditions covered by the All Wales Common Ailments Formulary where CAS supply is inappropriate |
| Urinary tract: <ul style="list-style-type: none"> • Lower urinary tract infection • Upper urinary tract infection (pyelonephritis) | Contraception <ul style="list-style-type: none"> • Emergency contraception • UKMEC 1 • UKMEC 2 |

Where clinical conditions or circumstances in addition to the above are within the scope of a pharmacist provider of this service, they may be added to the service scope for that pharmacist, with **prior** agreement of the relevant Local Health Board, via LHB authorisation of a '*PIPS Request for Clinical Conditions & Circumstances outside Appendix 1*' form.

Circumstances when it would be appropriate to offer the service

Patients who have signs and symptoms that are suggestive of one of more conditions that are included in the general scope of the service (or any agreed expanded scope applicable at that pharmacy) and that are in the competence of the Pharmacist Independent Prescriber, should be invited to have a consultation with the pharmacist. Where the pharmacist has a high degree of confidence in their working diagnosis, and this is for one or more of the conditions included in the scope of the service, advice and treatment should be provided within the competence of the pharmacist. Where the diagnosis is unclear, or it is suspected that the patient is suffering from a condition outside the scope of the service, the pharmacist should appropriately refer to another healthcare provider that is able to meet the patient's needs. In such circumstances, treatment would not normally be provided, but it may be appropriate in exceptional circumstances to initiate treatment

⁹ Patients presenting with a first presentation of migraine can be provided with treatment, but must be referred to their own GP for follow up within 2-8 weeks in line with NICE guidance. Patients with an existing diagnosis who are seeking a supply of medication would normally be managed under the Emergency Medicines Service, but where this is not practical, a PIPS consultation may be carried out.

in the pharmacy in advance of the patient attending another setting for care where not doing this would significantly increase the risk of patient harm or suffering (e.g. when the patient is in significant pain, analgesia may be initiated where clinically appropriate and within the competence of the pharmacist).

Note: Where the pharmacist independent prescriber has conducted a PIPS consultation for a condition listed within the All Wales Common Ailments Formulary it would normally be expected that only those medicines listed in the formulary would be prescribed/supplied – where a prescriber chooses to deviate from this formulary, clear reasons why a product from this evidence based formulary is not considered appropriate for the patient **MUST** be documented in the clinical record for the consultation

In most cases, a single consultation will suffice for conditions appropriate under the service. A follow-up consultation may be appropriate to confirm therapeutic success and offer second line treatment, where this is in line with good clinical practice for the relevant condition or circumstances.

Repeat presentations for the same clinical condition or circumstances are only appropriate under this service where no tests or investigations are indicated, and there are no red-flag symptoms – for example provision of ongoing contraception, ongoing treatment of a minor condition (allergies, rosacea), or a flare up of a previously resolved issue. Ongoing management of chronic conditions (aside from flare-up/exacerbation of symptoms) is not appropriate under this service specification.