



Dear colleague,

List of medicines subject to prescribing directions

Treatment of Erectile Dysfunction (ED): Patients with Severe Distress

Gonadotrophin releasing hormone (GnRH) analogues when used to suppress puberty as part of treating gender incongruence or gender dysphoria in children and young people who are under 18 years of age.

Summary

1. This circular introduces revised Directions as to the drugs, medicines and other substances to be ordered by contractors in the provision of primary medical services under a general medical services contract. Schedule 2, which lists the drugs that can be provided only in certain circumstances, has been amended to:

- i. make generic 5-PDEIs available as a routine prescribing option without the need for Selected List Scheme¹ (SLS) criteria by removing from Schedule 2:
 - apomorphine hydrochloride
 - moxisylyte hydrochloride
 - thymoxamine hydrochloride
 - sildenafil
- ii. change the criteria in the Directions from 'severe distress' to 'distress' in relation to ED medicines.
- iii. Added GnRH analogues to the list of medicines which can be prescribed by NHS general practitioners only in limited circumstances.

¹ Some medicines are restricted to prescribing in certain circumstances under the NHS Drug Tariff and these are placed on the Selected List Scheme. These medicines and devices are only for patients with the stated medical conditions, and not for any other purpose.

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Addresses

For action

Chief Executives, NHS
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For information

Directors of Pharmacy
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Background

Erectile Dysfunction

2. In 1999, when Viagra (sildenafil) the first drug treatment for erectile dysfunction received a marketing authorisation, restrictions were put in place to limit the NHS prescribing of Viagra to men suffering from certain clinical conditions.
3. Further to similar exercises conducted in 2013 and 2017, a targeted consultation was carried out from 24 August until 6 October 2023, to gather views from key stakeholders on the restrictions, set out in the 2011 NHS Circular and Directions (which are now being revoked) for the NHS Scotland prescribing of medicines used to treat erectile dysfunction (ED). Feedback received in consultations in 2013 and 2017 was very sparse and inconclusive, therefore no amendments were made to the 2011 Directions at that time. Since then, following changes to ED medicines' access, clinicians treating patients with ED highlighted to the Scottish Government a need for a further review of the 2011 Directions. As a result, the Scottish Government issued the targeted consultation in 2023 and the results of this consultation have resulted in subsequent changes set out in the 2024 Directions.
4. Following the consultation on patients suffering severe distress because of their ED, Ministers have agreed that there is no longer a need for GPs to refer patients to be referred to a consultant before prescribing ED medication. This also applies to non-medical prescribing practitioners with sufficient clinical competence.
5. Patients with primary penile disease are now also exempt from the 'severe distress' assessment and are now routinely entitled to an NHS prescription for ED medicines if they are suffering from 'distress'.

Gonadotrophin releasing hormone (GnRH) analogues

6. The NHS has stopped the routine prescription of puberty blockers for the purpose of treating gender incongruence and/or gender dysphoria to children and young people in line with the recommendations of the Independent Review of gender identity services for children and young people led by Dr Hilary Cass ([The Cass Review](#)). This action has been taken to address risks to patient safety. Patients already established on these medicines by a UK prescriber for these purposes can continue to access them. They will also remain available for patients receiving the drugs for other indications, from a UK-registered prescriber.
7. On 3 June 2024, the UK Government introduced emergency restrictions on the prescribing, and supply, of gonadotrophin releasing hormone (GnRH) analogues if they are used to suppress puberty as part of treating gender incongruence or gender dysphoria in young people who are under 18 years of age. This followed recommendations in the Cass Review.
8. These restrictions applied to all new prescriptions written by UK private prescribers and all prescriptions from prescribers registered in the European Economic Area (EEA) or Switzerland from 3 June until 2 September in Great Britain.

On 22 August 2024, the UK government renewed the temporary ban, (which from 27 August also extended to Northern Ireland), which will now expire on 26 November 2024.

9. With the changes to the Directions, from 17 September 2024, GPs in Scotland will only be able to supply prescriptions for GnRH analogues if a patient is (a) aged 18 years or over; or (b) is under 18 years old, and the purpose of the prescription is for a purpose other than puberty suppression in respect of gender incongruence or gender dysphoria (or a combination of both); or (c) is under 18 years old and has, on or after 3 December 2023, been issued with an NHS or private prescription for these medicines for the purpose of puberty suppression in respect of gender incongruence/gender dysphoria, even if the prescription has not been dispensed or if they have not yet started taking the medicines; or (d) is being treated with the medicines as part of a NICE clinical trial related to treatment for the purpose of puberty suppression in respect of gender incongruence/dysphoria.

Statutory Position

10. Section 17N(6) of the NHS (Scotland) Act 1978 allows the Scottish Ministers to issue Directions which set out the drugs, medicines and other substances which may not be ordered (Schedule 1 of the Directions), or may be ordered only under certain circumstances (Schedule 2 of the Directions), in the provision of primary medical services. The 2024 Directions make changes as described above, and revoke the previous Directions issued in 2011. A GP who has prescribed a drug specified in Schedule 2 must endorse the prescription form "SLS" as the community pharmacist cannot dispense such a medicine without this endorsement.

11. An electronic copy of the new Directions can be found at:

<https://www.publications.scot.nhs.uk/files/dcprescribing-controls.pdf>

Action

12. NHS Boards are requested to bring this Circular to the attention of Directors of Public Health, Directors of Pharmacy, Lead Clinicians for Sexual Health, GP practices, Medical Directors and community pharmacy contractors in their area. A copy should also go to the Local Medical Committee for the attention of the Secretary of the GP sub-committee.

Yours sincerely,



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