

Extended government restrictions on use of puberty suppressing hormones (puberty blockers): information for prescribers and pharmacists / dispensing doctors

Since 3 June 2024, in Great Britain, temporary emergency restrictions have been in place preventing the use of gonadotrophin releasing hormone (GnRH) analogues used to suppress puberty as part of treatment for gender incongruence or gender dysphoria in children and young people under 18 years of age.

The government has now passed further legislation to maintain the restrictions in Great Britain and extend them to Northern Ireland for the first time. The restrictions will come into effect in Northern Ireland on 27 August 2024 and expire across the UK at the end of 26 November 2024.

The government launched a consultation and engagement exercise, in August 2024, to inform a decision as to whether to make the restrictions permanent.

Who will be affected most from the extended restrictions?

People who are planning to receive – or who were previously receiving – a private prescription for GnRH analogues for any reason from a professional who is in the European Economic Area (EEA) or Switzerland, but not UK-registered, will continue to be impacted.

Pharmacies in Great Britain remain unable to dispense private prescriptions, dated on or after 3 June 2024, for GnRH analogues from the EEA or Switzerland for anyone under 18 years old. This applies in Northern Ireland from 27 August 2024.

Who will be less affected but may need advice and reassurance?

Individuals who are already receiving NHS or private prescriptions from a UK prescriber can continue to receive their prescriptions.

However, they and/or their families are strongly advised to meet with their prescribing clinician to fully understand the safety risks associated with GnRH analogues when prescribed for gender incongruence or gender dysphoria.

Information for patients can be found on the website for the <u>NHS National Referral Support</u> <u>Service for the Children and Young People's Gender Service</u>.

What are the specifics of the restrictions?

As a result of the government policy, it remains a **criminal offence** for a doctor, pharmacist or any other individual in Great Britain (and becomes an offence in Northern Ireland) to sell or supply these drugs to patients under the age of 18 – **except in the following circumstances:**

- The child or young person is prescribed these medicines on an NHS prescription (for example, from the NHS Children and Young People's Gender Service). All NHS prescriptions and directions are outside of this ban.
- The child or young person is prescribed these medicines on a private prescription from a UK prescriber that fulfils the following criteria:
 - The prescription was dated prior to 3 June 2024 in Great Britain (27 August 2024 in Northern Ireland).

or

- It is a repeat prescription but only when the initial prescription was written in the 6 months prior to 3 June 2024 in Great Britain (27 August 2024 in Northern Ireland).
- There are also requirements for prescriptions issued from 3 June 2024 in Great Britain (27 August 2024 in Northern Ireland) to be marked with the person's age, annotated by the prescriber with "SLS", and in the case of prescriptions issued before that date, for the person to provide proof of identity and age.
- The prescription is for a purpose other than the treatment of gender incongruence or gender dysphoria, or for gender incongruence/dysphoria if the patient started treatment for gender incongruence/dysphoria before 3 June 2024 in Great Britain (27 August 2024) in Northern Ireland.

Additionally, general practitioners (GPs) in England are only able to supply prescriptions for GnRH analogues in the following circumstances:

- The patient is aged 18 years or over.
- or
- The patient is under 18 years old, and the purpose of the prescription is for a medical condition other than gender incongruence or gender dysphoria.
- or
- The patient is under 18 years old and has started treatment with these medicines, and for these purposes they will be treated as having started treatment if they have been issued with a prescription for these medicines since 3 December 2023, even if they have not yet started taking the medicines.

As indicated above, new private prescriptions for GnRH analogues, from a prescriber in the EEA or Switzerland who is not UK-registered, are banned from being supplied in the United Kingdom in all circumstances for patients aged under 18.

For patients aged 18 or over with a prescription from an EEA or Switzerland-registered prescriber, their prescription can be dispensed in the United Kingdom, providing verification of age and identity can be shown to the dispensing pharmacist.

The effect of the order is that emergency supply under the Human Medicines Regulations 2012 is prohibited.

Further information about specific cases can be found in Appendix 1 of this guidance.

These restrictions are reflected in the Drug Tariff, and in the dictionary of medicines and devices.

Support for children and young people affected

We understand some children and young people and families may be concerned or distressed by the initial government restrictions and their extension.

If they are already under the care of Children's and Young People's (CYP) mental health provider/Child and Adolescent Mental Health Services (CAMHS) they can contact their team for advice.

If they are not, their GP team should offer to see and assess whether referrals for the CYP Gender Service or for mental health support are required.

Patients can also be signposted to advice on getting mental health support available at <u>NHS.UK</u>. Anyone in need of urgent support can contact NHS 111 and choose the mental

health option (option 2). The NHS.UK website also has information on where to get urgent help for mental health.

NHS England published national clinical policy on puberty suppressing hormones on 12 March 2024 alongside an evidence review; these can be found on the <u>NHS England website</u>.

The General Pharmaceutical Council has published a resource for pharmacy professionals to support them in providing information, support and services to children and young people with gender incongruence or dysphoria: <u>'Gender identity services for children and young people: making compassionate, professional and ethical decisions'</u> (via pharmacyregulation.org).

Appendix 1: Advice for prescribers and dispensers

Puberty suppressing hormones

Patient group

Under 18 years old and not prescribed GnRH analogues

Advice

Nobody who is under 18 years old should be started on GnRH analogues to supress puberty for gender incongruence or gender dysphoria.

Prescriber

The initiation of GnRH analogues is not possible in the NHS specialist Children and Young People's Gender Service unless this is part of a future NIHR research study, or the patient was referred to an NHS paediatric endocrinology team for assessment of suitability of GnRH analogues for gender incongruence or gender dysphoria on or before 31 March 2024.

Other NHS clinicians cannot initiate a new NHS prescription from 26 June 2024.

Private practitioners cannot initiate a new prescription from 3 June 2024 to patients who have not yet started treatment.

Dispenser: Pharmacies in Great Britain cannot dispense a new (initiation) prescription issued by a prescriber, unless the patient started treatment before the restrictions came into effect.

This includes prescriptions issued in the UK, European Economic Area (EEA) or Switzerland.

Patient group

Patient is under 18 years old and already being prescribed GnRH analogues **through the NHS** for gender incongruence or gender dysphoria.

Advice

Patients under 18 are strongly advised to meet with their clinician to fully understand the risks of continuing taking GnRH analogues for puberty suppression.

These medications can be stopped and do not need to be weaned off.

Prescriber

If, during a shared decision-making conversation considering the risks, a decision is made to continue, the Children and Young People Gender Service or another NHS clinician can continue to prescribe.

NHS prescriptions in primary care must be marked SLS if they are issued on or after 26 June 2024.

Dispenser

NHS primary care prescriptions for continuation of existing treatment marked SLS may be dispensed. NHS prescriptions are not covered by the Prohibition Order.

Patient group

Patient is under 18 years old and is already being prescribed GnRH analogues by a **UKregistered private practitioner** in Great Britain for gender incongruence or gender dysphoria.

Advice

Patients under 18 are strongly advised to meet with their clinician to fully understand the risks of continuing taking GnRH analogues for puberty suppression.

These medications can be stopped and do not need to be weaned off.

Prescriber

If during a shared decision-making conversation considering the risks a decision is made to continue the private practitioner can continue to prescribe.

New prescriptions must be marked SLS and include the patient's age.

Dispenser

Private prescriptions for continuation of existing treatment marked SLS and including the patient's age may be dispensed.

Existing prescriptions, issued before 3 June 2024, can only be supplied if proof of age and identity is produced.

Patient group

Patient under 18 years old and is already being prescribed GnRH analogues through a prescription from the **EEA or Switzerland** for gender incongruence or gender dysphoria.

Advice

Patients under 18 are strongly advised to meet with their clinician to fully understand the risks of continuing taking GnRH analogues for puberty suppression.

These medications can be stopped and do not need to be weaned off.

Prescriber

An NHS prescriber (including the GP) or private UK prescriber can decide to start to prescribe GnRH analogues to maintain continuity of care if they consider it appropriate to do so.

The prescription needs to be endorsed 'SLS' to satisfy NHS Regulations.

For a GP to (for the first time) prescribe continuation of medicine, they would need to take due diligence to determine whether the patient had been issued with a prescription in the 6-month period before 3 June 2024.

This would need to be in the form of documentary evidence. The form of the evidence (letters, prescriptions...) which a GP should rely on to decide whether a course of treatment has started has not been specified in legislation, but whether treatment has previously started is ultimately a question of fact. The GP should document how they have confirmed there have been previous prescriptions.

However, as the EU-based service who initiated the prescription is outside the jurisdiction of UK health regulators, the prescriber must only agree to continuing the prescribing if they feel competent to do so; and they are reassured about the professional competence of the EU-based service in its diagnosis of the patient and its decision to initiate prescribing; and only if they conclude that continuation is in the best interests of the patient.

Alternatively, if a decision is made that prescriptions should be discontinued, they should consider the individual's need for further professional support such as a referral to CYP mental health or to the specialist gender pathway.

Dispenser

Prescriptions from EEA or Switzerland for GnRH analogues for puberty suppression cannot be dispensed unless they were issued before 3 June 2024 and are still valid, and the dispenser has proof of age and identity.

Patient group

Patient is under 18 years old and is an **overseas visitor** who has run out of their GnRH analogues for gender incongruence or gender dysphoria.

Advice

The patient may see a private practitioner, or temporarily register with a GP for advice and support.

Prescriber

If the patient started treatment before 3 June 2024, the private practitioner or the GP can prescribe a repeat prescription if this is within their clinical scope of practice, and they are satisfied this is urgently needed continuation therapy.

Prescription must be marked SLS and have proof of age.

Dispenser

The patient should secure further medications from their home nation specialist if possible.

However, a private prescription marked SLS from 3 June 2024, or an NHS prescription marked SLS from 26 June 2024, for continuation of treatment may be dispensed.

Patient group

Patient is **18 years or older** and remains on GnRH analogues and have not started on gender affirming hormones.

Advice

Patients are strongly advised to meet with their clinician to fully understand the risks of continuing taking GnRH analogues for puberty suppression.

These medications can be stopped and do not need to be weaned off.

Prescriber

Patients are advised to meet with their clinician so that the risks of continuation are fully understood.

If after a shared decision-making conversation, the patient wishes to continue treatment the practitioner can continue NHS or private prescribing.

Prescription must be marked SLS.

Dispenser

NHS prescriptions from 26 June 2024, or private prescribers from 3 June 2024, marked SLS may be dispensed.

In the latter case, if it is not marked SLS, the patient may instead provide proof of age and identity.

Prescriptions from the EEA or Switzerland can be dispensed if the patient is able to provide proof of age and identity.

SLS cannot be used by such prescribers.

Gender affirming hormones

GnRH analogue are being prescribed **NOT** for the purpose of puberty suppression

Patient group

Patient is under 18 years old and not yet taking gender affirming hormones.

Advice

No-one under 18 years old should be **initiated** on gender affirming hormones by the NHS (except by Children and Young People's Gender Service, in extreme circumstances).

Prescriber

NHS prescribers are advised not to initiate gender affirming hormones under the age of 18.

Children and Young People's Gender Service will consider initiating this treatment in extreme circumstances.

A private practitioner may after a shared decision-making conversation about the risks initiate prescriptions for GnRH analogues as part of gender affirmation.

Prescription must be marked SLS.

Dispenser

NHS GnRH analogue prescriptions may not be dispensed unless marked SLS.

Private prescriptions marked SLS may be dispensed.

Prescriptions from the EEA or Switzerland for GnRH analogues cannot be dispensed.

Patient group

Patient is under 18 years old and is already being prescribed GnRH analogues **by the NHS** as part of gender affirmation and not for purpose of puberty suppression.

Advice

Patients are advised to continue taking GnRH analogues as part of gender affirmation.

They should consult their prescriber if they wish to consider withdrawing.

Prescriber

Patients should have a shared decision-making conversation about risks of treatment with the CYP Gender Service or other NHS prescriber.

If the patient decides to continue treatment this can be prescribed.

Prescription must be marked SLS.

Dispenser

NHS prescriptions continuing treatment marked SLS may be dispensed.

Patient group

Patient is under 18 years old and is already being prescribed GnRH analogues **by a private practitioner in England** as part of gender affirmation, and not for purpose of puberty suppression.

Advice

Patients are advised to continue taking GnRH analogues as part of gender affirmation. They should consult their prescriber if they wish to consider withdrawing.

Prescriber

Patients should have a shared decision-making conversation about risks of treatment with their private prescriber.

If the patient wishes to continue treatment the private practitioner (or an NHS prescriber, where appropriate) can continue to prescribe.

Prescription must be marked SLS.

Dispenser

Private and NHS prescriptions for continuation of treatment marked SLS may be dispensed.

Prescriptions from the EEA or Switzerland for GnRH analogues cannot be dispensed.

Patient group

Patient is under 18 years old and is already being prescribed GnRH analogues **through a prescription from the EEA or Switzerland** as part of gender affirmation, and not for the purpose of puberty suppression.

Advice

This treatment should **not** be withdrawn abruptly.

Patients are advised to meet with the clinician who initiated treatment for further advice and support.

If that is not possible, they should meet with their GP or specialist to consider options.

Prescriber

Private or NHS prescribers may prescribe treatment for these patients following a shared decision-making conversation about the risks of treatment.

Prescription must be marked SLS.

Dispenser

Prescriptions from EEA or Switzerland for GnRH analogues cannot be dispensed.

NHS or private prescriptions marked SLS may be dispensed.

Patient group

Patient is **under** 18 years old and **visiting the UK** and has run out of their GnRH analogues as part of gender affirmation.

Advice

The patient may see a private practitioner, or temporarily register with a GP for advice and support.

Prescriber

The private or NHS prescriber can prescribe a repeat prescription if this is within their clinical scope of practice, and they are satisfied this is urgently needed continuation therapy.

Prescription must be marked SLS.

Dispenser

The patient should secure further medications from their home nation specialist if possible.

However, a private or NHS prescription for continuation of treatment may be dispensed.

Prescriptions from the EEA or Switzerland for GnRH analogues cannot be dispensed.

Patient group

Patient is **over** 18 years old and **visiting the UK** and has run out of their GnRH analogues as part of gender affirmation.

Advice

The patient may see a private practitioner, or temporarily register with a GP for advice and support.

Prescriber

The private or NHS prescriber can prescribe a repeat prescription if this is within their clinical scope of practice, and they are satisfied this is urgently needed continuation therapy.

Prescription must be marked SLS.

Dispenser

Prescriptions from NHS prescribers marked SLS may be dispensed if the patient is able to provide proof of age and identity.

Prescriptions from private prescribers, if not marked SLS, the patient may instead provide proof of age and identity.

Prescriptions from the EEA or Switzerland can be dispensed if the patient is able to provide proof of age and identity.

Prescriptions for GnRH analogues for conditions not including gender dysphoria or gender incongruence

Patient group

Patient is under 18 years old and is already being prescribed GnRH analogues for other reasons.

Advice

NHS and private patients can continue to receive prescriptions.

Patients receiving a prescription from an EEA or Swiss registered prescriber are advised to seek advice from their GP or private practitioner.

Prescriber

NHS and private prescriptions can be issued.

Both NHS and private prescriptions for GnRH analogues need to be endorsed SLS by the prescriber to demonstrate that the prescription is in accordance with the new arrangements.

Dispenser

Both NHS and private prescriptions endorsed SLS can be dispensed.

Prescriptions from the EEA or Switzerland registered for GnRH analogues cannot be dispensed.

Patient group

Patients 18 years old and over who are already being prescribed GnRH analogues for other reasons.

Advice

Patients will be able to continue to receive their prescriptions.

Prescriber

Both NHS and private prescriptions for GnRH analogues need to be endorsed SLS by the prescriber to demonstrate that the prescription is in accordance with the new arrangements.

Dispenser

Prescriptions from NHS prescribers marked SLS may be dispensed if the patient is able to provide proof of age and identity.

Prescriptions from private prescribers, if not marked SLS, the patient may instead provide proof of age and identity.

Prescriptions from the EEA or Switzerland can be dispensed if the patient is able to provide proof of age and identity.