

June 2024 (Revised 28 June 2024)

Briefing: 011/24: New restrictions on the prescriptions and supply of puberty blockers

Regulations have been introduced to restrict the prescribing and supply of puberty suppressing hormones / gonadotrophin releasing hormone (GnRH) analogues to children and young people under 18 for the purposes of gender dysphoria / gender incongruence.

During the period of the emergency ban (currently from 3 June to 3 September 2024), no new patients under 18 will be allowed to begin use of these medicines for the purposes of puberty suppression in those experiencing gender dysphoria/incongruence, outside of designated specialist NHS services.

Children and young people under 18 already established on these medicines for these purposes can continue to receive these medicines from a UK-registered prescriber, but generally the prescriptions must be endorsed 'SLS' by the prescriber.

Children and young people under 18 already established on these medicines for these purposes **cannot** access these medicines using a prescription issued after 3 June 2024 by an EEA-or Swiss-registered prescriber.

Patients over 18 years of age can continue to receive these medicines, but for private prescriptions either the prescription must be endorsed 'SLS' by the prescriber or the pharmacy must see proof of the patient's identity and age before dispensing the medicine. For NHS prescriptions, the prescription must be endorsed 'SLS' by the prescriber.

NHS BSA will reimburse in line with the Drug Tariff any NHS prescriptions not endorsed 'SLS' from 26th June onwards.

For full guidance, you should refer to the <u>NHS England guidance</u> which provides information on:

- Specifics of the change and who it will affect,
- Support for children and young people affected by this change





 Advice for prescribers and pharmacy teams (including for prescriptions for those 18 or over)

FAQs

- 1. What is being banned? (See also the answers to question 7)
- Dispensing of GnRH analogues through a prescription issued by an EEA- or Swissregistered prescriber, for anyone under 18.
- Dispensing of GnRH analogues through a prescription issued by a UK-registered private prescriber for anyone under 18, if they are to be used for treating gender dysphoria/ gender incongruence, unless the patient is already established on these medicines.
- Prescribing of GnRH analogues within NHS primary care for anyone under 18, if they are to be used for treating gender dysphoria/ gender incongruence, unless the patient is already established on these medicines.

2. What is being permitted?

- Prescribing and dispensing of GnRH analogues for adults aged 18 or over.
- Prescribing or dispensing of GnRH analogues to patients under 18 for the purposes of treating gender dysphoria/ gender incongruence, if the patient is already established on them, and if the prescription is a UK private or NHS prescription – i.e. not if the prescription is issued by an EEA/Swiss registered prescriber.
- Prescribing or dispensing of GnRH analogues to patients under 18 for other purposes than treating gender dysphoria/ gender incongruence – but again not if the prescription is issued by an EEA- or Swiss-registered prescriber.

3. What legislation has introduced these changes?

• Two Statutory Instruments have been laid on 29 May 2024 to introduce these changes:





An emergency Order under section 62 of the Medicines Act 1968 that applies to prescriptions from the UK independent sector and EEA (and Switzerland) prescribers. <u>The Medicines (Gonadotrophin-Releasing Hormone Analogues) (Emergency Prohibition)</u> (England, Wales and Scotland) Order 2024 (legislation.gov.uk)

AND

Regulations in parallel under the NHS (General Medical Services Contracts) Regulations that apply to prescribing within NHS primary care. <u>The National Health Service (General Medical</u> <u>Services Contracts) (Prescription of Drugs etc.) (Amendment) Regulations 2024</u> <u>(legislation.gov.uk)</u>.

4. When do these changes become effective?

 The emergency order came into effect on 3rd June and remains in place until at least the end of the day on 2nd September. The NHS regulations will come into effect on 26th June and remain in place indefinitely.

5. What medicines are covered by these arrangements?

The new arrangements apply to medicines that consist of or contain buserelin, gonadorelin, goserelin, leuprorelin acetate, nafarelin, or triptorelin. This includes, but is not limited to, medicines sold under the brand names: Decapeptyl[®], Gonapeptyl Depot[®], Salvacyl[®], Prostap[®], Staladex[®], Zoladex[®], Synarel[®]. Refer to Appendix 1 for a full list of medicines covered by the arrangements.

6. What are the accepted proofs of age and identity?

 Valid proof of age and identity include a passport or driving licence, a UK birth certificate, a current national identity document, a blue badge, specified passes for local travel, and a PASS card. A full list can be found at <u>Accepted forms of photo ID | Electoral Commission</u>. Pharmacists will need to be satisfied that they can verify the patient's age and identity.





7. What do you do if a prescription for a GnRH analogue is not annotated with SLS, where required?

If a medicine which is found in the Selected List Scheme (Part XVIIIB of DT), or which is required to be endorsed under the emergency Order, has not been endorsed by the prescriber, the prescription for a child or young person under 18 would need to be returned to the prescriber for amendment. The 'SLS' endorsement must be added by the prescriber to confirm the product has been prescribed in accordance with the Regulations and/or the Order – a dispenser / pharmacy staff must not add this endorsement themselves. Please see below when SLS endorsement is required on prescriptions for GnRH analogues.

EEA/Swiss prescriptions

- Private prescriptions for patients under 18 years of age issued by EEA/Swiss prescribers issued after 3 June 2024 may not be dispensed.
- Private prescriptions for patients over 18 years of age issued by EEA/Swiss prescribers may be dispensed. The pharmacy must see proof of age and identity of the patient before dispensing the prescription.

Private prescriptions – UK prescriber

- Private prescriptions dated 3 June 2024 or later for patients under 18 years of age and already on established treatment with GnRH analogues may be dispensed, but the prescription must have the SLS endorsement and the patient's age to be dispensed.
- Private prescriptions dated 3 June 2024 or later for patients over 18 years of age may be dispensed if the prescription has the SLS endorsement and the patient's age. If the SLS endorsement is missing, the pharmacy must see proof of the age and identity of the patient before dispensing the prescription.

NHS prescriptions – UK prescriber – all must have the SLS endorsement





 NHS prescriptions issued 26 June 2024 or later for patients under 18 years of age and already on established treatment with GnRH analogues, must have the SLS endorsement.

 NHS prescriptions dated 26 June 2024 or later for patients over 18 years of age may be dispensed if the prescription has the SLS endorsement.

Related links

In addition to the communications published by the government, further information and advice can be found in the following resources:

- NHS England: <u>Clinical Policy: puberty suppressing hormones</u> (NHS England has also issued a <u>letter</u> with advice for patients in light of new Government restrictions on the prescription and supply of puberty blockers).
- **RPS:** <u>New restrictions on the prescription and supply of puberty blockers</u>
- The Cass Review: <u>Final Report</u>

If you have any queries or require more information, please contact: <u>regulations.team@cpe.org.uk</u>





Appendix 1: List of drugs covered by the arrangements

Generic Name	Actual Medicinal Product Pack	VMPP Code	AMPP Code
Buserelin 150micrograms/dose nasal	Suprecur 150micrograms/dose nasal spray (Neon	4256411000001103	4256611000001100
spray	Healthcare Ltd) 168 dose 2 x 84 doses		
Buserelin 5.5mg/5.5ml solution for	Suprecur 5.5mg/5.5ml solution for injection vials (Neon	3928711000001105	3929611000001105
injection vials	Healthcare Ltd) 2 vial		
Buserelin 5.5mg/5.5ml solution for	Suprefact 5.5mg/5.5ml solution for injection vials (Neon	3928711000001105	3929311000001100
injection vials	Healthcare Ltd) 2 vial		
Gonadorelin 100microgram powder for	Gonadorelin 100microgram powder for solution for injection	35843411000001106	35843611000001109
solution for injection vials	vials (Esteve Pharmaceuticals Ltd) 1 vial		
Goserelin 10.8mg implant pre-filled	Zoladex LA 10.8mg implant SafeSystem pre-filled syringes	1030111000001107	2481711000001100
syringes	(AstraZeneca UK Ltd) 1 pre-filled disposable injection		
Goserelin 3.6mg implant pre-filled	Zoladex 3.6mg implant SafeSystem pre-filled syringes	1311811000001101	2481111000001101
syringes	(AstraZeneca UK Ltd) 1 pre-filled disposable injection		
Leuprorelin 10.72mg implant pre-filled	Staladex 10.72mg implant pre-filled syringes (Aspire Pharma	38001711000001104	38001911000001102
syringes	Ltd) 1 pre-filled disposable injection		
Leuprorelin 11.25mg powder and solvent	Prostap 3 DCS 11.25mg powder and solvent for suspension		
for suspension for injection pre-filled	for injection pre-filled syringes (Takeda UK Ltd) 1 pre-filled	19305711000001103	19306011000001109
syringes	disposable injection		







Generic Name	Actual Medicinal Product Pack	VMPP Code	AMPP Code
Leuprorelin 3.75mg powder and solvent	Prostap SR DCS 3.75mg powder and solvent for suspension		
for suspension for injection pre-filled	for injection pre-filled syringes (Takeda UK Ltd) 1 pre-filled	19305011000001100	19305211000001105
syringes	disposable injection		
Nafarelin 200micrograms/dose nasal	Synarel 200micrograms/dose nasal spray (Pfizer Ltd) 30	3822411000001107	3822711000001101
spray	dose		
Nafarelin 200micrograms/dose nasal	Synarel 200micrograms/dose nasal spray (Pfizer Ltd) 60	3822411000001107	3822811000001109
spray	dose		
Triptorelin 11.25mg powder and solvent	Decapeptyl SR 11.25mg powder and solvent for suspension	8172711000001105	8172911000001107
for suspension for injection vials	for injection vials (Ipsen Ltd) 1 vial		
Triptorelin 11.25mg powder and solvent	Salvacyl 11.25mg powder and solvent for suspension for	8172711000001105	34732611000001105
for suspension for injection vials	injection vials (Ipsen Ltd) 1 vial		
Triptorelin acetate 3.75mg powder and	Gonapeptyl Depot 3.75mg powder and solvent for		
solvent for suspension for injection pre-	suspension for injection pre-filled syringes (Ferring	5614711000001100	5615811000001109
filled syringes	Pharmaceuticals Ltd) 1 pre-filled disposable injection		
Triptorelin acetate 3mg powder and	Decapeptyl SR 3mg powder and solvent for suspension for	4146411000001103	4146611000001100
solvent for suspension for injection vials	injection vials (Ipsen Ltd) 1 vial		
Triptorelin embonate 22.5mg powder	Decemental SP 22 Emg newdor and solvent for succession		
and solvent for suspension for injection	Decapeptyl SR 22.5mg powder and solvent for suspension	18478511000001101	18479711000001102
vials	for injection vials (Ipsen Ltd) 1 vial		

