



SERIOUS SHORTAGE PROTOCOL (SSP)

Reference Number: SSP010

This SSP applies to the following medicine:

Name of medicine (including strength and formulation)	Levothyroxine 12.5 microgram tablets
Legal category	POM

1. Details of medication to be supplied under this SSP

Name of medicine (including formulation and strength) to be supplied	Levothyroxine 25 microgram tablets
Quantity of this formulation (if applicable)	<p>Total quantity supplied under this protocol to be equivalent to the number of days treatment supplied on original prescription.</p> <p>For every 2 x levothyroxine 12.5 microgram tablets originally prescribed, the following quantity must be supplied in accordance with this protocol:</p> <p>1 x 25 microgram levothyroxine tablet must be supplied</p>
Dosage	<p>Where the original dosage regime is 1 x levothyroxine 12.5 microgram tablet daily, the dosage regime will be amended to:</p> <p>1 x 25 microgram levothyroxine tablet to be taken on alternate days*</p> <p>*Levothyroxine has a long half-life and because of this it is not uncommon for patients to have varying doses on different days.</p>
Substitution results in a change to whether the use is licenced	Yes, alternate daily dosing regime is off-label

Scope for which this Serious Shortage Protocol (SSP) applies

The SSP applies to the following parts of the UK	England, Wales and Scotland
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Clinical situation to which this Serious Shortage Protocol (SSP) applies

Scope of SSP	<p>All NHS and private prescriptions.</p> <p>This protocol does not allow for the quantity supplied to be less treatment days than the number of treatment days prescribed on original prescription.</p>
Criteria for inclusion	<ul style="list-style-type: none"> • The patient presents with a valid prescription (meeting the requirements of the Human Medicines Regulations 2012) for levothyroxine 12.5 microgram tablets. • The patient/carer consents to receiving the medicine supplied under this SSP. • The patient should only be supplied in accordance with this SSP, if the pharmacist is satisfied the patient understands and is able to accommodate alternate daily dosing regime and understands the risk of taking the medicine every day.
Criteria for exclusion	<ul style="list-style-type: none"> • Where the pharmacist, using their professional judgement, determines that the patient is not suitable to receive alternative dosage regime in accordance with this SSP, whilst also taking into account its off-label use. • The patient presents with a prescription for a medicine other than levothyroxine 12.5microgram tablets. • The patient presents a prescription which is not valid. • The patient/carer does not consent to receiving the medicine(s) supplied under this SSP. • Patients who have had previous allergic reaction to levothyroxine 25 microgram tablets or their excipients. • All patients aged 18 years of age or under. • Patients considered unstable or at higher risk need to be referred back to their prescriber promptly for further advice.
Cautions including any relevant action to be taken	<ul style="list-style-type: none"> • Ensure that the pharmacist explains to patients for whom this protocol is going to be supplied to, on how to recognize and respond to signs of toxicity. • Ensure that patients considered unsuitable for inclusion are promptly referred to their prescriber for further advice.

Special considerations for specific populations of patients	<ul style="list-style-type: none"> Consider if it would be helpful to provide with an aide-memoire or record to keep track of the days when they took their medicine.
Action to be taken if the patient is excluded	<ul style="list-style-type: none"> If a patient does not meet the criteria within this SSP then they should be referred back to their prescriber promptly.
Action to be taken if the patient or carer declines the supply	<ul style="list-style-type: none"> If a patient/carer declines to receive medicine under this SSP then they should be referred back to their prescriber promptly.

Valid from:	3 February 2021
Expiry date:	5 March 2021
Reference number:	SSP010
Version number:	1.0

Any queries regarding the content of this SSP which was issued by the Secretary of State for Health and Social Care, should be addressed to NHS Prescription Services.

You can get in contact by:

Email: nhsbsa.prescriptionservices@nhsbsa.nhs.uk

Telephone: 0300 330 1349

Textphone: 18001 0300 330 1349

You can also write to us at:


Newcastle	Middlebrook	Wakefield
NHS Prescription Services Bridge House 152 Pilgrim Street Newcastle upon Tyne NE1 6SN	NHS Prescription Services Ridgway House Northgate Close Middlebrook Horwich Bolton BL6 6PQ	NHS Prescription Services 4th Floor Wakefield House Borough Road Wakefield WF1 3UB

Change history

Version number	Change details	Date

2. Conditions under which this Serious Shortage Protocol (SSP) will operate

- The decision to supply any medicine under this protocol rests with the individual registered pharmacist who must abide by the protocol.
- Whilst pharmacy staff may support the dispensing process of the protocol, this must be carried out under the supervision of the registered pharmacist.
- Pharmacists using this SSP must ensure that it is only used within its authorised dates and within the criteria set out within the SSP. Pharmacists must check that they are using the current version of the SSP, particularly when referring to a hard copy version. Amendments may become necessary prior to the published expiry date. Current versions of SSP templates can be found at <https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/serious-shortage-protocols-ssps>.
- Users must not alter, amend or add to the content of this document; such action will invalidate the SSP.

Ministerial ratification by:			
Name	Position	Signature	Date
Lord Bethell	Minister for Innovation, DHSC		03.02.21

ADDENDUM

Supporting information on notifying other healthcare professionals

- Any items supplied in accordance with an SSP in response to an NHS prescription also needs to be supplied in accordance with NHS Pharmaceutical and Local Pharmaceutical Services Regulations.
- Those Regulations provide that where a therapeutic equivalent is supplied, a pharmacist will need to inform a patient's GP practice. This would generally be expected within the next working day, but further guidance would be given in any case where this applied.
- Where a different quantity, an alternative pharmaceutical form, an alternative strength or a generic equivalent is provided, it may not always be necessary that the patient's prescriber is informed, as the existence of the SSP may be enough for the prescriber to be aware that these changes in dispensing may take place, unless national arrangements agreed with the relevant representative bodies state otherwise. However, guidance may be issued on particular SSPs to indicate that prescribers should be informed of any patients that receive supply under it.
- In the absence of any preferred local alternate communication channels, all feedback to prescribers should be sent by NHSmail. The NHS 111 Directory of Service finder is a way for pharmacies to look up the email address of the patient's GP.