



Australian Government

Department of Health,
Disability and Ageing

Life Saving Drugs Program (LSDP)

Initial application form for subsidised treatment for Hereditary Tyrosinaemia Type I (HT1)

About this Program

The LSDP is administered by the Department of Health, Disability and Ageing (the Department). Access to treatment for HT1 is provided in accordance with the [Guidelines for the treatment of HT1 through the Life Saving Drugs Program](#) (the Guidelines).

It is recommended that you read the Guidelines before completing this application form.

Patient Administration

Patient applications are processed within 30 calendar days of the receipt of the complete data package to support the application.

Should subsidised treatment be approved, it is the responsibility of the treating physician to ensure that the patient/patient's family is informed of:

- a) Treatment arrangements, including approved dose
- b) The requirement to submit a reapplication for subsidised treatment through the LSDP by 1 May each year to request ongoing subsidised treatment
- c) The requirement to notify the LSDP in writing immediately if a change to the treatment location is planned and
- d) The requirement to notify the LSDP in writing immediately if treatment is ceased.

Filling in this form

The application form must be filled out by a treating physician with relevant specialist registration, with the consent of the patient or parent/guardian. The patient or their parent/guardian is required to sign the application form to provide consent to the Department to collect personal information.

Please complete electronically, print and sign; or
Use black or blue pen and print in BLOCK LETTERS.

All pages of this application form must be completed and submitted. Incomplete applications will not be processed.

Information Requirements

All assessments to support eligibility, excluding genetic testing, must have been undertaken within the 12 months prior to the date of application.

For more information

For more information go to the LSDP website:
www.health.gov.au/lscp

If you need assistance completing this form, or for more information call **(02) 6289 2336**, Monday to Friday, between 9.00 am and 4.00 pm, Australian Eastern Time.

Submitting your form

Send the completed application form and all relevant attachments:

By email to: lscp@health.gov.au

By fax to: **(02) 6289 8537**

Privacy notice

The Department is collecting personal information about the patient identified on this application form to process this patient's initial application to receive subsidised treatment through the LSDP. If subsidised treatment through the LSDP is approved, the Department will continue to collect personal information about this patient in order to process a confirmation of ongoing eligibility.

If all of the personal information required is not provided, the Department will not be able to process the initial application to confirm eligibility to receive subsidised treatment through the LSDP.

The Department will disclose personal information to this patient's treating physician, pharmacists, clinic nurses and other health care professionals who may be involved in the administration of this patient's treatment.

The Department will disclose this patient's personal information including Medicare number to Services Australia in order to confirm Medicare eligibility and permanent Australian residency requirements.

'De-identified' personal information will be used for the purpose of the evaluation of the LSDP, which may include the provision of these data to third parties contracted by the Department for this purpose.

The Department has an Australian Privacy Principles (APP) privacy policy which can be read at <https://www.health.gov.au/resources/publications/privacy-policy>

The Department can be contacted by telephone on (02) 6289 1555 or freecall 1800 020 103 or by using the online enquiries form at www.health.gov.au

A copy of the APP privacy policy can be obtained by contacting the Department using the contact details set out above. The APP privacy policy contains information about:

- how to access personal information the Department holds and how to seek correction of it; and
- how to complain about a breach of the APP.

The Department is unlikely to disclose personal information to overseas recipients.

Patient's details

Medicare card number

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Ref no.

Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other ☐

Given name

Family name

Residential address

Suburb

State

Post Code

Date of birth

Consent to collection of sensitive information for treatment and after cessation of treatment

I consent to the Department collecting genetic and health information about the patient identified on this application form for the purpose indicated above.

I consent to the Department requesting and obtaining sensitive information and supplemental information from my treating physician regarding the reason(s) for ceasing treatment including cause of death, if applicable.

If this information is not able to be obtained from my treating physician, I consent to the Department requesting and obtaining this information from other Government agencies and non-government organisations.

The information collected in this process is for the purpose of determining the cause of discontinuation of subsidised treatment.

Continuing eligibility for subsidised treatment for HT1 through the LSDP

I understand that:

- if I/the patient fail to comply with the associated monitoring and assessment requirements, without an acceptable reason to do so, I/the patient will no longer be eligible to receive subsidised treatment through the LSDP.
- if treatment does not result in a clinically meaningful effect, subsidised treatment through the LSDP may be discontinued.

Signature

Patient ☐ Parent ☐ Responsible Person* ☐ (tick one only)

Full name (print in BLOCK LETTERS)

Date

*A Responsible Person is an individual authorised to act on behalf of the patient and can include (please tick only one as appropriate):

- A guardian of the patient who is a child ☐
- An enduring guardian ☐
- A person with an enduring power of attorney in relation to the patient, recognised under a relevant state or territory law ☐
- A person who has been nominated in writing by the patient while the patient was capable of giving consent ☐
- A person authorised to act on the patient's behalf as recognised by other relevant laws ☐

Treating physician's details

Prescriber number

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Given name

Family name

Work phone number

Mobile phone number

Email address

Hospital/Department

Postal address

Suburb

State

Post Code

--	--	--

Clinic nurse's details

Given name

Family name

Work phone number

Email address

Hospital/Department

Postal address

Suburb

State

Post Code

--	--	--

Pharmacist's details

Given name

Family name

Work phone number

Email address

Hospital/Department

Delivery address (for LSDP stock)

Suburb

State

Post Code

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Secondary pharmacy contact's details

Given name

Family name

Work phone number

Email address

Dosing details

Form of nitisinone requested

Orfadin capsules ☐

Orfadin oral suspension ☐

Patient's weight

kg

Dosage of medicine requested: (eg. x mg/kg/day)

The LSDP requires the below information to determine the quantity of suspension/capsules to be supplied to your patient each month.

Prescriptions are to be written in accordance with the Product Information.

For patients who require twice daily dosing, please indicate the dosing regime:

MORNING Dose (mg for capsules, mL for Orfadin oral suspension)

EVENING Dose (mg for capsules, mL for Orfadin oral suspension)

Dose adjustments can be requested at any time by emailing lsdp@health.gov.au

Eligibility confirmation checklist

To qualify for LSDP subsidised treatment, all of the following initial eligibility requirements must be met.

The treating physician must initial the box to confirm that the requirement is met.

1. The diagnosis of HT1 has been confirmed by detection of succinylacetone in the urine and/or blood by a National Association of Testing Authorities (NATA) accredited laboratory. ☐

OR

2. The diagnosis of HT1 has previously been confirmed by detection of succinylacetone in the urine and/or blood by a NATA accredited laboratory. ☐

3. Please provide :

a) Test results showing succinylacetone detection in blood and/or urine ☐

AND

b) For patients currently treated with nitisinone, in combination with dietary restriction of phenylalanine and tyrosine, a recent copy of a prescription or hospital dispensing record. ☐

4. The patient does not have any of the conditions listed in the exclusion criteria in the HT1 Guidelines. ☐

5. I have advised the LSDP if the patient is participating in a clinical trial. ☐

Data requirement checklist

6. I have provided a clinic letter outlining the patient's recent medical and surgical history and general description of their health status. ☐

7. I have provided copies of all relevant reports and the completed Excel spreadsheet for HT1. ☐

Treating physician's declaration

I confirm that:

I am the treating physician of the patient as stated in this form, and have relevant specialist registration. I hereby apply for Australian Government subsidised access to treatment for HT1 through the LSDP on behalf of my patient.

I declare that:

- The information provided in this form is complete and correct.
- To the best of my knowledge, my patient is eligible to receive subsidised treatment for HT1 through the LSDP in accordance with the Guidelines.
- I am aware that the patient must be an Australian citizen or permanent Australian resident who qualifies for Medicare.

I understand that:

- I have an ongoing obligation to ensure that my patient continues to meet the eligibility criteria to receive subsidised treatment through the LSDP.
- Making a false or misleading declaration is a serious offence and may lead to further investigations.
- I must submit a separate reapplication for subsidised treatment through the LSDP by 1 May each year if I wish for my patient to continue to receive subsidised treatment.

I agree that:

If I become aware that my patient no longer meets the eligibility criteria for subsidised access to treatment through the LSDP at any time, I will notify the LSDP immediately.

Treating physician's full name

Treating physician signature

Date