



Australian Government

Department of Health,
Disability and Ageing

Life Saving Drugs Program (LSDP) Reapplication form for subsidised treatment for Hereditary Tyrosinaemia Type I (HT1)

Patient ID: HT1

Dosing details

Form of nitisinone requested

Orfadin capsules ☐ Orfadin oral suspension ☐

Patient's weight

 kg

Dosage of medicine requested:

Is this a dose change for the patient?

☐ Yes, this is a dose change ☐ No dose change

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.

Dose (mg for capsules, mL for oral suspension)

MORNING EVENING

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

Eligibility confirmation checklist

The treating physician must initial each box to confirm that the patient meets the eligibility criteria and data requirements for ongoing LSDP subsidised treatment.

1. I have assessed the patient since the initial application/previous reapplication and within the last 12 months. ☐
2. The patient continues to meet all eligibility requirements listed in the [Guidelines for the treatment of HT1 through the Life Saving Drugs Program](#) (the Guidelines). ☐
3. The patient has demonstrated clinical improvement or stabilisation of HT1. ☐
4. The patient has not developed any of the conditions listed in the exclusion criteria in the Guidelines. ☐

Data requirement checklist

5. I have submitted a clinic letter outlining the patient's recent medical and surgical history and general description of their health status. ☐
6. I have provided copies of all relevant reports and the completed Excel spreadsheet for HT1. ☐
7. I confirm the test results and clinic letter provided are not more than 12 months old and have not been used to support a previous application or reapplication. ☐

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 reapply 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 and supporting documents is complete and correct.
- To the best of my knowledge and belief, my patient continues to be 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 continues to qualify 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's signature

Date

Privacy notice

The Australian Government Department of Health, Disability and Ageing (the Department) is collecting this patient's personal information, including sensitive health information, for the purpose of re-assessing this patient's eligibility to receive subsidised treatment for HT1 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 reapplication 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 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 or the Australian Government Agencies Privacy Code and how the Department will deal with complaints.

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

Patient's details

Medicare care 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 the 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 the 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.

Tick only one as appropriate:

Patient ☐ Parent ☐ Responsible Person* ☐

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 ☐

If it is not possible or if it is impracticable to obtain written consent, a member of the patient's clinical care team may obtain verbal consent from the patient or where relevant, the patient's parent or other Responsible Person.

Verbal Consent Form and Privacy Notice

Please read the below Privacy Notice and consent wording to the patient or their parent or Responsible Person; and complete the rest of the form below.

To be read to the patient or their parent or Responsible Person

Privacy Notice

The Australian Government Department of Health, Disability and Ageing (the Department) needs to collect [your/the patient's] personal information, including sensitive health information, from [your/their] treating physician for the purpose of re-assessing [your/the patient's] eligibility to receive subsidised treatment through the LSDP.

[Your/the patient's] personal information being collected by the Department for the purpose of re-assessment includes [your/the patient's]:

- Name
- Address
- Medicare number
- Date of birth
- Genetic and health information
- Sensitive information and supplemental information regarding the reason or reasons for ceasing treatment including cause of death

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

The Department will disclose [your/the patient's] personal information including Medicare number to Services Australia to confirm Medicare eligibility and permanent Australian residency requirements.

The Department will use 'de-identified' information for the purpose of evaluating the LSDP, which may include the provision of de-identified information to third parties contracted by the Department for this purpose.

The Department is unlikely to disclose [your/the patient's] personal information to overseas recipients.

If you do not provide the personal information required, the Department will not be able to process [your/the patient's] reapplication to receive subsidised treatment through the LSDP.

Do you consent to the Department's collection of [your/the patient's] health information from your treating physician?

If the above information cannot be obtained from your treating physician, do you consent to the Department obtaining this information from other government agencies and non-government organisations?

Ongoing eligibility for subsidised treatment for HT1 through the LSDP

Access to treatment through the LSDP is provided in accordance with the *Guidelines for the treatment of HT1 through the Life Saving Drugs Program*. A copy of this Guideline can be found on the Department's website.

Do you understand that subsidised treatment through the LSDP may be discontinued if:

- [you/the patient] fail/s to comply adequately with treatment; or
- [you/the patient] fail/s to provide test results evidencing the effectiveness of the therapy; or
- the treatment does not result in a clinically meaningful effect?

To be completed by the appropriate clinical care team member once verbal consent has been obtained:

Please tick the boxes and complete Parts A to B below.

I have read the above Privacy Notice to the patient or their parent or Responsible Person, or have otherwise explained how the patient's personal information will be collected, used and disclosed for the purposes of the patient's reapplication for continuing treatment through the LSDP. ☐

The patient or their parent or Responsible Person has provided their verbal consent for the patient's personal information to be collected, used and disclosed in the manner described in the Privacy Notice above. ☐

The patient or their parent or Responsible Person understands the requirements for maintaining eligibility for subsidised treatment through the LSDP. ☐

I have recorded the consent of the patient or their parent or Responsible Person in the relevant clinical notes. ☐

Part A: Details of person who provided consent

Please indicate who provided the consent:

Patient ☐ Parent ☐ Responsible Person* ☐

*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 ☐

Name of person providing consent (print in BLOCK LETTERS)

Part B: Details of person who obtained the consent:

Name of person who obtained consent (print in BLOCK LETTERS)

Signature of person who obtained consent

Date