



Life Saving Drugs Program

Fact sheet for treating physicians

This document provides answers to some common questions about the role and responsibilities of treating physicians in prescribing LSDP medicines for eligible patients.

What is the LSDP

The Australian Government provides fully subsidised access for eligible patients with ultra-rare life-threatening diseases to essential medicines through the LSDP.

The LSDP Expert Panel assesses applications to include new medicines on the LSDP. It provides advice to the Australian Government Chief Medical Officer (CMO), including on reviews of existing LSDP medicines. The CMO advises the Minister for Health and Aged Care (the Minister) on medicines suitable for listing.

The Department of Health and Aged Care (the Department) orders medicines for delivery to a nominated pharmacy on behalf of patients. The sponsor delivers the medicines directly to pharmacies to store and dispense to LSDP patients for treatment in a hospital or at home (if appropriate).

What are the contact details for the LSDP?

The LSDP can be contacted via:

- Telephone: (02) 6289 2336
- Email: LSDP@health.gov.au
- Fax: (02) 6289 8537

Medicines currently funded through the LSDP

A list of the LSDP conditions and the medicines currently available for eligible patients can be found on the [About the LSDP](#) web page.

Common questions

Is my patient eligible to receive an LSDP medicine?

A patient must meet the following conditions to receive subsidised medicines through the LSDP:

- Satisfy the relevant criteria for treatment with the medicine, as detailed in the relevant medicine/condition [LSDP Guidelines](#) (with evidence provided as required)
- Participate in the evaluation of effectiveness of the medicine by periodic assessment, as detailed in the relevant LSDP condition Guidelines
- Not be suffering from any other medical condition, including complications or sequelae of the primary condition that might compromise the effectiveness of the medicine treatment, and
- Be an Australian citizen or permanent Australian resident who qualifies for Medicare.

The treating physician must provide a completed and signed application form to the Department on behalf of the patient. As per the declaration on the application form, where a change to a patient's eligibility occurs at any time during treatment, the treating physician must inform the Department immediately.

How can a patient access subsidised treatment?

To apply for a patient to access an LSDP medicine, the treating physician must provide the following information to the Department via the LSDP inbox: lsdp@health.gov.au

- A fully completed initial application form for the specific disease (available on the [LSDP website](#))
- Copies of all required test results as evidence (results must be less than 12 months old)
- A clinic letter (less than 12 months old) to outline your patient's recent medical and surgical history and general description of their health status
- A completed excel spreadsheet for the specific disease (in excel format).

How long does approval take?

The Department must receive all the relevant documentation from the treating physician before an application can be processed.

New applications are prioritised by program staff and are actioned as soon as possible. If the application is urgent, please mark it 'urgent' and provide the reason in the covering letter or email.

Program staff must follow several steps to confirm patient eligibility:

- The application is assessed to see if it is completed correctly, and all the required information submitted.
- Confirmation of Medicare eligibility must be sought from Services Australia.
- Individual test results need to be compared to the requirements in the disease guidelines.
- Documentation must be assessed to determine that all eligibility criteria have been met.
- The prescribed dose needs to be confirmed for appropriateness based on the patient characteristics (for example age or weight).
- The number of vials/tablets required for each dose needs to be calculated to determine the annual cost of treating the patient.
- For complex applications, additional expert advice may be needed prior to processing or making a decision on the application.
- The information is collated, and approval sought from the LSDP approval delegate.

If an application is incomplete, the treating physician will be notified, and the application will be put on hold pending a response. Where an application is complete a decision is provided within 30 days. The majority of applications are processed within 8 days, and most urgent applications will be processed within 48 hours.

What do I have to provide as part of the annual reapplication process?

By 1 May each year, every patient on the LSDP must be reassessed to confirm they remain eligible for and compliant with the requirements of ongoing treatment. This process also ensures that LSDP patients are reviewed by their treating physician (at least) annually.

Where it is not possible for a patient to complete a test required for the reapplication process, their treating physician should advise the LSDP. Tests may be done at any point in the 12-month period (where appropriate).

Please note that the patient will need to sign the consent form each year to consent to ongoing data collection for the purposes of the reviews.

Documentation is to be supplied to lsdp@health.gov.au.

Can my patient participate in a clinical trial while receiving LSDP funded medicine?

In most cases, participation in a clinical trial will not affect a patient's eligibility to access LSDP medicines. However, treating physicians are required to advise the LSDP if their patient is participating in a clinical trial.

Previous involvement in a clinical trial does not affect eligibility for the LSDP.

My patient has returned from a break or clinical trial. Can I reapply on behalf of my patient to the LSDP?

If your patient wishes to reapply to the LSDP following a break due to participation in a clinical trial or any other reason, the reapplication form for the relevant condition must be used.

Please check the relevant guidelines and if unsure, please email lsdp@health.gov.au.

What do I do if my patient wants to change or cease treatment?

A patient must adhere to the treatment regime as well as continue to meet the relevant eligibility criteria to ensure they remain eligible for ongoing subsidised treatment.

If you become aware that your patient wishes to change or cease treatment, you must notify the LSDP team immediately. Please email lsdp@health.gov.au.

How do I request a dose increase?

To request a dose increase within the LSDP Guidelines, please email lsdp@health.gov.au outlining your request, along with the clinical justification.

What do I need to do if my patient wishes to travel?

The patient must notify you, as their treating physician, of the dates of travel. It is the treating physician's responsibility to:

Ensure that the patient is fit to travel and will continue to meet the ongoing eligibility requirements of the LSDP.

Advise the LSDP by emailing lsdp@health.gov.au.

Arrange for a treating physician at the new location (this includes domestic and overseas travel), and

Ensure that the patient is aware that out-of-pocket costs may be incurred for their treatment when travelling outside Australia.

Do patients pay for LSDP medicines?

LSDP medicines are not part of the PBS and therefore are not subject to PBS patient co-payments.

Where a pharmacy (public or private) agrees to participate in the provision of LSDP medicines to patients under the program, the pharmacy must not charge patients a co-payment or similar fee for this service.

Pharmacies may charge a reasonable fee for the provision of a 'cooler' or similar transport and handling material as required provided the patient is advised of the cost and agrees prior to the LSDP medicine being provided.

If you have concerns or questions around charging of fees, please contact lsdp@health.gov.au.

Can patients pick up their LSDP medicine from a community pharmacy?

Yes. If the community pharmacy agrees, the LSDP can deliver your patient's LSDP medicine to a community pharmacy. The obligations of the pharmacy (public or private) are noted above and also available in the Information for Pharmacies leaflet on the LSDP website.

Can a patient collect more than one month's supply of LSDP medicine at a time?

No. Due to the high cost of LSDP medicines, the LSDP only orders and provides one month's supply of medicine for each patient.

Can a patient change their nominated hospital/pharmacy?

Yes. Patients wishing to change their hospital or pharmacy must first contact you as their treating physician to ensure that you have prescribing rights for that hospital and that the nominated pharmacy agrees to provide LSDP medicines.

If you do not have prescribing rights at that hospital, you may need to arrange for a proxy to prescribe for them on your behalf.

Any new nominated hospital or community pharmacy must also agree to participate in the LSDP. A leaflet is available on the [LSDP website](#) that outlines the obligations of a nominated pharmacy.

As the treating physician, you must then notify the LSDP, so that stock is delivered to the new location.

Can my patient change treating physician?

Yes. If a new treating physician takes over the care of the patient, a [Change of Treating Physician form](#) must be submitted to the LSDP.

If I take leave, can I refer my patient to another treating physician?

Yes. When a primary physician is temporarily unavailable (for example, due to holidays or illness), they may transfer care temporarily or seek advice from colleagues in a shared-care manner.

Any treatment of patients in a holiday/shared-care arrangement is generally under instruction from the primary physician so this arrangement does not require a formal transfer of care from one physician to another for the purposes of the LSDP if the duration of the arrangement is less than three months.

The LSDP should be advised of the temporary arrangements, including temporary physician details and start and end date, so that we are aware of the best contact for clinical matters relating to the patient.

Can my patient receive infusions through the home infusion service?

If your patient wishes to commence home infusions, they must contact you as their treating physician.

As the treating physician, you will need to determine if the patient is medically stable, meaning that any infusion-associated reactions are well controlled prior to home infusion.

Most home infusion services are funded by the medicine sponsor (pharmaceutical company) and provided by a contracted nursing agency. As the treating physician, you will need to contact the sponsor to complete an enrolment form which includes patient consent.

Not all LSDP medicines can be delivered via a home infusion service. Please refer to the guidelines for specific information.

Which medicines are available for home infusion?

There are currently seven medicines available for home infusion:

Medicine(s)	Condition
Agalsidase alfa (Replagal®) Agalsidase beta (Fabrazyme®)	Fabry disease
Imiglucerase (Cerezyme®) Velaglucerase (VPRIV®) Taliglucerase (Elelyso®)	Gaucher disease (type 1)
Idursulfase (Elaprase®)	Mucopolysaccharidosis type II (MPS II) disease
Avalglucosidase alfa (Nexviazyme®)	Pompe disease (infantile onset and late-onset)