



Life Saving Drugs Program

Information for patients

About the program

The Life Saving Drugs Program (LSDP) pays for specific essential medicines to treat patients with rare and life-threatening diseases.

Most medicines in Australia are subsidised through listing on the Pharmaceutical Benefits Scheme (PBS). Funding for medicines on the LSDP is separate to the PBS.

The LSDP covers medicines if:

- they are clinically effective, but not cost effective enough to list on the PBS
- they treat life threatening and rare conditions (defined as 1 case per 50,000 people or fewer in the Australian population)
- the pharmaceutical company (sponsor) applies for an LSDP listing.

There are currently 16 medicines available through the program, which treat 10 rare conditions.

Because these medicines are critical for patients, we assess all applications within 30 days. We process most applications in around 7 days.

Medicines covered under the LSDP

This table lists the 16 medicines covered under the LSDP and the conditions they treat.

| Medicine(s) | Condition |
|--|--|
| Agalsidase alfa (Replagal®) Agalsidase beta (Fabrazyme®) Migalastat (Galafold®) | Fabry disease |
| Imiglucerase (Cerezyme®) Velaglucerase (VPRIV®) Taliglucerase (Elelyso®) Miglustat (Zavesca®) | Gaucher disease (Type 1) |
| Nitisinone (Orfadin® and Nityr™) | Hereditary Tyrosinaemia Type I (HTI) |
| Cerliponase alfa (Brineura®) | Late-Infantile Onset Batten disease (CLN2) |
| Laronidase (Aldurazyme®) | Mucopolysaccharidosis Type I (MPS I) |
| Idursulfase (Elaprase®) | Mucopolysaccharidosis Type II (MPS II) |
| Elosulfase alfa (Vimizim®) | Mucopolysaccharidosis Type IVA (MPSIVA) |

| Medicine(s) | Condition |
|-------------------------------|--|
| Galsulfase (Naglazyme®) | Mucopolysaccharidosis Type VI (MPS VI) |
| Eculizumab (Soliris®) | Paroxysmal Nocturnal Haemoglobinuria (PNH) |
| Alglucosidase alfa (Myozyme®) | Pompe disease: Infantile-onset Juvenile Late-onset Adult Late-onset |

How the LSDP works

Several groups of people work together on the LSDP program.

- **Australian Government Department of Health** –funds and administers the program, and orders medicines to be delivered to the patient’s nominated pharmacy.
- **Pharmaceutical companies** – apply to list relevant medicines on the LSDP, if their PBS application was rejected; supply medicines to participating pharmacies.
- **Life Saving Drugs Program Expert Panel (LSDPEP)** – considers applications to list new medicines on the program; advises the Chief Medical Officer; reviews the drugs after 2 years.
- **Chief Medical Officer** – recommends to the Minister for Health if a medicine should be listed on the LSDP or not.
- **Treating physicians** – check if patients are eligible; prescribe the medicines; complete and submit application forms; complete the annual review paperwork.
- **Pharmacists** (usually at hospitals) – dispense medicines to patients according to the program rules.
- **Patients** – take the medicine according to their doctor’s instructions, and follow the program requirements about regular reviews.

Patient eligibility criteria

To get a medicine under the LSDP, you must meet these criteria:

- Be eligible according to the criteria in the LSDP guidelines for your condition.
- Participate in regular assessment, as detailed in the guidelines. This helps us check how effective the medicine is. If you do not want to participate, you must have a valid reason why not.
- Not have any other medical condition that might make the drug less effective. This includes complications of the primary condition.
- Be eligible to receive Medicare benefits.

Accessing medicine through the LSDP

If you are eligible, your treating physician will fill in the LSDP application forms and submit them to us.

Your treating physician must provide copies of all required test results as evidence of your condition. These results must be less than 12 months old.

How we assess patient applications

After your treating physician sends us the application, we check and process it. We may seek internal clinical advice for complex applications.

We tell your treating physician our decision within a maximum of 30 days.

If we approve the application, your treating physician must reapply for you every year to keep your treatment going.

How your medicine gets to you

Once approved, we order your medicine directly from the supplier. They will ship your medicine to a hospital pharmacy, or other pharmacy of your choice, to dispense to you.

Due to the high cost of LSDP medicines, we only order 1 month's supply of medicine at a time.

Picking up your medicine

Other people can pick up your LSDP medicines if need be. Examples include:

- patient caregivers
- guardians
- contract nurses (for example, for home infusion).

If you are receiving treatment at a hospital, suppliers can also send LSDP medicine directly to the hospital unit, just before you attend (as per hospital procedure).

Storing your medicine

Please ensure that you store your LSDP medicine according to the instructions in the Product Information. Your pharmacist can give you the medicine's Product Information leaflet.

If you do not store your medicine correctly, it may not be safe to use or may not work as expected. In this situation, due to the high cost of these medicines, we may consider restricting supply to minimise extra costs to the Government.

If you are concerned about how your medicine has been transported, used or stored, please tell your treating physician immediately.

Changing hospital pharmacy

Contact your treating physician if you want to change your hospital pharmacy. Your treating physician must have prescribing rights for that hospital, and the nominated pharmacy must agree to provide LSDP medicines.

If the treating physician does not have prescribing rights at that hospital, they may arrange for a proxy to prescribe for them.

The treating physician must then tell us, so we can order stock to go to the new location.

Using a community pharmacy

You can use a community pharmacy if they agree to provide LSDP medicines according to the program's requirements.

Please speak to your treating physician if you want to use a community pharmacy.

Using the home infusion service

Please contact your treating physician if you want to start home infusions. Please note the home infusion service is only available to some LSDP medicines.

Costs

The Australian Government provides LSDP medicines at no cost to the patient. LSDP medicines are not part of the Pharmaceutical Benefits Scheme (PBS), so PBS patient co-payments do not apply.

Your pharmacy might charge you a fee for cold transport and handling of your medicines as required. They must tell you about this cost up front and you must agree to it before the pharmacy dispenses the LSDP medicines. They cannot charge you any other co-payment or fee.

Annual treatment review and tests

Every patient receiving LSDP medicines must be reviewed every year. This makes sure that patients are:

- still eligible for the program
- taking the medicine as prescribed
- responding to the medicine in the expected way.

Each disease has different tests that should be done each year. We state the required tests in the LSDP guidelines for each condition.

Your treating physician must submit certain test results to us, along with a signed reapplication form showing you are still eligible for funding. If you have any concerns about why certain tests are needed, or how often, discuss this with your treating physician. They can then tell us about it.

You must sign a privacy and data consent form **each year** as part of the reapplication process.

Your treating physician must submit your reapplication to us by 1 May each year, unless we advise otherwise.

Your obligations under the program

To stay eligible for subsidised medicines through the LSDP, you must:

- continue to regularly see your treating physician during your treatment
- take your medicines as prescribed by your treating physician
- tell your treating physician immediately if you start to experience any adverse effects while using your LSDP medicine
- take any required tests for reapplication each year
- store your LSDP medicine (where applicable) according to the instructions on the labelling or leaflet accompanying the medicine
- tell your treating general practitioner and/or treating physician if you believe your medicine may be compromised in any way
- continue to qualify for Medicare (be an Australian citizen or permanent resident).

What you need to do if you want to travel

You will need your treating physician's authorisation to travel, if that travel affects your access to the LSDP medicine you are taking.

You must tell your treating physician the dates that you will be travelling. They must:

- ensure that you are fit to travel and will continue to meet the ongoing eligibility requirements of the LSDP
- notify the LSDP team at the Department of Health
- arrange for a treating physician at the new location (this includes domestic and overseas travel)
- ensure you understand that you may have to pay out-of-pocket costs when travelling outside Australia.

How you can give feedback

We welcome your feedback about the program. You can have your say on submissions for new medicines, or medicine reviews.

The LSDP expert panel welcomes input from the public, including patients, carers, family members, treating physicians and advocates. You can email your input to LSDPEP@health.gov.au after we publish the agenda 4 weeks before the relevant meeting. We must receive your input by 2 weeks before the meeting.

Contact details for the LSDP team

Contact us with enquiries relating to the program.

Email: lsvp@health.gov.au

Telephone: (02) 6289 2336

Fax: (02) 6289 8537