

## Information for prescribers relating to the Life Saving Drugs Program (LSDP)

### 1. *Is my patient eligible to receive an LSDP medicine?*

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

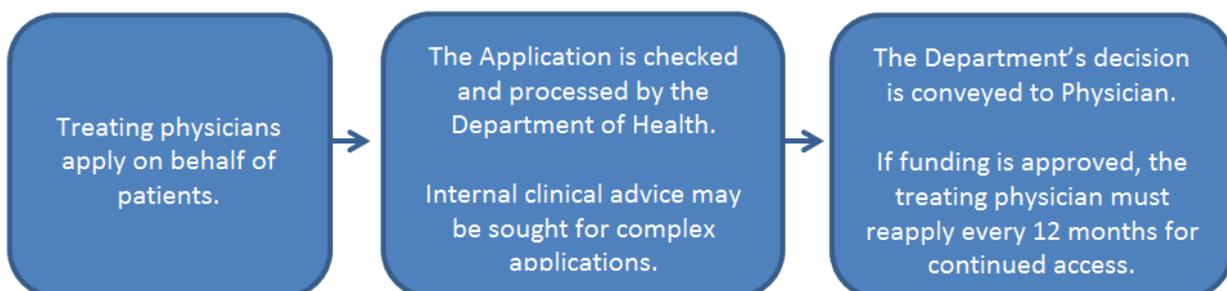
1. Satisfy the relevant criteria for treatment with the drug, as detailed in the relevant drug/condition LSDP Guidelines.
2. Participate in the evaluation of effectiveness of the drug by periodic assessment, as directed by the relevant LSDP drug/condition Guidelines, or have an acceptable reason not to participate.
3. Not be suffering from any other medical condition, including complications or sequelae of the primary condition that might compromise the effectiveness of the drug treatment.
4. Be an Australian citizen or permanent Australian resident who qualifies for Medicare.

### 2. *How do I start my patient on subsidised treatment?*

To apply for a patient to access an LSDP medicine, the treating physician must provide the following information to the Department at [lsdp@health.gov.au](mailto:lsdp@health.gov.au):

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

The flowchart below summarises the application process:



### **3. How long does it take for a patient to be approved?**

Thirty days is the maximum amount of time that it could take for approval to be granted, though this length of time is rarely required.

If an application is incomplete, the physician will be notified of which documents are outstanding. The Department must receive all the relevant documentation from the prescriber before a patient can be approved to the program.

Once the Department has received all relevant documentation for an application to access LSDP medicines, the physician will be notified as soon as possible whether their patient has been approved.

The approval process can take several days. A number of eligibility checks must be undertaken, for example:

- the form has to be checked to see if it is completed correctly and all the required information submitted. The Department cannot process an incomplete application;
- the individual test results need to be compared to the specifications in the disease guidelines;
- confirmation of Medicare eligibility must be sought from the Department of Human Services;
- the documentation must be assessed to determine that all necessary eligibility criteria have been met;
- the dose prescribed by the physician needs to be confirmed for appropriateness based on the patient characteristics (such as 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; and
- the information is collated and approval must be sought from the Department approval delegate.

New patient applications are prioritised and are actioned as soon as possible. Thirty days is the maximum amount of time that it could take for the physician to be notified of the outcome of their correctly completed application.

The Department of Health will contact the nominated pharmacy for confirmation that they are willing to manage the storage of the high cost medicine. If the pharmacy has not stocked LSDP medicines before, they will be provided with all relevant information required. Training in the correct administration of the medicine can be arranged by the supplier of the medicine.

New applications are prioritised by the program staff and are actioned as soon as possible.

Physicians can contact the LSDP via public phone line (02 6289 2336) 9am-5pm Monday to Friday, or via email at [lsdp@health.gov.au](mailto:lsdp@health.gov.au)

#### **4. What do I have to do for the annual reapplication for my patient?**

To obtain ongoing access for their patients, the treating physician must submit a separate reapplication form along with copies of all test results and a clinic letter outlining the patient's recent treatment and general health conditions as evidence of ongoing eligibility to the LSDP by **1 May** every year. The relevant reapplication forms can be found on the LSDP [website](#). 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](mailto:lsdp@health.gov.au)

Continued eligibility will be subject to the assessment of the evidence provided, as outlined in the relevant drug/condition LSDP Guidelines, which clearly demonstrates:

1. clinical improvement in the patient, or
2. stabilisation of the patient's condition.

The assessment of eligibility will also include consideration of the natural course and stage of the disease, as described in the relevant drug/condition LSDP Guidelines, and any exceptional circumstances that may apply.

#### **5. Can I change my patient's dose?**

If you consider a change in dosage is required, you can send an email to [lsdp@health.gov.au](mailto:lsdp@health.gov.au) requesting to change the dose, along with the clinical basis for the change and the requested dose.

Acceptance/rejection of your request will be based on an assessment of the medicine's criteria.

Note that if you do not seek permission from the Department for a dose change, the incorrect amount of stock will be ordered.

#### **6. What do I need to do if my patient wishes to travel?**

In accordance with the LSDP guidelines, physicians are required to authorise any travel their patients wish to undertake that would affect their access to their prescribed treatment.

If your patient wishes to travel, you should discuss with your patient how to manage their treatment during this time. After a treatment regime is agreed, it is the treating physician's responsibility to:

- a) arrange for a treating physician and dispensing pharmacy at the new location, including an overseas location (if required);
- b) provide the LSDP with patient travel details (ie. location, travel period, treating physician and pharmacy, any other relevant details); and
- c) inform your patient that out-of-pocket costs may be incurred (such as in-hospital costs).

If you have any further queries, please send an email to [lsdp@health.gov.au](mailto:lsdp@health.gov.au).

### **7. How will the review of medicines affect my patient?**

There are reviews of new medicines conducted after the first two years of funding as well as reviews of all existing medicines on the program.

Reviews of PBS medicines occur after two years to see whether they are being used in the way that the sponsor of the medicine predicted when they applied to the PBAC. It was agreed within the Compact between the Australian Government and Medicines Australia that a similar process would be established for this program, as well as a review of all existing LSDP medicines.

The reviews aim to:

- develop a better understanding of the real-world use of a medicine;
- review and confirm the clinical benefits achieved through medicine use;
- ensure the ongoing viability of the program;
- ensure testing and access requirements and the price paid for the medicine remain appropriate and;
- improve our understanding of whether or not the medicine significantly extends life.

All patients will continue to access their medicine on the program during the course of a review, and outcomes will be published on the LSDP website.

Pending the outcome of each review, the Department and the sponsor may renegotiate who should access the medicine to ensure that subsidisation continues at prices that reflect the effectiveness of the medicine.

### **8. Can I provide input into the review of LSDP medicines for my patients?**

Interested parties will have multiple opportunities to provide input to reviews of existing LSDP medicines. Written input is collected from the time the review Terms of Reference are published until the draft report is assessed by the Panel. The planned reviews for each LSDP medicine are staggered over the course of two years. As such, input is collected at different times. The timelines and deadlines are announced on the [LSDP webpage](#) and input can be provided to the [LSDPEP@health.gov.au](mailto:LSDPEP@health.gov.au) inbox.