

Old criteria

Section A states that the drug must be found to meet each of the following criteria:

1. There is a rare but clinically definable disease for which the drug is regarded as a proven therapeutic modality, ie approved for that indication by the Therapeutic Goods Administration.
2. The disease is identifiable with reasonable diagnostic precision.
3. Epidemiological and other studies provide evidence acceptable to the PBAC that the disease causes a significant reduction in age-specific life expectancy for those suffering from the disease.
4. There is evidence acceptable to the PBAC to predict that a patient's lifespan will be substantially extended as a direct consequence of the use of the drug.
5. The drug must be accepted as clinically effective, but rejected for Pharmaceutical Benefits Scheme (PBS) listing because it fails to meet the required cost effectiveness criteria.
6. There is no alternative drug listed on the PBS or available for public hospital in-patients, which can be used as lifesaving treatment for the disease. However, the availability of an alternative drug under the LSDP does not disqualify the proposed drug from consideration for the LSDP.
7. There is no alternative non-drug therapeutic modality (e.g. surgery, radiotherapy) which is recognised by medical authorities as a suitable and cost effective treatment for this medical condition.
8. The cost of the drug, defined as the cost per dose multiplied by the expected number of doses in a one year period for the patient, would constitute an unreasonable financial burden on the patient or his/her guardian.

The Department of Health website on the LSDP criteria was updated on 17 August 2016. The LSDP funding criteria is now listed as follows.

Criteria for the Funding of a Drug

Source:

<http://www.health.gov.au/internet/main/publishing.nsf/Content/lstdp-criteria>

The following issues must be addressed in considering a submission to fund a drug through the Life Saving Drugs Program, and in formulating a recommendation to the Minister for Health.

A) The drug must be found to meet each of the following criteria:

1. There is a rare but clinically definable disease for which the drug is regarded as a proven therapeutic modality, ie. approved for that indication by the Therapeutic Goods Administration.
2. The disease is identifiable with reasonable diagnostic precision.
3. Epidemiological and other studies provide evidence that the disease causes a significant reduction in age-specific life expectancy for those suffering from the disease.
4. There is evidence to predict that a patient's lifespan will be substantially extended as a direct consequence of the use of the drug.
5. The drug must be accepted as clinically effective, but rejected for Pharmaceutical Benefits Scheme (PBS) listing because it fails to meet the required cost effectiveness criteria.
6. There is no alternative drug listed on the PBS or available for public hospital in-patients, which can be used as lifesaving treatment for the disease. However, the availability of an alternative drug under the LSDP does not disqualify the proposed drug from consideration for the LSDP.
7. There is no alternative non-drug therapeutic modality (eg. surgery, radiotherapy) which is recognised by medical authorities as a suitable and cost effective treatment for this condition.
8. The cost of the drug, defined as the cost per dose multiplied by the expected number of doses in a one year period for the patient, would constitute an unreasonable financial burden on the patient or his/her guardian.