

# Life Saving Drugs Program (LSDP) Initial application form for subsidised treatment of infantile-onset lysosomal acid lipase deficiency (LAL-D)

## **About this Program**

The LSDP is administered by the Department of Health and Aged Care (the Department). Access to treatment for infantile-onset LAL-D is provided in accordance with the *Guidelines for the treatment of infantile-onset LAL-D through the Life Saving Drugs Program* (the Guidelines).

It is recommended that you read the Guidelines before completing this application form.

#### **Patient Administration**

Patient applications are processed within 30 calendar days of the receipt of the complete package to support the application.

Should subsidised treatment be approved, it is the responsibility of the treating physician to ensure that the patient/patient's family is informed of:

- a) Treatment arrangements, including approved dose
- b) The requirement to submit a reapplication for subsidised treatment through the LSDP by 1 May each year to request ongoing subsidised treatment
- c) The requirement to notify the LSDP in writing immediately if a change to the treatment location is planned and
- d) The requirement to notify the LSDP in writing immediately if treatment is ceased.

#### Filling in this form

The application form must be filled out by a treating physician with relevant specialist registration, with the consent of the patient or parent/guardian. The patient or their parent/guardian is required to sign the application form to provide consent to the Department to collect personal information.

Please complete electronically, print and sign; or Use black or blue pen and print in BLOCK LETTERS.

All pages of this application form must be completed and submitted. Incomplete applications will not be processed.

### **Information Requirements**

All assessments to support eligibility, excluding genetic testing, must have been undertaken within the 12 months prior to the date of application.

#### For more information

For more information go to the LSDP website: www.health.gov.au/lsdp

If you need assistance completing this form, or for more information call **(02) 6289 2336**, Monday to Friday, between 9.00 am and 5.00 pm, Australian Eastern Time.

#### Submitting your form

Send the completed application form and all relevant attachments:

By email to: lsdp@health.gov.au

By fax to: (02) 6289 8537

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## **Privacy notice**

The Department is collecting personal information about the patient identified on this application form to process this patient's initial application to receive subsidised treatment 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 initial application 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

https://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.

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

#### Patient's details

Medicare card number							
		Ref no.					
Mr Mrs Mis	ss 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 my 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 my 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 infantile-onset LAL-D 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.

Signature			
Patient	Parent	Guardian	(tick one only)
Full name (pri	nt in BLOCK LET	TTERS)	
Date			

Treat	ting p	hysic	ian's (	details	<b>;</b>				Pharmacist's details			
Presc	riber r	numbe	er						Given name			
Given	name	<u> </u>							Family name			
									Work phone number			
Famil	y nam	e							work phone number			
									Email address			
Work	phon	e num	ber									
									Hospital/Department			
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Hospi	ital/De	epartn	nent						Suburb		State	Post Code
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Posta	l addr	ess					,		Secondary pharmacy co	ntac	t's details	
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									Email address			
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									Dosing details			
Work	phone	e num	ber						Generic name of medicine r	eque	sted:	
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Email	l addre	ess						1	Patient's weight			
Hospi	ital/De	nartn	nant						kg			
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Subui	rb				State	e	Post Code					

Eligibility confirmation checklist	Treating physician's declaration
To qualify for LSDP subsidised treatment, all of the following initial eligibility requirements must be met.  The treating physician must initial the box to confirm that the requirement is met.  1. Infantile-onset LAL-D must be confirmed before 12 months of age.	I confirm that:  I am the treating physician of the patient as stated in this form, and have relevant specialist registration. I hereby apply for Australian Government subsidised access to treatment for infantile-onset LAL-D through the LSDP on behalf of my patient.  I declare that:
<ul> <li>2. Diagnosis of infantile-onset LAL-D has been confirmed by: <ol> <li>LAL (LIPA) mutations on genetic testing (noting treatment may commence prior to the results of the genetic test being available if necessary)</li> </ol> </li> <li>AND <ol> <li>No detectable or severe deficiency in LAL enzyme activity when tested at the National Referral Laboratory.</li> </ol> </li> <li>The patient does not have any of the conditions listed in the exclusion criteria.</li> <li>I have advised the LSDP if the patient is participating in a clinical trial.</li> </ul> <li>Data requirement checklist <ol> <li>I have provided a clinic letter outlining the patient's recent medical and surgical history and general description of their health status.</li> <li>I have provided copies of all relevant reports and the completed Excel spreadsheet for infantile-onset LAL-D.</li> </ol></li>	I declare that:  The information provided in this form is complete and correct.  To the best of my knowledge, my patient is eligible to receive subsidised treatment for infantile-onset LAL-D through the LSDP in accordance with the Guidelines.  I am aware that the patient must be an Australian citizen or permanent Australian resident who qualifies for Medicare.  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