

#### **Australian Government**

Department of Health and Aged Care

# Life Saving Drugs Program (LSDP) Initial application form for subsidised treatment for Mucopolysaccharidosis type II (MPS II)

#### About this Program

The LSDP is administered by the Department of Health and Aged Care (the Department). Access to treatment for MPS II is provided in accordance with the *Guidelines for the treatment of MPS II 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 data 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

#### **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 <u>www.health.gov.au</u>

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 nu	mber		
			Ref no.
Mr Mrs [	Miss	Ms	Other
Given name			
Family name			
Residential addre	ess		
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 MPS II 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	TERS)	
Date			

Given name   Given name   Family name   Family name   Family name   Work phone number   Mobile phone number   Mobile phone number   Banil address   Bospital/Department   Hospital/Department   Bostal address   Given name   Suburb   State   Post Code   Family name   Clinic nurse details   Given name   Clinic nurse details   Given name   Email address   Dosing details   Generic name of medicine requested:   Patient's weight   Nosage of medicine requested:   kg	Treating physician's details	Pharmacist's details
Given name  Family name  Work phone number  Mobile	Prescriber number	Given name
Given name  Family name  Work phone number  Mobile		Family name
Family name   Work phone number   Mobile phone number   Mobile phone number   Benail address   Hospital/Department   Postal address   Suburb   State   Post Code   Given name   Suburb   State   Post Code   Family name   State   Post Code   Family name   State   Posing details   Ceneric name of medicine requested:   Linail address   Patient's weight   kg   Postal address	Given name	
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Mobile phone number   Email address   Hospital/Department   Postal address   Suburb State   Post Code   Suburb   State   Post Code   Given name   Clinic nurse details   Given name   Family name   Family name   Suburb   State   Post Code   Family name   Given name   Email address   Given name   Family name   Bail address   Family name   Suburb   State   Post Code   Family name   State   Post Dosage of medicine requested:   kg   Dosage of medicine requested:	Work phone number	
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Family name   Family name   Work phone number   Email address   Email address   Hospital/Department   Postal address   Postal address	Clinic nurse details	Work phone number
Family name   Family name   Work phone number   Email address   Hospital/Department   Postal address   Postal address	Given name	
Work phone number   Email address   Hospital/Department   Postal address		Email address
Work phone number       Generic name of medicine requested:         Email address       Patient's weight         Hospital/Department       kg         Postal address       Dosage of medicine requested:	Family name	
Email address       Generic name of medicine requested:         Email address       Patient's weight         Mospital/Department       kg         Postal address       Dosage of medicine requested:		Dosing details
Hospital/Department     Patient's weight       Bostal address     Dosage of medicine requested:	Work phone number	Generic name of medicine requested:
Patient's weight kg Dosage of medicine requested:		
Hospital/Department Dosage of medicine requested:	Email address	Patient's weight
Dosage of medicine requested:	Legnitel (Department	kg
Postal address		
	Postal address	Dosage of medicine requested:
mg vials		mg vials
Suburb State Post Code	Suburb State Post Code	

# **Eligibility confirmation checklist**

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. Diagnosis of MPS II has been confirmed by:

i) demonstration of deficiency of iduronate 2-sulfatase in white blood cells. OR



ii) the detection of a disease causing mutation for siblings of a known patient.

2. The patient meets at least one of the following criteria demonstrating severity of MPS II:

#### a) Sleep disordered breathing:

Apnoea/hypopnoea incidence of >5 events/hour of total sleep time, or more than 2 severe episodes of desaturation (oxygen saturation <80%) in an overnight sleep study.

#### b) Respiratory function tests:

FVC of less than 80% of the predicted value for height.

#### c) Cardiac complications:

Myocardial dysfunction as indicated by a reduction in
ejection fraction to less than 56% (normal range
56-78%), or a reduction in fraction shortening to <25%
(normal range 25-46%).

#### d) Joint contractures:

Restricted range of movement of joints of greater than 10 degrees from normal in shoulders, neck, hips, knees, elbows or hands.

# e) The patient is an infant or child less than 5 years

old and not yet demonstrating symptoms consistent with other eligibility criteria but where as a result of diagnostic testing, disease progression or severe disease can be predicted.

3. The patient does not have any of the conditions listed in the exclusion criteria in the MPS II Guidelines.

4. I have advised the LSDP if the patient is participating in a clinical trial.

# Data requirement checklist

5. I have provided a clinic letter outlining the patient's recent medical and surgical history and general description of their health status.

6. I have provided copies of all relevant reports and the completed Excel spreadsheet for MPS II.

#### **Treating physician's declaration**

#### 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 MPS II through the LSDP on behalf of my patient.

#### 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 MPS II 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 understand that:

- 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