Myelodysplastic syndrome
Initial PBS authority application
and supporting information

When to use this form
You must lodge this form for a patient:

• starting initial Pharmaceutical Benefits Scheme (PBS) subsidised treatment with lenalidomide for myelodysplastic syndrome classified as low risk or intermediate-1 according to the International Prognostic Scoring System (IPSS). Patients must have a deletion 5q cytogenetic abnormality and must be red blood cell transfusion dependent,
or
• applying for the first continuing PBS subsidised treatment for patients who do not have progressive disease and who have achieved and maintained transfusion independence or a 50% reduction in red blood cell unit transfusion requirements compared with the 4 month period prior to commencing PBS subsidised therapy.

Subsequent continuing treatment is available by phone.

The following pathology reports are required with each initial application:

• a copy of the bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome
• a copy of the full blood examination report
• a copy of the pathology report detailing the cytogenetics.

All applications must be in writing and must include sufficient information to determine the patient’s eligibility according to the PBS criteria.

The information on this form is correct at the time of publishing and is subject to change.

Section 100 arrangements
This item is only available to a patient who is attending either:

• an approved private hospital
• a public participating hospital, or
• a public hospital and is either
  – a day admitted patient
  – a non-admitted patient, or
  – a patient on discharge

This is not a PBS benefit for in-patients of the hospital. The hospital provider number must be included on the application form.

Acknowledgements
The patient’s and the prescriber’s acknowledgements must be signed in the presence of a witness (over 18 years of age).

Authority prescription form
Complete the appropriate authority prescription form and attach to this application.

The medical indication section of the authority prescription form does not need to be completed when submitted with this application. Initial treatment is for a maximum of 16 weeks. Continuing treatment is for a maximum of 16 weeks.

Phone approvals
Under no circumstance will phone approvals be granted for complete initial or first continuing authority applications, or for treatment that would otherwise extend the treatment period.

For more information
For more information about myelodysplastic syndrome go to our website humanservices.gov.au/healthprofessionals > PBS > Specialised drugs (PBS) J-Z > Myelodysplastic syndrome or call 1800 700 270 and select option 3, Monday to Friday, between 8.00 am and 5.00 pm, Australian Eastern Standard Time.

Note: Call charges apply from mobile phones.

Filling in this form
• Please use black or blue pen
• Print in BLOCK LETTERS
• Mark boxes like this ✓ or ✗
• Where you see a box like this  ☐  Go to 5 skip to the question number shown. You do not need to answer the questions in between.

Returning your form
Check that you have answered all the questions you need to answer and that you have signed and dated this form.

Send the completed authority application, a completed authority prescription form and all relevant attachments to:

Prior written approval of specialised drugs
Department of Human Services
Reply Paid 9826
Hobart TAS 7001
Myelodysplastic syndrome
Initial PBS authority application

Patient’s details

1 Medicare card number

[ ] [ ] [ ] - [ ] [ ] - [ ] Ref no. [ ]

or

Department of Veterans’ Affairs card number

[ ] [ ] [ ] - [ ] [ ] - [ ] Ref no. [ ]

2 Mr [ ] Mrs [ ] Miss [ ] Ms [ ] Other [ ]

Family name

First given name

3 Date of birth

/ /

Patient’s declaration

4 I acknowledge that:

• PBS subsidised treatment with lenalidomide for the treatment of myelodysplastic syndrome will stop if subsequent testing demonstrates that the disease has progressed, or if transfusion independence, or a 50% reduction in red blood cell unit transfusion requirements have not been maintained.

• My prescriber has explained the nature of the ongoing monitoring and testing required to demonstrate that the patient is transfusion independent or has reduced transfusion requirements according to the criteria and the disease has not progressed to acute myeloid leukaemia (AML).

I declare that:

• giving false or misleading information is a serious offence.

Patient’s signature

Date

/ /

Prescriber’s details

5 Prescriber number

6 Family name

First given name

7 Work phone number ( )

Alternative phone number ( )

Fax number ( )

Hospital details

8 Hospital name

9 Hospital provider number

Prescriber’s acknowledgement

10 I have explained to the patient:

• the circumstances governing PBS subsidised treatment with lenalidomide

• the nature of the ongoing monitoring and testing required to demonstrate that the patient is transfusion independent or has reduced transfusion requirements according to the criteria and the disease has not progressed to acute myeloid leukaemia (AML).

I acknowledge that:

• If disease progresses to AML or if the patient is unable to maintain transfusion independence, or adequate transfusion response according to the criteria, I will stop treatment with lenalidomide.

I declare that:

• the information I have provided in this form is complete and correct.

I understand that:

• giving false or misleading information is a serious offence.

Prescriber’s signature

Date

/ /

Witness’ acknowledgement

11 I have witnessed the signatures of BOTH the patient and the prescriber.

Witness’ full name (over 18 years of age)

I declare that:

• the information I have provided in this form is complete and correct.

I understand that:

• giving false or misleading information is a serious offence.

Witness’ signature

Date

/ /
Application type

12 This application is for:
- initial treatment  □  Go to 13
- first continuing treatment □  Go to 15

Conditions and criteria

13 The patient:
□ has signed the patient acknowledgement
□ has been diagnosed with myelodysplastic syndrome classified as low risk or intermediate-1 according to the International Prognostic Scoring System (IPSS).

Complete the table below.

<table>
<thead>
<tr>
<th>Myelodysplastic syndrome classification</th>
<th>Parameter</th>
<th>value</th>
<th>score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marrow blasts</td>
<td>&lt;5%</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>5% – 10%</td>
<td></td>
<td>0.5</td>
</tr>
<tr>
<td></td>
<td>11% – 20%</td>
<td></td>
<td>1.5</td>
</tr>
<tr>
<td></td>
<td>21% – 30%</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Cytogenetic abnormalities</td>
<td>normal</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>(-Y) alone</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>del (5q) alone</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>del (20q) alone</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>other abnormalities</td>
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<td></td>
<td>3 or more abnormalities</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>chromosome 7 abnormalities</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Cytopenias</td>
<td>Hb &lt; 100g/L</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>&lt; 1.8 x 10^9/L neutrophils</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>&lt; 100 x 10^9/L platelets</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>0 or 1 cytopenia</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>2 or 3 cytopenia</td>
<td></td>
<td>0.5</td>
</tr>
</tbody>
</table>

TOTAL SCORE (must be ≤ 1)

and
□ has a deletion 5q cytogenetic abnormality, with or without additional cytogenetic abnormalities
and
□ is red blood cell transfusion dependent and has been transfused within the last 8 weeks
and
□ in the last 6 months prior to commencing PBS subsidised therapy with lenalidomide has received at least 8 units of red blood cells and would be expected to continue this requirement without lenalidomide treatment

14 Provide:

a) date of last transfusion  / /

b) haemoglobin level at this time
and total number of red blood cell units transfused

c) within the last 4 months
and
d) within the last 6 months

Go to 17 Attachments

15 The patient:
□ has received initial PBS subsidised treatment with lenalidomide
and
□ has achieved and maintained transfusion independence
or
□ has achieved at least a 50% reduction in red blood cell units transfused during the initial treatment period compared with the most recent 4 month period prior to commencing PBS subsidised therapy
and
□ has not progressed to acute myeloid leukaemia.

16 Provide:

a) date of last transfusion  / /

b) haemoglobin level within the last 4 weeks

c) and total number of red blood cell units transfused in the 4 months immediately preceding this application

17 Attachments

Attach all relevant bone marrow pathology reports, full blood examination report, cytogenetic report and a completed authority prescription form.

Prescriber’s declaration

18 I declare that:

- the information I have provided in this form is complete and correct.

I understand that:

- giving false or misleading information is a serious offence.

Prescriber’s’ signature

Privacy notice

Your personal information is protected by law, including the Privacy Act 1988, and is collected by the Australian Government Department of Human Services for the assessment and administration of payments and services. This information is required to process your application or claim.

Your information may be used by the department or given to other parties for the purposes of research, investigation or where you have agreed or it is required or authorised by law.

You can get more information about the way in which the Department of Human Services will manage your personal information, including our privacy policy at humanservices.gov.au/privacy or requesting a copy from the department.