NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

13 August 2014

Decision to fund azacitidine and lenalidomide

PHARMAC is pleased to announce the approval of a proposal for azacitidine (Vidaza), lenalidomide (Revlimid) and thalidomide (Thalomid) that was the subject of a consultation letter dated 26 June 2014, available on PHARMAC's website at:

http://www.pharmac.health.nz/news/consultation-2014-06-26-azacitidine-lenalidomide-thalidomide/

In summary, the effect of the decision is that from 1 September 2014:

- Azacitidine (Vidaza) 100 mg injection and 1 mg for ECP will be funded for patients with intermediate-2 or high risk myelodysplastic syndrome (MDS), chronic myelomonocytic leukaemia (CMML) or MDS-associated acute myeloid leukaemia (AML); and
- Lenalidomide (Revlimid) 10 and 25 mg capsules will be funded for patients with relapsed refractory multiple myeloma (MM); and
- The price and subsidy for thalidomide (Thalomid) 50 mg and 100 mg capsules will be reduced.

The decision is as consulted on, with a few minor changes as follows:

- minor changes to the Special Authority/Restriction applying to lenalidomide;
- the application of the Wastage rule to lenalidomide; and
- a further decrease in the price and subsidy on thalidomide.

This decision is expected to result in approximately 360 new patients having access to these treatments each year. Further details of the decision and feedback can be found below and on the following pages.

Details of the decision

Azacitidine (Vidaza)

- Azacitidine 100 mg vial (Vidaza) and 1 mg for ECP (Baxter) will be listed in the Antimetabolites (Oncology Agents and Immunosuppressants) therapeutic subgroup in Section B, and Part II of Section H, of the Pharmaceutical Schedule from 1 September 2014 at the following prices and subsidies (ex-manufacturer, excl. GST):

Chemical	Presentation	Brand	Pack size	Price/Subsidy
azacitidine	Inj 100 mg vial	Vidaza	1	$605.00
azacitidine	Inj 1 mg for ECP	Baxter	1 mg	$6.66

- Vidaza will be subject to a confidential rebate which will reduce the price to the Funder.

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- The following Special Authority criteria and Restriction will apply to all presentations of azacitidine listed in Section B and Part II of Section H of the Pharmaceutical Schedule respectively from 1 September 2014:

Section B:

Azacitidine – PCT only – Specialist - Special Authority for Subsidy
Initial application — only from a haematologist or medical practitioner on the recommendation of a haematologist. Approvals valid for 12 months for applications meeting the following criteria:
All of the following

1. Any of the following:
    1.1. The patient has International Prognostic Scoring System (IPSS) intermediate-2 or high risk myelodysplastic syndrome; or
    1.2. The patient has chronic myelomonocytic leukaemia (10%-29% marrow blasts without myeloproliferative disorder); or
    1.3. The patient has acute myeloid leukaemia with 20-30% blasts and multi-lineage dysplasia, according to World Health Organisation Classification (WHO); and
2. The patient has performance status (WHO/ECOG) grade 0-2; and
3. The patient does not have secondary myelodysplastic syndrome resulting from chemical injury or prior treatment with chemotherapy and/or radiation for other diseases; and
4. The patient has an estimated life expectancy of at least 3 months.

Renewal application — only from a haematologist or medical practitioner on the recommendation of a haematologist. Approvals valid for 12 months for applications meeting the following criteria:
Both:

1. No evidence of disease progression, and
2. The treatment remains appropriate and patient is benefitting from treatment.

Part II of Section H:

Restricted
Initiation
Haematologist
Re-assessment required after 12 months
All of the following:

1. Any of the following:
    1.1. The patient has International Prognostic Scoring System (IPSS) intermediate-2 or high risk myelodysplastic syndrome; or
    1.2. The patient has chronic myelomonocytic leukaemia (10%-29% marrow blasts without myeloproliferative disorder); or
    1.3. The patient has acute myeloid leukaemia with 20-30% blasts and multi-lineage dysplasia, according to World Health Organisation Classification (WHO); and
2. The patient has performance status (WHO/ECOG) grade 0-2; and
3. The patient does not have secondary myelodysplastic syndrome resulting from chemical injury or prior treatment with chemotherapy and/or radiation for other diseases; and
4. The patient has an estimated life expectancy of at least 3 months.

Continuation
Haematologist
Re-assessment required after 12 months
Both
1. No evidence of disease progression, and
2. The treatment remains appropriate and patient is benefitting from treatment.

Lenalidomide (Revlimid)

- Lenalidomide 10 mg and 25 mg capsules (Revlimid) will be listed in the Other Cytotoxic Agents (Oncology Agents and Immunosuppressants) therapeutic subgroup of Section B, and Part II of Section H, of the Pharmaceutical Schedule from 1 September 2014 at the following prices and subsidies (ex-manufacturer, excl. GST):

Chemical	Presentation	Brand	Pack size	Price/Subsidy
Lenalidomide	Cap 10 mg	Revlimid	21	$6,207.00
Lenalidomide	Cap 25 mg	Revlimid	21	$7,627.00

- Revlimid will be subject to a confidential rebate which will reduce the price to the Funder.

- The following Special Authority criteria and Restriction will apply to all presentations of lenalidomide listed in Section B and Part II of Section H of the Pharmaceutical Schedule respectively from 1 September 2014:

Section B:

Lenalidomide –Retail Pharmacy- Specialist - Special Authority for Subsidy
Initial application (Relapsed/refractory disease) — only from a haematologist or medical practitioner on the recommendation of a haematologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1. Patient has relapsed or refractory multiple myeloma with progressive disease; and
2. Either:
    2.1. Lenalidomide to be used as third line* treatment for multiple myeloma; or
    2.2. Both:
        2.2.1. Lenalidomide to be used as second line treatment for multiple myeloma, and
        2.2.2. The patient has experienced severe (grade ≥3), dose limiting, peripheral neuropathy with either bortezomib or thalidomide that precludes further treatment with either of these treatments; and
3. Lenalidomide to be administered at a maximum dose of 25 mg/day in combination with dexamethasone.

Renewal application — only from a haematologist or medical practitioner on the recommendation of a haematologist. Approvals valid for 6 months for applications meeting the following criteria:
Both:
1. No evidence of disease progression, and
2. The treatment remains appropriate and patient is benefitting from treatment.

Notes: Indication marked with * is an Unapproved Indication (refer to Interpretations and Definitions). A line of treatment is considered to comprise either: a) a known therapeutic chemotherapy regimen and supportive treatments or b) a transplant induction chemotherapy regimen, stem cell transplantation and supportive treatments.

Part II of Section H:

Restricted
Initiation
Haematologist
Re-assessment required after 6 months
All of the following
1. Patient has relapsed or refractory multiple myeloma with progressive disease; and
2. Either:
    2.1. Lenalidomide to be used as third line* treatment for multiple myeloma; or
    2.2. Both
        2.2.1. Lenalidomide to be used as second line treatment for multiple myeloma, and
        2.2.2. The patient has experienced severe (grade ≥3), dose limiting, peripheral neuropathy with either bortezomib or thalidomide that precludes further treatment with either of these treatments; and
3. Lenalidomide to be administered at a maximum dose of 25 mg/day in combination with dexamethasone.

Continuation
Haematologist
Re-assessment required after 6 months
Both:
1. No evidence of disease progression, and
2. The treatment remains appropriate and patient is benefitting from treatment.

Notes: Indication marked with * is an Unapproved Indication (refer to Interpretations and Definitions). A line of treatment is considered to comprise either: a) a known therapeutic chemotherapy regimen and supportive treatments or b) a transplant induction chemotherapy regimen, stem cell transplantation and supportive treatments.

- The Wastage rule will be applied to dispensings of lenalidomide in Section B of the Pharmaceutical Schedule from 1 September 2014.

Thalidomide (Thalomid)

- The prices and subsidies of thalidomide 50 mg and 100 mg capsules (Thalomid) listed in Section B and in Part II of Section H of the Pharmaceutical Schedule will be amended from 1 September 2014 as follows (ex-manufacturer, excl. GST):

Pharmaceutical	Brand	Pack size	Current price and subsidy	New price and subsidy
Thalidomide cap 50 mg	Thalomid	28	$504.00	$378.00
Thalidomide cap 100 mg	Thalomid	28	$1,008.00	$756.00

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 10 July 2014 were considered in their entirety in making a decision on the proposed changes. While all responses were supportive of the proposal, the following issues were raised in relation to specific aspects of the proposal:

Theme	Comment
Request that funding for lenalidomide be extended to include patients who had received two or more lines of prior therapy but had not had prior bortezomib.	PHARMAC considers that funding of lenalidomide in the second and third line settings proposed is consistent with our Decision Criteria, but 4th line treatment or beyond is not (regardless of prior treatments received). The Special Authority criteria and HML Restriction have been amended to clarify that funding is limited to second and third line.
Lenalidomide and thalidomide are expensive, therefore could result in pharmacies being left with unused part packs if prescribers deviate from standard dosing which would be a significant cost to pharmacies. Requests that they be funded as "Original Pack" to avoid adverse financial impacts on pharmacies.	PHARMAC notes that lenalidomide comes in packs of 21 caps, which is consistent with its standard dosing regimens. However, if dose adjustments or alternative regimens are prescribed there is the potential for significant cost impacts to pharmacy. The 'Wastage rule' has been applied to lenalidomide to allow pharmacies to claim for unused part-packs. We do not consider it necessary to apply the wastage rule to thalidomide as this is a PCT-only product dispensed and managed through Hospital Pharmacy; further it is considerably cheaper than lenalidomide.

More information

If you have any questions about this decision, you can email us at enquiry@pharmac.govt.nz or call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.