

ANASTROZOLE

**tablet, 1 mg,
various brands, various sponsors.**

EVEROLIMUS

**tablets, 5 mg and 10 mg,
Afinitor[®], Novartis Pharmaceuticals Australia Pty Ltd.**

EXEMESTANE

tablet, 25 mg, various brand, various sponsors.

GOSERELIN

**implant, 3.6 mg,
Zoladex Implant[®], AstraZeneca Pty Ltd.**

LETROZOLE

**tablet, 2.5 mg,
various brands, various sponsors**

Correspondence from the Medical Oncology Group of Australia (MOGA) seeking to make the PBS restrictions less restrictive dated 18 September 2014. (12.5)

1 Purpose of Item

- 1.1 The Medical Oncology Group of Australia (MOGA) sought to have the drugs anastrozole, everolimus, exemestane, goserelin and letrozole made available to males with breast cancer on equity grounds.

2 Background

- 2.1 At the time of MOGA's request, the five drugs referred to by MOGA had the following PBS breast cancer indications in November 2014, with the limitation of PBS subsidy to women underlined in bolded text:

ANASTROZOLE:

Restricted Benefit

Treatment of hormone-dependent breast cancer in **post-menopausal women**

Note

This drug is not PBS-subsidised for primary prevention of breast cancer.

This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years.

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Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

EVEROLIMUS:

Authority Required

Metastatic (Stage IV) breast cancer

Clinical criteria:

The condition must be hormone receptor positive,
AND

The condition must be human epidermal growth factor receptor 2 (HER2) negative,
AND

The condition must have acquired endocrine resistance as demonstrated by initial response and then recurrence or progression of disease after treatment with letrozole or anastrozole,
AND

The treatment must be in combination with exemestane.

Population criteria:

Patient must be **female**,

AND

Patient must be **post-menopausal**.

EXEMESTANE:

Restricted Benefit

Metastatic (Stage IV) breast cancer

Clinical criteria:

The condition must be hormone receptor positive,
AND

The condition must be human epidermal growth factor receptor 2 (HER2) negative,
AND

Patient must be receiving PBS-subsidised everolimus concomitantly for this condition.

Population criteria:

Patient must be **female**,

AND

Patient must be **post-menopausal**.

Restricted Benefit

Treatment of hormone-dependent advanced breast cancer in **post-menopausal women** with disease progression following treatment with tamoxifen citrate

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Restricted Benefit

Treatment of hormone-dependent early breast cancer in **post-menopausal women** following a minimum of 2 years' treatment with tamoxifen citrate

NOTE:

This drug is not PBS-subsidised for primary prevention of breast cancer.

This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years, i.e. a patient who has received 2 years of tamoxifen therapy may only receive 3 years of PBS-subsidised treatment with exemestane.

NOTE:

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

GOSERELIN:

Authority Required

Hormone-dependent locally advanced (equivalent to stage III) or metastatic (equivalent to stage IV) breast cancer in **pre-menopausal women**

Authority Required

Hormone-dependent breast cancer as an alternative to adjuvant chemotherapy in **peri- or pre-menopausal women**

LETROZOLE:

Restricted Benefit

Treatment of hormone-dependent advanced breast cancer in **post-menopausal women**

Restricted Benefit

Treatment of hormone-dependent early breast cancer in **post-menopausal women**

Restricted Benefit

Extended adjuvant treatment of hormone-dependent early breast cancer in **post-menopausal women** commencing within 6 months of ceasing treatment with tamoxifen citrate

Note

This drug is not PBS-subsidised for primary prevention of breast cancer.

This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years.

This drug is not PBS-subsidised for extended adjuvant early breast cancer treatment where the total duration of letrozole (or any other aromatase inhibitor) treatment extends beyond 5 years.

Note

Shared Care Model:

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For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

- 2.2 The PBAC noted that MOGA's request also included tamoxifen but that tamoxifen's current PBS restriction does not limit subsidy by a gender population criterion.
- 2.3 The PBAC also noted that all these drugs have TGA indications that specify use in post-menopausal women, with the exception of goserelin, which in breast cancer is indicated for pre and peri-menopausal women.

3 PBAC Outcome

- 3.1 The PBAC agreed with the MOGA view that the small number of male patients requiring treatment for breast cancer should not be denied PBS subsidised access to effective treatments based on their gender. The PBAC considered that a similar equity in access issue also occurs for the paediatric population and that this is often circumvented by recommending restrictions which do not necessarily preclude use in that certain patient population. Therefore, the PBAC recommended amending the restrictions for these five drugs and their breast cancer indications in such a way that male patients are not precluded from access to subsidy. In relation to goserelin, the PBAC noted that it would be unlikely that goserelin would be prescribed for post-menopausal women and so recommended that the restriction need not refer to menopausal status.

Outcome:

Recommended

4 Recommended listing

- 4.1 Amend the existing breast cancer restrictions as shown by *italics* (additions/new text) or ~~strikethrough~~-(deletions):

ANASTROZOLE:

Restricted Benefit

~~Treatment of hormone dependent breast cancer in~~ **post-menopausal women**

PBS indication: Breast cancer

Clinical criteria: The condition must be hormone receptor positive

Population criteria: Patient must not be pre-menopausal

Note

This drug is not PBS-subsidised for primary prevention of breast cancer.

This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years.

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Note

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

EVEROLIMUS:

Authority Required

Metastatic (Stage IV) breast cancer

Clinical criteria:

The condition must be hormone receptor positive,
AND

The condition must be human epidermal growth factor receptor 2 (HER2) negative,
AND

The condition must have acquired endocrine resistance as demonstrated by initial response and then recurrence or progression of disease after treatment with letrozole or anastrozole,
AND

The treatment must be in combination with exemestane.

Population criteria:

~~Patient must be female,~~
AND

~~Patient must be post-menopausal.~~

Patient must not be pre-menopausal

EXEMESTANE:

Restricted Benefit

Metastatic (Stage IV) breast cancer

Clinical criteria:

The condition must be hormone receptor positive,
AND

The condition must be human epidermal growth factor receptor 2 (HER2) negative,
AND

Patient must be receiving PBS-subsidised everolimus concomitantly for this condition.

Population criteria:

~~Patient must be female,~~
AND

~~Patient must be post-menopausal.~~

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Patient must not be pre-menopausal

Restricted Benefit

~~Treatment of hormone dependent advanced breast cancer in post-menopausal women with disease progression following treatment with tamoxifen citrate~~

Severity: *Advanced*
Episodicity: *---*
Condition: *breast cancer*

PBS indication: *Advanced breast cancer*

Clinical criteria: *The condition must be hormone receptor positive
AND
The condition must have progressed following treatment with tamoxifen*

Population criteria: *Patient must not be pre-menopausal*

NOTE:

This drug is not PBS-subsidised for primary prevention of breast cancer.

This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years, i.e. a patient who has received 2 years of tamoxifen therapy may only receive 3 years of PBS-subsidised treatment with exemestane.

NOTE:

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

Restricted Benefit

~~Treatment of hormone dependent early breast cancer in post-menopausal women following a minimum of 2 years' treatment with tamoxifen citrate~~

Severity: *Early*
Episodicity: *---*
Condition: *breast cancer*

PBS indication: *Early breast cancer*

Clinical criteria: *The condition must be hormone receptor positive
AND
The condition must have previously been treated with tamoxifen for a minimum of 2 years*

Population criteria: *Patient must not be pre-menopausal*

NOTE:

This drug is not PBS-subsidised for primary prevention of breast cancer.

This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years, i.e. a patient who has received 2 years of tamoxifen therapy may only receive 3 years of PBS-subsidised treatment with exemestane.

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NOTE:

Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

GOSERELIN:

Authority Required

~~Hormone dependent locally advanced (equivalent to stage III) or metastatic (equivalent to stage IV) breast cancer in pre-menopausal women~~

Severity: *Locally advanced (stage III) or metastatic (stage IV)*

Episodicity: *---*

Condition: *breast cancer*

PBS indication: *Locally advanced (stage III) or metastatic (stage IV) breast cancer*

Clinical criteria: *The condition must be hormone receptor positive*

Authority Required

~~Hormone dependent breast cancer as an alternative to adjuvant chemotherapy in peri- or pre-menopausal women~~

PBS indication: *Breast cancer*

Clinical criteria: *The condition must be hormone receptor positive*

AND

The treatment must be an alternative to adjuvant chemotherapy

The current prostate cancer and endometriosis indications are re-modelled as follows:

Authority Required

~~Locally advanced (equivalent to stage C) or metastatic (equivalent to stage D) carcinoma of the prostate.~~

Severity: *Locally advanced (stage C) or metastatic (stage D)*

Episodicity: *---*

Condition: *carcinoma of the prostate*

PBS indication: *Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate*

Authority Required

~~Short term treatment (up to 6 months) of visually proven endometriosis (only 1 course of not more than 6 months' therapy will be authorised).~~

Severity: *---*

Episodicity: *---*

Condition: *Endometriosis*

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PBS indication: Endometriosis

*Clinical criteria: The condition must be visually proven
AND
The treatment must be for the short-term (up to 6 months)*

NOTE:

Only 1 course of not more than 6 months' therapy will be authorised.

LETROZOLE:

Restricted Benefit

~~Treatment of hormone dependent advanced breast cancer in **post-menopausal women**~~

Restricted Benefit

~~Treatment of hormone dependent early breast cancer in **post-menopausal women**~~

{Combine advanced and early breast cancer into one indication as follows:}

PBS indication: Breast cancer

Clinical criteria: The condition must be hormone receptor positive

Population criteria: Patient must not be pre-menopausal

Restricted Benefit

~~Extended adjuvant treatment of hormone dependent early breast cancer in **post-menopausal women** commencing within 6 months of ceasing treatment with tamoxifen citrate~~

*Severity: Early
Episodicity: ---
Condition: breast cancer*

PBS indication: Early breast cancer

*Clinical criteria: The condition must be hormone receptor positive
AND
The treatment must be for extended adjuvant treatment of the condition commencing within 6 months of ceasing treatment with tamoxifen*

Population criteria: Patient must not be pre-menopausal

{The following NOTES apply to both restrictions:}

Note

This drug is not PBS-subsidised for primary prevention of breast cancer.

This drug is not PBS-subsidised for adjuvant hormonal treatment of early breast cancer extended beyond 5 years.

This drug is not PBS-subsidised for extended adjuvant early breast cancer treatment where the total duration of letrozole (or any other aromatase inhibitor) treatment extends beyond 5 years.

Note

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Shared Care Model:

For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

5 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.