

# Recommendations for Aromatase inhibitors as adjuvant endocrine therapy

for post-menopausal women with hormone receptor-positive early breast cancer

**JULY 2006** | Incorporates published evidence to May 2005

## **A CLINICAL PRACTICE GUIDELINE DEVELOPED BY THE NATIONAL BREAST CANCER CENTRE\* (NBCC\*)**

This document supplements guideline recommendation 19 about the use of tamoxifen for the management of post-menopausal women with hormone receptor-positive *early breast cancer* contained in the NBCC\* *Clinical Practice Guidelines for the Management of Early Breast Cancer*, 2nd edition, 2001 (page 9).<sup>1</sup>

ISBN Print: 1741270103 Online: 1741270111 CIP: 616.99449061

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\* In February 2008, National Breast Cancer Centre (NBCC), incorporating the Ovarian Cancer Program, changed its name to National Breast and Ovarian Cancer Centre (NBOCC). In July 2011, NBOCC amalgamated with Cancer Australia to form a single national agency, Cancer Australia, to provide leadership in cancer control and improve outcomes for Australians affected by cancer.

## **Purpose**

To provide statements and recommendations, based on the best available evidence, about the use of *aromatase inhibitors as adjuvant endocrine therapy* for post-menopausal women with hormone receptor-positive early *invasive breast cancer*.

## **Endorsed by:**



The Royal Australian  
and New Zealand  
College of Radiologists\*

The Faculty of Radiation Oncology



The Royal  
Australasian  
College  
of Physicians



The Royal Australasian  
College of Surgeons

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## Background

Aromatase inhibitors are a class of endocrine drugs that are suitable for post-menopausal women with hormone receptor-positive breast cancer. They are ineffective in pre-menopausal women, including those rendered amenorrhic by *chemotherapy* who subsequently regain menstrual function.

## Clinical practice recommendations

Recommendations to an individual should be based on their risks without treatment, the benefits and harms of treatment, and their preferences. Recommendations should also take account of any uncertainties about long-term effects. In women at high risk of breast cancer *recurrence*, the known benefits of *aromatase inhibitors* are likely to outweigh their harms (both known and unknown). Conversely, in women at low risk of breast cancer recurrence, known or unknown harms of *aromatase inhibitors* could outweigh the known benefits. In women at intermediate risk of recurrence, the balance between benefits and harms is unclear.

Women at **high risk of recurrence** include those with involved *lymph nodes*, large primary tumours (>2cm) and high-grade tumours (grade 2–3). Women at **low risk of recurrence** include those with small, well-differentiated tumours and uninvolved *lymph nodes*. More extensive discussion of these issues can be found in the NBCC\* *Clinical Practice Guidelines for the Management of Early Breast Cancer*.<sup>1</sup>

RECOMMENDATIONS	LEVEL OF EVIDENCE	AROMATASE INHIBITOR USED  in trials on which recommendation is based
<b>Adjuvant endocrine therapy is recommended for most women with hormone receptor-positive early breast cancer</b>		
Women should be informed of the potential side effects of the adjuvant endocrine therapy recommended to them, regardless of their risk of recurrence, and should be informed of any uncertainties about long-term effects		
Women receiving adjuvant endocrine therapy should be reviewed regularly and monitored for side effects by clinicians familiar with these drugs		
Reduction of <i>bone mineral density</i> in women receiving an aromatase inhibitor should be managed according to existing guidelines for women in general. <sup>8</sup> This includes the identification and treatment of women at high risk of osteoporosis	I	
<b>For post-menopausal women with hormone receptor-positive early breast cancer who are at HIGH risk of breast cancer recurrence:</b>		
If the woman has not started adjuvant endocrine therapy, it is recommended that adjuvant endocrine therapy starts with an aromatase inhibitor (rather than tamoxifen)	II	Anastrozole, Letrozole
If the woman has been on adjuvant endocrine therapy with tamoxifen for 2–3 years it is recommended that therapy be switched to an aromatase inhibitor	II	Anastrozole, Exemestane



RECOMMENDATIONS	LEVEL OF EVIDENCE	AROMATASE INHIBITOR USED in trials on which recommendation is based
If the woman has been on adjuvant endocrine therapy with tamoxifen for 5 years it is recommended that adjuvant endocrine therapy be extended with Letrozole	II	Letrozole
<b>For post-menopausal women with hormone receptor-positive early breast cancer who are at INTERMEDIATE risk of breast cancer recurrence:</b>		
Decisions about whether to use an aromatase inhibitor or tamoxifen should be based on an assessment of the risks and benefits of treatment for that individual	II	
<b>For post-menopausal women with hormone receptor-positive early breast cancer who are at LOW risk of breast cancer recurrence:</b>		
Adjuvant endocrine therapy with tamoxifen is recommended (rather than with an aromatase inhibitor) for most low-risk women as described in the NBCC* <i>Clinical Practice Guidelines for the Management of Early Breast Cancer (2001)</i> <sup>1</sup> because the balance between long-term benefits and harms of aromatase inhibitors is presently unclear for such women	II	
<b>For post-menopausal women with hormone receptor-positive early breast cancer who are intolerant of tamoxifen or who have a contra-indication to tamoxifen (regardless of risk of breast cancer recurrence):</b>		
Adjuvant endocrine therapy with an aromatase inhibitor is recommended	II	

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## Statements of evidence

STATEMENTS	LEVEL OF EVIDENCE	TRIAL AND REFERENCE (see Table 1 for details)
<b>In post-menopausal women with hormone receptor-positive early breast cancer:</b>		
Starting <i>adjuvant endocrine therapy</i> with an <i>aromatase inhibitor</i> leads to fewer breast cancer recurrences than starting with tamoxifen	II	ATAC <sup>2</sup> ; BIG 1-98 <sup>3</sup>
Switching to an aromatase inhibitor after 2–3 years of tamoxifen for a total of 5 years leads to fewer breast cancer <i>recurrences</i> than continuing with tamoxifen for 5 years	II	IES <sup>4</sup> ; ITA <sup>5</sup> ; ABCSG/ARNO <sup>6</sup>



STATEMENTS	LEVEL OF EVIDENCE	TRIAL AND REFERENCE (see Table 1 for details)
Extending treatment with letrozole for 5 years leads to fewer breast cancer recurrences than observation without further treatment in women who have recently completed 5 years of adjuvant tamoxifen	II	MA.17 <sup>7</sup>
Treatment with an aromatase inhibitor leads to fewer <i>contralateral breast</i> cancers than treatment with tamoxifen or placebo	II	ATAC <sup>2</sup> ; BIG 1-98 <sup>3</sup> ; IES <sup>4</sup> ; ITA <sup>5</sup> ; ABCSG/ARNO <sup>6</sup> ; MA.17 <sup>7</sup>
Arthralgia, loss of <i>bone mineral density</i> and fractures occur more frequently with <i>aromatase inhibitors</i> than with tamoxifen or placebo	II	ATAC <sup>2</sup> ; BIG 1-98 <sup>3</sup> ; IES <sup>4</sup> ; MA.17 <sup>7</sup>
Venous thromboembolic events and endometrial cancer occur less frequently with aromatase inhibitors than with tamoxifen	II	ATAC <sup>2</sup> ; BIG 1-98 <sup>3</sup>
Hot flushes, vaginal discharge and bleeding may occur less frequently and sexual dysfunction may occur more frequently with aromatase inhibitors than with tamoxifen	II	ATAC <sup>2</sup> ; MA.17 <sup>7</sup>
The effects of aromatase inhibitors (compared with tamoxifen or placebo) on the risks of myocardial infarction and stroke are unclear and require results from trials with longer follow-up	II	ATAC <sup>2</sup> ; BIG 1-98 <sup>3</sup> ; IES <sup>4</sup> ; MA.17 <sup>7</sup>

## Summary of evidence

This clinical practice guideline is based on available evidence from six randomised trials assessing three different ways of incorporating *aromatase inhibitors* in adjuvant *endocrine therapy* for hormone receptor-positive *early breast cancer* in post-menopausal women:

- starting adjuvant endocrine therapy with an *aromatase inhibitor* compared with starting with tamoxifen (ATAC, BIG-98)
- switching to an aromatase inhibitor after 2–3 years of tamoxifen compared with continuing on tamoxifen, both for total of 5 years of adjuvant endocrine therapy (IES, ITA, ABCSG/ARNO)
- extending adjuvant endocrine therapy by adding 5 years of an aromatase inhibitor after an initial 5 years of tamoxifen (MA.17). **(see Table 1 for details)**

Adjuvant endocrine therapy with an aromatase inhibitor significantly improved *disease-free survival* in post-menopausal women with hormone receptor-positive early breast cancer compared with tamoxifen or placebo in all six available randomised trials. Improvements in overall survival have not been demonstrated but follow-up to date is relatively short. Most women had few side effects on either aromatase inhibitors or tamoxifen and, where reported, quality of life was comparable for aromatase inhibitors and tamoxifen. The long-term effects of aromatase inhibitors are not yet known. While some trials have examined the use of aromatase inhibitors for 5 years, the optimal duration of aromatase inhibitor therapy and the optimal sequence in which different adjuvant *endocrine therapies* should be administered for the management of early breast cancer is not yet established.

## Details of trials or studies



TRIAL	FULL NAME	AROMATASE INHIBITOR	MEDIAN FOLLOW-UP	REFERENCE
ATAC	Arimidex, Tamoxifen Alone or in Combination	Anastrozole	68 months	2, 9-12
BIG 1-98	Breast International Group 1-98	Letrozole	26 months	3
IES	Intergroup Exemestane Study	Exemestane	31 months	4
ITA	Italian Tamoxifen Arimidex	Anastrozole	52 months	5
ABCSG/ ARNO	Austrian Breast Cancer Study Group/Arimidex-Nolvadex	Anastrozole	26 months	6
MA.17	Late Letrozole Trial	Letrozole	28 months	7, 13, 14

## Summary of trial or study results

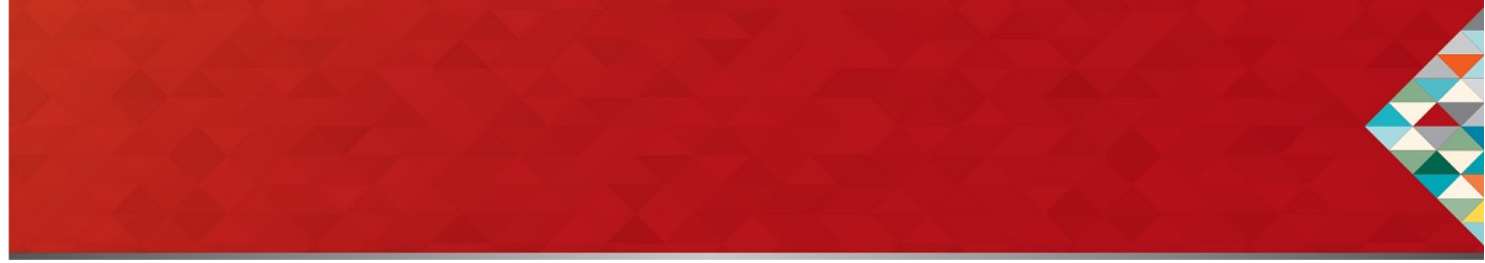
### Disease-free survival

All trials showed statistically significant improvements in *disease-free survival* with *relative* risk reductions of about 15-40% for the use of *aromatase inhibitors* compared with tamoxifen either as initial therapy or after 2-3 years of tamoxifen; or around 46% for the use of an *aromatase inhibitor* compared with placebo after 5 years of tamoxifen. In general, similar improvements were seen in all components of disease-free survival - risk of *local recurrence*, distant *recurrence* or development of a contralateral primary tumor - although not every component of disease-free survival reached statistical significance on its own. With the short follow-up and the relatively good prognosis seen in most trials to date, *absolute* differences in disease-free survival are small (<4%) and *absolute* differences in *distant* disease-free survival are even smaller. However such differences would be expected to increase over time and to be larger in women with a poorer prognosis.

### Overall survival

No trial has shown a statistically significant improvement in overall survival for the whole group randomised to an *aromatase inhibitor*. Of the trials comparing an aromatase inhibitor with tamoxifen, the trial with the most mature follow-up (ATAC) shows no difference in overall survival, while the other trials show non-significant trends favouring the aromatase inhibitor compared with tamoxifen or placebo.<sup>2</sup> Reducing distant *recurrences* might be expected to translate into improved overall survival, but further follow-up is required to confirm this. Where an aromatase inhibitor was compared with placebo after 5 years of tamoxifen (MA.17), no overall survival benefit was seen in the group as a whole.<sup>7</sup> However, a survival benefit was seen in the pre-specified subgroup with node-positive disease (p=0.04). Early reporting of the results and subsequent substantial crossover from placebo to aromatase inhibitor make it unlikely that a statistically significant survival difference will be seen in MA.17 overall.<sup>7</sup>

### Adverse events



Aromatase inhibitors and tamoxifen were generally well tolerated in all six trials. Serious adverse events were rare and withdrawals due to adverse events were generally less frequent with aromatase inhibitors than with tamoxifen, and equally frequent with an aromatase inhibitor (letrozole) and placebo. *Arthralgia*, loss of *bone mineral density* and fractures were significantly more frequent with aromatase inhibitors compared with tamoxifen or placebo. *Menopausal symptoms*, venous thromboembolic events and endometrial cancer were significantly less frequent with aromatase inhibitors compared with tamoxifen. Longer follow-up is needed to determine whether differences in serum lipids and the small numbers of myocardial infarcts and strokes seen in these trials are attributable to aromatase inhibitors or tamoxifen or are merely due to chance.

## Quality of life

Formal analyses of quality of life have been reported for two trials (ATAC and MA.17).<sup>2,7</sup> Global assessments of quality of life were similar in women receiving anastrozole and tamoxifen in ATAC, and in women receiving letrozole and placebo in MA.17. Menopausal symptom scores were similar in women receiving anastrozole and tamoxifen in ATAC – scores in both arms worsened initially and then improved over time. There were no significant differences in overall quality of life or the aggregate of endocrine symptoms in this trial. Women receiving anastrozole reported more vaginal dryness, painful intercourse, and loss of sexual interest, but fewer cold sweats and vaginal discharge than women receiving tamoxifen. In MA.17, letrozole was associated with slightly worse *menopausal symptoms*, sexual function, vitality, bodily pain, and physical function than placebo, but these differences affected only a small proportion of the women (6% or less).

## Strengths and weaknesses of the evidence

The randomised trials discussed in this report are large, well designed, and well conducted. The short-term effects of *aromatase inhibitors* on *disease-free survival* in post-menopausal women with hormone receptor-positive *early breast cancer* are strong and consistent across a range of populations, agents and settings. Information about long-term effects on overall survival and adverse events is not yet available, and even with longer follow-up will be limited by unblinding and crossover in some trials. Clinical practice recommendations developed by the NBOCC\* will be reviewed as additional significant evidence becomes available and revised as required.

## Unresolved hypotheses raised by the current data

Whether particular subgroups of women with hormone receptor-positive *early breast cancer* might benefit more or less from the use of *adjuvant endocrine therapy* with an *aromatase inhibitor* compared with tamoxifen is of particular clinical relevance, but difficult to establish with any degree of certainty. For example, an exploratory analysis within ATAC suggested that the subset of women with *oestrogen* receptor-positive, *progesterone* receptor-negative breast cancers particularly benefited from the use of anastrozole. While there are plausible biological explanations for why this could be so, it is not a consistent finding across all trials (A. Howell, personal communication). This and other subgroup analyses (for example the effect of HER2 status) remain important questions for further research, but cannot be relied upon to inform current clinical practice.

## Unanswered questions

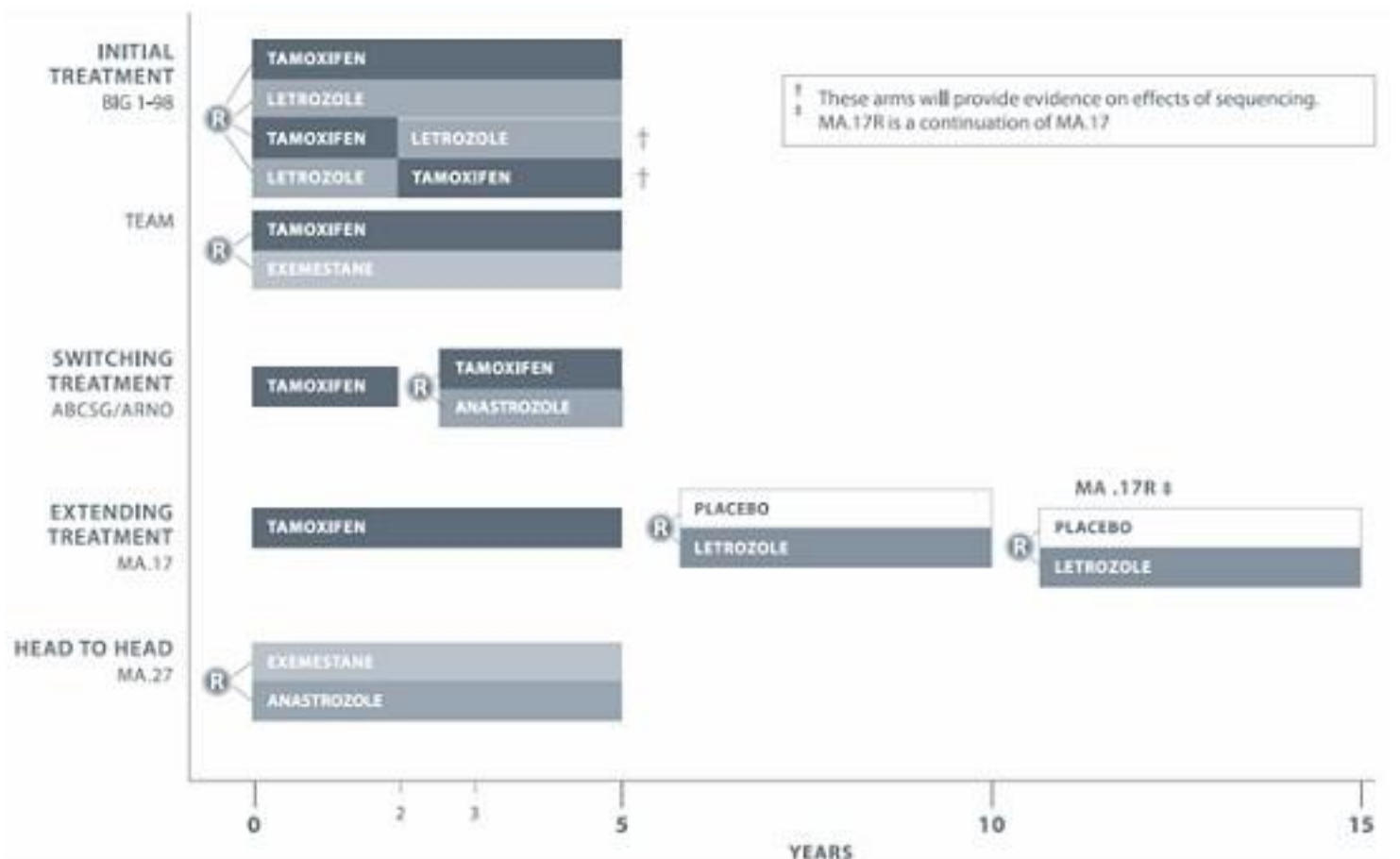
Important unanswered questions about the use of *aromatase inhibitors* as *adjuvant endocrine therapy* for *early breast cancer* that are being addressed by ongoing trials include:



- the optimal duration of *aromatase inhibitor* therapy
- whether it is better to start adjuvant endocrine therapy with an aromatase inhibitor or to start with tamoxifen and switch to an aromatase inhibitor after 2–3 years, or vice versa
- the relative benefits and harms of different aromatase inhibitors
- the relative benefits and harms of aromatase inhibitors compared with tamoxifen in pre-menopausal women receiving *ovarian suppression* therapy, or in women rendered post-menopausal by chemotherapy
- the effects of aromatase inhibitors on cognitive function
- the management of *bone mineral density* reduction due to aromatase inhibitors.

The determination of menopausal status can be difficult, particularly in younger women who no longer have a *uterus* or who have become amenorrhic during *chemotherapy*.

### Ongoing and additional trials or studies<sup>3,6,15-18</sup>



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### **Articles containing information considered by the Working Group but published after May 2005**

(Note: the following references do not represent a systematic review but are selected articles of relevance to this guideline)

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Markopoulos C, Polychronis A, Zobolas V *et al.* The effect of exemestane on the lipidemic profile of postmenopausal early breast cancer patients: preliminary results of the TEAM Greek sub-study. *Breast Cancer Res Treat* 2005; 93: 61-66.

Whelan TJ, Goss PE, Ingle JN *et al.* Assessment of Quality of Life in MA.17: a randomized, placebo-controlled trial of letrozole after 5 years of tamoxifen in postmenopausal women. *J Clin Oncol* 2005; 23: 6931-6940.

### **Other articles of interest published subsequent to development of this guideline**

Mann BS, Johnson JR, Kelly R *et al.* Letrozole in the extended adjuvant treatment of postmenopausal women with history of early-stage breast cancer who have completed 5 years of adjuvant tamoxifen. *Clin Cancer Res* 2005; 11: 5671-5677.

Dowsett M, Cuzick J, Wale C *et al.* Retrospective analysis of time to recurrence in the ATAC trial according to hormone receptor status: an hypothesis generating study. *J Clin Oncol* 2005; 23: 7512-7517.



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\* In February 2008, National Breast Cancer Centre (NBCC), incorporating the Ovarian Cancer Program, changed its name to National Breast and Ovarian Cancer Centre (NBOCC). In July 2011, NBOCC amalgamated with Cancer Australia to form a single national agency, Cancer Australia, to provide leadership in cancer control and improve outcomes for Australians affected by cancer.

## Acknowledgements

### Membership of the NBCC\*\* Hormonal Therapies Guideline Working Group

This guideline was developed by a multidisciplinary working group convened by the National Breast Cancer Centre\*\*.

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Full details of trial results are provided in the document Aromatase Inhibitors as *Adjuvant* Therapy for Post-Menopausal Women with Hormone Receptor-Positive Early Breast Cancer: Evidence Summary which can be accessed via the NBCC\*\* website at [www.nbcc.org.au](http://www.nbcc.org.au)

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### Pharmaceutical Benefits Scheme Indications for drugs mentioned in this guideline

As of July 2006. For updates after this date go to <http://www.health.gov.au/pbs/>

Tamoxifen:	Treatment of hormone-dependent breast cancer.
Anastrozole:	Treatment of hormone-dependent breast cancer in post-menopausal women. Not subsidised for primary prevention of breast cancer.

Letrozole:	Treatment of hormone-dependent <i>advanced breast cancer</i> in post-menopausal women. Not subsidised for primary prevention of breast cancer.
Exemestane:	Treatment of hormone-dependent advanced breast cancer in post-menopausal women with disease progression following treatment with tamoxifen citrate. Not subsidised for primary prevention of breast cancer.

## Development process

Priority topic areas for NBOCC guideline development are determined in consultation with key stakeholders including experts in relevant disciplines and consumer representatives. A specific multidisciplinary Working Group, including consumers, is established for each topic identified and is involved in all aspects of guideline development. A systematic evidence review is undertaken for each guideline. All members are asked to declare any conflicts of interest and these declarations are recorded. The content of the guideline is not influenced by any external funding body. The guideline is reviewed externally by key stakeholders and the wider community and endorsement is sought from relevant professional colleges and groups in Australia.

Recommendations for *aromatase inhibitors as adjuvant endocrine therapy* for post-menopausal women with hormone receptor-positive *early breast cancer* was prepared and produced by:

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 ISBN Print: 978-1-74127-010-5 Online: 978-174127-011-2 CIP: 616.99449061

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### Recommended citation

National Breast Cancer Centre. Recommendations for *aromatase inhibitors* as adjuvant endocrine therapy for post-menopausal women with hormone receptor-positive early breast cancer. National Breast Cancer Centre, Camperdown, NSW, 1450.

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National Breast and Ovarian Cancer Centre is funded by the Australian Government Department of Health and Ageing.

