

5.17 APALUTAMIDE, Tablet 240 mg, Erlyand[®], JANSSEN-CILAG PTY LTD

1 Purpose of Submission

- 1.1 The Category 4 submission requested a General Schedule Authority Required (Telephone/Online) Pharmaceutical Benefits Scheme (PBS) listing of a new strength of apalutamide (tablet 240 mg) (Erlyand[®]) under the same conditions as the currently listed strength of apalutamide (tablet 60 mg) for the treatment of castration resistant non-metastatic carcinoma of the prostate (mOCRPC) and metastatic castration sensitive carcinoma of the prostate (mHSPC) for patients undergoing concurrent androgen deprivation therapy.

2 Background

- 2.1 Apalutamide 60 mg is currently listed on the PBS as an Authority Required (Telephone/Online) listing for mOCRPC and mHSPC for patients undergoing concurrent androgen deprivation therapy.
- 2.2 The current listing requires patients to take 4 x 60 mg tablets to meet the daily 240 mg dose.
- 2.3 The submission stated that the new listing for apalutamide 240 mg will reduce the pill burden for some patients and will also provide alternative methods of administration for patients who cannot swallow the tablet whole.

Registration status

- 2.4 Apalutamide 240 mg tablets were Therapeutic Goods Administration (TGA) registered on 28 February 2024 for the treatment of patients with metastatic castration-sensitive prostate cancer or non-metastatic, castration resistant prostate cancer.

Previous PBAC consideration

- 2.5 Apalutamide 240 mg tablets have not been considered by the PBAC previously.
- 2.6 Apalutamide 60 mg tablets were PBS listed for the treatment of mOCRPC on 1 May 2022 and for the treatment of mHSPC on 1 June 2023.
- 2.7 At its March 2022 meeting, the PBAC considered apalutamide, darolutamide and enzalutamide to be non-inferior to each other in terms of efficacy and safety for mOCRPC (paragraph 7.7, enzalutamide, Public Summary Document (PSD), March 2022 PBAC Meeting).

Public Summary Document – July 2024 PBAC Meeting

- 2.8 At its March 2023 meeting, the PBAC considered enzalutamide non-inferior in terms of safety and efficacy to apalutamide in the treatment of mHSPC (paragraph 7.1, enzalutamide, PSD, March 2023 PBAC Meeting).
- 2.9 At its May 2023 meeting, the PBAC considered that darolutamide does not provide a significant improvement in efficacy and/or reduction of toxicity over apalutamide or enzalutamide in the treatment of mHSPC (paragraph 7.11, darolutamide, PSD, May 2023 PBAC Meeting).
- 2.10 At its July 2023 meeting, the PBAC considered abiraterone in combination with methylprednisolone to be non-inferior in efficacy but inferior in safety to apalutamide, enzalutamide, darolutamide for the treatment of mHSPC (paragraph 7.15, abiraterone and methylprednisolone, PSD, July 2023 PBAC Meeting).

Public Summary Document – July 2024 PBAC Meeting

Table 1: Summary of previous PBAC recommendations for m0CRPC and mHSPC

PBAC Meeting	Item	Outcome
November 2021	7.02 Apalutamide for m0CRPC	The PBAC recommended the listing of apalutamide for the treatment of patients with m0CRPC. The PBAC was satisfied that apalutamide provides, for some patients, a moderate OS benefit compared to SOC and was non-inferior in terms of efficacy and safety compared to darolutamide. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of apalutamide would be acceptable if it were cost-minimised to darolutamide.
March 2022	6.04 Enzalutamide for m0CRPC	The PBAC recommended the listing of enzalutamide for the treatment of patients with m0CRPC. The PBAC was satisfied that enzalutamide was non-inferior in terms of efficacy and safety compared to darolutamide, the primary comparator. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost minimisation approach between enzalutamide and darolutamide was acceptable and that the listing would be cost neutral to Government.
July 2022	7.02 Apalutamide for mHSPC	The PBAC recommended apalutamide for the treatment of mHSPC. The PBAC considered that apalutamide plus ADT was superior in terms of efficacy and inferior in terms of safety compared to placebo plus ADT for LV and HV mHSPC patients.
March 2023	6.02 Enzalutamide for mHSPC	The PBAC recommended listing enzalutamide for the treatment of patients with mHSPC irrespective of disease volume or suitability for docetaxel. The PBAC considered that enzalutamide was an alternative therapy to apalutamide, and that enzalutamide does not provide a significant improvement in efficacy and/or reduction of toxicity over apalutamide. The PBAC advised that the price of enzalutamide should therefore be not higher than the price of apalutamide, based on the daily cost at recommended doses.
May 2023	6.01 Darolutamide for mHSPC	The PBAC recommended darolutamide for the treatment of metastatic hormone sensitive prostate cancer (mHSPC). The PBAC considered that darolutamide was an alternative therapy to apalutamide and enzalutamide, and that darolutamide does not provide a significant improvement in efficacy and/or reduction of toxicity over apalutamide or enzalutamide. The PBAC advised that the price of darolutamide should therefore be not higher than the price of apalutamide or enzalutamide.
July 2023	6.01 Abiraterone and methylprednisolone (SAA+MPRED) for mHSPC	The PBAC recommended the listing of the composite pack of SAA+MPRED tablets for the treatment of mHSPC on a CMA versus apalutamide. The PBAC considered that SAA+MPRED, in combination with ADT, was non-inferior to apalutamide plus ADT in terms of efficacy and although it was inferior in terms of safety that the cost offsets applied in the CMA were reasonable.

Abbreviations: ADT = androgen deprivation therapy, CMA = cost minimisation approach, HV = high volume, LV = low volume, mHSPC = metastatic hormone sensitive prostate cancer, m0CRPC = non-metastatic castration resistant prostate cancer, OS = overall survival, PBAC = pharmaceutical benefits advisory committee, SOC = standard of care

Table 2: Summary of previous PBAC accepted equi-effective doses for m0CRPC and mHSPC

m0CRPC			mHSPC		
Drug	Equi-effective dose	Dosage	Drug	Equi-effective dose	Dosage
Apalutamide	240 mg daily	4 x 60 mg QD	Apalutamide	240 mg daily	4 x 60 mg QD
Enzalutamide	160 mg daily	4 x 40 mg QD	Enzalutamide	160 mg daily	4 x 40 mg QD
Darolutamide	1,200 mg daily	2 x 300 mg BID	Darolutamide	1,200 mg daily	2 x 300 mg BID
			Abiraterone and methylprednisolone	500 mg + 4 mg daily	4 x 125 mg QD + 4 mg QD

Abbreviations: BID = twice daily, mHSPC = metastatic hormone sensitive prostate cancer, m0CRPC = non-metastatic castration resistant prostate cancer, QD = once daily

3 Requested listing

3.1 The submission requested the following new listings, identical to the current restrictions for apalutamide 60 mg.

Add new medicinal product pack as follows:

MEDICINAL PRODUCT medicinal product pack		PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
APALUTAMIDE						
apalutamide 240 mg tablet, 30		NEW	1	30	5	Eryand
apalutamide 60 mg tablet, 120		12992T	1	120	5	Eryand
Restriction Summary: 12851 / Treatment of Concept: 12895						
Concept ID (for internal Dept. use)	Category / Program: GENERAL – General Schedule (Code GE)					
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)					
Prescribing rule level	Administrative Advice: Special Pricing Arrangements apply.					
	Administrative Advice: Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.					
Indication: Castration resistant non-metastatic carcinoma of the prostate						
Clinical criteria:						
The condition must have evidence of an absence of distant metastases on the most recently performed conventional medical imaging used to evaluate the condition						
AND						
Clinical criteria:						
The condition must be associated with a prostate-specific antigen level that was observed to have at least doubled in value in a time period of within 10 months anytime prior to first commencing treatment with this drug						
AND						
Clinical criteria:						
Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation						
AND						
Clinical criteria:						
Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug						
AND						
Clinical criteria:						
Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); or						
Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation						
Treatment criteria:						
Patient must be undergoing concurrent treatment with androgen deprivation therapy						

Public Summary Document – July 2024 PBAC Meeting

	<p>Prescribing Instructions: Prescribing instructions: Retain the results of all investigative imaging and prostate-specific antigen (PSA) level measurements on the patient's medical records - do not submit copies of these with this authority application. The PSA level doubling time must be based on at least three PSA levels obtained within a time period of 10 months any time prior to first commencing a novel hormonal drug for this condition. The third reading is to demonstrate that the doubling was durable and must be at least 1 week apart from the second reading.</p>
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MEDICINAL PRODUCT medicinal product pack		PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
APALUTAMIDE						
apalutamide 240 mg tablet, 30		NEW	1	30	5	Eryand
apalutamide 60 mg tablet, 120		13288J	1	120	5	Eryand
Restriction Summary: 14034 / Treatment of Concept: 14034						
Concept ID (for internal Dept. use)	Category / Program: GENERAL – General Schedule (Code GE)					
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)					
Prescribing rule level	Administrative Advice: Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.					
	Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.					
	Administrative Advice: No increase in the maximum quantity or number of units may be authorised.					
	Administrative Advice: No increase in the maximum number of repeats may be authorised.					
	Administrative Advice: Special Pricing Arrangements apply.					
Indication: Metastatic castration sensitive carcinoma of the prostate						
Clinical criteria:						
The treatment must be/have been initiated within 6 months of treatment initiation with androgen deprivation therapy						
AND						
Clinical criteria:						
Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); or						
Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation						
AND						
Clinical criteria:						
Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug						
Treatment criteria:						
Patient must be undergoing concurrent androgen deprivation therapy						

- 3.2 The submission requested prices equivalent to the effective approved ex-manufacturer prices (AEMP) for apalutamide 60 mg tablets (\$| for mOCRPC and \$| for mHSPC).
- 3.3 The submission also requested that Special Pricing Arrangements (SPAs) apply, consistent with the current listing of apalutamide 60 mg with a published AEMP of \$3,553.30 for both mOCRPC and mHSPC.

4 Comparator

- 4.1 The submission nominated apalutamide 60 mg as the main comparator for both indications. This was appropriate.
- 4.2 The PBAC considered that darolutamide and enzalutamide are also appropriate comparators for the treatment of both indications.

5 Consideration of the evidence

Sponsor hearing

- 5.1 There was no hearing for this item.

Consumer comments

- 5.2 The PBAC noted and welcomed the input from one organisation via the Consumer Comments facility on the PBS website. The comments from Rare Cancers Australia (RCA) described a range of benefits of treatment with apalutamide, including improved quality of life, where despite experiences with fatigue and hot flushes, patients stated that these side effects are significantly manageable. The RCA noted that treatment with apalutamide increased metastasis-free survival and improved other clinical outcomes. The comments also describe how apalutamide 240 mg would be more convenient for patients, supporting consistent use and better management of the condition.

TGA bioequivalence

- 5.3 The TGA stated apalutamide 240 mg film-coated tablet and apalutamide 4 x 60 mg film-coated tablets can be considered bioequivalent.

Clinical trials

- 5.4 The clinical trials presented in the submission formed part of the TGA submission to claim bioequivalence of apalutamide 240 mg with 4 x 60 mg tablets.
- 5.5 As a Category 4 submission, no evaluation of the clinical evidence was undertaken.

Table 3: Studies presented in the submission

Study Number	Protocol/Publication title	Study Objectives (Related to Safety)	Study Drug and Dose
56021927PCR1028	A single-dose, open-label, randomized, 2 part pivotal study to assess bioequivalence of a new apalutamide film-coated tablet with respect to current commercial film-coated tablets and food effect of the new tablet in healthy male participants	<p>Primary Objective</p> <p>Part One: To evaluate the bioequivalence of a new apalutamide film-coated tablet formulation relative to the current commercial apalutamide film-coated tablet formulation when administered in healthy male participants under fasted conditions.</p> <p>Part Two: To evaluate the bioavailability of a new apalutamide film-coated tablet formulation when administered under fed or fasted conditions in healthy male participants.</p> <p>Secondary Objective: To assess the safety profile of apalutamide following a single-dose administration as a new film-coated tablet formulation and as the current commercial film-coated tablet formulation in healthy male participants.</p>	<p>Subjects were randomized to receive 1 of 4 different treatments; part one: 240 mg apalutamide as a single dose of 4 x 60 mg fasted, 240 mg apalutamide as a single dose of 1 x 240 mg tablet fasted, part two: 240 mg apalutamide given as a single dose of 1 x 240 mg fasted, 240 mg apalutamide given as a single dose of 1 x 240 mg fed.</p> <p>On day 1 of each treatment period, a single-dose of the appropriate study treatment was administered to each participant in the morning approximately between 7:00 AM and 10:00 AM, followed by sequential collection of blood samples over 72 hours for the measurement of plasma concentrations of apalutamide.</p>

Source: Study Number: 56021927PCR1028 Full Clinical Study Report (Attachment 12 of the PBAC submission)

Clinical claim

- 5.6 The submission claimed non-inferior comparative effectiveness and non-inferior comparative safety of apalutamide 240 mg compared with apalutamide 4 x 60 mg.
- 5.7 The PBAC considered that, because the TGA determined bioequivalence, the claim of non-inferior comparative effectiveness and non-inferior comparative safety was reasonable.

Economic analysis

- 5.8 The submission presented a cost-minimisation approach (CMA) of apalutamide 240 mg (30 pack) versus apalutamide 4 x 60 mg (120 pack).
- 5.9 The equi-effective dose proposed by the submission is apalutamide 240 mg = apalutamide 4 x 60 mg.
- 5.10 The PBAC could only recommend listing apalutamide 240 mg at a higher price than the alternative therapy or therapies if it is satisfied that it provides, for some patients, a significant improvement in efficacy or reduction of toxicity over the alternative therapy or therapies (*National Health Act 1953, Section 101(3B)*).
- 5.11 As a Category 4 submission, the economic analysis has not been independently evaluated.

Estimated PBS usage and financial implications

- 5.12 The submission used a market-share approach to estimate the financial impact to the PBS/RPBS of the requested listing.
- 5.13 The submission assumed that 85% of patients currently on apalutamide 60 mg tablets will switch to apalutamide 240 mg tablets from Year 1. The high substitution rate assumes that most patients would switch due to the reduced pill burden of 1 x 240 mg tablet vs 4 x 60 mg tablets. In addition, apalutamide 240 mg tablets can be dispersed in more types of liquid and soft food which may be preferable for some patients. The same substitution rate was assumed for both indications.
- 5.14 The submission assumed there would be no uptake from other PBS-listed medicines indicated for mOCRPC and mHSPC.
- 5.15 Table 4 presents the estimated extent of use, cost of apalutamide to the PBS/RPBS and the net financial implications to the PBS/RPBS. The financial impact to Services Australia will be determined by that agency as part of the post PBAC process.
- 5.16 The submission estimated that 100,000 to < 200,000scripts of apalutamide 240 mg would be supplied over the first six years of listing (10,000 to < 20,000in Year 1 to 20,000 to < 30,000in Year 6).
- 5.17 The submission stated that the proposed listing was not expected to impact the overall market size and therefore estimated a nil net financial impact to the PBS/RPBS.

Table 4: Estimated use and financial implications – effective price

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of scripts for apalutamide 60 mg	1	2	2	3	3	3
Estimated uptake rate	85%	85%	85%	85%	85%	85%
Number of scripts for apalutamide 240 mg	1	2	2	2	2	2
Estimated financial implications of apalutamide 240 mg						
Cost to PBS/RPBS less co-payment	4	5	6	6	6	6
Estimated financial implications of apalutamide 60 mg						
Cost to PBS/RPBS less co-payment	7	7	7	7	7	7
Net financial implications						
Net cost to PBS/RPBS	Nil	Nil	Nil	Nil	Nil	Nil

Abbreviations: PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.

Source: Table 3a and 3c, Submission Utilisation and Cost Model workbook

The redacted values correspond to the following ranges

1 10,000 to < 20,000

2 20,000 to < 30,000

3 30,000 to < 40,000

4 \$10 million to < \$20 million

5 \$20 million to < \$30 million

6 \$30 million to < \$40 million

7 net cost saving

Risk Sharing Arrangements

- 5.18 The submission proposed that apalutamide 240 mg be subject to the existing Risk Sharing Arrangement (RSA) for mHSPC.

6 PBAC Outcome

- 6.1 The PBAC recommended a General Schedule Authority Required (Telephone/Online) PBS listing of a new strength of apalutamide (tablet 240 mg) under the same conditions as the currently listed strength of apalutamide (tablet 60 mg) for the treatment of mOCRPC and mHSPC for patients undergoing concurrent androgen deprivation therapy. The PBAC's recommendation for listing was based on, among other matters, its assessment that apalutamide 240 mg would be cost-effective if it were cost-minimised to the lowest cost comparator of apalutamide (60 mg), enzalutamide or darolutamide, for the treatment of mOCRPC and mHSPC.
- 6.2 The PBAC advised the equi-effective doses to be apalutamide 240 mg and apalutamide 4 x 60 mg.
- 6.3 The PBAC advised that the proposed restrictions were appropriate.
- 6.4 The PBAC noted the comments from RCA which supported the listing of apalutamide 240 mg. The comments stated it would be more convenient for patients, and support consistent use and better management of the condition.
- 6.5 The PBAC considered the proposed uptake rate was appropriate and considered it was reasonable to assume that the majority of apalutamide 240 mg use would replace apalutamide 60 mg.
- 6.6 The PBAC considered that the proposed listing should not result in any additional cost to Government. The PBAC advised that apalutamide 240 mg be subject to the existing RSA for mHSPC.
- 6.7 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because apalutamide 240 mg is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over apalutamide 60 mg, or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.
- 6.8 The PBAC noted that this submission is not eligible for an Independent Review because it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

7.1 Add new medicinal product pack:

MEDICINAL PRODUCT medicinal product pack		PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
APALUTAMIDE						
apalutamide 240 mg tablet, 30		NEW	1	30	5	Eryand
apalutamide 60 mg tablet, 120		12992T	1	120	5	Eryand
Restriction Summary: 12851 / Treatment of Concept: 12895						
Concept ID (for internal Dept. use)	Category / Program: GENERAL – General Schedule (Code GE)					
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)					
Prescribing rule level	Administrative Advice: Special Pricing Arrangements apply.					
	Administrative Advice: Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.					
Indication: Castration resistant non-metastatic carcinoma of the prostate						
Clinical criteria:						
The condition must have evidence of an absence of distant metastases on the most recently performed conventional medical imaging used to evaluate the condition						
AND						
Clinical criteria:						
The condition must be associated with a prostate-specific antigen level that was observed to have at least doubled in value in a time period of within 10 months anytime prior to first commencing treatment with this drug						
AND						
Clinical criteria:						
Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation						
AND						
Clinical criteria:						
Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug						
AND						
Clinical criteria:						
Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); or						
Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation						
Treatment criteria:						
Patient must be undergoing concurrent treatment with androgen deprivation therapy						

Public Summary Document – July 2024 PBAC Meeting

	<p>Prescribing Instructions: Prescribing instructions: Retain the results of all investigative imaging and prostate-specific antigen (PSA) level measurements on the patient's medical records - do not submit copies of these with this authority application. The PSA level doubling time must be based on at least three PSA levels obtained within a time period of 10 months any time prior to first commencing a novel hormonal drug for this condition. The third reading is to demonstrate that the doubling was durable and must be at least 1 week apart from the second reading.</p>
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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
APALUTAMIDE					
apalutamide 240 mg tablet, 30	NEW	1	30	5	Eryland
apalutamide 60 mg tablet, 120	13288J	1	120	5	Eryland

Restriction Summary: 14034 / Treatment of Concept: 14034

Concept ID (for internal Dept. use)	Category / Program: GENERAL – General Schedule (Code GE)
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)
Prescribing rule level	Administrative Advice: Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) apalutamide, (iv) darolutamide, (v) enzalutamide.
	Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.
	Administrative Advice: No increase in the maximum quantity or number of units may be authorised.
	Administrative Advice: No increase in the maximum number of repeats may be authorised.
	Administrative Advice: Special Pricing Arrangements apply.
	Indication: Metastatic castration sensitive carcinoma of the prostate
	Clinical criteria:
	The treatment must be/have been initiated within 6 months of treatment initiation with androgen deprivation therapy
	AND
	Clinical criteria:
	Patient must only receive subsidy for one novel hormonal drug per lifetime for prostate cancer (regardless of whether a drug was subsidised under a metastatic/non-metastatic indication); or
	Patient must only receive subsidy for a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation
	AND
	Clinical criteria:
	Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug
	Treatment criteria:
30645	Patient must be undergoing concurrent androgen deprivation therapy

These restrictions may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

9 Sponsor's Comment

The sponsor had no comment.