5.16 ABIRATERONE ACETATE AND PREDNISOLONE, Pack containing 56 tablets abiraterone acetate 500 mg and 56 tablets prednisolone 5 mg, Andriga-10, Actor Pharmaceuticals Pty Ltd

1 Purpose of Submission

1.1 The Category 3 submission requested a General Schedule Authority Required (Telephone/Online) listing of a composite pack containing abiraterone acetate and prednisolone (ANDRIGA-10; hereafter referred to as ANDRIGA-10) for the treatment of patients with metastatic castration resistant prostate cancer (mCRPC).

1.2 Listing was requested on the basis of a cost-minimisation approach versus abiraterone acetate (Zytiga®) and prednisolone used concomitantly for the treatment of mCRPC.

2 Background

2.1 There is no composite pack of abiraterone acetate and prednisolone currently listed on the PBS.

2.2 Abiraterone is currently listed on the PBS as an Authority Required (Telephone/Online) listing for castration resistant metastatic carcinoma of the prostate. Prednisolone is currently listed on the PBS as an unrestricted benefit for a quantity of 30, and as a restricted benefit for a quantity of 60 (60-day dispensing).

Registration status

2.3 ANDRIGA-10 was Therapeutic Goods Administration (TGA) registered on 7 July 2025 for the treatment of patients with mCRPC who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy (ADT) or patients with mCRPC who have received prior chemotherapy containing a taxane.

2.4 The TGA Delegate's Overview (p3) noted the approved therapeutic indication for the reference abiraterone product, ZYTIGA, requires coadministration with prednisolone to improve safety. The proposed doses and indications for ANDRIGA are identical to ZYTIGA. Hence, the efficacy and safety have been established for abiraterone + prednisolone at the proposed doses and for the proposed indications in people with mHSPC or mCRPC.

Previous PBAC consideration

2.5 In November 2012 the PBAC recommended listing abiraterone 250 mg tablets (Zytiga) on the PBS as an Authority Required listing for the treatment, in combination with

prednisone or prednisolone, of castration resistant metastatic carcinoma of the prostate in a patient who has failed treatment with docetaxel on a cost-minimisation basis with cabazitaxel and a cost-effectiveness basis compared with best supportive care.

2.6 Abiraterone acetate 250 mg tablets (Zytiga) was listed on the PBS for the treatment of patients with mCRPC on 1 August 2013. Abiraterone acetate 500 mg (Zytiga) was listed on the PBS on 1 December 2017.

3 Requested listing

3.1 The submission requested the following new listing. Suggested additions are in italics and deletions are in strikethrough.

Add new medicinal product as follows:

MEDICINAL PRODUCT **medicinal product pack**		**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
ABIRATERONE (&) PREDNISOLONE						
Abiraterone acetate 500 mg tablet [56] (&) prednisolone 5 mg tablet [56], 112		NEW	1	1	2	Andriga 10
Concept ID	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)					
	Prescriber type: ☒Medical Practitioners					
	Benefit type: ☒ Authority Required (telephone/online PBS Authorities system)					
Prescribing rule	**Caution:** The bioavailability on a mg to mg basis of abiraterone combination product ~~(Item 13263C;~~ Yonsa MPred~~)~~ ~~and~~ *to* ANDRIGA-10~~ is not equivalent.~~ *or abiraterone single drug product is not equivalent. When changing between abiraterone products, exercise caution in explaining correct dosing directions to the patient.*					
Prescribing rule	**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.					
Prescribing rule	**Administrative Advice:** Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) *abiraterone and prednisolone, (iv)* apalutamide, (~~iv~~) darolutamide, (v*i*) enzalutamide.					
Restriction Summary [13992] / Treatment of Concept: [13992]						
	Indication: Castration resistant metastatic carcinoma of the prostate					
	Clinical criteria:					
	The treatment must not be used in combination with chemotherapy					
	AND					
	Clinical criteria:					
	Patient must have a WHO performance status of 2 or less					
	AND					
	Clinical criteria:					
	The treatment must not be a PBS benefit where disease progression occurs whilst being treated with any of: (i) a combination treatment containing the individual drugs in one pharmaceutical benefit, (ii) the individual drugs obtained as separate pharmaceutical benefits					

	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 treatment with a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation

3.2 The requested PBS listing for ANDRIGA-10 is aligned with the listing for Zytiga 500 mg for mCRPC of the prostate. The PBAC considered this was appropriate given the listing for prednisolone is unrestricted on the PBS. The requested PBS listing for ANDRIGA-10 is also aligned with the authority required listing for composite pack Yonsa Mpred (fine particle formulation abiraterone and methylprednisolone; PBS item code 13263C), noting that Yonsa Mpred contains abiraterone 125 mg and ANDRIGA-10 contains abiraterone 500 mg and different corticosteroids.

3.3 Given the inclusion of prednisolone tablets in the ANDRIGA-10 composite pack, the criteria for use with a corticosteroid was removed. The PBAC considered this was appropriate as it aligned with Yonsa Mpred which also does not include this criterion.

3.4 The requested listing aligns with the proposed TGA indication for ANDRIGA-10.

3.5 The submission noted that brand substitution between ANDRIGA-10 and the reference products Zytiga 500 mg and prednisolone 5 mg is not expected to occur at a pharmacy-level due to the nature of the composite pack containing two generic products. Therefore, a-flagging was not requested. The PBAC considered this was appropriate.

3.6 The submission noted the bioavailability on a mg to mg basis of Yonsa MPred and ANDRIGA-10 (or the single drug product) is not equivalent. Therefore, the submission and Pre-PBAC Response proposed changes to the caution note to highlight this difference. The PBAC considered it appropriate to include the proposed caution note to highlight the difference between abiraterone acetate and fine particle formulation abiraterone and have this flow on to Yonsa Mpred to avoid prescriber confusion. Additionally, the submission did not request interchangeability between ANDRIGA-10 and Yonsa Mpred. The PBAC considered this was appropriate.

3.7 The proposed restriction included clinical criteria that a patient must only receive subsidy for one 'novel hormonal drug' per lifetime for prostate cancer. The restriction included administrative advice specifying which therapies 'novel hormonal drug' refers to. The PBAC considered ANDRIGA-10 should be included in this list ('abiraterone & prednisolone'), so that it is included as one of the subsidised novel hormonal drugs for prostate cancer. The PBAC considered this administrative advice should be updated for all other PBS listed novel hormonal agents.

3.8 At this meeting, the PBAC considered the review of PBS-listed medicines for nurse practitioner prescribing. The PBAC recommended that nurse practitioners be permitted to authorise PBS benefits for abiraterone and abiraterone combination

products where the benefit is limited to continuing existing treatment with abiraterone and where the patient's care is shared with a medical practitioner. The PBAC considered this advice would apply to the listing for ANDRIGA-10.

4 Comparator

4.1 The submission nominated abiraterone acetate 500 mg tablets (Zytiga) and prednisolone 5 mg tablets (Panafcortelone) used concomitantly as the main comparator. The PBAC considered the comparator to be appropriate.

4.2 Under Section 101 (3B) of the *National Health Act*, the PBAC cannot recommend to the Minister that a drug or medicinal preparation be made available as a Pharmaceutical Benefit if it is substantially more costly than an alternate therapy or therapies unless for some patients, it provides a significant improvement in efficacy or reduction of toxicity over the alternate therapy or therapies.

4.3 For the requested population, Yonsa Mpred and enzalutamide may be considered alternative therapies because they could be replaced in practice for the treatment of mCRPC. These alternative therapies may be less costly than ANDRIGA-10. At its November 2022 meeting, the PBAC recommended the listing of a composite pack comprising of abiraterone acetate tablets in a fine particle formulation and oral methylprednisolone (Yonsa Mpred) for the treatment of mCRPC. The PBAC considered the claim of noninferior effectiveness and safety of Yonsa Mpred to the oral originator abiraterone and prednisone was reasonable. However, for the purposes of satisfying Section 101(3B) of the *National Health Act 1953*, the PBAC considered that any treatments for mCRPC were relevant alternative therapies. The PBAC's recommendation for listing was therefore based on, among other matters, its assessment that the cost effectiveness for Yonsa Mpred would be acceptable if it was cost-minimised against the least costly alternative therapy for mCRPC. The PBAC recalled its March 2022 consideration that the nominated comparator, originator abiraterone acetate given with prednisone, was acceptable given these would likely be replaced by Yonsa Mpred in practice, although considered that enzalutamide was also a relevant comparator (para 7.2, 7.3, Yonsa Mpred Public Summary Document).

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 health care organisations (1) and consumer groups (1) via the Consumer Comments facility on the PBS website.

5.3 Rare Cancers Australia noted that mCRPC can significantly impact patients' physical health which can lead to social isolation and financial hardship due to loss of income

and ability to work. The comment stated that ANDRIGA-10 is generally well tolerated by patients and offers a more convenient oral option that may help patients maintain a more normal, less interrupted daily life.

5.4 The Medical Oncology Group of Australia (MOGA) expressed its support for the ANDRIGA-10 submission and its listing on the PBS.

Clinical trials

5.5 The submission stated a literature search failed to identify any clinical studies specifically relating to ANDRIGA-10 or its generic components. Therefore, the submission was based on the regulatory submission for ANDRIGA-10 which concluded that abiraterone 500 mg and prednisolone 5 mg contained in ANDRIGA-10 are generics of PBS-listed Zytiga 500 mg and prednisolone 5 mg, respectively where clinical data of the reference products can be applied to this composite medicine pack. The submission also stated that effectiveness and cost effectiveness of Zytiga 500 mg + prednisolone 5 mg for the treatment of mCRPC have been established and accepted previously by the PBAC and were therefore not provided in this submission, such that, as a composite medicine pack containing two generics components, similar health outcomes can be expected with ANDRIGA-10 when given at the equivalent dose for the treatment of patients with mCRPC.

5.6 As a Category 3 submission, no evaluation of the clinical evidence was undertaken.

Clinical claim

5.7 The submission claimed non-inferior comparative effectiveness and non-inferior comparative safety of ANDRIGA-10 compared with Zytiga 500 mg tablets and prednisolone 5 mg tablets.

5.8 The PBAC considered that the claim of noninferior comparative effectiveness and safety was reasonable.

Economic analysis

5.9 As a Category 3 submission, the economic analysis was not independently evaluated.

5.10 The proposed AEMP of ANDRIGA-10 is $821.06 for a 28-day supply which is the same cost per day ($29.32) as abiraterone acetate and prednisolone used concomitantly. Only drug costs at the AEMP were considered in the submission, with the key outcome being the AEMP per day of treatment to account for the 28-day supply of ANDRIGA-10 versus the 30-day supply of the Zytiga and prednisolone.

5.11 The submission presented a cost-minimisation approach of ANDRIGA-10 compared with Zytiga and prednisolone used concomitantly. The equi-effective doses were estimated as ANDRIGA-10 abiraterone 1000 mg (500 mg tablet x 2) and prednisolone 10 mg (5 mg tablet x 2) = abiraterone 1000 mg (500 mg tablet x 2 or 250 mg tablet x 4) and prednisolone 10 mg (5 mg tablet x 2).

Table 1: Sum of component pricing of abiraterone and prednisolone

			Dose (mg)					
Sum of component pricing	**PBS code**	**Max Qty**	**per tab**	**Daily**	**Tabs/day**	**Pack duration**	**AEMP**	**AEMP per day**
Abiraterone 500 mg	11206T	60	500	1000	2	30	$876.42	$29.21
Prednisolone 5 mg	1917X	60	5	10	2	30	$3.29	$0.11
Sum of component pricing							**$879.71**	**$29.32**

Source: Attachment 3.1 – ANDRIGA-10 CMA.xlsx of submission. max = maximum; qty = quantity, AEMP = approved ex-manufacturer price

Table 2: Proposed AEMP and AEMP per day of ANDRIGA-10

			Dose (mg)					
Proposed product Andriga-10	**PBS code**	**Max Qty**	**per tab**	**Daily**	**Tabs/day**	**Pack duration**	**AEMP**	**AEMP per day**
Abiraterone component	NA	56	500	1000	2	28	$817.99	$29.21
Prednisolone component	NA	56	5	10	2	28	$3.07	$0.11
							$821.06	**$29.32**

Source: Attachment 3.1 – ANDRIGA-10 CMA.xlsx of submission. max = maximum; qty = quantity, AEMP = approved ex-manufacturer price

5.12 In the context of the cost-minimisation approach taken by the submission, a further consideration for PBAC is that, under Section 101(3B) of the *National Health Act 1953*, when the proposed medicine is substantially more costly than an alternative therapy, the committee cannot make a positive recommendation unless it is satisfied that, for some patients, the proposed medicine provides a significant improvement in efficacy and/or reduction of toxicity over the alternative therapy. If the committee is so satisfied, it must make a statement to this effect.

5.13 As noted in paragraph 4.2, for the requested population, Yonsa Mpred and enzalutamide may be considered alternative therapies because they could be replaced in practice for the treatment of mCRPC. These alternative therapies may be less costly than ANDRIGA-10.

Drug cost/patient/year: $12,427.43

5.14 The estimated drug cost/patient per year would be $12,427.43, based on the DPMQ of $927.42 presented in the submission and the number of scripts per year (13.4) as estimated in the Utilisation and Cost Model workbook (UCM).

Estimated PBS usage and financial implications

5.15 Table 3 presents the estimated use and the net financial implications to the PBS/RPBS of listing ANDRIGA-10. The financial impact to Services Australia will be determined by that agency as part of the post PBAC process.

Table 3: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of scripts dispensed[a]	[redacted][1]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][3]	[redacted][3]
Estimated financial implications of ANDRIGA-10						
Cost to PBS/RPBS less co-payment	$[redacted][4]	[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]
Estimated financial implications of Abiraterone 250 mg tablet, 4 per day						
Cost to PBS/RPBS less co-payment	-$[redacted][4]	-$[redacted][4]	-$[redacted][4]	-$[redacted][4]	-$[redacted][4]	-$[redacted][4]
Estimated financial implications of Abiraterone 500 mg tablet, 2 per day						
Cost to PBS/RPBS less co-payment	-$[redacted][4]	-$[redacted][4]	-$[redacted][4]	-$[redacted][4]	-$[redacted][4]	-$[redacted][4]
Estimated financial implications of Abiraterone and methylprednisolone (Yonsa Mpred) 125 mg tablet, 4 per day						
Cost to PBS/RPBS less co-payment	-$[redacted][4]	-$[redacted][4]	-$[redacted][4]	-$[redacted][4]	-$[redacted][4]	-$[redacted][4]
Estimated financial implications of prednisolone 5 mg tablet, 2 per day						
Cost to PBS/RPBS less co-payment	-$[redacted][4]	-$[redacted][4]	-$[redacted][4]	-$[redacted][4]	-$[redacted][4]	-$[redacted][4]
Net financial implications						
Net cost to PBS/RPBS	-$[redacted][4]	-$[redacted][4]	-$[redacted][4]	-$[redacted][4]	-$[redacted][4]	-$[redacted][4]

[a] Assuming 13.04 per patient per year as estimated by the submission.

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

Source: Sheet 3b. Impact – proposed (pub), Sheet 5. Impact – net of submission

The redacted values correspond to the following ranges:

[1] 500 to < 5,000

[2] 5,000 to < 10,000

[3] 10,000 to < 20,000

[4] $0 to < $10 million

5.16 The submission stated the net financial impact to the PBS/RPBS for the listing of ANDRIGA-10 was estimated to be a saving of $0 to < $10 million in Year 6, and a total saving of $0 to < $10 million over six years. The submission noted that the savings associated with the listing of ANDRIGA-10 to the R/PBS is a result of the small changes due to reduced supply chain markups that exceed patient copayments for the prednisolone component.

5.17 The submission noted there are four brands of abiraterone acetate 500 mg tablets and two brands of prednisolone 5 mg available on the PBS. All brands of the respective drugs are a-flagged and expected to be replaced to some extent in practice by ANDRIGA-10.

5.18 The submission presented PBS items statistics showing that the mCRPC market is not growing, with no change expected as a result of the proposed listing. Abiraterone estimated growth rates for 2025-2031 used in this submission were calculated in the UCM using a linear approach. Based on the Medicare statistics data for abiraterone from 2018 to 2024, the abiraterone market has remained stable. The submission noted that within the abiraterone market, Zytiga was losing market share to Yonsa Mpred (PBS item code 13263C). The submission stated the bioavailability on a mg to mg basis of Yonsa MPred and ANDRIGA-10 (or the single drug product) is not

equivalent. As such, the submission stated that whilst ANDRIGA-10 may replace new initiations of the Yonsa Mpred, it is not anticipated that there would be any significant switching from existing Yonsa Mpred patients. The PBAC noted that based on the Medicare statistics data for Yonsa Mpred from 2023 to 2024, the Yonsa Mpred market appeared to be growing in a linear trend.

5.19 Additionally, the submission acknowledged that as a prodrug of prednisolone, there may also be some substitution of prednisone (listed brands include Predsone, Panafcort and Sone), where this is currently given in combination with abiraterone acetate. As both prednisolone and prednisone are unrestricted items and used for several different indications, it was not possible for the submission to determine the proportion of use of each for mCRPC. However based on PBS utilisation statistics, the submission assumed that there is limited use of prednisone. The submission assumed there would be much greater displacement of prednisolone in practice and therefore prednisone was not considered further in this submission.

Quality use of medicines

5.20 The submission claimed that the listing of ANDRIGA-10, as a composite medicine pack, offers additional benefits and may serve to further improve health and economic outcomes by:

- The simplification of therapy, leading to improved medical compliance.
- A composite medicine pack may increase prednisolone compliance, mitigating against potential safety risks.
- Reduced financial burden associated with treatment for vulnerable patients with mCRPC.
- Reduced cost to Government associated with treatment of mCRPC.

6 PBAC Outcome

6.1 The PBAC recommended the General Schedule Authority Required (Telephone/Online) listing of a composite pack containing abiraterone acetate 500 mg tablets and prednisolone 5 mg tablets (ANDRIGA-10) for the treatment of patients with metastatic castration resistant prostate cancer (mCRPC).

6.2 The PBAC considered the claim of noninferior effectiveness and safety of ANDRIGA-10 to abiraterone and prednisolone was reasonable. However, the PBAC considered for the purposes of satisfying Section 101(3B) of the *National Health Act 1953*, any treatments for mCRPC are relevant alternative therapies. The PBAC's recommendation for listing was therefore based on, among other matters, its assessment that the cost effectiveness for ANDRIGA-10 would be acceptable if it was cost-minimised against the least costly alternative therapy for mCRPC.

6.3 The PBAC considered the equi-effective doses of ANDRIGA-10 and the alternative therapies were:

- ANDRIGA-10 abiraterone 1000 mg (500 mg tablet x 2) and prednisolone 10 mg (5 mg tablet x 2) is equivalent to abiraterone 1000 mg (500 mg tablet x 2 or 250 mg tablet x 4) and prednisolone 10 mg (5 mg tablet x 2)
- Yonsa Mpred abiraterone acetate tablets (fine particle formulation) 500 mg + methylprednisolone 8 mg is equivalent to abiraterone acetate 1000 mg + prednisolone/prednisone 10 mg
- enzalutamide 160 mg is equivalent to abiraterone 1000 mg

6.4 The PBAC welcomed input from Rare Cancers Australia and the Medical Oncology Group of Australia (MOGA) supporting the submission.

6.5 The PBAC considered the submission nominated comparator, abiraterone acetate 500 mg tablets (Zytiga) and prednisolone 5 mg tablets (Panafcortelone) used concomitantly, was acceptable given these would likely be replaced by ANDRIGA-10 in practice.

6.6 The PBAC noted the regulatory submission for ANDRIGA-10 concluded that abiraterone 500 mg and prednisolone 5 mg contained in ANDRIGA-10 are generics of PBS-listed Zytiga 500 mg and prednisolone 5 mg, respectively, where clinical data of the reference products can be applied to this composite medicine pack. Therefore, the PBAC accepted the claim of non-inferior comparative effectiveness and non-inferior comparative safety of ANDRIGA-10 compared with combination use of abiraterone acetate and prednisolone.

6.7 The PBAC considered the approach taken in the submission for the economic analysis and utilisation estimates were reasonable.

6.8 The PBAC accepted the proposed restrictions and noted the requested listing aligns with the approved TGA indication for ANDRIGA-10

6.9 The PBAC recommended the following updates to the restriction for ANDRIGA-10 and restriction flow-ons to the following listings:

- For abiraterone & methylprednisolone: Update the caution note to highlight the difference in bioavailability of abiraterone on a mg to mg basis between abiraterone fine particle formulation (Yonsa Mpred) and ANDRIGA-10 or single abiraterone acetate drug products.
- For abiraterone, abiraterone & methylprednisolone, apalutamide, cabazitaxel, darolutamide, enzalutamide, olaparib, talazoparib: Add ANDRIGA-10 ('abiraterone & prednisolone') to the administrative advice so that it is included as one of the subsidised novel hormonal drugs for prostate cancer.

6.10 The PBAC recommended that nurse practitioners be permitted to authorise PBS benefits for ANDRIGA-10 where the benefit is limited to continuing existing treatment with ANDRIGA-10 and where the patient's care is shared with a medical practitioner. The PBAC noted that this is consistent with its advice for abiraterone and abiraterone

combination products in the review of PBS-listed medicines for nurse practitioner prescribing which was also considered at its July 2025 PBAC meeting.

6.11 The PBAC recommended that abiraterone and prednisolone should not be treated as interchangeable with any other drugs.

6.12 The PBAC recommended the Early Supply Rule should not apply.

6.13 The PBAC advised that as ANDRIGA-10 is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over abiraterone acetate and prednisolone used concomitantly, or 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.

6.14 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 as follows:

<table>
<tr><td colspan="7">Category / Program: GENERAL - General Schedule (Code GE)</td></tr>
<tr><td colspan="2">MEDICINAL PRODUCT
medicinal product pack</td><td>PBS item code</td><td>Max. qty packs</td><td>Max. qty units</td><td>№.of Rpts</td><td>Available brands</td></tr>
<tr><td colspan="7">ABIRATERONE (&) PREDNISOLONE</td></tr>
<tr><td colspan="2">abiraterone acetate 500 mg tablet [56] (&) prednisolone 5 mg tablet [56], 112</td><td>NEW MP NP</td><td>1</td><td>1</td><td>2</td><td>ANDRIGA-10</td></tr>
<tr><td colspan="7"></td></tr>
<tr><td colspan="2">Concept ID</td><td colspan="5">☒</td></tr>
<tr><td colspan="2"></td><td colspan="5">Benefit type: ☒ Authority Required (telephone/online PBS Authorities system)</td></tr>
<tr><td>Prescribi</td><td></td><td colspan="5">Caution:
The bioavailability on a mg to mg basis of abiraterone combination product Yonsa MPred to ANDRIGA-10 or abiraterone single drug product is not equivalent. When changing between abiraterone products, exercise caution in explaining correct dosing directions to the patient</td></tr>
<tr><td rowspan="2"></td><td></td><td colspan="5">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.</td></tr>
<tr><td></td><td colspan="5">Administrative Advice:
Where the term ‘novel hormonal drug’ appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone & methylprednisolone, (iii) abiraterone & prednisolone, (iv) apalutamide, (iv) darolutamide, (vi) enzalutamide.</td></tr>
<tr><td colspan="7">Restriction Summary [13992 modified] / Treatment of Concept: [13992 modified]</td></tr>
<tr><td colspan="2"></td><td colspan="5">Indication: Castration resistant metastatic carcinoma of the prostate</td></tr>
</table>

	Clinical criteria:
	The treatment must not be used in combination with chemotherapy
	AND
	Clinical criteria:
	Patient must have a WHO performance status of 2 or less
	AND
	Clinical criteria:
	The treatment must not be a PBS benefit where disease progression occurs whilst being treated with any of: (i) a combination treatment containing the individual drugs in one pharmaceutical benefit, (ii) the individual drugs obtained as separate pharmaceutical benefits
	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 treatment with a subsequent novel hormonal drug where there has been a severe intolerance to another novel hormonal drug leading to permanent treatment cessation.
	Treatment criteria
	Must be treated by a medical practitioner, **OR**
	Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, (ii) the prescription continues existing therapy with this medicine

Flow on changes:

7.2 Amend the following listings to reflect recommendations from paragraphs 6.9 and 6.10:

PBS Item code	Drug	Description of flow on change
7236W	Cabazitaxel	Replace 31722 with AA1
4376H	Cabazitaxel	Replace 31722 with AA1
10174L	Enzalutamide	Replace 31722 with AA1
13118K	Enzalutamide	Replace 31722 with AA1
13353T	Enzalutamide	Replace 31722 with AA1
14684W	Talazoparib	Replace 31722 with AA1
14685X	Talazoparib	Replace 31722 with AA1
14690E	Talazoparib	Replace 31722 with AA1
14683T	Talazoparib	Replace 31722 with AA1
12932P	Olaparib	Replace 31722 with AA1
12929L	Olaparib	Replace 31722 with AA1
12921C	Olaparib	Replace 31722 with AA1
12913P	Olaparib	Replace 31722 with AA1
13288J	Apalutamide	Replace 31722 with AA1
12992T	Apalutamide	Replace 31722 with AA1
13769Q	Darolutamide	Replace 31722 with AA1
12684N	Darolutamide	Replace 31722 with AA1
2698B	Abiraterone	Replace 31722 with AA1

		Insert 33255 and TC1
11206T	Abiraterone	Replace 31722 with AA1 Insert 33255 and TC1
14078Y	Abiraterone acetate & methylprednisolone	Replace 31722 with AA1 Replace existing Caution with C01 Insert 33255 and TC1
13263C	Abiraterone acetate & methylprednisolone	Replace 31722 with AA1 Replace existing Caution with C01 Insert 33255 and TC1
	Administrative Advice: Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, *(ii) abiraterone & methylprednisolone, (iii) abiraterone & prednisolone,* (~~ii~~*iv*) apalutamide, (~~iii~~*v*) darolutamide, (~~iv~~*vi*) enzalutamide.	
	Caution The bioavailability on a mg to mg basis of abiraterone combination product *Yonsa Mpred to* ~~and~~ *ANDRIGA-10 or* abiraterone single drug product is not equivalent. When changing between abiraterone products, exercise caution in explaining correct dosing directions to the patient.	
	Treatment criteria	
	Must be treated by a medical practitioner, **OR**	
	Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, (ii) the prescription continues existing therapy with this medicine	

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

9 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.

10 Sponsor's Comment

The sponsor had no comment.