

5.16 NANDROLONE DECANOATE

Injection 50 mg in 1 mL ampoule

Deca-Durabolin[®], Aspen Australia

1 Purpose of Application

- 1.1 The minor submission requested an Authority Required listing of a new form of nandrolone decanoate for the treatment of osteoporosis.
- 1.2 The submission also requested a price increase for the new form of nandrolone decanoate. However, the Secretariat notes the PBAC is required to consider if there is a clinical need for nandrolone decanoate to be retained on the PBS prior to consideration of a price adjustment.

2 Requested listing

- 2.1 The submission requested the same PBS listing as the existing form of nandrolone decanoate:

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
NANDROLONE DECANOATE injection 50 mg in 1 mL ampoule	1	7	\$ [REDACTED]	Deca-durabolin®	Aspen Australia

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners
Condition:	Osteoporosis
PBS Indication:	Osteoporosis
Restriction Level / Method:	<input checked="" type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input checked="" type="checkbox"/> Authority Required – Emergency <input checked="" type="checkbox"/> Authority Required - Electronic
Clinical criteria:	The treatment must be as monotherapy, AND The treatment must be where other treatment has failed and where specialist advice confirms that this is the only suitable treatment option for the patient.
Administrative Advice	Monotherapy for the treatment of osteoporosis does not exclude calcium supplementation. Specialist advice need only be obtained for the first authority approval.

Public Summary Document – March 2018 PBAC Meeting

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners
Condition:	Osteoporosis
PBS Indication:	Osteoporosis
Restriction Level / Method:	<input checked="" type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input checked="" type="checkbox"/> Authority Required – Emergency <input checked="" type="checkbox"/> Authority Required - Electronic
Clinical criteria:	<p>The treatment must be as monotherapy, AND The treatment must be where other treatment is not tolerated and where specialist advice confirms that this is the only suitable treatment option for the patient.</p>
Administrative Advice	<p>Monotherapy for the treatment of osteoporosis does not exclude calcium supplementation.</p> <p>Specialist advice need only be obtained for the first authority approval.</p>

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners
Condition:	Osteoporosis
PBS Indication:	Osteoporosis
Restriction Level / Method:	<input checked="" type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input checked="" type="checkbox"/> Authority Required – Emergency <input checked="" type="checkbox"/> Authority Required - Electronic
Clinical criteria:	<p>The treatment must be as monotherapy, AND The treatment must be where other treatment is contraindicated and where specialist advice confirms that this is the only suitable treatment option for the patient.</p>
Administrative Advice	<p>Monotherapy for the treatment of osteoporosis does not exclude calcium supplementation.</p> <p>Specialist advice need only be obtained for the first authority approval.</p>

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners
Restriction Level / Method:	<input checked="" type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input checked="" type="checkbox"/> Authority Required – Emergency <input checked="" type="checkbox"/> Authority Required - Electronic
Clinical criteria:	Patients receiving this drug as a pharmaceutical benefit prior to 1 February 2004

Administrative Advice	Monotherapy for the treatment of osteoporosis does not exclude calcium supplementation.
Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners
Restriction Level / Method:	<input checked="" type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input checked="" type="checkbox"/> Authority Required – Emergency <input checked="" type="checkbox"/> Authority Required - Electronic
Clinical criteria:	Patients on long-term treatment with corticosteroids.
Administrative Advice	Monotherapy for the treatment of osteoporosis does not exclude calcium supplementation.

For more detail on PBAC’s view, see section 6 PBAC outcome.

3 Background

- 3.1 Nandrolone decanoate is an anabolic steroid which has been available in Australia for several decades, and is TGA registered for “acute renal failure, chronic renal insufficiency and anaemia of chronic renal failure; for the palliative treatment of inoperable mammary carcinoma; osteoporosis (where oestrogen therapy is contraindicated), aplastic anaemia, and patients on long-term treatment with corticosteroids”.
- 3.2 The existing form of nandrolone decanoate was PBS listed more than 15 years ago. The Secretariat notes that the utilisation nandrolone decanoate declined between 2010 and 2012. The sponsor has acknowledged that the product has been out of stock for four years.

4 Comparator

- 4.1 The submission nominated nandrolone decanoate pre-filled syringe as the comparator.

For more detail on PBAC’s view, see section 6 PBAC outcome.

5 Consideration of the evidence

Sponsor hearing

- 5.1 There was no hearing for this item as it was a minor submission.

Consumer comments

- 5.2 The PBAC noted the advice received from the Royal Australian College of General Practitioners (RACGP) clarifying the likely use of nandrolone decanoate in clinical practice. The PBAC specifically noted the advice that there is little clinical benefit in the use of nandrolone decanoate for the treatment of osteoporosis. The RACGP advised that nandrolone decanoate should not be indicated in patients with osteoporosis unless there is an additional need for muscle gain. The PBAC noted that this advice was not supportive of listing a new form of nandrolone decanoate on the PBS.

Clinical trials

- 5.3 As a minor submission, no new clinical trials were presented in the submission.

Economic analysis

- 5.4 As a minor submission, there was no economic comparison presented.

Drug cost/patient/ year: \$ [REDACTED] (current), \$ [REDACTED] (requested)

- 5.5 Based on the current DPMQ of \$ [REDACTED] and the recommended dosage of 50 mg every 2 to 3 weeks, the estimated drug cost per patient per year will be ranged from \$403.69 to \$ [REDACTED] for 52 weeks' treatment.
- 5.6 The submission requested a price increase to a DPMQ of \$ [REDACTED]. The Sponsor stated that higher cost of product from the new manufacturer necessitated the requested price increase.
- 5.7 While a pricing request is not a matter for PBAC consideration, due to the extended period of drug shortage, the PBAC may wish to provide advice on whether there is a clinical need of nandrolone decanoate for the treatment of osteoporosis and other PBS listed indications.

Estimated PBS usage & financial implications

- 5.8 The minor submission estimated a cost to the PBS of \$ [REDACTED] annually based on the script data from [REDACTED], which at the requested price equates to approximately [REDACTED]. The Sponsor did not provide any further information regarding financial implication, such as market share and growth in drug utilisation.
- 5.9 While not a matter for the PBAC the Committee noted that as a new pharmaceutical item of nandrolone decanoate, the proposed listing would trigger a 16% statutory price reduction in accordance with division 3A of Part VII of the *National Health Act 1953*. As a result, nandrolone decanoate will be moved from F1 Formulary to F2 Formulary, and will also be subject to price disclosure.

For more detail on PBAC's view, see section 6 PBAC outcome.

6 PBAC Outcome

- 6.1 The PBAC did not recommend the request of Authority Required listing of a new form of nandrolone decanoate on the basis that there was no clinical need for a new form of this drug on the PBS for the treatment of osteoporosis.
- 6.2 The PBAC noted that the advice received from the Royal Australian College of General Practitioners (RACGP) stated there is little benefit in the use of nandrolone decanoate for the treatment of osteoporosis. The RACGP also advised that general practitioners are unlikely to prescribe this drug without the support of another specialist (e.g. endocrinologists).
- 6.3 Based on the available evidence and noted lack of clinical context for nandrolone decanoate in this setting, the PBAC also agreed it had no objection to delisting the existing PBS listed (and out of supply) nandrolone decanoate form from the PBS.
- 6.4 The PBAC considered that the submission would not meet the criteria for an Independent Review as Independent Review is not available in response to a request for listing a new form of an existing PBS listed drug.

Outcome:

Rejected

7 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.

8 Sponsor's Comment

The use/indication of the product was subject of evaluation during a PBAC meeting. Aspen was disappointed and disagrees with the PBAC's view on clinical need of this 'grandfather' product.