5.21 DENOSUMAB, Injection 60 mg in 1 mL pre-filled syringe, Stoboclo®, Injection 120 mg in 1.7 mL, Osenvelt®, CELLTRION HEALTHCARE AUSTRALIA PTY LTD

1 Purpose of Submission

1.1 The Category 3 submission requested General Schedule Authority Required (STREAMLINED) listings of two new denosumab biosimilars (Stoboclo® [Injection 60 mg in 1 mL pre-filled syringe] and Osenvelt® [Injection 120 mg in 1.7 mL]) on a cost-minimisation basis and under the same conditions as their reference biologics (Prolia® and Xgeva® respectively) for the same indications.

2 Background

2.1 Stoboclo and Osenvelt were TGA registered on 4 April 2025 and determined to be biosimilar medicines to their reference brands Prolia and Xgeva respectively.

2.2 Stoboclo and Osenvelt are not the first biosimilar brands of denosumab (there are other denosumab biosimilars already listed on the PBS, see Section 3).

3 Requested listing

3.1 The submission requested that Stoboclo and Osenvelt be listed under the same circumstances (and for the same indications [Stoboclo for osteoporosis and established osteoporosis; Osenvelt for giant cell tumour of bone and bone metastases]) as Prolia and Xgeva respectively.

3.2 The submission also requested that the listings for Stoboclo and Osenvelt be consistent with the biosimilar uptake driver policy.

3.3 As the submission requested the same restrictions as the reference brands, the full restrictions have not been reproduced here.

3.4 Add brands to existing item codes:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№. of Rpts	Available brands
DENOSUMAB					
denosumab 60 mg/mL injection, 1 mL syringe	5457F	1	1	0	CORORA[a] Jubbonti[a] Prolia[a] *Stoboclo*[a]
denosumab 120 mg/1.7 mL injection, 1.7 mL vial	10061M	1	1	5	GANVADO[a] Wyost[a] Xgeva[a] *Osenvelt*[a]
denosumab 120 mg/1.7 mL injection, 1.7 mL vial	5110Y	1	1	5	GANVADO[a] Wyost[a] Xgeva[a] *Osenvelt*[a]
Prescribing rule		***Administrative Advice:*** ***Biosimilar prescribing policy*** *Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.*			
		Administrative Advice *Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Awareness Initiative webpage (www.health.gov.au/biosimilars).*			

3.5 The submission requested that Stoboclo and Osenvelt be considered equivalent ('a' flagged) to Prolia and Xgeva respectively for the purpose of substitution.

3.6 Stoboclo and Osenvelt will have the same drug, form and manner of administration as the existing denosumab brands and, as such, will be required to have the same approved ex-manufacturer price (AEMP) as the existing denosumab brands as per Section 85C of the *National Health Act 1953*.

4 Consideration of the evidence

Sponsor hearing

4.1 There was no hearing for this item.

Consumer comments

4.2 The PBAC noted that no consumer comments were received for this item.

Clinical evidence

4.3 As per the Product Information, the TGA has confirmed that "Stoboclo is a biosimilar medicine to Prolia. The comparability of Stoboclo with Prolia has been demonstrated with regard to physiochemical characteristics and efficacy and safety outcomes."

4.4 As per the Product Information, the TGA has confirmed that "Osenvelt is a biosimilar medicine to Xgeva. The comparability of Osenvelt with Xgeva has been demonstrated with regard to physiochemical characteristics and efficacy and safety outcomes."

4.5 The submission stated that the equi-effective doses are: 1 mg Stoboclo = 1 mg Prolia and 1 mg Osenvelt = 1 mg Xgeva.

Estimated PBS usage and financial implications

4.6 Listing of biosimilar brands does not change overall utilisation of the drug.

4.7 Stoboclo and Osenvelt is expected to substitute for Prolia and Xgeva respectively and, as such, there is expected to be nil financial impact to the PBS/RPBS with the proposed listing.

5 PBAC Outcome

5.1 The PBAC recommended the General Schedule Authority Required (STREAMLINED) listings of two new denosumab biosimilars (Stoboclo® [Injection 60 mg in 1 mL pre-filled syringe] and Osenvelt® [Injection 120 mg in 1.7 mL]) on a cost-minimisation basis and under the same conditions as their reference biologics (Prolia® and Xgeva® respectively) for the same indications.

5.2 The PBAC advised the equi-effective doses to be 1 mg Stoboclo = 1 mg Prolia and 1 mg Osenvelt = 1 mg Xgeva.

5.3 The PBAC noted that the TGA has confirmed that Stoboclo is a biosimilar medicine to Prolia, and Osenvelt is a biosimilar medicine to Xgeva.

5.4 The PBAC noted that lowering the authority level for the two new biosimilars won't apply as all existing listings of denosumab (including for the reference brands) are already streamlined authority. The PBAC also noted that for the existing biosimilar brands of denosumab, there is already administrative advice reflecting the biosimilar uptake policy (i.e. encouraging biosimilar prescribing for treatment-naïve patients). The PBAC considered this administrative advice is clinically appropriate for Stoboclo and Osenvelt.

5.5 The PBAC advised that, under Section 101(4AACD) of the *National Health Act 1953*, Stoboclo and Prolia should be treated as equivalent to each other (i.e., 'a' flagged in the Schedule), and Osenvelt and Xgeva should be treated as equivalent to each other (i.e., 'a' flagged in the Schedule).

5.6 The PBAC considered that the listings of Stoboclo and Osenvelt would not result in a net cost to the PBS as they would likely substitute for Prolia and Xgeva respectively and not increase the overall market utilisation.

5.7 The PBAC noted its recommendation was on a cost-minimisation basis and advised that, because Stoboclo and Osenvelt are not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity over Prolia and Xgeva respectively, and are not expected to address a high and urgent unmet clinical need given the presence of alternative therapies, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.

5.8 The PBAC noted this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:
Recommended

6 Recommended listing

6.1 As the submission requested the same restrictions as the reference brands, the full restrictions have not been reproduced here.

6.2 Add new brands to existing item codes (shown in *italics*):

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№. of Rpts	Available brands
DENOSUMAB					
denosumab 60 mg/mL injection, 1 mL syringe	5457F	1	1	0	CORORA[a] Jubbonti[a] Prolia[a] *Stoboclo*[a]
denosumab 120 mg/1.7 mL injection, 1.7 mL vial	10061M	1	1	5	GANVADO[a] Wyost[a] Xgeva[a] *Osenvelt*[a]
denosumab 120 mg/1.7 mL injection, 1.7 mL vial	5110Y	1	1	5	GANVADO[a] Wyost[a] Xgeva[a] *Osenvelt*[a]

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.