6.16 EVEROLIMUS tablets, 250mcg, 500mcg, 750mcg, 1mg Certican®, Novartis Pharmaceuticals Australia

1 Purpose of Application

1.1 The minor submission sought change to the PBS listing of everolimus (Certican®) under the General Schedule, from "authority required" to "unrestricted listing", in transplant indications.

2 Requested listing

2.1 The submission sought change of authority for everolimus 250 microgram, 500 microgram, 750 microgram and 1mg tablets.

2.2 Details of the everolimus PBS listings under General Category program are presented below (all listings are General Schedule Authority Required).

Everolimus PBS listing in General Category (transplant indications)

Australian approved name	**everolimus**	**everolimus**	**everolimus**	**everolimus**
Brand name	**Certican®**	**Certican®**	**Certican®**	**Certican®**
(Name, form & strength and pack size)	everolimus 250 microgram tablet, 60	everolimus 500 microgram tablet, 60	everolimus 750 microgram tablet, 60	everolimus 1mg tablet, 60
PBS status	PBS-listed	PBS-listed	PBS-listed	PBS-listed
Max Qty	60	60	120	120
Number of repeats	3	3	3	3
DPMQ	$268.79	$527.16	$1522.17	$2002.77
Everolimus mg for Max Qty.	15mg	30mg	90mg	120mg
Proportion of Certican use in General Category	12%	35%	26%	27%

2.3 No change is requested for the authority requirement for Certican® (everolimus) under Section 100 (Highly Specialised Drugs) – Public Hospitals and Section 100 (Highly Specialised Drugs) – Private Hospitals in transplant indications.

2.4 Everolimus exists in two brands on the PBS. Everolimus, as an immunosuppressant for transplant indications, is PBS-listed as Certican® in low dose tablets containing everolimus 250 microgram, 500 microgram, 750 microgram and 1mg. Everolimus is also PBS-listed for oncology indications, where it is employed at the starting dose of 10 mg once daily, as Afinitor®.

2.5 The two brands Certican® and Afinitor® are used for separate indications, dosage, dose strengths, PBS maximum quantity, co-administered therapies and duration of treatment and are not interchangeable in clinical practice.

2.6 The submission stated that a change in authority requirement for everolimus is consistent with the recent changes to the authority requirements for currently PBS listed comparator immunosuppressive drugs for transplant indications, under the General Schedule.

2.7 The submission proposed that removal of the authority restrictions to prescribe Certican® under the General Schedule would reduce administrative burden for clinicians.

2.8 The submission anticipated that any requested change in the authority for transplant indications would not be expected to result in any leakage to oncology indications. The submission attributed this to the higher dosage of everolimus in oncology indications with a starting dose of 10mg once daily which would imply that multiple Certican® prescriptions would be required per month for each patient.

3 Background

3.1 Everolimus (Certican®) is TGA registered for the prophylaxis of organ rejection in adult patients at mild to moderate immunological risk receiving an allogeneic renal or cardiac transplant and in adult patients receiving an allogeneic hepatic transplant.

3.2 Everolimus tablet, 250 microgram, 500 microgram, 750 microgram and dispersible tablet 250 microgram, Certican® were recommended for listing at the March 2005 PBAC meeting for the management of renal and cardiac transplant.

3.3 Everolimus tablet, 1 mg, Certican® was recommended as a new strength of everolimus for the management of renal and cardiac transplant at the November 2009 PBAC meeting.

3.4 As part of the Post-Market Review of Authority Required PBS listings (the Review), on 1 May 2015, listings for the following immunomodulating drugs: cyclosporin, mycophenolate, sirolimus, tacrolimus for the management of transplant rejection were amended from Section 85 Authority Required to Unrestricted. The restriction for initiation, stabilisation and review of therapy remained as Section 100 listing.

3.5 The listings for everolimus 250mcg, 500mcg, 750mcg and 1mg and dispersible tablet 250mcg are also being considered in the context of the Review. To date, no changes to these listings have been made as a result of the Review.

4 Consideration of the evidence

Sponsor hearing

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

Consumer comments

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

Estimated PBS usage & financial implications

The minor submission estimated there to be no financial implications to the PBS as the majority of the eligible patients would continue to receive everolimus Certican® in the general category. The sponsor stated that given the finite number of patients shared across indications amongst commonly used immunosuppressive agents, the requested change will remain cost neutral to the PBS and government budget.

5 PBAC Outcome

5.1 The PBAC rejected the general listing request of everolimus for transplant indications.

5.2 The PBAC noted that the listings for everolimus referred to in the minor submission are also being considered in the context of the Post Market Review of PBS Authorities. The PBAC therefore declined to recommend any changes to these listings until the Review is complete and its recommendations have been implemented.

5.3 The PBAC noted that the submission is not eligible for an independent review.

Outcome:
Rejected

6 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.

7 Sponsor's Comment

Novartis looks forward to a speedy publication of the report on the Post Market Review of PBS Authorities to resolve access issues related to everolimus for transplant indications.