

**5.32 RIVAROXABAN,  
Tablet 2.5 mg  
Tablet 10 mg  
Xarelto®  
Alphapharm Pty Ltd**

**1 Purpose of Submission**

1.1 The Category 4 submission requested to list new pack sizes of rivaroxaban (Xarelto®) tablets 2.5 mg (for the treatment of chronic stable atherosclerotic disease (CSAD) - chronic coronary artery disease (CAD) and/or peripheral artery disease (PAD)) and 10 mg (for prevention of venous thromboembolism (VTE) in total hip or knee replacement) under the same circumstances as the PBS-listed Xarelto tablets 2.5 mg and 10 mg. Specifically, the submission requested:

- Xarelto 2.5 mg tablet: 98-pack to replace the 60-pack
- Xarelto 10 mg tablet: 14-pack to replace the 15-pack

Due to the pack size difference, the submission requested a maximum number of 3 repeats of the 98-pack size of Xarelto tablets 2.5 mg in place of 5 repeats of the 60 pack size.

1.2 The submission also requested a 60-day dispensing listing of Xarelto 2.5 mg with a maximum quantity of 2 packs (196 units).

1.3 The listing was requested based on a cost-minimisation analysis, evaluating the cost-per-tablet compared to the existing pack sizes for each strength.

1.4 The submission advised that, in addition to the request to list the new pack sizes of Xarelto on the PBS, the sponsor intends to delist the current pack sizes. The sponsor has been advised that a separate delisting request must be lodged via the Health Products Portal.

**2 Background**

2.1 Xarelto 2.5 mg tablets, 60-pack is currently listed on the PBS as an Authority Required (STREAMLINED) listing for the treatment of CSAD.

2.2 Xarelto 10 mg tablets, 15 pack is currently listed on the PBS as an Authority Required (STREAMLINED) listing for the prevention of VTE (pVTE) in patients undergoing total hip replacement and separately listed for the pVTE in patients undergoing a total knee replacement.

### Registration status

- 2.3 Xarelto 2.5 mg was Therapeutic Goods Administration (TGA) registered on 11 January 2019 and the 10 mg strength was registered on 24 November 2008. Both strengths are TGA indicated for:
- pVTE in adult patients who have undergone major orthopaedic surgery of the lower limbs (elective total hip replacement, treatment for up to 5 weeks; elective total knee replacement, treatment for up to 2 weeks).
  - Prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation and at least one additional risk factor for stroke.
  - Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and for the prevention of recurrent DVT and PE,
  - In combination with aspirin, the prevention of major cardiovascular events (composite of stroke, myocardial infarction and cardiovascular death) in patients with CAD and/or PAD.
- 2.4 The recommended dose for the prevention of major cardiovascular events in patients with CAD and/or PAD is one tablet of 2.5 mg XARELTO twice daily in combination with a daily dose of 100 mg aspirin.
- 2.5 The recommended dose of XARELTO for pVTE in major orthopaedic surgery of the lower limbs (elective total hip or knee replacement) is a 10 mg tablet taken once daily.

### Previous PBAC consideration

- 2.6 Xarelto 10 mg was recommended for pVTE in patients undergoing total hip replacement or total knee replacement by the PBAC at its March 2009 meeting.
- 2.7 Xarelto 2.5 mg was recommended for prevention of major cardiovascular events in patients with CSAD by the PBAC at its July 2020 meeting.
- 2.8 Xarelto 2.5 mg was recommended by the PBAC for an increased maximum dispensed quantity (MDQ) for prevention of major cardiovascular events in patients with CSAD at its December 2022 meeting and increased MDQ prescriptions were implemented for this medicine on 1 September 2023.

## 3 Requested listing

- 3.1 The submission requested the following changes (additions marked in italics and deletions in strikethrough) to the existing listing to accommodate the new pack sizes.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
RIVAROXABAN					
rivaroxaban 10 mg tablet, <del>4514</del>	9469J	1	<del>1514</del>	0	Xarelto

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Restriction Summary / Treatment of Concept	
	<b>Category / Program:</b> <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (Streamlined) [4382]
	<b>Administrative Advice:</b> No increase in the maximum quantity or number of units may be authorised.
	<b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised.
	<b>Indication:</b> Prevention of venous thromboembolism
	<b>Clinical criteria:</b>
	Patient must require up to <del>45</del> 14 days of therapy.
	<b>Treatment criteria:</b>
	Patient must be undergoing total knee replacement.
	<b>Administrative Advice:</b>
	<b>Shared Care Model:</b>
	For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
RIVAROXABAN					
rivaroxaban 10 mg tablet, <del>45</del> 14	9466F	1	<del>45</del> 14	1	Xarelto

Restriction Summary / Treatment of Concept	
	<b>Category / Program:</b> <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (Streamlined) [4402]
	<b>Administrative Advice:</b> No increase in the maximum quantity or number of units may be authorised.
	<b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised.
	<b>Indication:</b> Prevention of venous thromboembolism
	<b>Clinical criteria:</b>
	Patient must require up to <del>2830</del> days' supply to complete a course of treatment.
	<b>Treatment criteria:</b>
	Patient must be undergoing total hip replacement.
	<b>Administrative Advice:</b>
	<b>Shared Care Model:</b>
	For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
RIVAROXABAN					
rivaroxaban 2.5 mg tablet, <del>6098</del>	12197Y	1	<del>6098</del>	53	Xarelto
rivaroxaban 2.5 mg tablet, <del>6098</del>	12192Q	1	<del>6098</del>	53	Xarelto

Restriction Summary / Treatment of Concept:	

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	<b>Category / Program:</b> <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (Streamlined) [11013]
	<b>Administrative Advice:</b> No increase in the maximum quantity or number of units may be authorised.
	<b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised.
	<b>Indication:</b> Chronic stable atherosclerotic disease
	<b>Treatment Phase:</b> Initial
	<b>Clinical criteria:</b>
	The treatment must be in combination with aspirin, but not with any other anti-platelet therapy.
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must have a diagnosis of coronary artery disease in addition to at least one of the following risk factors: (i) diagnosed heart failure (left ventricular ejection fraction of at least 30% but less than 50%) (ii) diagnosed kidney disease classified by an eGFR in the range of 15-60 mL/min (iii) diabetes mellitus combined with at least one of the following: (a) age at least 60 years (b) concomitant microalbuminuria (c) Aboriginal/Torres Strait Islander descent; or
	Patient must have a diagnosis of peripheral artery disease in addition to at least one of the following risk factors: (i) concomitant coronary artery disease (ii) diagnosed heart failure (left ventricular ejection fraction of at least 30% but less than 50%) (iii) diagnosed kidney disease classified by an eGFR in the range of 15-60 mL/min (iv) diabetes mellitus combined with at least one of the following: (a) age at least 60 years (b) concomitant microalbuminuria (c) Aboriginal/Torres Strait Islander descent
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must have at least one of the following if coronary artery disease is present: (i) a previous multi-vessel coronary revascularisation procedure (ii) significant stenosis in at least 2 coronary arteries (iii) a previous single vessel coronary revascularisation procedure with significant stenosis in more than 1 coronary artery; or
	Patient must have at least one of the following if peripheral arterial disease is present: (i) a previous peripheral/carotid artery revascularisation intervention (ii) intermittent claudication with an ankle-brachial index less than 0.9 (iii) asymptomatic carotid artery stenosis greater than 50%.
	<b>AND</b>
	<b>Clinical criteria:</b>
	The condition must be diagnosed by at least one of: (i) invasive (selective) angiography (ii) non-invasive imaging (i.e. CT scan, ultrasound) (iii) ankle-brachial index measurement in the case of peripheral arterial disease with intermittent claudication.
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must have clinical findings/observations by the treating physician that exclude each of the following: (i) high risk of bleeding (ii) prior stroke within one month of treatment initiation (iii) prior haemorrhagic / lacunar stroke (iv) severe heart failure with a known ejection fraction less than 30% (v) New York Heart Association class III to IV heart failure symptoms (i.e. symptoms corresponding to moderate to severe limitation on physical activity, whereby any of fatigue/palpitations/dyspnoea occur upon zero to minimal activity) (vi) an estimated glomerular filtration rate less than 15 mL/minute (vii) a requirement for dual antiplatelet therapy (viii) a requirement for non-acetylsalicylic acid antiplatelet therapy (ix) a requirement for a higher dose of oral anticoagulant therapy
	<b>Treatment criteria:</b>
	Must be treated by a specialist physician; or
	Must be treated by a physician who has consulted a specialist physician

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	<b>Category / Program:</b> <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (Streamlined) [10992]
	<b>Indication:</b> Chronic stable atherosclerotic disease
	<b>Treatment Phase:</b> Continuing treatment
	<b>Clinical criteria:</b>
	Patient must have received PBS-subsidised treatment with this drug for this condition.
	<b>AND</b>
	<b>Clinical criteria:</b>
	The treatment must be in combination with aspirin, but not with any other anti-platelet therapy.
	<b>Administrative Advice:</b>
	Treatment may be continued by a non-specialist prescriber without need for consultation with a specialist.
	<b>Administrative Advice:</b>
	<b>Shared Care Model:</b> For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
RIVAROXABAN					
rivaroxaban 2.5 mg tablet, 6098	13366L	2	120196	5 3	Xarelto

Restriction Summary / Treatment of Concept:	
	<b>Category / Program:</b> <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (Streamlined) [14298]
	<b>Administrative Advice:</b> No increase in the maximum quantity or number of units may be authorised.
	<b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised.
	<b>Indication:</b> Chronic stable atherosclerotic disease
	<b>Treatment Phase:</b> Continuing treatment
	<b>Clinical criteria:</b>
	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must have received PBS-subsidised treatment with this drug for this condition.
	<b>AND</b>
	<b>Clinical criteria:</b>
	The treatment must be in combination with aspirin, but not with any other anti-platelet therapy.
	<b>Administrative Advice:</b>
	Treatment may be continued by a non-specialist prescriber without need for consultation with a specialist.
	<b>Administrative Advice:</b>
	<b>Shared Care Model:</b> For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

3.2 The TGA product information (PI) for Xarelto recommends that treatment for patients undergoing a hip replacement is 5 weeks (35 tablets) and for a knee replacement is 2 weeks (14 tablets). The current Xarelto 10 mg restrictions allow for a maximum supply of 30 tablets for a hip replacement and 15 tablets for a knee replacement. The clinical criteria of the current listings include wording about the length of treatment required by the patient:

- For a knee replacement, the criterion is  
“Patient must require up to 15 days of therapy,” and
- For a full hip replacement, it is  
“Patient must require up to 30 days supply to complete a course of treatment.”

The listing for a knee replacement is appropriate, as the new 14-pack covers the 14 days of treatment recommended in the PI. However, both the current listing (30 tablets total) and the requested listing (28 tablets total) for hip replacement provide a supply that is less than the PI-recommended 35 days of treatment. At its March 2009 consideration of rivaroxaban, the PBAC noted that treatment duration could vary from 13 to 36 days in Australian practice. The PBAC advised that “the maximum quantities should align with the pack sizes and the Therapeutic Goods Administration (TGA)-recommended durations of use (five weeks for hip replacement and two weeks for knee replacement) to minimise wastage. The PBAC noted that the quantities to be subsidised by the PBS would differ according to “whether the therapy is initiated in the public hospital setting or the private hospital setting.” (Rivaroxaban Public Summary Document [PSD], March 2009 PBAC Meeting, p.6). At that time the PBAC recommended a maximum quantity of 1 pack with 1 repeat (30 days’ supply). The submission stated that it expects patients during their hospital stay and after discharge would be prescribed 3 packs of Xarelto 10 mg 15-pack (a total of 45 tablets) to cover the PI recommended 5-week treatment duration. 3 of the new pack size of 14 tablets totalling 42 tablets would also cover the PI recommended treatment. The total number of prescriptions would therefore remain unchanged. The submission did not specify how the third pack would be supplied noting that the listing only allows for a maximum total supply of 2 packs and does not allow an increase to the maximum quantity or repeats.

3.3 There is a rivaroxaban 10 mg 30-unit pack listed (item 9467G) for pVTE in total hip replacement, for which Xarelto and two other brands are listed. Prescribers can prescribe this as an alternative to the 15-tablet pack with one repeat.

3.4 Xarelto 2.5 mg is used twice daily for the treatment of CSAD. Table 1 shows a comparison of the days of treatment between the current and requested listings.

**Table 1: Maximum days of treatment**

Listing	MQ (units)	MR	Total tablets (2/day)	Days of treatment
60-pack	60	5	360	180
Requested 98-pack	98	3	392	196
Current increased MDQ listing	120	5	720	360
Requested increased MDQ listing	196	3	784	392

Source: compiled during evaluation

MDQ – maximum dispensed quantity, MQ – maximum quantity, MR – maximum repeats

- 3.5 The requested listing would supply more than 30 days treatment per dispensing (49 days) and more than 6 months of treatment per script. In the case of the requested increased MDQ listing, each supply of 196 tablets would provide greater than 60 days of treatment (98 days of treatment per dispensing) and a prescription would provide a supply of greater than 12 months of treatment, noting that prescriptions expire 12 months from the date of issue. The PBAC Guidelines recommend that for chronic-use therapy the maximum quantity or amount is consistent with “the likely use of the proposed medicine for one month of therapy between each dispensing by the pharmacist, and that the number of repeats (usually) permits six months of therapy between each prescription.” Submissions must “justify proposed deviations from this general approach.” (p.19, Guidelines for preparing a submission to the PBAC, Version 5.0). The pre-PBAC response from the sponsor advised that the manufacturer was consolidating its global pack sizes, and that the 98-pack size would still meet the patients’ needs as the indication is for chronic stable atherosclerotic disease, and that these patients would not require dosage changes. The sponsor also proposed reducing the number of repeats for the requested increased MDQ listing, limiting each prescription to 294 days of treatment. The PBAC advised that the reduction in the number of repeats for the MDQ listing to ensure not more than 12 months of treatment be available on one script.
- 3.6 A second brand of the rivaroxaban 2.5 mg 60-pack was listed on the PBS on 1 October 2024 under the brand Rivaroxaban-Teva®. As such, the requested change to restrictions, if recommended, would result in three new PBS item codes, as the two products, now with two different maximum quantities, cannot share the same listing. It was noted that several other brands of the 15-pack of 10 mg rivaroxaban are ARTG registered, and their respective sponsors may request PBS listing. The PBAC noted if these listings were to occur prior to the implementation of the above requested changes to the restrictions for pVTE in total hip or knee replacement (9469J and 9466F), new items would also need to be added to the PBS for the 14-pack.

## 4 Comparator

- 4.1 The submission nominated the existing pack sizes for each strength as the comparator. That is, Xarelto 2.5 mg 60-pack and Xarelto 10 mg 15-pack.
- 4.2 There are no other brands listed on the PBS for rivaroxaban 10 mg 15-pack. As of 1 October 2024, a new brand of 2.5 mg rivaroxaban 60-pack, Rivaroxaban-Teva, was

listed on the PBS for the CSAD item numbers (12197Y, 12192Q and 13366L). This should also be considered a comparator for the proposed Xarelto 2.5 mg 98-pack.

- 4.3 Rivaroxaban 10 mg 30-pack for pVTE total hip replacement is currently listed (9467G) under three different brands: Xarelto, Rivaroxaban-Teva and iXarola.

## **5 Consideration of the evidence**

### ***Sponsor hearing***

- 5.1 There was no hearing for this item.

### ***Consumer comments***

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

### ***Rationale for requested listing***

- 5.3 The submission stated that the new Xarelto pack sizes (14-pack and 98-pack) were designed to minimise wastage and reduce the need for frequent prescriptions, leading to cost savings for the PBS. The 14-pack provides the exact required amount for treatment following a knee replacement, while the 98-pack allows for 49 days of treatment per dispensing. Under the requested increased MDQ listing, patients can access 98 days of treatment per dispensing. According to PBAC guidelines, chronic-use therapies should have a maximum quantity consistent with one month of use per dispensing and repeat prescriptions covering six months of therapy. Deviations to minimise waste or facilitate intermittent therapy must be justified.
- 5.4 The submission justified the new pack sizes stating that the Xarelto 10 mg 15-pack and Xarelto 2.5 mg 60-pack would be discontinued and the market supply would be depleted by 1 April 2025 and 1 December 2025 respectively. The submission stated that listing the new pack sizes would ensure patients continue to access their treatment after the discontinuation of the current pack sizes. The submission did not provide a rationale for the discontinuation and did not justify how the 98-pack would minimise wastage or how both new pack sizes would facilitate intermittent therapy. The pre-PBAC response stated that the discontinuation of the currently available pack sizes was due to a manufacturing change required at a global level.
- 5.5 No new clinical evidence was provided and no clinical claim was provided or required. The pack sizes (requested and discontinuing) are listed under the relevant ARTG entries for Xarelto.
- 5.6 Listing larger pack sizes of Xarelto in the presence of other brands may provide a market advantage due to reduced co-payments. Other sponsors would need to create a new pack size or request a change in maximum quantity, which could result in broken packs of their product. This would lead to a cost to the PBS. The PBAC guidelines state that a cost-minimisation approach is appropriate where there is a therapeutic claim of noninferiority (or superiority), the safety profile is equivalent or superior, and the use of the proposed medicine is anticipated to result in equivalent

or lesser costs to the health system. Listing a new listing of a larger pack size with a larger maximum quantity (MQ) (units) without flowing-on the larger MQ to the existing listings would create complexity in the current PBS listings. The pre-PBAC response presented the argument that the larger pack sizes would mean less packs sold for the company, and it did not consider this a market advantage. The pre-PBAC response also argued that most patients would continue being prescribed their current pack size.

### **Economic analysis**

- 5.7 The submission presented a cost-minimisation analysis of the new Xarelto pack sizes compared with currently listed pack size of the same strength, on a price per tablet basis. As pack size is the only difference between the requested and current listings, the medicine is equivalent per mg.
- 5.8 The submission used an approved ex-manufacturer price (AEMP) that was estimated on the assumption of first new brand price reductions on 1 October 2024. The evaluation has replaced these estimated prices with the AEMP of Xarelto as at 1 November 2024.
- 5.9 Table 2 shows the price per tablet comparison for the 10 mg and 2.5 mg packets.

**Table 2: CMA of proposed AEMP per pack**

Strength	Current quantity	Current AEMP	Current Price per Tablet	Proposed quantity	Proposed AEMP	Proposed DMPQ
10 mg tablet	15	\$18.62	\$1.24	14	\$17.38	\$32.15 <sup>b</sup>
2.5 mg tablet	60	\$32.87	\$0.55 <sup>a</sup>	98	\$53.69 <sup>a</sup>	\$71.19 (98 MQ) <sup>b</sup> \$129.69 (196 MQ) <sup>c</sup>

Source: Table 4 of the submission, p. 5. Prices in italics have been updated to the AEMP at 1 November 2024.

Abbreviations: AEMP = approved ex-manufacturer price; CMA = cost-minimisation analysis; DPMQ = Dispensed price maximum quantity. Note: The currently listed 10 mg 30-pack for pVTE for total hip replacement has an AEMP of \$18.62 and pricing quantity of 15, such that the package ex-manufacturer price (PEMP) is  $2 \times \$18.62 = \$37.24$ . This is equivalent on a per tablet basis of \$1.24 however the DPMQ for 1x 30-pack prescription is \$53.50 compared to the cost of 2x 14-pack prescriptions of \$64.30.

<sup>a</sup> Per tablet price is presented as a rounded whole-cent figure, whereas the proposed AEMP is calculated as  $(\$32.87/60) \times 98$  which results in \$53.69 as opposed to \$53.90 calculated by  $\$0.55 \times 98$ .

<sup>b</sup>  $\text{AEMP} \times 1.0752$  (wholesale mark-up) + \$4.79 (AHI fee) + \$8.67 (Dispensing fee).

<sup>c</sup>  $(\text{AEMP} \times 2) \times 1.0752 + (0.05 \times \$15.455) + \$4.79 + \$8.67$

### **Drug cost/patient/year (CSAD): \$574.32 (98 tablet MDQ); \$518.76 (196 tablet MDQ)**

- 5.10 The estimated drug cost/patient per year for the 2.5 mg tablets would be \$574.32 based on 8 prescriptions dispensed for the increased MDQ of 98 tablets, and \$518.76 based on 4 prescriptions dispensed for the increased MDQ of 196.

### **Drug cost/patient/course (total knee replacement): \$32.15**

- 5.11 The estimated drug cost/patient per course for the pVTE in patients with a total knee replacement would be \$32.15, based on a course of 2 weeks.

**Drug cost/patient/course (total hip replacement): \$96.45**

- 5.12 The estimated drug cost/patient per course of the pVTE in patients with total hip replacement would be \$64.30, based on a 28-day course to supplement a patient to 5 weeks treatment.

**Estimated PBS usage and financial implications**

- 5.13 The requested prices for the new pack sizes were based on the cost-minimised DPMQ of 14-pack Xarelto for VTE prevention in total knee or total hip replacement of \$32.15.
- 5.14 Table 3 and Table 4 present the estimated financial implications to the PBS/RPBS of Xarelto 10 mg 14-pack for the pVTE in total hip and knee replacement respectively. The estimates assumed that there would be 3 prescriptions per patient and 1 prescription per patient respectively. Table 5 presents the estimated financial implications of Xarelto 2.5 mg 96-pack for CSAD patients to the PBS/RPBS. The estimates assumed that there would be 7.45 prescriptions per patient per year, and 3.73 prescriptions per patient per year if using the increased MDQ item. The submission assumed a decline in patient numbers across the six years corresponding to a decline in the market share of Xarelto as competitor brands are added to the market. The submission estimated this to be -█████% for 2026 compared to 2025, followed by -█████% (2027), -█████% (2028), -█████% (2029) and -█████% (2030).
- 5.15 The submission estimated that 5,000 to < 10,000 hip replacement prescriptions would be supplied over the first six years of listing (500 to < 5,000 in Year 1 to 500 to < 5,000 in Year 6).
- 5.16 The submission stated that the estimated net financial impact to the PBS/RPBS for the listing of the 14-pack of Xarelto for total hip replacement is a net cost saving six years (Year 1 net cost saving to Year 6 net cost saving).

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Table 3: Estimated use and financial implications for total hip replacement patients

	Year 1 (2025)	Year 2 (2026)	Year 3 (2027)	Year 4 (2028)	Year 5 (2029)	Year 6 (2030)
<b>Estimated extent of use</b>						
Number of patients treated	■ <sup>2</sup>	■ <sup>2</sup>	■ <sup>1</sup>	■ <sup>1</sup>	■ <sup>1</sup>	■ <sup>1</sup>
Number of prescriptions dispensed <sup>a</sup>	■ <sup>2</sup>	■ <sup>2</sup>	■ <sup>2</sup>	■ <sup>2</sup>	■ <sup>2</sup>	■ <sup>2</sup>
<b>Estimated financial implications of 14-pack Xarelto</b>						
Cost to PBS/RPBS less co-payment (\$)	■ <sup>3</sup>	■ <sup>3</sup>	■ <sup>3</sup>	■ <sup>3</sup>	■ <sup>3</sup>	■ <sup>3</sup>
<b>Estimated financial implications of replaced 15 pack Xarelto prescriptions</b>						
Cost to PBS/RPBS less co-payment (\$)	-■ <sup>4</sup>	-■ <sup>4</sup>	-■ <sup>4</sup>	-■ <sup>4</sup>	-■ <sup>4</sup>	-■ <sup>4</sup>
<b>Net financial implications</b>						
Net cost to PBS/RPBS (\$)	-■ <sup>4</sup>	-■ <sup>4</sup>	-■ <sup>4</sup>	-■ <sup>4</sup>	-■ <sup>4</sup>	-■ <sup>4</sup>

<sup>a</sup> Assuming 3 prescriptions per patient per year as estimated by the submission.

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

Source: Table 7, Table 8 and Table 9 pp7-8 of the submission.

Note that the estimates use a weighted copayment of \$17.10 for PBS prescriptions and \$6.65 for RPBS prescriptions.

The redacted values correspond to the following ranges:

<sup>1</sup> < 500

<sup>2</sup> 500 to < 5,000

<sup>3</sup> \$0 to < \$10 million

<sup>4</sup> Net cost saving

- 5.17 The submission estimated that 20,000 to < 30,000 patients and prescriptions would be supplied over the first six years of listing (5,000 to < 10,000 in Year 1 to 500 to < 5,000 in Year 6). These estimates did not include patients who had undergone a total hip replacement and were prescribed the 10 mg 30-pack instead of a 15-pack with one repeat.
- 5.18 The submission stated that the estimated net financial impact to the PBS/RPBS for the listing of the 14-pack of Xarelto for total knee replacement is a net cost saving over six years (Year 1 net cost saving to Year 6 net cost saving).

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Table 4: Estimated use and financial implications for total knee replacement patients

	Year 1 (2025)	Year 2 (2026)	Year 3 (2027)	Year 4 (2028)	Year 5 (2029)	Year 6 (2030)
<b>Estimated extent of use</b>						
Number of patients treated	■ <sup>2</sup>	■ <sup>2</sup>	■ <sup>1</sup>	■ <sup>1</sup>	■ <sup>1</sup>	■ <sup>1</sup>
Number of prescriptions dispensed <sup>a</sup>	■ <sup>2</sup>	■ <sup>2</sup>	■ <sup>1</sup>	■ <sup>1</sup>	■ <sup>1</sup>	■ <sup>1</sup>
<b>Estimated financial implications of 14-pack Xarelto</b>						
Cost to PBS/RPBS less co-payment (\$)	■ <sup>3</sup>	■ <sup>3</sup>	■ <sup>3</sup>	■ <sup>3</sup>	■ <sup>3</sup>	■ <sup>3</sup>
<b>Estimated financial implications of replaced 15 pack Xarelto prescriptions</b>						
Cost to PBS/RPBS less co-payment (\$)	-■ <sup>4</sup>	-■ <sup>4</sup>	-■ <sup>4</sup>	-■ <sup>4</sup>	-■ <sup>4</sup>	-■ <sup>4</sup>
<b>Net financial implications</b>						
Net cost to PBS/RPBS (\$)	-■ <sup>4</sup>	-■ <sup>4</sup>	-■ <sup>4</sup>	-■ <sup>4</sup>	-■ <sup>4</sup>	-■ <sup>4</sup>

<sup>a</sup> Assuming 1 prescription per patient per year as estimated by the submission.

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

Source: Table 10, Table 11 and Table 12 pp8-9 of the submission.

Note that the estimates use a weighted copayment of \$17.87 for PBS prescriptions and \$6.96 for RPBS prescriptions.

The redacted values correspond to the following ranges:

<sup>1</sup> 500 to < 5,000

<sup>2</sup> 5,000 to < 10,000

<sup>3</sup> \$0 to < \$10 million

<sup>4</sup> Net cost saving

- 5.19 Combined, the changes to these two listings would result in estimated net financial impact to the PBS/RPBS for the listing of 14-pack Xarelto for total hip or knee replacement is net cost saving over six years (Year 1 net cost saving to Year 6 net cost saving). The evaluation also noted that the impact of hospital-dispensed volumes on the number of prescriptions has not been included in these estimates, as prescription volumes were assumed to be those required for a full course (2 or 5 weeks) of Xarelto which is greater than what the PBS listing supplies.
- 5.20 The estimates were based on the requested DPMQ for the 98-pack Xarelto which was \$71.33 for the 98 unit listing and \$129.99 for the 196 unit (increased MDQ) listing. Applying the current AEMP, the evaluation calculated that these DPMQ would be \$71.19 and \$129.69 respectively.
- 5.21 The current assumed prescriptions per patient for the 2.5 mg listings were 12.18 prescriptions per year for the 60 tablet maximum quantity and 6.09 prescriptions per year for the increased MDQ prescription of 120 tablets.
- 5.22 The submission estimated that 50,000 to < 60,000 prescriptions would be supplied over the first six years of listing the new 2.5 mg pack size (10,000 to < 20,000 in Year 1 to 5,000 to < 10,000 in Year 6).
- 5.23 The submission stated that the estimated net financial impact to the PBS/RPBS for the listing of 98-pack size 2.5 mg Xarelto for patients with CSAD is a net saving over six years (Year 1 net cost saving to Year 6 net cost saving).

Table 5: Estimated use and financial implications for CSAD patients

	Year 1 (2025)	Year 2 (2026)	Year 3 (2027)	Year 4 (2028)	Year 5 (2029)	Year 6 (2030)
<b>Estimated extent of use</b>						
Number of patients treated	■ <sup>1</sup>	■ <sup>1</sup>	■ <sup>1</sup>	■ <sup>1</sup>	■ <sup>1</sup>	■ <sup>1</sup>
Number of prescriptions dispensed <sup>a</sup>	■ <sup>4</sup>	■ <sup>4</sup>	■ <sup>2</sup>	■ <sup>2</sup>	■ <sup>2</sup>	■ <sup>2</sup>
<b>Estimated financial implications of the 98-pack Xarelto</b>						
Cost to PBS/RPBS less co-payment (\$)	■ <sup>3</sup>	■ <sup>3</sup>	■ <sup>3</sup>	■ <sup>3</sup>	■ <sup>3</sup>	■ <sup>3</sup>
<b>Estimated financial implications of 60 pack Xarelto</b>						
Number of prescriptions replaced <sup>b</sup>	■ <sup>4</sup>	■ <sup>4</sup>	■ <sup>4</sup>	■ <sup>4</sup>	■ <sup>4</sup>	■ <sup>4</sup>
Cost to PBS/RPBS less co-payment (\$)	-■ <sup>5</sup>	-■ <sup>5</sup>	-■ <sup>5</sup>	-■ <sup>5</sup>	-■ <sup>5</sup>	-■ <sup>5</sup>
<b>Net financial implications</b>						
Net cost to PBS/RPBS (\$)	-■ <sup>5</sup>	-■ <sup>5</sup>	-■ <sup>5</sup>	-■ <sup>5</sup>	-■ <sup>5</sup>	-■ <sup>5</sup>

<sup>a</sup> Assuming 7.45 prescriptions per patient per year for one month/98 tables, and 3.73 prescriptions per patient per year for the increased MDQ/2-month/196 tablet prescriptions as estimated by the submission.

<sup>b</sup> Assuming 12.18 prescriptions per patient per year for one month/60 tables, and 6.09 prescriptions per patient per year for the increased MDQ/2-month/120 tablet prescriptions as estimated by the submission

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

Source: Table 13, Table 14 and Table 15 p10 of the submission.

Note that the estimates used 3 copayments of \$10.13, \$10.10 and \$12.97 for PBS prescriptions and \$3.37, \$3.64 and \$2.20 for RPBS prescriptions.

Note that the costs are presented using the prices calculated by the submission, with \$48.89 DPMQ for 60-pack and \$84.32 for 2x 60 packs under an increased MDQ script. Current DPMQ is actually \$48.80 and \$84.15 respectively.

The redacted values correspond to the following ranges:

<sup>1</sup> 500 to < 5,000

<sup>2</sup> 5,000 to < 10,000

<sup>3</sup> \$0 to < \$10 million

<sup>4</sup> 10,000 to < 20,000

<sup>5</sup> net cost saving

5.24 The submission stated that the estimated net financial impact to the PBS/RPBS for the listing of the new pack sizes for both strengths of Xarelto is a net cost saving over six years (Year 1 net cost saving to Year 6 net cost saving).

5.25 At the time of submission, new brands of rivaroxaban had not yet listed on the PBS. As such, the estimates assume no changes to the population of the product.

5.26 Regarding the methodology of the estimates, the submission estimated patient numbers from projected script volumes divided by an average number of scripts per patient. This approach was not justified in the submission and is likely to be highly inaccurate due to the conversion of script-based estimates into patient numbers to derive a patient estimate which would then be applied to a number of scripts.

### Quality Use of Medicines

5.27 The pre-PBAC response advised that the sponsor intends to inform and educate prescribers regarding the new pack sizes to support QUM.

- 5.28 The pre-PBAC response also presented that the new packs have the days of the week printed above each blister for each tablet. This would support patients to keep track of their doses.

## **6 PBAC Outcome**

- 6.1 The PBAC recommended the listing of rivaroxaban (Xarelto®) tablets 2.5 mg 98-pack (for treatment of chronic stable atherosclerotic disease (CSAD), chronic coronary artery disease (CAD) and/or peripheral artery disease (PAD)) and 10 mg 14-pack (for prevention of venous thromboembolism (VTE) in total hip or knee replacement), as a General Schedule Authority Required (Streamlined) listing, as per the currently listed rivaroxaban 2.5 mg 60-pack and 10 mg 15-pack, for the same indications. The PBAC recommendation was, among other matters, made on a cost-minimisation basis with equivalent price per tablet.
- 6.2 The PBAC noted that the requested listing of the 10 mg 14-pack of rivaroxaban for the prevention of VTE in total hip replacement would supply 28 days of treatment while the recommended treatment regime is 35 days. The PBAC advised that 28 days of treatment was sufficient and considered the first 7 days of treatment would generally be managed through the hospital.
- 6.3 The PBAC noted that the requested listing for the 2.5 mg 98-pack would supply more than 30 days of treatment per dispensing and more than 6 months of treatment per script. The PBAC advised that the requested listing was appropriate noting that the indication is for a chronic, stable condition. The PBAC noted that the requested increased MDQ listing for the 98-pack would provide greater than 60 days of treatment (196 tablets – 98 days of treatment per dispensing) and a prescription would provide a supply of greater than 12 months of treatment, while prescriptions expire 12 months from the date of issue. The evaluation noted the 98-unit pack already provides 49 days of treatment per dispensing.
- 6.4 The PBAC recalled its December 2022 consideration of changes to the Maximum Dispensed Quantity where it recommended “listing with increased MDQs per dispensing, from one months’ supply to up to three months’ supply per dispensing,” while also “... allowing up to 12 months’ supply in total.” The PBAC advised that the maximum repeats for the increased MDQ listing be reduced from 3 to 2 to ensure that no more than 12 months’ supply is available on one prescription.
- 6.5 The PBAC noted that the presence of different pack sizes on the PBS for the same drug, strength and indication may present quality use of medicines (QUM) concerns. The PBAC acknowledged the sponsor’s intention to support prescribers regarding QUM of the new pack sizes. The PBAC advised that it is preferential to avoid proliferation of various pack sizes so as to minimise QUM risk, broken packs and wastage related to broken packs.
- 6.6 The PBAC considered the appropriate comparator for each strength (2.5 mg and 10 mg) was the equivalent strength of rivaroxaban listed on the PBS.

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- 6.7 The PBAC advised that the cost-minimisation approach on a price per tablet (within the equivalent strength) was appropriate.
- 6.8 The PBAC considered that the estimated patient numbers contained significant uncertainty due to the conversion of script-based estimates into patient numbers to derive a patient estimate that would be applied to a number of scripts. The PBAC considered the market is not expected to grow as a result of the listing of the new pack sizes. However, the PBAC advised a revised estimates model would be required and the sponsor would need to work with the Department to provide this. The PBAC considered that there should be no additional cost to the Commonwealth as a result of the listing of the new pack sizes.
- 6.9 The PBAC advised, under Section 101 (4AACD) of the *National Health Act*, that the new pack sizes should not be considered equivalent for the purposes of substitution with any brands of the existing pack sizes, noting that allowing substitution between pack sizes may result in increased fees to Government through broken pack fees.
- 6.10 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because rivaroxaban is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over currently listed forms of rivaroxaban 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.

**Outcome:**

Recommended

## 7 Recommended listing

7.1 Add new items as follows:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
RIVAROXABAN					
rivaroxaban 10 mg tablet, 14	[new]	1	14	0	Xarelto
<b>Restriction Summary [new] / Treatment of Concept: [new]</b>					
<b>Category / Program:</b> <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners					
<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (Streamlined) [new]					
<b>Administrative Advice:</b> No increase in the maximum quantity or number of units may be authorised.					
<b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised.					
<b>Indication:</b> Prevention of venous thromboembolism					
<b>Clinical criteria:</b>					
Patient must require up to 14 days of therapy.					

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	<b>Treatment criteria:</b>
	Patient must be undergoing total knee replacement.
	<b>Administrative Advice:</b>
	<b>Shared Care Model:</b>
	For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
RIVAROXABAN					
rivaroxaban 10 mg tablet, 14	[new]	1	14	1	Xarelto
<b>Restriction Summary [new] / Treatment of Concept: [new]</b>					
	<b>Category / Program:</b> <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners				
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (Streamlined) [new]				
	<b>Administrative Advice:</b> No increase in the maximum quantity or number of units may be authorised.				
	<b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised.				
	<b>Indication:</b> Prevention of venous thromboembolism				
	<b>Clinical criteria:</b>				
	Patient must require up to 28 days' supply to complete a course of treatment.				
	<b>Treatment criteria:</b>				
	Patient must be undergoing total hip replacement.				
	<b>Administrative Advice:</b>				
	<b>Shared Care Model:</b>				
	For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.				

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
RIVAROXABAN					
rivaroxaban 2.5 mg tablet, 98	[new1]	1	98	3	Xarelto
rivaroxaban 2.5 mg tablet, 98	[new2]	1	98	3	Xarelto
<b>Restriction Summary 11013 / Treatment of Concept: 11013</b>					
	<b>Category / Program:</b> <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners				
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (Streamlined) [new]				
	<b>Administrative Advice:</b> No increase in the maximum quantity or number of units may be authorised.				
	<b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised.				
	<b>Indication:</b> Chronic stable atherosclerotic disease				
	<b>Treatment Phase:</b> Initial				
	<b>Clinical criteria:</b>				
	The treatment must be in combination with aspirin, but not with any other anti-platelet therapy.				
	<b>AND</b>				

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	<b>Clinical criteria:</b>
	Patient must have a diagnosis of coronary artery disease in addition to at least one of the following risk factors: (i) diagnosed heart failure (left ventricular ejection fraction of at least 30% but less than 50%) (ii) diagnosed kidney disease classified by an eGFR in the range of 15-60 mL/min (iii) diabetes mellitus combined with at least one of the following: (a) age at least 60 years (b) concomitant microalbuminuria (c) Aboriginal/Torres Strait Islander descent; or
	Patient must have a diagnosis of peripheral artery disease in addition to at least one of the following risk factors: (i) concomitant coronary artery disease (ii) diagnosed heart failure (left ventricular ejection fraction of at least 30% but less than 50%) (iii) diagnosed kidney disease classified by an eGFR in the range of 15-60 mL/min (iv) diabetes mellitus combined with at least one of the following: (a) age at least 60 years (b) concomitant microalbuminuria (c) Aboriginal/Torres Strait Islander descent
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must have at least one of the following if coronary artery disease is present: (i) a previous multi-vessel coronary revascularisation procedure (ii) significant stenosis in at least 2 coronary arteries (iii) a previous single vessel coronary revascularisation procedure with significant stenosis in more than 1 coronary artery; or
	Patient must have at least one of the following if peripheral arterial disease is present: (i) a previous peripheral/carotid artery revascularisation intervention (ii) intermittent claudication with an ankle-brachial index less than 0.9 (iii) asymptomatic carotid artery stenosis greater than 50%.
	<b>AND</b>
	<b>Clinical criteria:</b>
	The condition must be diagnosed by at least one of: (i) invasive (selective) angiography (ii) non-invasive imaging (i.e. CT scan, ultrasound) (iii) ankle-brachial index measurement in the case of peripheral arterial disease with intermittent claudication.
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must have clinical findings/observations by the treating physician that exclude each of the following: (i) high risk of bleeding (ii) prior stroke within one month of treatment initiation (iii) prior haemorrhagic / lacunar stroke (iv) severe heart failure with a known ejection fraction less than 30% (v) New York Heart Association class III to IV heart failure symptoms (i.e. symptoms corresponding to moderate to severe limitation on physical activity, whereby any of fatigue/palpitations/dyspnoea occur upon zero to minimal activity) (vi) an estimated glomerular filtration rate less than 15 mL/minute (vii) a requirement for dual antiplatelet therapy (viii) a requirement for non-acetylsalicylic acid antiplatelet therapy (ix) a requirement for a higher dose of oral anticoagulant therapy
	<b>Treatment criteria:</b>
	Must be treated by a specialist physician; or
	Must be treated by a physician who has consulted a specialist physician
<b>Restriction Summary 10992/ Treatment of Concept: 10992</b>	
	<b>Category / Program:</b> <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (Streamlined) [10992]
	<b>Indication:</b> Chronic stable atherosclerotic disease
	<b>Treatment Phase:</b> Continuing treatment
	<b>Clinical criteria:</b>
	Patient must have received PBS-subsidised treatment with this drug for this condition.
	<b>AND</b>
	<b>Clinical criteria:</b>

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	The treatment must be in combination with aspirin, but not with any other anti-platelet therapy.
	<b>Administrative Advice:</b>
	Treatment may be continued by a non-specialist prescriber without need for consultation with a specialist.
	<b>Administrative Advice:</b>
	<b>Shared Care Model:</b> For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
RIVAROXABAN					
rivaroxaban 2.5 mg tablet,98	[new] 60DD	2	196	2	Xarelto
<b>Restriction Summary / Treatment of Concept:</b>					
	<b>Category / Program:</b> <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners				
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (Streamlined) [new]				
	<b>Administrative Advice:</b> No increase in the maximum quantity or number of units may be authorised.				
	<b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised.				
	<b>Indication:</b> Chronic stable atherosclerotic disease				
	<b>Treatment Phase:</b> Continuing treatment				
	<b>Clinical criteria:</b>				
	The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient				
	<b>AND</b>				
	<b>Clinical criteria:</b>				
	Patient must have received PBS-subsidised treatment with this drug for this condition.				
	<b>AND</b>				
	<b>Clinical criteria:</b>				
	The treatment must be in combination with aspirin, but not with any other anti-platelet therapy.				
	<b>Administrative Advice:</b>				
	Treatment may be continued by a non-specialist prescriber without need for consultation with a specialist.				
	<b>Administrative Advice:</b>				
	<b>Shared Care Model:</b> For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.				

***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.