9.04 Updates to the restrictions for ezetimibe and its fixed dose combinations (FDCs)

1 Purpose of item

To request that the PBAC:

1.1 **PROVIDE ADVICE** regarding proposed changes to simplify the PBS restrictions for ezetimibe and its FDCs, and any likely impacts on utilisation.

1.2 **PROVIDE ADVICE** on the need to consult relevant prescriber and consumer groups regarding the proposed restriction changes, and/or any further research on this topic that the PBAC requires to inform its recommendation.

1.3 **NOTE** that if restriction changes are recommended, the Department would consult with sponsors prior to implementation.

2 Background

Restriction reviews for low-cost medicines

2.1 The PMR of Authority Required (AR) PBS Listings (2014-2015) considered the criteria to determine AR listings, and reviewed all AR listings, with the objective of reducing the administrative burden on prescribers and dispensers. The PBAC recommended that there should be two key criteria for determining whether a pharmaceutical benefit requires an AR listing:

1. Potential for use in a population in which the medicines is not cost effective or where the PBAC has not determined the comparative effectiveness and cost.
2. Potential for high cost per patient or high total cost to the health system and Government's budget.

2.2 The PBAC noted that other important factors to be considered on a case-by-case basis included: quality use of medicines (QUM), safety, and administrative burden.

2.3 In December 2014, when considering the basis on which to review an AR listing, the PBAC considered that one reason to prompt a review of the authority level was a recommendation by the PBAC of an application for a generic formulation of an existing PBS listing that would result in a price reduction in the listed product (including products moving to the F2 formulary or following price negotiations).

2.4 In September 2023, as part of consideration of the PMR Workplan, the PBAC recommended that the Department consider on a rolling basis whether medicines that have moved to the F2 formulary would be suitable for a restriction review.

PBS listings

2.5 Ezetimibe is PBS listed as a second-line medication to HMG-CoA reductase inhibitors (statins) for the treatment of hypercholesterolaemia. Use through the PBS is restricted to a specific range of patients through an Authority Required (STREAMLINED) restriction.

2.6 Ezetimibe has been on the list of drugs subject to price disclosure since October 2019. On 1 May 2024, ezetimibe was listed on the PBS with a dispensed price for maximum quantity (DPMQ) of $18.63/pack (1 pack of 30, 10 mg tablets, excluding brand premiums). Fixed dose combinations (FDCs) or co-packaged combination products are available through the PBS in combination with rosuvastatin, atorvastatin and simvastatin with a DPMQ of approximately $21-25/pack (varying dose of statin, excluding brand premiums). Sixty-day prescriptions are available for all products containing ezetimibe.

2.7 The Department conducted a Post-market Review (PMR) of Ezetimibe in 2017-18. In October 2018, the PBS restrictions for ezetimibe were revised to be more succinct and align with contemporary treatment guidelines, allowing access to patients with high cardiovascular (CV) risk (>15% absolute risk of a CV event over 5 years) who did not qualify for access under other clinical criteria at the time. The PBAC agreed at that time that the *Australian Absolute Cardiovascular Disease Risk Calculator (National Vascular Disease Prevention Alliance)* was the best way of objectively assessing that risk. The PBAC noted the risk of references like this in PBS restrictions becoming outdated.

2.8 The *Australian Absolute Cardiovascular Disease Risk Calculator* (1 April 2018) ('the Calculator') has subsequently been updated, with 'high' risk now defined as a ≥10% absolute risk of a CV event over 5 years, noting that '…this risk level for initiating treatment is likely to be comparable to the previously recommended 15% CV risk level calculated using the Framingham equation".[1] The current Calculator provides a percentage risk, so can still be used to determine >15% risk, but the PBS restriction no longer refers to the current Calculator.

2.9 When considering the PMR of Ezetimibe in July 2017, the PBAC recommended that the PBS listings for statins, fenofibrate, gemfibrozil, and atorvastatin + amlodipine FDC could be changed to Unrestricted listings, as it was considered that the clinical place of these medications was well established and that derestriction was unlikely to result in inappropriate prescribing or changes in prescribing patterns.

[1] Australian Chronic Disease Prevention Alliance, CVD Risk Guideline - 3. Identify CVD risk category, accessed 20 March 2024.

2.10 The PMR of Ezetimibe also resulted in a price reduction to ezetimibe of 35% to account for use of ezetimibe outside of the PBS restrictions, specifically use in patients without prior use of a statin.

Therapeutic Goods Administration (TGA) indication

2.11 The TGA indication for ezetimibe is broader than the PBS listing, with ezetimibe indicated for the treatment of primary hypercholesterolaemia, administered alone or with a statin, as adjunctive therapy to diet in adults with primary (heterozygous familial and non-familial) hypercholesterolaemia. It is also indicated for the treatment of:

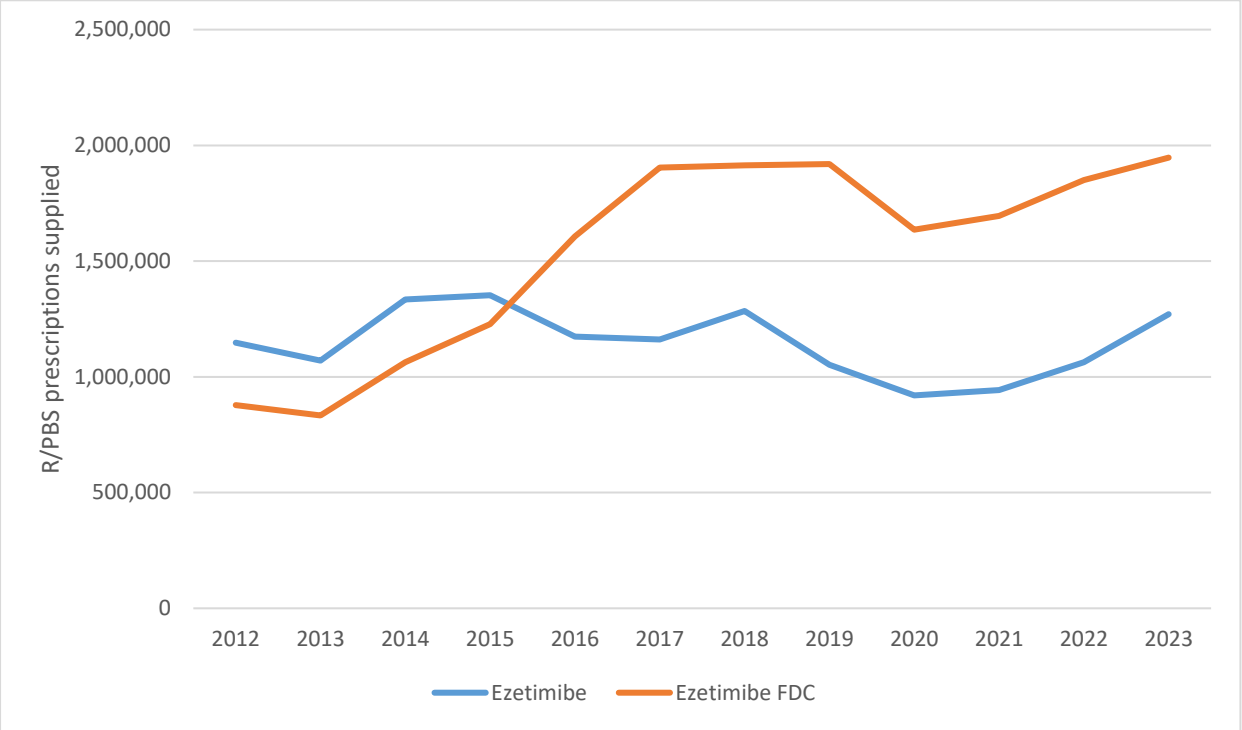
- homozygous familial hypercholesterolaemia (HoFH) in adults
- prevention of cardiovascular disease (CVD) in adult patients with coronary heart disease or history of acute coronary syndrome
- HoFH or heterozygous familial hypercholesterolaemia (HeFH) in patients aged 10-17 years.[2]

R/PBS utilisation and expenditure

2.12 Annual R/PBS expenditure on ezetimibe and ezetimibe + statin FDCs peaked in 2014 at around $185 million, declining to around $59 million in 2023. Utilisation generally increased to 2017, but then remained relatively stable between 2017 to 2019. Utilisation declined in 2020-2021, likely associated with the COVID-19 pandemic, but by 2023 had returned to pre-pandemic levels with little impact on expenditure because of price reductions (Figures 1 and 2).

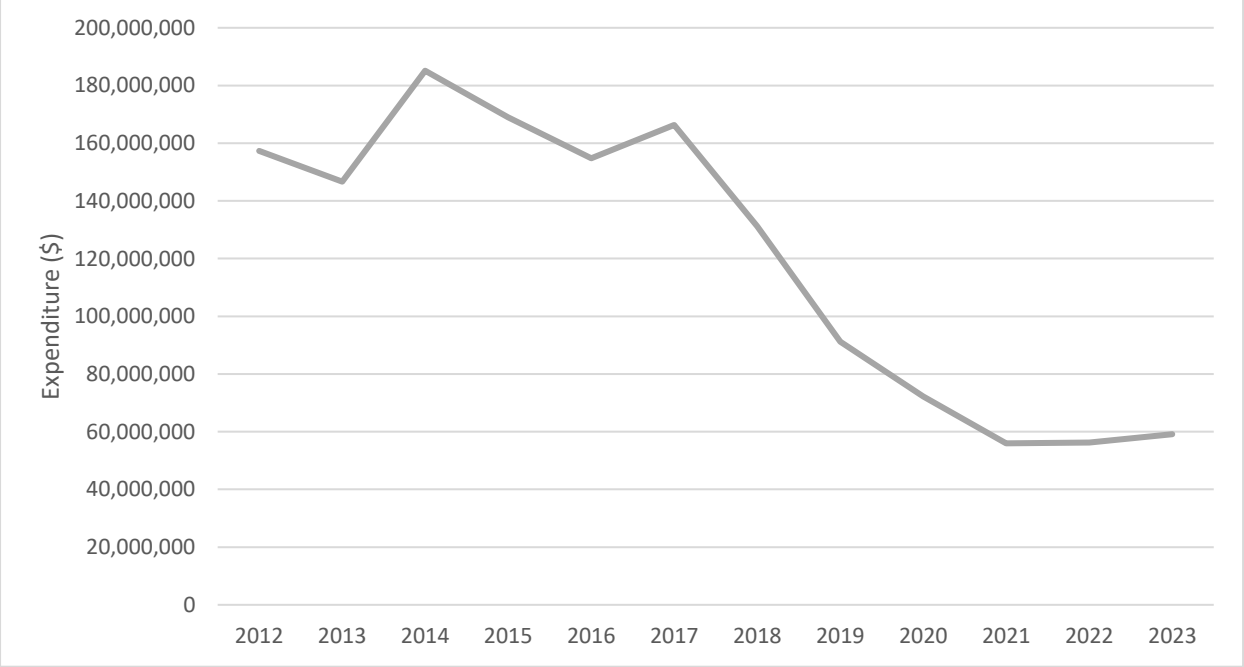
[2] ARTG, Australian Product Information, Pharmacor Ezetimibe tablets v4, accessed 20 March 2024.

Figure 1: Annual R/PBS prescriptions supplied for ezetimibe and ezetimibe FDCs – 2012 to 2023.



Source: Services Australia, PBS Item Reports, accessed 15 April 2024. Includes 60-day prescriptions from September 2023.

Figure 2: Annual R/PBS expenditure for ezetimibe and ezetimibe FDCs – 2012 to 2023.



Source: Services Australia, PBS Item Reports, accessed 15 April 2024. Includes 60-day prescriptions from September 2023.

Clinical guidelines

2.13 The recommendations for ezetimibe use in clinical guidelines are broader than the PBS listings. The Australian Therapeutic Guidelines for Lipid Modification state that ezetimibe should be considered as an add-on therapy to the maximum tolerated dose of statin if low-density lipoprotein cholesterol (LDL-C) targets are not met after six weeks; no specific patient populations are listed. These guidelines note that:

- addition of ezetimibe to statin therapy can further reduce LDL-C by 20-25%
- in patients with acute coronary syndrome (ACS), the addition of ezetimibe to statin therapy is associated with a modest reduction in CV events over 7 years, but no reduction in mortality
- for primary prevention of atherosclerotic cardiovascular disease (ASCVD), the effect of ezetimibe on CV outcomes has not been studied, although some evidence suggests reduced risk of coronary artery disease.[3]

2.14 The UK National Institute for Health Care Excellence (NICE) Technology appraisal guidance for ezetimibe for treating primary hypercholesterolaemia (2016) recommends ezetimibe co-administered with a statin as an option for the treatment of adults with primary hypercholesterolaemia when serum total cholesterol or LDL-C is not appropriately controlled after statin dose titration, or where a change from initial statin therapy to an alternative statin is being considered. Intolerance to a statin is defined as '…the presence of a clinically significant adverse effect that represents an unacceptable risk to the patient or that may reduce compliance with therapy'. However, cost-effectiveness was modelled on LDL-C reductions associated with ezetimibe linked to CV outcome data based on statin use.[4]

2.15 A clinical practice guideline published in the British Medical Journal in 2022 recommended against the use of ezetimibe in patients with low-moderate CV risk (<15% risk of major adverse CV events [MACE] within 5 years) irrespective of statin use; and recommended addition of ezetimibe to high-dose statin therapy, or use of ezetimibe in those intolerant to statins, for patients with high and very high CV risk (≥15% risk of MACE within 5 years). This guideline was based on a systematic review and network meta-analysis and concluded that ezetimibe probably reduced myocardial infarction (MI) and stroke, but not mortality, in patients with high and very high CV risk, but not patients with low-moderate CV risk.[5]

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[3] Therapeutic Guidelines, Lipid Modification, accessed 7 August 2023.
[4] NICE, Technology appraisal guidance: Ezetimibe for treating primary heterozygous-familial and non-familial hypercholesterolaemia (24 February 2016), accessed 22 March 2024.
[5] (2022) 'PCSK9 inhibitors and ezetimibe for the reduction of cardiovascular events: a clinical practice guideline with risk-stratified recommendations', *BMJ*, 377:e069066.

For more detail on PBAC's view, see section 5 PBAC outcome.

3 Issues

3.1 The PBAC noted that the Department had received correspondence from a cardiologist raising the issue that the CVD risk calculator referenced in the PBS restrictions for ezetimibe was no longer current and that the definition of high risk had also changed since the restrictions were implemented.

3.2 The PBAC noted that ezetimibe and ezetimibe FDCs are listed on the F2 formulary, subject to price disclosure and have reduced substantially in price. The PBAC noted that on 1 May 2024, the listed DPMQ of ezetimibe was $16.63/pack, and that this was comparable to the DMPQs for statins ($16-$17/pack), fenofibrate ($19-22/pack) and gemfibrozil ($22.89/pack), other treatments for hypercholesterolaemia which all have Unrestricted PBS listings (apart from the 60-day prescription items which are Restricted Benefit listings).

3.3 The PBAC noted that the PBS restrictions for ezetimibe are complex, reference a CVD risk calculator that is no longer current, and are more restrictive than some current Australian and international clinical guidelines.

For more detail on PBAC's view, see section 5 PBAC outcome.

4 Proposed PBS listing changes

4.1 The PBAC was requested to provide advice on two options for proposed changes to simplify the PBS restrictions for ezetimibe and ezetimibe FDCs.

<u>Option 1: Simplified Authority Required (STREAMLINED) listings</u>

Option 1 proposed subsidising use of ezetimibe in patients on the maximum tolerated dose of statin, or who are contraindicated/intolerant to a statin, and who have high CV risk, without specifying a CVD risk calculator or definition of high CV risk or intolerance (Table 1). The 60-day prescription items would include an additional clinical criterion requiring the patient's condition to be stable.

Table 1: Proposed PBS restrictions for ezetimibe and ezetimibe FDCs – Option 1

Medicine	Proposed PBS restriction text
Ezetimibe	**Hypercholesterolaemia** **Clinical criteria:** • The treatment must be co-administered with the maximum tolerated dose of an HMG CoA reductase inhibitor (statin), OR • Patient must be contraindicated/intolerant to treatment with an HMG CoA reductase inhibitor (statin) **AND** • Patient must be considered at high risk of a cardiovascular event.
	Hypercholesterolaemia **Clinical criteria:** Patient must have homozygous sitosterolaemia.
Ezetimibe + Statin FDC	**Hypercholesterolaemia** **Clinical criteria:** • Patient must have cholesterol concentrations that are inadequately controlled with the maximum tolerated dose of an HMG CoA reductase inhibitor (statin), **AND** • Patient must be considered at high risk of a cardiovascular event.

Option 2: Unrestricted listings

Option 2 proposed changing the authority type for all ezetimibe and ezetimibe FDC products to Unrestricted listings, to align with the Unrestricted listings for statins, fenofibrate and gemfibrozil on the PBS. Under this option, the 60-day prescription items would be changed to Restricted Benefit listings and include a clinical criterion requiring the patient's condition to be stable.

For more detail on PBAC's view, see section 5 PBAC outcome.

Sponsor consultation

4.2 The PBAC noted that sponsors of PBS-listed ezetimibe and ezetimibe FDC products were not consulted on this item.

5 PBAC Outcome

5.1 The PBAC recommended that the restriction level for ezetimibe and ezetimibe + statin FDCs be changed from Authority Required (STREAMLINED) to Unrestricted benefit listings. The PBAC noted that this would involve the deletion of some PBS Authority Required (Streamlined) codes.

5.2 The PBAC considered that utilisation of ezetimibe and its FDCs had stabilised (factoring in fluctuations that were likely attributable to the COVID-19 pandemic) and noted that expenditure had reduced significantly since 2014. The PBAC considered that the

clinical place of ezetimibe and its FDCs was well established and that the change to an Unrestricted PBS listing was unlikely to result in increased utilisation or expenditure.

5.3 The PBAC noted that the TGA-registered indication for ezetimibe was broader than the current PBS restrictions and that some clinical guidelines also recommended broader use of ezetimibe than subsidised under the current PBS restrictions.

5.4 The PBAC considered that while there was limited clinical trial evidence to support the CV benefits of ezetimibe monotherapy, addition of ezetimibe to a statin was associated with a 20-25% reduction in LDL-C,[6] and a reduced risk of MACE (RR 0.94, 95% CI: 0.90 to 0.98), non-fatal myocardial infarction (RR 0.88, 95% CI: 0.81 to 0.95), and non-fatal stroke (RR 0.83, 95%CI: 0.71 to 0.97) versus statins alone.[7] The PBAC considered that it was plausible that ezetimibe monotherapy lowers the risk of adverse CV outcomes.

5.5 The PBAC did not consider that any further research on the utilisation or cost-effectiveness of ezetimibe was required to inform its recommendation.

5.6 The PBAC considered that consultation with prescriber and consumer groups on the authority type change was unnecessary, as these groups were unlikely to object to a broader PBS listing.

5.7 The PBAC noted that sponsors would be consulted on the restriction level change and if any objections were raised, these would be brought to the PBAC at a future meeting.

5.8 The PBAC noted that this work would be included on the published PMR Work Plan.

Outcome:
Recommended

[6] Therapeutic Guidelines, Lipid Modification, accessed 7 August 2023.
[7] Zhan S et al (2018), 'Ezetimibe for the prevention of cardiovascular disease and all-cause mortality events', *Cochrane Database Syst Rev*, 11(11):CD012502.

6 Recommended Listing

6.1 Amend existing/recommended listings as follows:

Ezetimibe

Category / Program: GENERAL – General Schedule (Code GE)					
MEDICINAL PRODUCT medicinal product pack	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
EZETIMIBE					
Ezetimibe 10 mg tablet, 30	8757X MP NP	1	30	5	[a] APO-Ezetimibe [a] BTC Ezetimibe [a] Blooms The Chemist Ezetimibe [a] EZEMICHOL [a] Ezetimibe GH [a] Ezetimibe Sandoz [a] Pharmacor Ezetimibe 10 [a] Zient 10mg [a] Ezetrol
Remove the following restriction summaries: 7996 (hypercholesterolaemia, statin coadministration) 7966 (hypercholesterolaemia, statin intolerance/contraindication/dose reduction) 7990 (homozygous sitosterolaemia)					
Administrative Advice: Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.					

Category / Program: GENERAL – General Schedule (Code GE)					
MEDICINAL PRODUCT medicinal product pack	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
EZETIMIBE					
Ezetimibe 10 mg tablet, 30	13440J MP NP	2	60	5	[a] APO-Ezetimibe [a] BTC Ezetimibe [a] Blooms The Chemist Ezetimibe [a] EZEMICHOL [a] Ezetimibe GH [a] Ezetimibe Sandoz [a] Pharmacor Ezetimibe 10 [a] Zient 10mg [a] Ezetrol
Remove the following restriction summaries: 14249 (hypercholesterolaemia, statin coadministration) 14238 (hypercholesterolaemia, statin intolerance/contraindication/dose reduction) 7990 (homozygous sitosterolaemia)					
Restriction: Restricted Benefit					
Indication: The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.					
Administrative Advice: Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.					

Ezetimibe (&) rosuvastatin

Category / Program: GENERAL – General Schedule (Code GE)					
MEDICINAL PRODUCT medicinal product pack	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
EZETIMIBE (&) ROSUVASTATIN					
Ezetimibe 10 mg tablet [30] (&) rosuvastatin 5 mg tablet [30], 60	10204C MP NP	1	1	5	[a] Ezalo Composite Pack 10mg+5mg [a] Rosuzet Composite Pack
Ezetimibe 10 mg tablet [30] (&) rosuvastatin 10 mg tablet [30], 60	10208G MP NP	1	1	5	[a] Ezalo Composite Pack 10mg+10mg [a] Pharmacor Ezetimibe Rosuvastatin Composite Pack [a] Rosuzet Composite Pack
Ezetimibe 10 mg tablet [30] (&) rosuvastatin 20 mg tablet [30], 60	10201X MP NP	1	1	5	[a] Ezalo Composite Pack 10mg+20mg [a] Pharmacor Ezetimibe Rosuvastatin Composite Pack [a] Rosuzet Composite Pack
Ezetimibe 10 mg tablet [30] (&) rosuvastatin 40 mg tablet [30], 60	10207F MP NP	1	1	5	[a] Ezalo Composite Pack 10mg+40mg [a] Pharmacor Ezetimibe Rosuvastatin Composite Pack [a] Rosuzet Composite Pack
Remove the following restriction summaries: 7958 (hypercholesterolaemia, reduced statin dose) – for item 10204C 7957 (hypercholesterolaemia) – for items 10208G, 10201X and 10207F					
Administrative Advice: Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.					

Category / Program: GENERAL – General Schedule (Code GE)					
MEDICINAL PRODUCT medicinal product pack	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
EZETIMIBE (&) ROSUVASTATIN					
Ezetimibe 10 mg tablet [30] (&) rosuvastatin 5 mg tablet [30], 60	13629H MP NP	2	2	5	[a] Ezalo Composite Pack 10mg+5mg [a] Rosuzet Composite Pack
Ezetimibe 10 mg tablet [30] (&) rosuvastatin 10 mg tablet [30], 60	13569E MP NP	2	2	5	[a] Ezalo Composite Pack 10mg+10mg [a] Pharmacor Ezetimibe Rosuvastatin Composite Pack [a] Rosuzet Composite Pack
Ezetimibe 10 mg tablet [30] (&) rosuvastatin 20 mg tablet [30], 60	13480L MP NP	2	2	5	[a] Ezalo Composite Pack 10mg+20mg [a] Pharmacor Ezetimibe Rosuvastatin Composite Pack [a] Rosuzet Composite Pack
Ezetimibe 10 mg tablet [30] (&) rosuvastatin 40 mg tablet [30], 60	13537L MP NP	2	2	5	[a] Ezalo Composite Pack 10mg+40mg [a] Pharmacor Ezetimibe Rosuvastatin Composite Pack [a] Rosuzet Composite Pack
Remove the following restriction summaries: 14350 (hypercholesterolaemia, reduced statin dose) – for item 13629H 14284 (hypercholesterolaemia) – for items 13569E, 13480L and 13537L					
Restriction: Restricted Benefit					
Indication: The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.					
Administrative Advice: Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.					

Ezetimibe + atorvastatin

Category / Program: GENERAL – General Schedule (Code GE)					
MEDICINAL PRODUCT medicinal product pack	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
EZETIMIBE + ATORVASTATIN					
Ezetimibe 10 mg tablet + atorvastatin 10 mg tablet, 30	10392Y MP NP	1	30	5	[a] Ezetast [a] Ezetimibe/Atorvastatin GH 10/10 [a] Atozet
Ezetimibe 10 mg tablet + atorvastatin 20 mg tablet, 30	10393B MP NP	1	30	5	Ezetast [a] Ezetimibe/Atorvastatin GH 10/20 [a] Atozet
Ezetimibe 10 mg tablet + atorvastatin 40 mg tablet, 30	10377E MP NP	1	30	5	Ezetast [a] Ezetimibe/Atorvastatin GH 10/40 [a] Atozet
Ezetimibe 10 mg tablet + atorvastatin 80 mg tablet, 30	10376D MP NP	1	30	5	Ezetast [a] Ezetimibe/Atorvastatin GH 10/80 [a] Atozet
Remove the following restriction summaries: 7958 (hypercholesterolaemia, reduced statin dose) – for item 10392Y 7957 (hypercholesterolaemia) – for items 10393B, 10377E and 10376D					
Administrative Advice: Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.					

Category / Program: GENERAL – General Schedule (Code GE)					
MEDICINAL PRODUCT medicinal product pack	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
EZETIMIBE + ATORVASTATIN					
Ezetimibe 10 mg tablet + atorvastatin 10 mg tablet, 30	13539N MP NP	2	60	5	[a] Ezetast [a] Ezetimibe/Atorvastatin GH 10/10 [a] Atozet
Ezetimibe 10 mg tablet + atorvastatin 20 mg tablet, 30	13622Y MP NP	2	60	5	Ezetast [a] Ezetimibe/Atorvastatin GH 10/20 [a] Atozet
Ezetimibe 10 mg tablet + atorvastatin 40 mg tablet, 30	13416D MP NP	2	60	5	Ezetast [a] Ezetimibe/Atorvastatin GH 10/40 [a] Atozet
Ezetimibe 10 mg tablet + atorvastatin 80 mg tablet, 30	13538M MP NP	2	60	5	Ezetast [a] Ezetimibe/Atorvastatin GH 10/80 [a] Atozet
Remove the following restriction summaries: 14269 (hypercholesterolaemia, reduced statin dose) – for item 13539N 14284 (hypercholesterolaemia) – for items 13622Y,13416D and 13538M					
Restriction: Restricted Benefit					
Indication: The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.					
Administrative Advice: Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.					

Ezetimibe + simvastatin

Category / Program: GENERAL – General Schedule (Code GE)					
MEDICINAL PRODUCT medicinal product pack	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
EZETIMIBE + SIMVASTATIN					
Ezetimibe 10 mg tablet + simvastatin 10 mg tablet, 30	9483D MP NP	1	30	5	[a] APO-Ezetimibe/Simvastatin 10/10 [a] EZETIMIBE/SIMVASTATIN SANDOZ [a] EZETORIN [a] EzSimva GH 10/10 [a] Pharmacor Ezetimibe Simvastatin 10/10 [a] Vytorin [a] Zeklen 10/10 mg [a] Zimybe 10/10
Ezetimibe 10 mg tablet + simvastatin 20 mg tablet, 30	9484E MP NP	1	30	5	[a] APO-Ezetimibe/Simvastatin 10/20 [a] EZETIMIBE/SIMVASTATIN SANDOZ [a] EZETORIN [a] EzSimva GH 10/20 [a] Pharmacor Ezetimibe Simvastatin 10/20 [a] Vytorin [a] Zeklen 10/20 mg [a] Zimybe 10/20
Ezetimibe 10 mg tablet + simvastatin 40 mg tablet, 30	8881K MP NP	1	30	5	[a] APO-Ezetimibe/Simvastatin 10/40 [a] EZETIMIBE/SIMVASTATIN SANDOZ [a] EZETORIN [a] EzSimva GH 10/40 [a] Pharmacor Ezetimibe Simvastatin 10/40 [a] Vytorin [a] Zeklen 10/40 mg [a] Zimybe 10/40
Ezetimibe 10 mg tablet + simvastatin 80 mg tablet, 30	8882L MP NP	1	30	5	[a] APO-Ezetimibe/Simvastatin 10/80 [a] EZETIMIBE/SIMVASTATIN SANDOZ [a] EZETORIN [a] EzSimva GH 10/80 [a] Pharmacor Ezetimibe Simvastatin 10/80 [a] Vytorin [a] Zeklen 10/80 mg [a] Zimybe 10/80
Remove the following restriction summaries: 7958 (hypercholesterolaemia, reduced statin dose) – for item 9483D and 9484E 7957 (hypercholesterolaemia) – for items 8881K and 8882L					
Administrative Advice: Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.					

Category / Program: GENERAL – General Schedule (Code GE)					
MEDICINAL PRODUCT medicinal product pack	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
EZETIMIBE + SIMVASTATIN					
Ezetimibe 10 mg tablet + simvastatin 10 mg tablet, 30	13385L MP NP	2	60	5	[a] APO-Ezetimibe/Simvastatin 10/10 [a] EZETIMIBE/SIMVASTATIN SANDOZ [a] EZETORIN [a] EzSimva GH 10/10 [a] Pharmacor Ezetimibe Simvastatin 10/10 [a] Vytorin [a] Zeklen 10/10 mg [a] Zimybe 10/10
Ezetimibe 10 mg tablet + simvastatin 20 mg tablet, 30	13442L MP NP	2	60	5	[a] APO-Ezetimibe/Simvastatin 10/20 [a] EZETIMIBE/SIMVASTATIN SANDOZ [a] EZETORIN [a] EzSimva GH 10/20 [a] Pharmacor Ezetimibe Simvastatin 10/20 [a] Vytorin [a] Zeklen 10/20 mg [a] Zimybe 10/20
Ezetimibe 10 mg tablet + simvastatin 40 mg tablet, 30	13535J MP NP	2	60	5	[a] APO-Ezetimibe/Simvastatin 10/40 [a] EZETIMIBE/SIMVASTATIN SANDOZ [a] EZETORIN [a] EzSimva GH 10/40 [a] Pharmacor Ezetimibe Simvastatin 10/40 [a] Vytorin [a] Zeklen 10/40 mg [a] Zimybe 10/40
Ezetimibe 10 mg tablet + simvastatin 80 mg tablet, 30	13595M MP NP	2	60	5	[a] APO-Ezetimibe/Simvastatin 10/80 [a] EZETIMIBE/SIMVASTATIN SANDOZ [a] EZETORIN [a] EzSimva GH 10/80 [a] Pharmacor Ezetimibe Simvastatin 10/80 [a] Vytorin [a] Zeklen 10/80 mg [a] Zimybe 10/80
Remove the following restriction summaries: 14269 (hypercholesterolaemia, reduced statin dose) – for item 13385L and 13442L 14284 (hypercholesterolaemia) – for items 13535J and 13595M					
Restriction: Restricted Benefit					
Indication: The condition must be stable for the prescriber to consider the listed maximum quantity of this medicine suitable for this patient.					
Administrative Advice: Continuing Therapy Only: For prescribing by nurse practitioners as continuing therapy only, where the treatment of, and prescribing of medicine for, a patient has been initiated by a medical practitioner. Further information can be found in the Explanatory Notes for Nurse Practitioners.					