# Appendix B – Ezetimibe Restrictions

**(Extract from Schedule of Pharmaceutical Benefits 01 December 2016)**

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Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the [Department of Human Services website](http://www.humanservices.gov.au).

## A. Ezetimibe 10 mg

**EZETIMIBE**

**Note 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.

### A.1. Co-administration with a Statin for Coronary Heart Disease

**Authority required (STREAMLINED)**

**5537**

Hypercholesterolaemia

**Clinical criteria:**

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### A.2. Co-administration with a Statin for Diabetes Mellitis

Authority required (STREAMLINED)

5543

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### A.3. Co-administration with a Statin for Peripheral Vascular Disease

Authority required (STREAMLINED)

5538

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### A.4. Co-administration with a Statin for Heterozygous Familial Hypercholesterolaemia

Authority required (STREAMLINED)

5544

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### A.5. Co-administration with a Statin for Symptomatic Cerebrovascular Disease

Authority required (STREAMLINED)

5594

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### A.6. Co-administration with a Statin for Family History Of Coronary Heart Disease

Authority required (STREAMLINED)

5586

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### A.7. Co-administration with a Statin for Hypertension

Authority required (STREAMLINED)

**5575**

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ The treatment must be co-administered with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have hypertension.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### A.8. Statin Contraindication

Authority required (STREAMLINED)

5576

Hypercholesterolaemia

Clinical criteria:

* + Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
	+ Patient must be one in whom treatment with an HMG CoA reductase inhibitor (statin) is contraindicated.

### A.9. Statin Adverse Event

Authority required (STREAMLINED)

5562

Hypercholesterolaemia

Clinical criteria:

* + Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
	+ Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose; **OR**
	+ Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a withdrawal of the statin treatment.

A clinically important product-related adverse event is defined as follows:

1. Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; **or**
2. Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; **or**
3. Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

### A.10. Homozygous Sitosterolaemia

Authority required (STREAMLINED)

5563

Homozygous sitosterolaemia

### A.11. Homozygous Familial Hypercholesterolaemia and Statin Co-administration

**Authority required (STREAMLINED)**

**5577**

Hypercholesterolaemia

Clinical criteria:

* + Patient must have homozygous familial hypercholesterolaemia, **AND**
	+ Patient must meet the criteria set out in the General Statement for Lipid-Lowering Drugs, **AND**
	+ The treatment must be co-administered with an HMG CoA reductase inhibitor (statin).

Name, form, strength and pack size: Ezetimibe 10 mg tablet, 30

Item Code: 8757X

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Max.Qty Packs** | **No. of Rpts** | **Premium $** | **DPMQ $** | **Max Safety Net** | **Brand Name and Manufacturer** |
| 1 | 5 | .. | 66.84 | 38.30 | Ezetrol (MSD) |

As at 1 August 2017

## B. Ezetimibe 10 mg + Atorvastatin 20 mg/40 mg/80 mg

EZETIMIBE + ATORVASTATIN

Note 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.

### B.1. Coronary Heart Disease

**Authority required (STREAMLINED)**

**4068**

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### B.2. Diabetes Mellitus

**Authority required (STREAMLINED)**

**4085**

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### B.3. Peripheral Vascular Disease

**Authority required (STREAMLINED)**

**4086**

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### B.4. Heterozygous Familial Hypercholesterolaemia

Authority required (STREAMLINED)

4069

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### B.5. Symptomatic Cerebrovascular Disease

Authority required (STREAMLINED)

4096

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### B.6. Family History of Coronary Heart Disease

Authority required (STREAMLINED)

4120

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### B.7. Hypertension

Authority required (STREAMLINED)

4121

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have hypertension.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### B.8. Homozygous Familial Hypercholesterolaemia

Authority required (STREAMLINED)

4097

Hypercholesterolaemia

Clinical criteria:

* + Patient must have homozygous familial hypercholesterolaemia, **AND**
	+ Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

Name, form, strength and pack size: ezetimibe 10 mg + atorvastatin 20 mg tablet, 30

Item Code: 10393B

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| --- | --- | --- | --- | --- | --- |
| **Max.Qty Packs** | **No. of Rpts** | **Premium $** | **DPMQ $** | **Max Safety Net $** | **Brand Name and Manufacturer** |
| 1 | 5 | - | 69.46 | 38.30 | Atozet (MSD) |

As at 1 August 2017

Name, form, strength and pack size: ezetimibe 10 mg + atorvastatin 40 mg tablet, 30

Item Code: 10377E

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| --- | --- | --- | --- | --- | --- |
| **Max.Qty Packs** | **No. of Rpts** | **Premium $** | **DPMQ $** | **Max Safety Net $** | **Brand Name and Manufacturer** |
| 1 | 5 | - | 70.53 | 38.30 | Atozet (MSD) |

As at 1 August 2017

Name, form, strength and pack size: ezetimibe 10 mg + atorvastatin 80 mg tablet, 30

Item Code: 10376D

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Max.Qty Packs** | **No. of Rpts** | **Premium $** | **DPMQ $** | **Max Safety Net $** | **Brand Name and Manufacturer** |
| 1 | 5 | - | 72.12 | 38.30 | Atozet (MSD) |

As at 1 August 2017

## C. Ezetimibe 10 mg + Atorvastatin 10 mg

EZETIMIBE + ATORVASTATIN

Note 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.

### C.1. Coronary Heart Disease

Authority required (STREAMLINED)

4068

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### C.2. Diabetes Mellitus

Authority required (STREAMLINED)

4085

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### C.3. Peripheral Vascular Disease

Authority required (STREAMLINED)

4086

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### C.4. Heterozygous Familial Hypercholesterolaemia

Authority required (STREAMLINED)

4069

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### C.5. Symptomatic Cerebrovascular Disease

Authority required (STREAMLINED)

4096

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### C.6. Family History of Coronary Heart Disease

Authority required (STREAMLINED)

4120

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### C.7. Hypertension

Authority required (STREAMLINED)

4121

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have hypertension.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### C.8. Homozygous Familial Hypercholesterolaemia

Authority required (STREAMLINED)

4097

Hypercholesterolaemia

Clinical criteria:

* + Patient must have homozygous familial hypercholesterolaemia, **AND**
	+ Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

### C.9. Statin Adverse Event

Authority required (STREAMLINED)

4353

Hypercholesterolaemia

Clinical criteria:

* + Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs), **AND**
	+ Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the atorvastatin dose.

A clinically important product-related adverse event is defined as follows:

* 1. Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or
	2. Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or
	3. Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Name, form, strength and pack size: ezetimibe 10 mg + atorvastatin 10 mg tablet, 30

Item Code: 10392Y

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| --- | --- | --- | --- | --- | --- |
| **Max.Qty Packs** | **No. of Rpts** | **Premium $** | **DPMQ $** | **Max Safety Net $** | **Brand Name and Manufacturer** |
| 1 | 5 | - | 68.61 | 38.30 | Atozet (MSD) |

As at 1 August 2017

## D. Ezetimibe 10 mg + Simvastatin 40 mg/80 mg

EZETIMIBE + SIMVASTATIN

Note 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.

### D.1. Coronary Heart Disease

Authority required (STREAMLINED)

4068

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### D.2. Diabetes Mellitus

Authority required (STREAMLINED)

4085

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### D.3. Peripheral Vascular Disease

Authority required (STREAMLINED)

4086

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### D.4. Heterozygous Familial Hypercholesterolaemia

Authority required (STREAMLINED)

4069

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### D.5. Symptomatic Cerebrovascular Disease

Authority required (STREAMLINED)

4096

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### D.6. Family History of Coronary Heart Disease

Authority required (STREAMLINED)

4120

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### D.7. Hypertension

Authority required (STREAMLINED)

4121

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have hypertension.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### D.8. Homozygous Familial Hypercholesterolaemia

Authority required (STREAMLINED)

4097

Hypercholesterolaemia

Clinical criteria:

* + Patient must have homozygous familial hypercholesterolaemia, **AND**
	+ Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

Name, form, strength and pack size: ezetimibe 10 mg + simvastatin 40 mg tablet, 30

Item Code: 8881K

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| --- | --- | --- | --- | --- | --- |
| **Max.Qty Packs** | **No. of Rpts** | **Premium $** | **DPMQ $** | **Max Safety Net $** | **Brand Name and Manufacturer** |
| 1 | 5 | - | 69.45 | 38.30 | Vytorin (MSD) |

As at 1 August 2017

Name, form, strength and pack size: ezetimibe 10 mg + simvastatin 80 mg tablet, 30

Item Code: 8882L

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| --- | --- | --- | --- | --- | --- |
| **Max.Qty Packs** | **No. of Rpts** | **Premium $** | **DPMQ $** | **Max Safety Net$** | **Brand Name and Manufacturer** |
| 1 | 5 | - | 70.58 | 38.30 | Vytorin (MSD)  |

As at 1 August 2017

## E. Ezetimibe 10 mg + Simvastatin 10 mg/20 mg

EZETIMIBE + SIMVASTATIN

Note 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.

### E.1. Coronary Heart Disease

Authority required (STREAMLINED)

4068

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### E.2. Diabetes Mellitus

Authority required (STREAMLINED)

4085

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### E.3. Peripheral Vascular Disease

Authority required (STREAMLINED)

4086

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### E.4. Heterozygous Familial Hypercholesterolaemia

Authority required (STREAMLINED)

4069

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### E.5. Symptomatic Cerebrovascular Disease

Authority required (STREAMLINED)

4096

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### E.6. Family History of Coronary Heart Disease

Authority required (STREAMLINED)

4120

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### E.7. Hypertension

Authority required (STREAMLINED)

4121

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have hypertension.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### E.8. Homozygous Familial Hypercholesterolaemia

Authority required (STREAMLINED)

4097

Hypercholesterolaemia

Clinical criteria:

* + Patient must have homozygous familial hypercholesterolaemia, **AND**
	+ Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

### E.9. Statin Adverse Event

Authority required (STREAMLINED)

4147

Hypercholesterolaemia

Clinical criteria:

* + Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs), **AND**
	+ Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose.

A clinically important product-related adverse event is defined as follows:

1. Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or
2. Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or
3. Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Name, form, strength and pack size: ezetimibe 10 mg + simvastatin 10 mg tablet, 30

Item Code: 9483D

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| **Max.Qty Packs** | **No. of Rpts** | **Premium $** | **DPMQ $** | **Max Safety Net $** | **Brand Name and Manufacturer** |
| 1 | 5 | - | 68.10 | 38.30 | Vytorin (MSD)  |

As at 1 August 2017

Name, form, strength and pack size: ezetimibe 10 mg + simvastatin 20 mg tablet, 30

Item Code: 9484E

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| --- | --- | --- | --- | --- | --- |
| **Max.Qty Packs** | **No. of Rpts** | **Premium $** | **DPMQ $** | **Max Safety Net $** | **Brand Name and Manufacturer** |
| 1 | 5 | - | 68.66 | 38.30 | Vytorin (MSD)  |

As at 1 August 2017

## F. Rosuvastatin 10 mg/20 mg/40 mg & Ezetimibe 10 mg Co-pack

ROSUVASTATIN (&) EZETIMIBE

Note 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.

### F.1. Coronary Heart Disease

Authority required (STREAMLINED)

4068

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### F.2. Diabetes Mellitus

Authority required (STREAMLINED)

4085

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### F.3. Peripheral Vascular Disease

Authority required (STREAMLINED)

4086

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### F.4. Heterozygous Familial Hypercholesterolaemia

Authority required (STREAMLINED)

4069

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### F.5. Symptomatic Cerebrovascular Disease

Authority required (STREAMLINED)

4096

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### F.6. Family History of Coronary Heart Disease

Authority required (STREAMLINED)

4120

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### F.7. Hypertension

Authority required (STREAMLINED)

4121

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have hypertension.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### F.8. Homozygous Familial Hypercholesterolaemia

Authority required (STREAMLINED)

4097

Hypercholesterolaemia

Clinical criteria:

* + Patient must have homozygous familial hypercholesterolaemia, **AND**
	+ Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

Name, form, strength and pack size: rosuvastatin 10 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack

Item Code: 10208G

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| --- | --- | --- | --- | --- | --- |
| **Max.Qty Packs** | **No. of Rpts** | **Premium $** | **DPMQ $** | **Max Safety Net $** | **Brand Name and Manufacturer** |
| 1 | 5 | - | 69.72 | 38.30 | Rosuzet Composite Pack (MSD)  |

As at 1 August 2017

Name, form, strength and pack size: rosuvastatin 20 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack

Item Code: 10201X

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| --- | --- | --- | --- | --- | --- |
| **Max.Qty Packs** | **No. of Rpts** | **Premium $** | **DPMQ $** | **Max Safety Net $** | **Brand Name and Manufacturer** |
| 1 | 5 | - | 70.89 | 38.30 | Rosuzet Composite Pack (MSD)  |

As at 1 August 2017

Name, form, strength and pack size: rosuvastatin 40 mg tablet [30] (&) ezetimibe 10 mg tablet [30 tablets], 1 pack

Item Code: 10207F

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| --- | --- | --- | --- | --- | --- |
| **Max.Qty Packs** | **No. of Rpts** | **Premium $** | **DPMQ $** | **Max Safety Net $** | **Brand Name and Manufacturer** |
| 1 | 5 | - | 72.65 | 38.30 | Rosuzet Composite Pack (MSD)  |

As at 1 August 2017

## G. Rosuvastatin 5 mg & Ezetimibe 10 mg Co-pack

ROSUVASTATIN (&) EZETIMIBE

Note 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.

### G.1. Coronary Heart Disease

Authority required (STREAMLINED)

4068

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have coronary heart disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### G.2. Diabetes Mellitus

Authority required (STREAMLINED)

4085

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have diabetes mellitus.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### G.3. Peripheral Vascular Disease

Authority required (STREAMLINED)

4086

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have peripheral vascular disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### G.4. Heterozygous Familial Hypercholesterolaemia

Authority required (STREAMLINED)

4069

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have heterozygous familial hypercholesterolaemia.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### G.5. Symptomatic Cerebrovascular Disease

Authority required (STREAMLINED)

4096

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have symptomatic cerebrovascular disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### G.6. Family History of Coronary Heart Disease

Authority required (STREAMLINED)

4120

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have a family history of coronary heart disease.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### G.7. Hypertension

Authority required (STREAMLINED)

4121

Hypercholesterolaemia

Clinical criteria:

* + The treatment must be in conjunction with dietary therapy and exercise, **AND**
	+ Patient must have cholesterol levels that are inadequately controlled with an HMG CoA reductase inhibitor (statin), **AND**
	+ Patient must have hypertension.

Inadequate control with a statin is defined as follows:

1. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs includes an initial cholesterol threshold for PBS-subsidy (i.e. a patient not in a very high risk category), a cholesterol level in excess of that threshold after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated; or
2. where the patient falls into a category for which the General Statement for Lipid-Lowering Drugs allows PBS-subsidised treatment with a statin at any cholesterol level (i.e. a very high risk category patient), a cholesterol level in excess of 4 mmol per L after at least 3 months of treatment at a maximum tolerated dose of a statin, in conjunction with dietary therapy and exercise. The dose and duration of statin treatment and the cholesterol level which shows inadequate control must be documented in the patient's medical records when ezetimibe is initiated. The cholesterol level which shows inadequate control must be no more than 2 months old when ezetimibe is initiated.

### G.8. Homozygous Familial Hypercholesterolaemia

Authority required (STREAMLINED)

4097

Hypercholesterolaemia

Clinical criteria:

* + Patient must have homozygous familial hypercholesterolaemia, **AND**
	+ Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs).

### G.9. Statin Adverse Event

Authority required (STREAMLINED)

4147

Hypercholesterolaemia

Clinical criteria:

* + Patient must be eligible for PBS-subsidised lipid-lowering medication (according to the criteria set out in the General Statement for Lipid-Lowering Drugs), **AND**
	+ Patient must have developed a clinically important product-related adverse event during treatment with an HMG CoA reductase inhibitor (statin) necessitating a reduction in the statin dose.

A clinically important product-related adverse event is defined as follows:

1. Severe myalgia (muscle symptoms without creatine kinase elevation) which is proven to be temporally associated with statin treatment; or
2. Myositis (clinically important creatine kinase elevation, with or without muscle symptoms) demonstrated by results twice the upper limit of normal on a single reading or a rising pattern on consecutive measurements and which is unexplained by other causes; or
3. Unexplained, persistent elevations of serum transaminases (greater than 3 times the upper limit of normal) during treatment with a statin.

Name, form, strength and pack size: rosuvastatin 5 mg tablet [30] (&) ezetimibe 10 mg tablet [30], 1 pack

Item Code: 10204C

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| --- | --- | --- | --- | --- | --- |
| **Max.Qty Packs** | **No. of Rpts** | **Premium $** | **DPMQ $** | **MRVSN $** | **Brand Name and Manufacturer** |
| 1 | 5 | - | 68.80 | 38.30 | Rosuzet Composite Pack (MSD)  |

As at 1 August 2017