SCHEDULE OF PHARMACEUTICAL BENEFITS EFFECTIVE 1 DECEMBER 2017

ERRATA

(1a) This Erratum corrects the entry for **Darunavir** in the 1 December 2017 Schedule by removing as pharmaceutical benefits the Darunavir Mylan brand of darunavir 600 mg tablet and 800 mg tablet, and removing equivalence for substitution indicators for the Prezista brand of these items.

(1b) This Erratum corrects the entry for **Darunavir** in the 1 December 2017 Schedule by restoring previous prices for all listed strengths for the Prezista brand, including combination flow-on prices for the Prezcobix brand of these items.

Highly Specialised Drugs Program (Community Access)

- **DARUNAVIR**

Authority required (STREAMLINED)

5094

Human immunodeficiency virus (HIV) infection

Clinical criteria:

- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- The treatment must be co-administered with 100 mg ritonavir twice daily, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

darunavir 600 mg tablet, 60

10329P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*2039.69	38.80	Prezista [JC]

darunavir 150 mg tablet, 240

10287K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	..	1043.27	38.80	Prezista [JC]

DARUNAVIR

Authority required (STREAMLINED)

4313

Human immunodeficiency virus (HIV) infection

Clinical criteria:

- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- The treatment must be co-administered with 100 mg ritonavir, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen, **AND**
- Patient must not have demonstrated darunavir resistance associated mutations detected on resistance testing.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

darunavir 800 mg tablet, 30

10367P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*1375.51	38.80	Prezista [JC]

▪ DARUNAVIR + COBICISTAT

Authority required (STREAMLINED)

6413

Human immunodeficiency virus (HIV) infection

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- The treatment must not be in combination with ritonavir.

Note The cobicistat component of the darunavir + cobicistat combination product provides the necessary pharmacokinetic enhancement of darunavir to achieve therapeutic levels of darunavir.

Authority required (STREAMLINED)

6428

Human immunodeficiency virus (HIV) infection

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**

- The treatment must not be in combination with ritonavir.

Note The cobicistat component of the darunavir + cobicistat combination product provides the necessary pharmacokinetic enhancement of darunavir to achieve therapeutic levels of darunavir.

Authority required (STREAMLINED)

6377

Human immunodeficiency virus (HIV) infection

Clinical criteria:

- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- The treatment must not be in combination with ritonavir, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

Note The cobicistat component of the darunavir + cobicistat combination product provides the necessary pharmacokinetic enhancement of darunavir to achieve therapeutic levels of darunavir.

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darunavir 800 mg + cobicistat 150 mg tablet, 30

10903W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	5	..	*1341.39	38.80	Prezcobix [JC]

(2) This Erratum corrects the entry for the advanced notice of deletion of **Metronidazole** in the 1 December 2017 Schedule for the Metronidazole Sandoz IV brand of metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags to a deletion date of 1 February 2018

Advance Notices

1 February 2018

Deletion – Brand

1821W *Metronidazole Sandoz IV, SZ* – METRONIDAZOLE, metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags

1832K *Metronidazole Sandoz IV, SZ* – METRONIDAZOLE, metronidazole 500 mg/100 mL (0.5%) injection, 10 x 100 mL bags