

**PB 13 of 2019**

**National Health (Highly specialised drugs program) Special Arrangement Amendment Instrument 2019 (No. 2)**

*National Health Act 1953*

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I, BEN SLADIC, Assistant Secretary, Pharmacy Branch, Technology Assessment and Access Division, Department of Health, delegate of the Minister for Health, make this Amendment Instrument under subsection 100(2) of the *National Health Act 1953*.

Dated 26 February 2019

BEN SLADIC

Assistant Secretary

Pharmacy Branch

Technology Assessment and Access Division

Department of Health

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1. **Name of Instrument**
2. This Instrument is the *National Health (Highly specialised drugs program) Special Arrangement Amendment Instrument 2019 (No. 2)*.
3. This Instrument may also be cited as PB 13 of 2019.
4. **Commencement**

This Instrument commences on 1 March 2019.

1. **Amendment of *National Health (Highly specialised drugs program) Special Arrangement 2010* (PB 116 of 2010)**

Schedule 1 amends the *National Health (Highly specialised drugs program) Special Arrangement 2010* (PB 116 of 2010).

**Schedule 1 Amendments**

1. **Part 1, Division 1, Section 4, definition for ‘medication for the treatment of HIV or AIDS’**

*insert in alphabetical order:* **(fa) bictegravir with emtricitabine with tenofovir alafenamide**

1. **Schedule 1, after entry for Benralizumab**

*insert:*

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Bictegravir with emtricitabine with tenofovir alafenamide | Tablet containing bictegravir 50 mg with emtricitabine 200 mg with tenofovir alafenamide 25 mg | Oral | Biktarvy | GI | EMP | C4470 C4522 |  | 60 | 5 | D |

1. **Schedule 1, entry for Valaciclovir**

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Valaciclovir APOTEX | GX | EMP | C5939 C5975 |  | 500 | 2 | C |

1. **Schedule 1, entry for Zoledronic acid in the form Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | DEZTRON | DZ | EMP | C5605 C5606 C5676 C5677 C5703 C5704 C5735 C5736 |  | 1 | 11 | PB |

1. **Schedule 3, after entry for Benralizumab**

*insert:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Bictegravir with emtricitabine with tenofovir alafenamide | C4470 |  | HIV infectionContinuingPatient must have previously received PBS-subsidised therapy for HIV infection. | Compliance with Authority Required procedures - Streamlined Authority Code 4470 |
| C4522 |  | HIV infectionInitialPatient must be antiretroviral treatment naive. | Compliance with Authority Required procedures - Streamlined Authority Code 4522 |