

**PB 13 of 2015**

**National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2015 (No. 2)**

*National Health Act 1953*

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I, Kim Bessell, Assistant Secretary, Pharmaceutical Access Branch, Pharmaceutical Benefits Division, Department of Health, delegate of the Minister for Health, make this instrument under subsections 100(1) and (2) of the *National Health Act 1953*.

Dated 26 February 2015

**KIM BESSELL**

Assistant Secretary

Pharmaceutical Access Branch

Principal Pharmacy Advisor

Pharmaceutical Benefits Division

Department of Health

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1 Name of Instrument

1. This Instrument is the *National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2015 (No.2).*

1. This Instrument may also be cited as PB 13 of 2015.

2 Commencement

 This Instrument commences on 1 March 2015.

3 Amendments to PB 79 of 2011

 Schedule 1 amends the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* (PB 79 of 2011).

Schedule 1 Amendments

1. Schedule 1 Part 1 entry for ‘Bevacizumab’ in each of the forms ‘Solution for I.V. infusion 100 mg in 4 mL’ and ‘Solution for I.V. infusion 400 mg in 16 mL’ with manner of administration Injection:

*omit from the column headed ‘Circumstances’ (all instances):* C4598

*insert in the column headed ‘Circumstances’ (all instances):* C4814

1. Schedule 1 Part 1 entry for ‘Vinorelbine’ in the form ‘Solution for I.V. infusion 10 mg (as tartrate) in 1 mL’ and ‘Solution for I.V. infusion 50 mg (as tartrate) in 5 mL’ with manner of administration Injection:

*omit from the column headed ‘Circumstances’ (all instances):* C3890 C3907

1. Schedule 1, Part 2 entry for Bevacizumab:

*substitute:*

|  |  |  |  |
| --- | --- | --- | --- |
| Bevacizumab | P4584  | 900 | 11 |
|  | P4587 |  |  |
|  | P4594 |  |  |
|  | P4814 | 900 | 5 |
|  |  |  |  |

1. Schedule 4, entry for Bevacizumab:

*omit:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| C4598 | P4598 | Advanced International Federation of Gynecology and Obstetrics (FIGO) Stage IIIB, IIIC or Stage IV epithelial ovarian, fallopian tube or primary peritoneal cancer Treatment Phase: Initial treatmentThe condition must be suboptimally debulked (maximum diameter of any gross residual disease greater than 1 cm), patient must have a WHO performance status of 2 or less, and the condition must be previously untreated. The treatment must be commenced in combination with platinum‑based chemotherapy, and must not exceed a dose of 7.5 mg per kg every 3 weeks, with a lifetime total of 18 cycles of bevacizumab for epithelial ovarian, fallopian tube or primary peritoneal cancer. The patient's WHO performance status and body weight must be documented in the patient's medical records at the time the treatment cycle is initiated. | Compliance with Authority Required procedures ‑ Streamlined Authority Code 4598 |  |

 *insert:*

|  |  |  |  |
| --- | --- | --- | --- |
| C4814 | P4814 | Advanced International Federation of Gynecology and Obstetrics (FIGO) Stage IIIB, IIIC or Stage IV epithelial ovarian, fallopian tube or primary peritoneal cancer. Treatment Phase: Initial treatment. The condition must be suboptimally debulked (maximum diameter of any gross residual disease greater than 1 cm) only if the patient presents with Stage IIIB or Stage IIIC disease, patient must have a WHO performance status of 2 or less, and the condition must be previously untreated. The treatment must be commenced in combination with platinum-based chemotherapy, and must not exceed a dose of 7.5 mg per kg every 3 weeks, with a lifetime total of 18 cycles of bevacizumab for epithelial ovarian, fallopian tube or primary peritoneal cancer. The patient's WHO performance status and body weight must be documented in the patient's medical records at the time the treatment cycle is initiated. | Compliance with Authority Required procedures - Streamlined Authority Code 4814 |

1. Schedule 4, entry for Vinorelbine:

*omit:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Vinorelbine | C3890 |  | Locally advanced or metastatic non‑small cell lung cancer | Compliance with Authority Required procedures – Streamlined Authority Code 3890 |
|  | C3907 |  | Advanced breast cancer after failure of prior therapy which includes an anthracycline | Compliance with Authority Required procedures – Streamlined Authority Code 3907 |