

**PB 107 of 2020**

**National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2020 (No. 9)**

*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 Instrument under subsection 100(2) of the *National Health Act 1953*.

Dated 29 October 2020

**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 (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2020 (No. 9)*.
3. This Instrument may also be cited as PB 107 of 2020.
4. **Commencement**

This Instrument commences on 1 November 2020.

1. **Amendment of *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* (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 Atezolizumab in the form Solution concentrate for I.V. infusion 840 mg in 14 mL**

*insert in numerical order in the column headed “Circumstances”:* **C10915 C10972**

1. **Schedule 1, Part 1, entry for Atezolizumab in the form Solution concentrate for I.V. infusion 1200 mg in 20 mL**

*insert in numerical order in the column headed “Circumstances”:* **C10915 C10917 C10939**

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**

*insert in numerical order in the column headed “Circumstances”:* **C10959**

1. **Schedule 1, Part 1, entry for Oxaliplatin**

*omit:*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Solution concentrate for I.V. infusion 50 mg in 10 mL | Injection | Oxaliplatin SUN | RA | MP |  | D |

1. **Schedule 1, Part 1, entry for Topotecan**

*omit from the column headed “Circumstances”:* **C6238**

1. **Schedule 1, Part 1, after entry for Topotecan in the form Powder for I.V. infusion 4 mg (as hydrochloride)**

*insert:*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Solution concentrate for I.V. infusion 4 mg in 4 mL (as hydrochloride) | Injection | Topotecan Accord | OC | MP |  | D |

1. **Schedule 1, Part 2, entry for Atezolizumab *[Maximum Amount: 1200; Number of Repeats: 3]***

*insert in numerical order in the column headed “Purposes”:* **P10939**

1. **Schedule 1, Part 2, after entry for Atezolizumab *[Maximum Amount: 1200; Number of Repeats: 7]***

*insert:*

|  |  |  |  |
| --- | --- | --- | --- |
|  | P10917 | 1200 | 8 |

1. **Schedule 1, Part 2, entry for Atezolizumab *[Maximum Amount: 1680; Number of Repeats: 5]***

*insert in numerical order in the column headed “Purposes”:* **P10915 P10972**

1. **Schedule 1, Part 2, after entry for Bevacizumab *[Maximum Amount: 1800; Number of Repeats: 7]***

*insert:*

|  |  |  |  |
| --- | --- | --- | --- |
|  | P10959 | 1800 | 8 |

1. **Schedule 4, entry for Atezolizumab**

*insert in numerical order after existing text*:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | C10915 | P10915 | Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma Transitioning from non-PBS-subsidised to PBS-subsidised supply - Grandfather treatment - 3 weekly treatment regimen (1,200 mg) or 4 weekly treatment regimen (1,680 mg where bevacizumab is discontinued) Patient must have commenced non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 November 2020; AND Patient must have met all the PBS eligibility criteria applying to a non-grandfather patient under the Initial treatment restriction for this PBS indication prior to having commenced non-PBS-subsidised treatment with this drug, which are: (i) WHO status score no greater than 1, (ii) Child Pugh class A chronic liver disease, (iii) the patient was unsuitable for transarterial chemoembolization, (iv) the condition was untreated with systemic therapy, unless an intolerance to a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal had occurred; AND Patient must not have developed disease progression while being treated with this drug for this condition. Patient must be undergoing combination treatment with bevacizumab until disease progression, unless not tolerated. A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria. | Compliance with Authority Required procedures - Streamlined Authority Code 10915 |
|  | C10917 | P10917 | Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma Continuing treatment of hepatocellular carcinoma - 3 weekly treatment regimen Patient must be undergoing combination treatment with bevacizumab until disease progression, unless not tolerated. Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition. PBS supply of this drug must be through only one of the two continuing treatment regimens at any given time | Compliance with Authority Required procedures - Streamlined Authority Code 10917 |
|  | C10939 | P10939 | Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma Initial treatment Patient must be undergoing combination treatment with bevacizumab and atezolizumab until disease progression, unless not tolerated. Patient must have a WHO performance status of 0 or 1; AND Patient must not be suitable for transarterial chemoembolisation; AND Patient must have Child Pugh class A; AND The condition must be untreated with systemic therapy; OR Patient must have developed intolerance to a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI) of a severity necessitating permanent treatment withdrawal. | Compliance with Authority Required procedures - Streamlined Authority Code 10939 |
|  | C10972 | P10972 | Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma Continuing treatment where bevacizumab is discontinued - 4 weekly treatment regimen Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition. PBS supply of this drug must be through only one of the two continuing treatment regimens at any given time | Compliance with Authority Required procedures - Streamlined Authority Code 10972 |

1. **Schedule 4, entry for Bevacizumab**

*insert in numerical order after existing text:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | C10959 | P10959 | Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma Concurrent use with atezolizumab in hepatocellular carcinoma Patient must be undergoing combination treatment with PBS-subsidised atezolizumab for this PBS indication. | Compliance with Authority Required procedures - Streamlined Authority Code 10959 |

1. **Schedule 4, omit entry for Topotecan**