**BOCEPREVIR**

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| Manner of administration and formOral, 200 mg capsule | Max.Qty | №.ofRpts | Dispensed Price for Max. Qty | Proprietary Name and Manufacturer |
| DRUG NAME (IN CAPITALS)**BOCEPREVIR**{Forms(s)} {strength(s)}200 mg capsule, 336 capsules, blister pack | 1 | 10 | $3920.00 | **VICTRELIS**Merck Sharp & Dohme (Australia) Pty Ltd |  |
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| **Category /** **Program** | Section 100 (Highly Specialised Drugs) – private Hospitals (Code HS) |
| **Prescriber type:** | [ ] Dental [x] Medical Practitioners [ ] Nurse practitioners [ ] Optometrists[ ] Midwives |
| **Episodicity:** | N/A |
| **Severity:** | N/A |
| **Condition:** | Chronic genotype 1 hepatitis C infection |
| **PBS Indication:** | Chronic genotype 1 hepatitis C infection |
| **Treatment phase:** | N/A |
| **Restriction Level / Method:** | [ ] Restricted benefit[ ] Authority Required - In Writing[ ] Authority Required - Telephone[ ] Authority Required – Emergency[ ] Authority Required - Electronic[x] Streamlined |
| **Treatment criteria:** | Must be treated in an accredited treatment centre. |
| **Clinical criteria:** | Patient must have compensated liver disease,**AND*** Patient must have received no more than one prior treatment with interferon alfa or peginterferon alfa for hepatitis C,

**AND*** The treatment must be in combination with peginterferon alfa and ribavirin,

**AND*** The treatment must be limited to a maximum duration of 32 weeks in patients without hepatic cirrhosis who were partial responders or relapsers to the prior course of interferon based therapy for hepatitis C; **OR**
* The treatment must be limited to a maximum duration of 44 weeks in patients without hepatic cirrhosis who were null responders to the prior course of interferon based therapy for hepatitis C; **OR**
* The treatment must be limited to a maximum duration of 44 weeks for all patients with hepatic cirrhosis,

**AND*** The treatment must cease after the first 8 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 12,

**AND*** The treatment must cease after the first 20 weeks of boceprevir treatment if plasma HCV RNA is detectable by an HCV RNA qualitative assay at treatment week 24.
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| **Population criteria:** | * Patient must be 18 years or older,

**AND*** Patient must not be pregnant or breastfeeding. Female partners of male patients must not be pregnant. Patients and their partners must each be using an effective form of contraception if of child-bearing age
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| **Foreword** | N/A |
| **Definitions** | No definitions are associated with this Purpose |
| **Prescriber Instructions** | * Chronic genotype 1 hepatitis C infection (repeated anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.
* Patients who have received prior treatment with an NS3/4A protease inhibitor are not eligible to receive PBS-subsidised boceprevir, except where the patient has developed an intolerance to the other NS3/4A protease inhibitor of a severity necessitating permanent treatment withdrawal. Details of the intolerance must be documented in the patient's medical records.
* For patients without hepatic cirrhosis who were partial responders or relapsers to the prior course of interferon based therapy, a maximum of 7 repeats may be prescribed
* For patients with hepatic cirrhosis, a maximum of 10 repeats may be prescribed.
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| **Administrative Advice** | * No increase in the maximum quantity or number of units may be authorised.
* Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:
	1. a nurse educator/counsellor for patients; and
	2. 24-hour access by patients to medical advice; and
	3. An established liver clinic.
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| **Cautions** | N/A |