

5.18 OCRIPLASMIN

Solution for intravitreal injection 0.375 mg in 0.3 mL, JETREA® RTU, I-Care Pharma Distributors Pty Ltd

1 Purpose of Application

- 1.1 The minor submission sought to request an Authority Required listing of a new form of ocriplasmin (0.375 mg in 0.3 mL) for vitreomacular traction syndrome (VTS).

2 Requested listing

- 2.1 The submission requested the following new form to the existing listing of ocriplasmin (0.5 mg/0.2 mL, PBS item code 10947E). The submission proposed no changes to the existing restriction:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
OCRIPLASMIN 0.375 mg/ 0.3 mL injection, 1 x 0.3 mL vial	1	0	\$4,151.0	JETREA® RTU	I-Care Pharma Distributors Pty Ltd

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners
PBS Indication:	Vitreomacular traction syndrome
Restriction Level / Method:	<input checked="" type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input checked="" type="checkbox"/> Authority Required – Emergency <input checked="" type="checkbox"/> Authority Required - Electronic
Treatment criteria:	Must be treated by an ophthalmologist

Clinical criteria:	<p>Patient must have visual impairment due to vitreomacular traction (VMT) without a full thickness macular hole (FTMH); OR Patient must have visual impairment due to vitreomacular traction (VMT) with a full thickness macular hole (FTMH) of a diameter of less than or equal to 400 micrometres, AND Patient must have documented visual impairment defined as a best corrected visual acuity score of approximate Snellen equivalent 20/25 or worse in the eye proposed for treatment, AND The condition must be diagnosed by optical coherence tomography, AND The condition must have a vitreomacular adhesion diameter less than or equal to 1500 micrometres, AND Patient must not have an epiretinal membrane attached to the vitreomacular traction, AND The condition must be previously untreated in the eye proposed for treatment, AND Patient must not have received prior vitrectomy in the eye proposed for treatment, AND Patient must be symptomatic.</p>
Prescriber Instructions	<p>The prescriber must state which eye(s) is being treated at the time of application.</p>
Administrative Advice	<p>Where authority approval for treatment for both eyes simultaneously is being sought, a maximum quantity of 2 vials may be requested. No increase in the maximum number of repeats may be authorised. Special Pricing Arrangements apply.</p>

For more detail on PBAC’s view, see section 5 PBAC outcome.

3 Background

- 3.1 Ocriplasmin was TGA registered on 2 November 2015 for the treatment of vitreomacular traction (VMT), including when associated with macular hole of diameter less than or equal to 400 microns. The 0.375 mg/0.3 mL formulation of ocriplasmin was TGA-registered on 13 December 2017.
- 3.2 The new formulation of ocriplasmin does not require prior 1:1 dilution with saline at the point of administration. The submission claimed that it aimed to optimise the fill volume in accordance with posology and to eliminate the risks associated with the dilution.

For more detail on PBAC’s view, see section 5 PBAC outcome.

4 Consideration of the evidence

Sponsor hearing

- 4.1 There was no hearing for this item as it was a minor submission.

Consumer comments

- 4.2 The PBAC noted that there were no consumer comments for this submission.

Clinical trials

- 4.3 As a minor submission, no new clinical trials were presented in the submission.
- 4.4 JETREA RTU and JETREA are equivalent products, with both providing a greater quantity of ocriplasmin than needed for one patient.

Economic analysis

- 4.5 As a minor submission, there was no economic comparison presented.

Estimated PBS usage & financial implications

- 4.6 The minor submission estimated there to be no financial implications to the PBS or changes in PBS usage as the submission expects JETREA RTU to only substitute for JETREA and both forms have the same price.

For more detail on PBAC's view, see section 5 PBAC outcome.

5 PBAC Outcome

- 5.1 The PBAC recommended the Authority Required listing of the new form of ocriplasmin (0.375 mg in 0.3 mL) for the treatment of vitriomacular traction syndrome, under the same circumstances as the current ocriplasmin listings.
- 5.2 The PBAC noted that JETREA RTU contains 0.375 mg of active ingredient instead of 0.5 mg in JETREA. The recommended dose is 0.125 mg in 0.1 mL by intravitreal injection to the affected eye once as a single dose, which is consistent with the TGA-approved Product Information (PI) and the existing PBS-subsidised form of ocriplasmin. The PBAC noted that the new form may reduce ocriplasmin wastage in each vial.
- 5.3 The PBAC noted that JETREA has a Special Pricing Arrangement (SPA) and there is an existing Deed of Agreement between the Commonwealth and Novartis. The sponsor indicated its intention for JETREA RTU to replace JETREA as the new form is a more convenient product to administer and requested this new formulation enter the same Deed of Agreement as the current form.
- 5.4 The PBAC noted that the sponsor also indicated that JETREA will be phased out eventually. The PBAC noted the sponsor is required to submit a formal deletion request to the Department regarding its intention to delete the 0.5 mg/0.2 mL formulation.
- 5.5 The PBAC recalled it had previously advised that ocriplasmin is not suitable for prescribing by nurse practitioners and agreed this remained appropriate.

- 5.6 The PBAC previously recommended that the Early Supply rule should not apply, as patients are only treated once with ocriplasmin.
- 5.7 The PBAC noted that the submission was not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

6 Recommended listing

6.1 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
OCRIPLASMIN 375 microgram/0.3 mL intraocular injection, 0.3 mL vial	1	0	Jetrea® RTU	I-Care Pharma Distributors Pty Ltd
Category / Program	GENERAL – General Schedule (Code GE)			
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioners			
PBS Indication:	Vitreomacular traction syndrome			
Restriction Level / Method:	<input checked="" type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input checked="" type="checkbox"/> Authority Required - Emergency <input checked="" type="checkbox"/> Authority Required - Electronic			
Treatment criteria:	Must be treated by an ophthalmologist			
Clinical criteria:	Patient must have visual impairment due to vitreomacular traction (VMT) without a full thickness macular hole (FTMH); OR Patient must have visual impairment due to vitreomacular traction (VMT) with a full thickness macular hole (FTMH) of a diameter of less than or equal to 400 micrometres, AND Patient must have documented visual impairment defined as a best corrected visual acuity score of approximate Snellen equivalent 20/25 or worse in the eye proposed for treatment, AND The condition must be diagnosed by optical coherence tomography, AND The condition must have a vitreomacular adhesion diameter less than or equal to 1500 micrometres, AND Patient must not have an epiretinal membrane attached to the vitreomacular traction, AND The condition must be previously untreated in the eye proposed for treatment, AND Patient must not have received prior vitrectomy in the eye proposed for treatment, AND Patient must be symptomatic.			
Prescriber Instructions	The prescriber must state which eye(s) is being treated at the time of application.			

Administrative Advice	Where authority approval for treatment for both eyes simultaneously is being sought, a maximum quantity of 2 vials may be requested. No increase in the maximum number of repeats may be authorised. Special Pricing Arrangements apply.
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7 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

8 Sponsor's Comment

The sponsor had no comment.