

6.12 ICATIBANT

Injection 30 mg (as acetate) in 3 mL single use pre-filled syringe, Firazyr[®], Shire Australia Pty Ltd

1 Purpose of Application

- 1.1 The minor submission requested the existing listing of icatibant be amended to allow for a limit to increase to the maximum quantity to 12 injections per script on the basis that this would encourage further clinical review of patients experiencing a high frequency of attacks.

2 Background

- 2.1 Icatibant was TGA registered on 3 September 2010 for symptomatic treatment of acute attacks of hereditary angioedema (HAE) in adults (with C1-esterase-inhibitor deficiency).
- 2.2 Icatibant was listed on the PBS for HAE treatment in August 2012 following two major (re)submissions considered at the July 2010 and July 2011 PBAC meetings, and two minor resubmissions considered at the November 2011 and March 2012 PBAC meetings.
- 2.3 At its July 2015 meeting, the PBAC considered the Drug Utilisation Sub-Committee's (DUSC's) 24 months predicted versus actual (PvA) report on icatibant. The report showed that the number of injections supplied per patient was higher than predicted and █% of prescriptions were for 12 or more injections (including repeats); this segment of authority scripts represented █% of the use of icatibant on the PBS.
- 2.4 In November 2016, the PBAC considered a major submission from the sponsor which presented a revised economic evaluation to support the cost effectiveness of the higher than expected number of icatibant injections per patient as identified by the DUSC PvA report. The submission also requested a renegotiation of the risk sharing arrangement (RSA) through a Deed of Agreement applied to the funding of icatibant. The PBAC considered that the revised economic evaluation did not adequately support the submission's claim that the higher than expected use of icatibant reported by DUSC was cost effective. Therefore the Committee recommended that their previous advice on icatibant remained unchanged. The PBAC considered that the submission did not provide adequate justification for the requested increase in the financial caps through the RSA, from \$10 – \$20 million to \$30 – \$60 million over 5 years. Therefore the PBAC considered it would be appropriate for any new Deed negotiated with the sponsor to be consistent with their previous recommendations with financial caps extrapolated from the financial estimates presented at the time

of the original listing. (Public Summary Document (PSD), November 2016, paragraphs 1.1, 7.1 and 7.8)

3 Population and disease

- 3.1 HAE is a rare, potentially fatal autosomal dominant disease caused by deficiency of the C1 esterase inhibitor (C1-INH) due to mutations of the C1-INH gene. HAE is characterised by spontaneous, unpredictable and recurrent attacks of oedema of the extremities, face, trunk, abdominal viscera and upper airways that can be painful and debilitating. Symptoms worsen in the first 12-36 hours as the oedema develops then gradually subside with untreated attacks usually lasting for 2-5 days.
- 3.2 The minor submission stated that in October 2016, the National Blood Authority announced funding of C1-INH for patients with HAE and that patients experiencing eight or more acute attacks per month are eligible for funded treatment.
- 3.3 The minor submission stated that limiting the number of syringes able to be authorised per script would encourage further clinical review of patients experiencing a high frequency of attacks and that these patients may be considered for second line routine prophylaxis with C1-INH.

For more detail on PBAC's view, see section 4 "PBAC outcome."

4 PBAC Outcome

- 4.1 The PBAC recommended limiting increases in the maximum quantity to 12 injections per authority prescription on the basis that this would encourage further clinical review of patients experiencing a high frequency of attacks.
- 4.2 The PBAC recommended that the current restrictions for icatibant include a prescribing instruction stating that 'Increased maximum quantities will be limited to 12 injections per authority prescription'.
- 4.3 The PBAC also recommended that the clinical criterion 'Patient must have previously been issued with an authority prescription for this drug for this condition' be updated to 'Patient must have previously received PBS-subsidised treatment with this drug for this condition'.

Outcome:

Recommended

5 Recommended listing

- 5.1 Amend the existing listing as follows (as shown in italics and strikethrough):

Public Summary Document – July 2017 PBAC Meeting

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
ICATIBANT Injection, 30 mg (as acetate) in 3 mL, 1 single use pre-filled syringe	1	1	Firazyr®	Shire Australia Pty Limited
Category / Program	GENERAL – General Schedule			
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives			
Condition:	Anticipated emergency treatment of an acute attack of hereditary angioedema			
PBS Indication:	Anticipated emergency treatment of an acute attack of hereditary angioedema			
Treatment phase:	Initial			
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <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 <input type="checkbox"/> Streamlined			
Clinical criteria:	Patient must have confirmed diagnosis of C1-esterase inhibitor deficiency, AND Patient must have been assessed to be at significant risk of an acute attack of hereditary angioedema, AND The condition must be assessed by a clinical immunologist; OR The condition must be assessed by a respiratory physician; OR The condition must be assessed by a specialist allergist; OR The condition must be assessed by a general physician experienced in the management of patients with hereditary angioedema.			
Prescriber Instructions	The name of the specialist consulted must be provided at the time of application for initial supply. The date of the pathology report and name of the Approved Pathology Authority must be provided at the time of application. <i>Increased maximum quantities will be limited to 12 injections per authority prescription</i>			
Administrative Advice	Icatibant should be provided in the framework of a comprehensive hereditary angioedema prophylaxis program and an emergency Action Plan including training in recognition of the symptoms of hereditary angioedema and the self-administration of icatibant. (For further information see the Australasian Society of Clinical Immunology and Allergy website)			
Treatment phase:	Continuing			
Clinical criteria:	Patient must have previously been issued with an authority prescription for this drug for this condition <i>Patient must have previously received PBS-subsidised treatment with this drug for this condition.</i>			
Prescriber Instructions	Increased maximum quantities will be limited to 12 injections per authority prescription.			
Administrative Advice	Icatibant should be provided in the framework of a comprehensive hereditary angioedema prophylaxis program and an emergency Action Plan including training in recognition of the symptoms of hereditary angioedema and the self-administration of icatibant. (For further information see the Australasian Society of Clinical Immunology and Allergy website)			

6 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.

7 Sponsor's Comment

The sponsor had no comment.