5.18 PIRFENIDONE
Tablet 267 mg, 90,
Tablet 801 mg, 90
Esbriet®, Roche Products Pty Ltd

1 Purpose of Application

1.1 The minor submission requested an Authority Required (STREAMLINED) listing for a new tablet form at the same strength as the currently listed capsule, as well as a higher strength, of pirfenidone for the treatment of idiopathic pulmonary fibrosis (IPF).

2 Requested listing

2.1 The submission sought the same listing (restriction and price per mg) as the currently listed 267 mg capsule form.

For more detail on PBAC's view, see section 6 PBAC outcome.

3 Background

3.1 Pirfenidone 267 mg and 801 mg tablets were TGA registered on 25 October 2017 for the treatment of idiopathic pulmonary fibrosis (IPF) on the basis of bioequivalence with the 267 mg capsule.

3.2 The PBAC previously considered submissions for a 267 mg capsule form at the November 2015, March 2016 and November 2016 with a subsequent recommendation at the December 2016 special meeting.

3.3 The PBAC considered at the November 2015, March 2016 and November 2016 meetings that there was a high clinical need for an effective treatment for IPF but was unable to recommend listing on the basis of unacceptably high cost-effectiveness, in the context of the total cost and uncertain utilisation.

3.4 The December 2016 recommendation was on the basis of a cost-minimisation analysis with nintedanib.

4 Comparator

4.1 The minor submission nominated pirfenidone 267 mg capsules as the comparator as the submission argued that this is the product that is most likely to be replaced by the new 801 mg dose strength and new 267 mg tablet form as it was considered to be bioequivalent to the 267 mg capsule.

5 Consideration of the evidence

Sponsor hearing

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

Consumer comments

5.2 The PBAC noted that no consumer comments were received for this item.

Clinical trials

5.3 As a minor submission, no clinical trials were presented in the submission.

Estimated PBS usage & financial implications

5.4 The submission proposed an equivalent price per milligram for the 267 mg and 801 mg tablet presentations of pirfenidone compared to the currently listed 267 mg capsule presentation.

5.5 The minor submission estimated there to be no financial implications to the PBS or changes in PBS usage as the submission expects the new form and strength to only substitute for the currently listed form of pirfenidone which have the same price per milligram, and it will not impact on the number of copayments a patient will make as all pack sizes allow for one month's treatment at the maintenance dose.

5.6 The submission stated that the new presentations would join the current Risk Sharing Arrangement for pirfenidone and nintedanib.

5.7 The application of any statutory price reduction to pirfenidone would result in a cost saving to government; however, the magnitude of any possible saving has not been calculated.

6 PBAC Outcome

6.1 The PBAC recommended the Authority Required listing of pirfenidone, as a 267 mg tablet form and as a 801 mg tablet, for continuing treatment only, for the treatment of idiopathic pulmonary fibrosis.

6.2 The PBAC noted that the recommended starting dose of pirfenidone is 1 x 267 mg capsule 3 times a day (tds) for 1 week, followed by 2 x 267 mg capsule tds for 1 week, and subsequently the maintenance dosage of 3 x 267 mg capsules tds to achieve 2,403 mg/day (Esbriet Product Information February 2016). The 801 mg tablet is to replace the requirement to take 3 x 267 mg capsules tds in the maintenance phase. In making this recommendation, the PBAC considered that the PBS listing of the 801 mg tablet could potentially reduce the pill burden for these patients.

6.3 The PBAC noted in the pre-PBAC response that the sponsor requested the same listing as the currently listed 267 mg capsule form. The PBAC considered that it

would be appropriate to recommend an Authority Required listing for both the 267 and 801 mg tablet forms.

6.4 The PBAC advised that pirfenidone is not suitable for prescribing by nurse practitioners.

6.5 The PBAC advised that pirfenidone should not be exempt from the Early Supply Rule, as it applies to the current PBS listing for pirfenidone capsules.

6.6 The PBAC advised that this submission would not meet the criteria for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

7.1 Add new items:

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
PIRFENIDONE 267 mg tablet, 90	3	5	Esbriet	Roche Products Pty Ltd

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	☐Dental ☒Medical Practitioners ☐Nurse practitioners ☐Optometrists ☐Midwives
Condition:	Idiopathic pulmonary fibrosis
PBS Indication:	Idiopathic pulmonary fibrosis
Treatment phase:	Initial treatment 1 - new patient
Restriction Level / Method:	☐Restricted benefit ☒Authority Required - In Writing ☐Authority Required - Telephone ☐Authority Required – Emergency ☐Authority Required - Electronic ☐Streamlined
Treatment criteria:	Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.

Clinical criteria:	The condition must be diagnosed through a multidisciplinary team, AND Patient must have chest high resolution computed tomography (HRCT) consistent with diagnosis of idiopathic pulmonary fibrosis within the previous 12 months, AND Patient must have a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height, AND Patient must have a forced expiratory volume in 1 second to forced vital capacity ratio (FEV1/FVC) greater than 0.7, AND Patient must have diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30%, AND Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity, AND The treatment must be the sole PBS-subsidised treatment for this condition.
Prescriber Instructions	A multidisciplinary team is defined as comprising at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis. Authority applications for initial treatment must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed IPF Initial PBS authority application form (c) a signed patient acknowledgement
Administrative Advice	Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 HOBART TAS 7001 No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised. Special Pricing Arrangements apply.

Treatment phase:	Initial treatment 2 - change or re-commencement of treatment
Restriction Level / Method:	☐Restricted benefit ☒Authority Required - In Writing ☒Authority Required - Telephone ☐Authority Required – Emergency ☐Authority Required - Electronic ☐Streamlined

Treatment criteria:	Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.
Clinical criteria:	Patient must have previously received PBS-subsidised treatment with nintedanib or pirfenidone for this condition, AND The treatment must be the sole PBS-subsidised treatment for this condition.
Administrative Advice	Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised. Special Pricing Arrangements apply.

Treatment phase:	Initial treatment 3 - Grandfathering treatment
Restriction Level / Method:	☐Restricted benefit ☒Authority Required - In Writing ☐Authority Required - Telephone ☐Authority Required – Emergency ☐Authority Required - Electronic ☐Streamlined
Treatment criteria:	Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.
Clinical criteria:	Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 July 2017, AND The condition must have been diagnosed through a multidisciplinary team, AND Patient must have had a forced vital capacity (FVC) greater than or equal to 50% predicted for age, gender and height at the time treatment with this drug for this condition was initiated, AND Patient must have had a forced expiratory volume in 1 second (FEV1)/FVC ratio greater than 0.7 at the time treatment with this drug for this condition was initiated, AND Patient must have had diffusing capacity of the lungs for carbon monoxide (DLCO) corrected for haemoglobin equal to or greater than 30% at the time treatment with this drug for this condition was initiated, AND Patient must not have interstitial lung disease due to other known causes including domestic and occupational environmental exposures, connective tissue disease, or drug toxicity, AND The treatment must be the sole PBS-subsidised treatment for this condition.

Prescriber Instructions	A multidisciplinary team is defined as comprising at least a specialist respiratory physician, a radiologist and where histological material is considered, a pathologist. If attendance is not possible because of geographical isolation, consultation with a multidisciplinary team is required for diagnosis. Patient must have not have an acute respiratory infection at the time of FVC testing. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria or change or recommencement of treatment criteria. A patient may qualify for PBS-subsidised treatment under this restriction once only. Applications for authorisation of initial treatment must be in writing and must include: a) a completed authority prescription form; and b) a completed IPF Authority Application Supporting Information Form; and c) a signed patient acknowledgement.
Administrative Advice	Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Prior Written Approval of Complex Drugs Reply Paid 9826 HOBART TAS 7001 No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised. Special Pricing Arrangements apply.

Name, Restriction, Manner of administration and form	**Max. Qty**	**№.of Rpts**	**Proprietary Name and Manufacturer**	
PIRFENIDONE				
267 mg tablet, 90	3	5	Esbriet	Roche Products Pty Ltd
801 mg tablet, 90	1	5		

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	☐Dental ☒Medical Practitioners ☐Nurse practitioners ☐Optometrists ☐Midwives
Condition:	Idiopathic pulmonary fibrosis
PBS Indication:	Idiopathic pulmonary fibrosis
Treatment phase:	Continuing treatment

Restriction Level / Method:	☐Restricted benefit ☒Authority Required - In Writing ☒Authority Required - Telephone ☐Authority Required – Emergency ☐Authority Required - Electronic ☐Streamlined
Treatment criteria:	Must be treated by a respiratory physician or specialist physician, or in consultation with a respiratory physician or specialist physician.
Clinical criteria:	Patient must have previously received PBS-subsidised treatment with this drug for this condition, AND The treatment must be the sole PBS-subsidised treatment for this condition.
Administrative Advice	Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised. Special Pricing Arrangements apply.

8 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.

9 Sponsor's Comment

The sponsor had no comment.