

## 5.22 METHOTREXATE

**Injection 7.5 mg in 0.3 mL pre-filled syringe**

**Injection 10 mg in 0.4 mL pre-filled syringe**

**Injection 15 mg in 0.6 mL pre-filled syringe**

**Injection 20 mg in 0.8 mL pre-filled syringe**

**Injection 25 mg in 1 mL pre-filled syringe**

**Methoblastin PFS<sup>®</sup>, Pfizer**

### 1 Purpose of Application

- 1.1 The minor submission requested a General Schedule Authority Required (Streamlined) listing of five forms of a new brand of subcutaneous (SC) methotrexate, Methoblastin PFS<sup>®</sup>, which is bioequivalent to the currently PBS-listed brand of SC methotrexate, Trexject<sup>®</sup>.

### 2 Requested listing

- 2.1 The minor submission requested listings for the following new forms of SC methotrexate, for the same indications as the currently PBS listed brand Trexject<sup>®</sup>:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
METHOTREXATE					
7.5 mg/0.3mL injection, 4 x 0.3 mL syringes	1	5	\$ [REDACTED]	Methoblastin PFS <sup>®</sup>	Pfizer
10 mg/0.4 mL injection, 4 x 0.4 mL syringes	1	5	\$ [REDACTED]		
15 mg/0.6 mL injection, 4 x 0.6 mL syringes	1	5	\$ [REDACTED]		
20 mg/0.8 mL injection, 4 x 0.8 mL syringes	1	5	\$ [REDACTED]		
25 mg/1 mL injection, 4 x 1 mL syringes	1	5	\$ [REDACTED]		

### 3 Background

- 3.1 Methoblastin PFS<sup>®</sup> was registered by the Therapeutic Goods Administration (TGA) on 26 September 2017 and was granted bioequivalence to Trexject<sup>®</sup> on 10 October 2017.

- 3.2 At its March 2017 meeting, the PBAC recommended listing Trexject<sup>®</sup> on the PBS for the treatment of rheumatoid arthritis or psoriasis when methotrexate oral tablets are unsuitable.

## 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 and welcomed the input from individuals (3) via the Consumer Comments facility on the PBS website. The comments focused on the effectiveness of methotrexate in treating psoriasis.

### **Interpretation of clinical evidence**

- 4.3 The PBAC considered that the claim of non-inferior comparative effectiveness was reasonable.
- 4.4 The PBAC considered that the claim of non-inferior comparative safety was reasonable.

### **Estimated PBS usage & financial implications**

- 4.5 The sponsor proposed an ex-manufacturer price of \$[REDACTED] for all strengths of Methoblastin PFS<sup>®</sup> for a pack of four pre-filled syringes. This is equivalent to the ex-manufacturer price per mg of Trexject<sup>®</sup>.
- 4.6 The minor submission estimated that there would be no changes in PBS usage of methotrexate as a result of listing Methoblastin PFS.
- 4.7 Although this was not explicitly stated in the submission, the Secretariat noted that given Methoblastin PFS is bioequivalent to Trexject, with the same delivery method, indication and price per mg, the cost to the Government is expected to be neutral.

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

## 5 PBAC Outcome

- 5.1 The PBAC recommended the Authority Required (STREAMLINED) listing of five new forms of subcutaneous methotrexate (7.5 mg/0.3 mL, 10 mg/0.4 mL, 15 mg/0.6 mL, 20 mg/0.8 mL, 25 mg/1 mL) for the same indications as the currently PBS listed brand of subcutaneous methotrexate, Trexject<sup>®</sup>.
- 5.2 The PBAC noted that Methoblastin PFS was considered bioequivalent to Trexject<sup>®</sup> by the TGA.
- 5.3 The PBAC noted that the proposed listings are expected to be cost neutral to Government, given that it is not expected to affect the overall PBS utilisation of methotrexate and the proposed ex-manufacturer price is the equivalent to that of

Trexject®.

- 5.4 The PBAC advised, under Section 101(4AACD) of the *National Health Act 1953* that methotrexate 7.5 mg in 0.3 mL syringe and 7.5 mg in 0.15 mL syringe; methotrexate 10 mg in 0.4 mL syringe and 10 mg in 0.2 mL syringe; methotrexate 15 mg in 0.6 mL syringe and 15 mg in 0.3 mL syringe; methotrexate 20 mg in 0.8 mL syringe and 20 mg in 0.4 mL syringe; methotrexate 25 mg in 1 mL syringe and 25 mg in 0.5 mL syringe could be marked as equivalent in the Schedule of Pharmaceutical Benefits for the purposes of substitution at the point of dispensing.
- 5.5 The PBAC recalled its previous advice that subcutaneous methotrexate is not suitable for prescribing by nurse practitioners under the PBS.
- 5.6 The PBAC advised that the Early Supply Rule should apply as it currently applies to Trexject®.
- 5.7 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

**Outcome:**

Recommended

## 6 Recommended listing

### 6.1 Add new items:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
METHOTREXATE				
7.5 mg/0.3mL injection, 4 x 0.3 mL syringes	1	5	Methoblastin PFS <sup>®</sup>	Pfizer
10 mg/0.4 mL injection, 4 x 0.4 mL syringes	1	5		
15 mg/0.6 mL injection, 4 x 0.6 mL syringes	1	5		
20 mg/0.8 mL injection, 4 x 0.8 mL syringes	1	5		
25 mg/1 mL injection, 4 x 1 mL syringes	1	5		

<b>Category / Program</b>	GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Severity:</b>	Severe
<b>Condition:</b>	Rheumatoid arthritis
<b>PBS Indication:</b>	Severe active rheumatoid arthritis
<b>Restriction Level / Method:</b>	<input checked="" type="checkbox"/> Streamlined
<b>Clinical criteria:</b>	Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

<b>Category / Program</b>	GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Severity:</b>	Severe
<b>Condition:</b>	Psoriasis
<b>PBS Indication:</b>	Severe psoriasis
<b>Restriction Level / Method:</b>	<input checked="" type="checkbox"/> Streamlined
<b>Clinical criteria:</b>	The condition must not have adequately responded to topical treatment,  AND  Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

Add the relevant administrative advice to the new listing of the corresponding form of methotrexate:

- Pharmaceutical benefits that have the form methotrexate Injection 7.5 mg in 0.15 mL pre-filled syringe and pharmaceutical benefits that have the form methotrexate Injection 7.5 mg in 0.3 mL pre-filled syringe are equivalent for the purposes of substitution.
- Pharmaceutical benefits that have the form methotrexate Injection 10 mg in 0.2 mL pre-filled syringe and pharmaceutical benefits that have the form methotrexate Injection 10 mg in 0.4 mL pre-filled syringe are equivalent for the purposes of substitution.
- Pharmaceutical benefits that have the form methotrexate Injection 15 mg in 0.3 mL pre-filled syringe and pharmaceutical benefits that have the form methotrexate Injection 15 mg in 0.6 mL pre-filled syringe are equivalent for the purposes of substitution.
- Pharmaceutical benefits that have the form methotrexate Injection 20 mg in 0.4 mL pre-filled syringe and pharmaceutical benefits that have the form methotrexate Injection 20 mg in 0.8 mL pre-filled syringe are equivalent for the purposes of substitution.
- Pharmaceutical benefits that have the form methotrexate Injection 25 mg in 0.5 mL pre-filled syringe and pharmaceutical benefits that have the form methotrexate Injection 25 mg in 1 mL pre-filled syringe are equivalent for the purposes of substitution.

Amend existing listings as follows:

Add the relevant administrative advice to the existing listing of the corresponding form of methotrexate:

- Pharmaceutical benefits that have the form methotrexate Injection 7.5 mg in 0.15 mL pre-filled syringe and pharmaceutical benefits that have the form methotrexate Injection 7.5 mg in 0.3 mL pre-filled syringe are equivalent for the purposes of substitution.
- Pharmaceutical benefits that have the form methotrexate Injection 10 mg in 0.2 mL pre-filled syringe and pharmaceutical benefits that have the form methotrexate Injection 10 mg in 0.4 mL pre-filled syringe are equivalent for the purposes of substitution.

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- Pharmaceutical benefits that have the form methotrexate Injection 15 mg in 0.3 mL pre-filled syringe and pharmaceutical benefits that have the form methotrexate Injection 15 mg in 0.6 mL pre-filled syringe are equivalent for the purposes of substitution.
- Pharmaceutical benefits that have the form methotrexate Injection 20 mg in 0.4 mL pre-filled syringe and pharmaceutical benefits that have the form methotrexate Injection 20 mg in 0.8 mL pre-filled syringe are equivalent for the purposes of substitution.
- Pharmaceutical benefits that have the form methotrexate Injection 25 mg in 0.5 mL pre-filled syringe and pharmaceutical benefits that have the form methotrexate Injection 25 mg in 1 mL pre-filled syringe are equivalent for the purposes of substitution.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
METHOTREXATE				
7.5 mg/0.15 mL injection, 0.15 mL syringe	4	5	Trexject®	Link Medical Products Pty Ltd
10 mg/0.2 mL injection, 0.2 mL syringe	4	5		
15 mg/0.3 mL injection, 0.3 mL syringe	4	5		
20 mg/0.4 mL injection, 0.4 mL syringe	4	5		
25 mg/0.5 mL injection, 0.5 mL syringe	4	5		

<b>Category / Program</b>	GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Severity:</b>	Severe
<b>Condition:</b>	Rheumatoid arthritis
<b>PBS Indication:</b>	Severe active rheumatoid arthritis
<b>Restriction Level / Method:</b>	<input checked="" type="checkbox"/> Streamlined
<b>Clinical criteria:</b>	Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

<b>Category / Program</b>	GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Severity:</b>	Severe
<b>Condition:</b>	Psoriasis

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<b>PBS Indication:</b>	Severe psoriasis
<b>Restriction Level / Method:</b>	<input checked="" type="checkbox"/> Streamlined
<b>Clinical criteria:</b>	The condition must not have adequately responded to topical treatment,  AND  Patient must be unsuitable for administration of an oral form of methotrexate for this condition.

## **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.