

An addendum to these minutes has been included at the end of the document.

## **6.22 METHOXSALEN, Solution for blood fraction 20 microgram per mL, 10 mL, Uvadex<sup>®</sup>, Terumo BCT Australia Pty Ltd**

### **1 Purpose of Application**

- 1.1 The Category 3 submission requested a Section 100 (Highly Specialised Drugs Program), Authority Required (STREAMLINED) listing for the treatment of patients with steroid dependent, steroid intolerant or steroid refractory chronic graft versus host disease (herein referred to as treatment refractory cGVHD), as part of treatment with integrated, closed system extracorporeal photopheresis (ECP).
- 1.2 As the medicine (PBAC relevant) component is substantially smaller in overall scope and financial implications compared to the procedure (Medical Services Advisory Committee [MSAC] relevant) component, the clinical and cost effectiveness, and estimated overall financial implications will be considered by MSAC.

### **2 Background**

#### ***Registration status***

- 2.1 Methoxsalen was TGA registered on 16 September 2019 for extracorporeal administration with the THERAKOS CELLEX Photopheresis System for the following indications:
  - treatment of steroid-refractory and steroid-intolerant chronic graft versus host disease (cGVHD) in adults following allogeneic HSC transplantation.
  - palliative treatment of the skin manifestations of cutaneous T-cell lymphoma (CTCL) that is unresponsive to other forms of treatment.
- 2.2 Integrated, closed system ECP plus methoxsalen is a co-dependent technology consisting of the ECP device component and its drug component, methoxsalen. The application for MBS listing of ECP for the treatment of cGVHD, received in February 2021, will be considered by the MSAC at its July 2021 meeting.

#### ***Previous PBAC/MSAC consideration***

- 2.3 An integrated co-dependent submission for methoxsalen, as part of the ECP service for the treatment of refractory CTCL, was first considered at the July 2017 PBAC and MSAC meetings. The PBAC deferred its consideration of methoxsalen at that time until both a TGA delegate's overview and an MSAC intention to support the co-dependent

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ECP service via the MBS are available (paragraph 6.1, methoxsalen Public Summary Document (PSD), July 2017).

- 2.4 Subsequently, MSAC also deferred its advice on public funding of ECP pending a revision of the economic model. In July 2017, MSAC noted that while the condition was a rare disease and would have a limited budgetary impact, the evidence base was weak with a high and uncertain incremental cost-effectiveness ratio (ICER). MSAC noted that the PBS listing of vorinostat had substantially changed the treatment pathway for refractory erythrodermic CTCL, and requested that the revised economic model only include comparators with accepted cost-effectiveness (methotrexate and vorinostat). MSAC also considered that there was a need to revisit the proposed MBS fee and align the MBS item descriptor and the proposed PBS restriction (p1, Application No. 1420 PSD, July 2017).
- 2.5 At its April 2020 meeting, following considerations of revisions made by the applicant, MSAC supported public funding of ECP in the treatment of CTCL.
- 2.6 The PBS-listing of methoxsalen for the treatment of refractory CTCL was subsequently considered by the PBAC at its May 2020 meeting. The PBAC recommended the Section 100 (Highly Specialised Drugs Program – Public and Private Hospital) Authority Required (STREAMLINED) listing of methoxsalen, as part of the ECP service for the treatment of refractory CTCL, either as monotherapy or in combination with peginterferon alfa-2a.
- 2.7 Methoxsalen has not been considered by the PBAC for the treatment of patients with treatment refractory cGVHD.

### 3 Requested listing

3.1 The requested restriction is provided below. Secretariat suggested additions are in italics and deletions are in strikethrough.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
METHOXSALEN					
methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials	New	0-4 0.083*	1	5	Uvadex
		Max.qty (packs) multiplier = 1 Repeat increases: nil			
<b>Restriction Summary [new] / Treatment of Concept: [new]</b>					
<b>Category / Program:</b> Section 100 – Highly Specialised Drugs Program - (Public/Private hospitals)					
<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners					
<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (STREAMLINED) [new code]					
<b>Episodicity:</b> [blank]					
<b>Severity:</b> <del>Steroid dependent or steroid intolerant or steroid refractory</del> [blank]					
<b>Condition:</b> Chronic graft versus host disease ( <del>cGVHD</del> )					
<b>Indication:</b> <del>Steroid dependent or steroid intolerant or steroid refractory</del> Chronic graft versus host disease					
<b>Treatment Phase:</b> <del>Initial treatment</del> [blank]					
<b>Clinical criteria</b>					
<del>Patient must have received prior systemic steroid treatment for this condition and has experienced refractory disease or is dependent or intolerant to steroid treatment.</del>					
The condition must be inadequately managed with systemic corticosteroid treatment at a therapeutic dose					
<b>AND</b>					
<b>Clinical criteria:</b>					
<del>Patient must be receiving the medical service as described in item xxxx of the Medicare Benefits Schedule.</del>					
<b>AND</b>					
<b>Clinical criteria:</b>					
Patient must have demonstrated a response to treatment with this drug if treatment is continuing beyond 6 months of treatment for the first time					
<b>Treatment criteria:</b>					
Patient must be undergoing treatment with this drug for the first time; or					
Patient must be undergoing re-initiation of treatment with this drug; or					
Patient must be undergoing continuing treatment with this drug					
<b>AND</b>					
<b>Treatment criteria:</b>					
Must be treated by a haematologist; or					
Must be treated by an oncologist with allogeneic bone marrow transplantation experience.					
<b>AND</b>					
<b>Treatment criteria:</b>					
Patient must be undergoing treatment with this drug following allogeneic haematopoietic stem cell transplantation.					
<b>AND</b>					
<b>Treatment criteria:</b>					
Patient must be undergoing concurrent treatment with extracorporeal photopheresis as described in item [insert MBS item code corresponding to initial treatment here] (initial PBS treatment) of the Medical Benefits Scheme Schedule; or					
Patient must be undergoing concurrent treatment with extracorporeal photopheresis as described in item [insert MBS item code corresponding to Continuing treatment here] (continuing PBS treatment) of the Medical Benefits Schedule					

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	<p><b>Prescribing Instructions:</b>  Steroid-refractory or steroid-dependent disease is defined as one of the following:  A lack of response or disease progression after a minimum of prednisone 1 mg/kg/day or equivalent for at least 1 week, OR  Disease persistence without improvement despite continued treatment with prednisone at &gt; 0.5 mg/kg/day or 1 mg/kg/every or equivalent other day for at least 4 weeks, OR  Increase to prednisolone dose to &gt; 0.25 mg/kg/day or equivalent after 2 unsuccessful attempts to taper the dose.</p>
	<p><b>Caution:</b>  Patient must not be pregnant or breastfeeding. Patients and their partners must each be using an effective form of contraception if of child-bearing age.</p>
	<p>Caution: This drug is for ex vivo administration and must not to be injected directly into the patient.</p>
<p><b>Restriction Summary [new] / Treatment of Concept: [new]</b></p>	
	<p><b>Category / Program:</b> Section 100 – Highly Specialised Drugs Program (Public/Private hospitals)</p>
	<p><b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners</p>
	<p><b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (STREAMLINED) [new code]</p>
	<p><b>Episodicity:</b> [blank]</p>
	<p><b>Severity:</b> Steroid dependent or steroid intolerant or steroid refractory [blank]</p>
	<p><b>Condition:</b> Chronic graft versus host disease (cGVHD)</p>
	<p><b>Indication:</b> Steroid dependent or steroid intolerant or steroid refractory Chronic graft versus host disease</p>
	<p><b>Treatment Phase:</b> Initial Continuing treatment</p>
	<p><b>Clinical criteria</b></p>
	<p>Patient must have received PBS-subsidised treatment with this drug for this PBS indication,</p>
	<p><b>AND</b></p>
	<p><b>Clinical criteria:</b></p>
	<p>Patient must have demonstrated a response to treatment with this drug if treatment is continuing beyond 6 months of treatment for the first time</p>
	<p><b>AND</b></p>
	<p><b>Clinical criteria:</b></p>
	<p>Patient must be receiving the medical service as described in item xxxx of the Medicare Benefits Schedule.</p>
	<p><b>Treatment criteria:</b></p>
	<p>Must be treated by a haematologist; or</p>
	<p>Must be treated by an oncologist with allogeneic bone marrow transplantation experience.</p>
	<p><b>Prescribing Instructions:</b>  A response, for the purposes of administering this continuing restriction, is defined as attaining a complete or partial response in at least one organ according to NIH criteria. Response only needs to be demonstrated after the first 12 weeks of treatment.</p>
	<p><b>Caution:</b>  Patient must not be pregnant or breastfeeding. Patients and their partners must each be using an effective form of contraception if of child-bearing age.</p>
	<p>Caution: This drug is for ex vivo administration and must not to be injected directly into the patient.</p>

\* Note: 0.083 will be rounded up and displayed as 0.1 on www.pbs.gov.au

3.2 The proposed definition of response in the continuing treatment restriction is consistent with that of the proposed MBS item descriptor for continuation of ECP. The pre-PBAC response noted that the 2014 NIH Clinical Response in cGVHD Guideline and associated clinical assessment forms are publicly available on PubMed’s free-full text archive. The pre-PBAC response noted this is the most current version of the Guidelines and that the current international guidelines for haematopoietic stem cell transplantation, Hematopoietic Cell Transplantation Version 2.2020, NCCN Clinical Practice Guidelines in Oncology, incorporates the NIH Clinical Response in cGVHD Guideline and associated clinical assessment forms.

- 3.3 The proposed PBS restriction included a caution around pregnancy and breast feeding. The pre-PBAC response noted these cautions are usually only included in PBS listings for category X drugs and as such, considered it could be removed from the restriction.
- 3.4 The pre-PBAC response proposed including a caution which specifies that methoxsalen is for *ex vivo* administration only and must not be injected directly into the patient, in line with the existing methoxsalen listing.

## **4 Comparator**

- 4.1 The submission nominated current standard of care, which consists of the continued use of steroids from first-line treatment, in combination with mycophenolate mofetil or calcineurin inhibitors with the view of reducing and/or displacing chronic high dose systemic steroidal treatment, as the main comparator. The submission stated this comparator was specified by the PICO Confirmation and ratified by the PASC in January.
- 4.2 PASC advised that the nominated comparators were not appropriate for the relatively small population with ‘steroid-intolerant’ cGVHD as these patients should not be able to continue steroids. PASC advised that further clarity is needed around the current standard of care in Australia for this group (for example, to ascertain whether mycophenolate or a calcineurin inhibitor would be used without steroids) ( Ratified PICO - Application 1651, December 2020 PASC).

## **5 Consideration of the evidence**

### ***Sponsor hearing***

- 5.1 There was no hearing for this item.

### ***Consumer comments***

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

### ***Clinical claim***

- 5.3 The submission claimed superior comparative effectiveness and non-inferior safety of ECP plus methoxsalen compared to current standard of care alone for the treatment of treatment refractory cGVHD.
- 5.4 The comparative efficacy and economic analysis will be considered by MSAC.

### ***Drug cost/patient: \$9,581.88***

- 5.5 The estimated drug cost/patient is \$9,581.88 based on a DPMQ of \$217.77 (weighted by private/public hospital split of 50%/50%), a total of 25 treatments over 12 weeks for initial treatment and an estimated average of 18.5 treatments (wastage included) in continuing treatment. The average duration of continuing treatment was calculated as an average of the median number of treatments reported in the Royal Prince Alfred Hospital and the Victorian Comprehensive Cancer Centre registry studies. Each ECP

treatment requires one 10 mL vial of methoxsalen. The submission proposed the same DPMQ as that of the current listing for the CTCL indication (\$208.94 for Public Hospital and \$226.59 for Private Hospital).

***Estimated PBS utilisation and financial implications***

- 5.6 Table 1 presents the estimated extent of use, cost of methoxsalen to the PBS/RPBS and the net financial implications to the PBS/RPBS and MBS. The financial impact to Services Australia will be determined by that agency as part of the post PBAC process.
- 5.7 The submission used an epidemiological approach to estimate the expected utilisation and financial impact of listing methoxsalen for the treatment of treatment resistant cGVHD. Data from the Australasian Bone Marrow Transplant Recipient Registry (ABMTRR 2019) was used to calculate the prevalence and incidence of patients who had undergone allogeneic haematopoietic stem cell transplantation (HSCT), as well as the incidence of patients with cGVHD. The proportion of cGVHD patients that develop treatment refractory cGVHD was based on data from a retrospective observational study which assessed the clinical outcomes of 721 allogeneic HSCT patients over a 10-year period (Axt et al., 2019).
- 5.8 The submission estimated a total of 500 to < 5,000 treatment refractory cGVHD patients would be supplied methoxsalen over the first six years of listing (< 500 in Year 1 to < 500 in Year 6).
- 5.9 The cost of methoxsalen to the PBS/RPBS is expected to be \$0 to < \$10 million over six years (\$0 to < \$10 million in Year 1 to \$0 to < \$10 million in Year 6).
- 5.10 The estimated net financial impact to the PBS/RPBS for the listing of methoxsalen for treatment resistant cGVHD is \$0 to < \$10 million over six years (\$0 to < \$10 million in Year 1 to \$0 to < \$10 million in Year 6).
- 5.11 The submission considered that ECP plus methoxsalen may reduce or displace corticosteroids, calcineurin inhibitors and mycophenolate mofetil in the second line treatment of cGVHD; however, this was not accounted for in the financial estimates.

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Table 1: Estimated use and financial implications

	2022	2023	2024	2025	2026	2027
<b>Estimated extent of use</b>						
Number of patients with treatment refractory cGVHD (both incident and prevalent populations)	■ <sup>1</sup>	■ <sup>2</sup>	■ <sup>2</sup>	■ <sup>2</sup>	■ <sup>2</sup>	■ <sup>2</sup>
Number of patients undertaking initial treatment	■ <sup>2</sup>	■ <sup>2</sup>	■ <sup>2</sup>	■ <sup>2</sup>	■ <sup>2</sup>	■ <sup>2</sup>
Number of patients undertaking continuing treatment <sup>a</sup>	■ <sup>2</sup>	■ <sup>2</sup>	■ <sup>2</sup>	■ <sup>2</sup>	■ <sup>2</sup>	■ <sup>2</sup>
Number of scripts dispensed (initial treatment) <sup>b</sup>	■ <sup>1</sup>	■ <sup>1</sup>	■ <sup>3</sup>	■ <sup>3</sup>	■ <sup>3</sup>	■ <sup>1</sup>
Number of scripts dispensed (continuing treatment) <sup>c</sup>	■ <sup>1</sup>	■ <sup>1</sup>	■ <sup>1</sup>	■ <sup>1</sup>	■ <sup>1</sup>	■ <sup>1</sup>
<b>Drug costs</b>						
Cost of methoxsalen to PBS/RPBS (excl. patient co-payments)	\$■ <sup>4</sup>	\$■ <sup>4</sup>	\$■ <sup>4</sup>	\$■ <sup>4</sup>	\$■ <sup>4</sup>	\$■ <sup>4</sup>
Cost of methoxsalen to the RPBS (excl. patient co-payments)	\$■ <sup>4</sup>	\$■ <sup>4</sup>	\$■ <sup>4</sup>	\$■ <sup>4</sup>	\$■ <sup>4</sup>	\$■ <sup>4</sup>
Less patient co-payments	-\$■ <sup>4</sup>	-\$■ <sup>4</sup>	-\$■ <sup>4</sup>	-\$■ <sup>4</sup>	-\$■ <sup>4</sup>	-\$■ <sup>4</sup>
<b>Estimated net financial implications</b>						
Net cost to the PBS	\$■ <sup>4</sup>	\$■ <sup>4</sup>	\$■ <sup>4</sup>	\$■ <sup>4</sup>	\$■ <sup>4</sup>	\$■ <sup>4</sup>
Net cost to the RPBS	\$■ <sup>4</sup>	\$■ <sup>4</sup>	\$■ <sup>4</sup>	\$■ <sup>4</sup>	\$■ <sup>4</sup>	\$■ <sup>4</sup>
Net cost to the MBS at 80% rebate	\$■ <sup>4</sup>	\$■ <sup>5</sup>	\$■ <sup>5</sup>	\$■ <sup>5</sup>	\$■ <sup>5</sup>	\$■ <sup>4</sup>
Net cost to the Government	\$■ <sup>4</sup>	\$■ <sup>5</sup>	\$■ <sup>5</sup>	\$■ <sup>5</sup>	\$■ <sup>5</sup>	\$■ <sup>5</sup>

<sup>a</sup> The submission assumed that following initial treatment, 80.2% of patients would have achieved a complete or partial clinical response and receive continuing treatment. This assumption was based on data from the Royal Prince Alfred Hospital and the Victorian Comprehensive Cancer Centre registry studies.

<sup>b</sup> Assuming 25 scripts per patient

<sup>c</sup> Assuming 18.5 scripts per patient

Source: Excel workbook Attachment E1\_financial estimates

Abbreviations: cGVHD: chronic graft versus host disease; MBS: Medicare Benefits Schedule PBS: Pharmaceutical Benefits Scheme; RPBS: Repatriation Pharmaceutical Benefits Scheme.

The redacted values correspond to the following ranges:

<sup>1</sup> 500 to < 5,000

<sup>2</sup> < 500

<sup>3</sup> 5,000 to < 10,000

<sup>4</sup> \$0 to < \$10 million

<sup>5</sup> \$10 million to < \$20 million

## **6 PBAC Outcome**

- 6.1 The PBAC deferred its consideration of methoxsalen for the treatment of patients with steroid dependent, steroid intolerant or steroid refractory chronic graft versus host disease (cGVHD), to await the outcome of the Medical Services Advisory Committee (MSAC) consideration on the funding of the co-dependent extracorporeal photopheresis (ECP), before making a final decision on PBS funding.

**Outcome:**

Deferred

**Addendum to the July 2021 PBAC Minutes:**

**4.01 METHOXSALEN,  
Solution for blood fraction 20 microgram per mL,  
10 mL,  
Uvadex<sup>®</sup>,  
Terumo BCT Australia Pty Ltd**

**7 Background**

- 7.1 At its July 2021 meeting, the PBAC deferred making a recommendation about the PBS listing of methoxsalen for the treatment of patients with steroid dependent, steroid intolerant or steroid refractory chronic graft versus host disease (cGVHD), as part of treatment with integrated, closed system extracorporeal photopheresis (ECP). The deferral was to await the outcome of the Medical Services Advisory Committee (MSAC) consideration on funding of the co-dependent ECP via the MBS.
- 7.2 At its 29-30 July 2021 meeting, MSAC supported creation of new Medicare Benefits Schedule (MBS) items for closed system ECP for the treatment of cGVHD. MSAC considered the uncertainties in the clinical evidence, however advised that ECP plus methoxsalen has acceptable safety and superior effectiveness and acceptable cost-effectiveness in the treatment of cGVHD compared with the current standard of care alone for the proposed patient population.

**8 PBAC Outcome**

- 8.1 The PBAC recommended the Section 100 (Highly Specialised Drugs Program – Public and Private Hospital) Authority Required (STREAMLINED) listing of methoxsalen, delivered as part of an integrated, closed system extracorporeal photopheresis (ECP) service for the treatment of patients with steroid dependent, steroid intolerant or steroid refractory chronic graft versus host disease (cGVHD). The PBAC was satisfied that ECP involving methoxsalen provides, for some patients, a significant improvement in efficacy over standard of care.
- 8.2 The PBAC noted that MSAC accepted that ECP likely had superior clinical effectiveness compared with standard of care, although the clinical studies presented involved small numbers of participants and short follow-up times.
- 8.3 The PBAC noted that MSAC accepted that ECP has non-inferior safety compared with standard of care and MSAC considered that reducing or displacing long-term steroid and immunosuppressant use was also an important outcome for alleviating their cumulative adverse effects for patients.

- 8.4 The PBAC noted that MSAC advised that ECP plus methoxsalen has acceptable cost-effectiveness in the treatment of cGVHD compared with the current standard of care alone for the proposed patient population. The PBAC noted that the respecified base case modelled economic evaluation which MSAC relied on in its deliberation on the cost-effectiveness of ECP for GVHD resulted in an incremental cost-effectiveness ratio similar to that previously accepted for ECP in cutaneous T-cell lymphoma.
- 8.5 The PBAC noted that the MSAC supported MBS item descriptor for continuing treatment requires the patient to have demonstrated a response according to the National Institutes of Health (NIH) criteria, for the purposes of administering the MBS item. On this basis, the PBAC considered that a definition of 'response' for ongoing PBS-subsidised treatment with methoxsalen would not be required in the PBS restriction if the PBS restriction specifies that patients must be undergoing concurrent treatment with ECP. The PBAC also considered that the definition of steroid-refractory or steroid-dependent disease would not be required in the restriction noting this definition was included in the MSAC supported MBS item descriptor for initial treatment.
- 8.6 The PBAC considered that separate initial and continuing treatment phase listings would be appropriate to account for differences in dosing between the first 12 weeks of treatment and the proceeding weeks. The PBAC noted initial treatment with ECP for cGVHD consisted of 12 weeks initial treatment which includes three ECP treatments in the first week followed by two ECP treatments per week for at least 12 weeks for a total of 25 ECP sessions. Following response to the initial 12-week treatment course, patients may receive a further 12 weeks of ECP where ECP is performed twice per month, for approximately six further ECP sessions. The PBAC noted this represents substantially higher dosage (in terms of vials administered per week) of methoxsalen relative to the cutaneous T-Cell lymphoma indication and therefore considered that applying the same maximum quantity and repeats as this listing would be inappropriate. The PBAC considered that the cGVHD listing should align with the Product Information as closely as possible in terms of maximum quantity and number of repeats. The PBAC noted that as methoxsalen is not suited to self-administration, the dispensing pharmacy would likely store the dispensed vials, which would reduce the risk of misuse if a quantity more than sufficient for one ECP treatment is dispensed per prescription.
- 8.7 The PBAC considered that the restriction should specify that patients must be undergoing treatment following allogeneic haematopoietic stem cell transplantation (HSCT) to limit use of methoxsalen to patients with cGVHD associated with allogeneic HSCT.
- 8.8 The PBAC considered that the restriction should include a caution specifying that methoxsalen is for *ex vivo* administration and must not to be injected directly into the patient, consistent with the current listing.
- 8.9 The PBAC found that the criteria prescribed by the *National Health (Pharmaceutical and Vaccines – Cost Recovery) Regulations 2009* for Pricing Pathway A were not met.

Specifically, the PBAC found that in the circumstances of its recommendation for methoxsalen as part of the ECP service:

- a) The medicine component alone is not expected to provide a substantial and clinically relevant improvement in efficacy or reduction of toxicity over the nominated comparators;
- b) The medicine component alone is not expected to address a high and urgent unmet clinical need; and
- c) It was not necessary to make a finding in relation to whether it would be in the public interest for the subsequent pricing application to be progressed under Pricing Pathway A.

8.10 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

**Outcome:**

Recommended

## **9 Recommended listing**

9.1 Add new indication (chronic graft versus host disease) as follows:

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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
METHOXSALEN					
methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials	New (Public) New (Private)	1	12	1	Uvadex
<b>Add new Restriction Summary / Treatment of Concept: [new 1]</b>					
	<b>Category / Program:</b> Section 100 – Highly Specialised Drugs Program - (Public/Private hospitals)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners				
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (STREAMLINED) [new 1]				
	<b>Caution:</b> This drug is for ex vivo administration and must not be injected directly into the patient.				
	<b>Indication:</b> Chronic graft versus host disease				
	<b>Treatment phase:</b> Initial treatment within the first 12 weeks				
	<b>Clinical criteria:</b>				
	The condition must be inadequately responsive to systemic corticosteroid treatment at a therapeutic dose; or				
	The condition must have relapsed within 8 weeks of a prior treatment course of this drug administered via extracorporeal photopheresis; or				
	The condition must have relapsed after 8 weeks following each of: (i) a prior treatment course of this drug administered via ECP (in full), (ii) a subsequent trial of systemic corticosteroids at therapeutic doses				
	<b>Treatment criteria:</b>				
	Patient must be undergoing treatment with this drug that is being administered within both: (i) the first 12 weeks of initiating treatment, (ii) the first 25 doses				
	<b>AND</b>				
	<b>Treatment criteria:</b>				
	Must be treated by a haematologist; or				
	Must be treated by an oncologist with allogeneic bone marrow transplantation experience.				
	Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types				
	<b>AND</b>				
	<b>Treatment criteria:</b>				
	Patient must be undergoing treatment with this drug following allogeneic haematopoietic stem cell transplantation				
	<b>AND</b>				
	<b>Treatment criteria:</b>				
	Patient must be undergoing concurrent treatment with extracorporeal photopheresis as described in item [insert MBS item code corresponding to initial treatment here] (initial PBS treatment) of the Medical Benefits Scheme Schedule				
	<b>Administrative advice:</b>				
	A maximum quantity (vials) of 12 with 1 repeat prescription provides 24 doses of this drug. An additional 25 <sup>th</sup> dose can be prescribed under this treatment phase by issuance of a further prescription made out for one vial with nil repeats. The 26 <sup>th</sup> dose and onwards must be requested under the continuing treatment restriction.				
	<b>Administrative advice:</b> No increase in the maximum quantity or number of units may be authorised.				
	<b>Administrative advice:</b> No increase in the maximum number of repeats may be authorised.				

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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
METHOXSALEN					
methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials	New (Public) New (Private)	0.16	2	0	Uvadex
<b>Add new Restriction Summary / Treatment of Concept: [new 2]</b>					
<b>Category / Program:</b> Section 100 – Highly Specialised Drugs Program - (Public/Private hospitals)					
<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners					
<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (STREAMLINED) [new 2]					
<b>Caution:</b> This drug is for ex vivo administration and must not be injected directly into the patient.					
<b>Indication:</b> Chronic graft versus host disease					
<b>Treatment phase:</b> Continuing treatment					
<b>Clinical criteria:</b>					
Patient must have received, at anytime prior to this pharmaceutical benefit, both: (i) this drug subsidised through the Initial treatment listing, (ii) the extracorporeal photopheresis-MBS benefit for initial treatment					
<b>AND</b>					
<b>Clinical criteria:</b>					
Patient must have demonstrated a response to an initial 25 doses of this drug (administered as part of MBS-subsidised extracorporeal photopheresis treatment) obtained through this drug's 'Initial treatment' PBS-listing					
<b>Treatment criteria:</b>					
Must be treated by a haematologist; or					
Must be treated by an oncologist with allogeneic bone marrow transplantation experience.					
Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types					
<b>AND</b>					
<b>Treatment criteria:</b>					
Patient must be undergoing concurrent treatment with extracorporeal photopheresis as described in item [insert MBS item code corresponding to Continuing treatment here] (continuing PBS treatment) of the Medical Benefits Schedule					
<b>Administrative advice:</b> Up to 2 additional repeats to that stated in this listing may be sought.					

***These restrictions may be subject to further review. Should there be any changes made to the restriction the Sponsor will be informed.***

## 10 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

## **11 Sponsor's Comment**

The sponsor had no comment.