6.14 Methoxsalen, Solution for blood fraction 20 microgram per mL, 10 mL Uvadex®, Therakos Australia Pty Ltd

1 Purpose of Submission

1.1 The Category 3 submission sought to change existing listings for methoxsalen (Uvadex®) indicated for cutaneous T-cell lymphoma (CTCL) and chronic graft-versus-host disease (cGVHD) to allow treatment by a consultant or specialist dermatologist or treatment by a medical practitioner working under the supervision of a dermatologist, as part of treatment with integrated, closed system extracorporeal photopheresis (ECP).

1.2 Currently, the Pharmaceutical Benefits Scheme (PBS) restrictions for methoxsalen indicated for CTCL require treatment to be by, or under the supervision of a haematologist, and the PBS restrictions for methoxsalen indicated for cGVHD require treatment to be by, or under the supervision of a haematologist or oncologist with allogeneic bone marrow transplantation experience.

1.3 The submission stated the proposed additions will better align treatment supervision requirements with current best practice and guidelines for the clinical management of CTCL and cGVHD.

1.4 Integrated, closed system ECP plus methoxsalen is a co-dependent technology consisting of the ECP service component and its drug component, methoxsalen. The application for MBS expansion of specialist supervision criteria for integrated, closed-system, ECP for the treatment of CTCL and cGVHD (application 1818) will be considered by the MSAC at its July 2026 meeting.

2 Background

2.1 Methoxsalen is currently listed on the PBS as an Authority Required (STREAMLINED) medicine under section 100 (S100) Highly Specialised Drugs (HSD) Public and Private Hospital listings for the treatment of CTCL and cGVHD.

Registration status

2.2 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 cGVHD in adults following allogeneic haematopoietic stem cell (HSC) transplantation.
- palliative treatment of the skin manifestations of CTCL that is unresponsive to other forms of treatment.

Previous PBAC consideration

2.3 As methoxsalen is a co-dependent component of ECP therapy, all PBAC considerations to date have been considered as co-dependent submissions with MSAC.

2.4 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 ECP service via the MBS were available (paragraph 6.1, methoxsalen Public Summary Document [PSD], July 2017).

2.5 In April 2020 the MSAC supported the supported public funding of extracorporeal photopheresis in the treatment of CTCL (MSAC Application 1420.1 PSD). At its May 2020 meeting the PBAC subsequently recommended methoxsalen for the treatment of refractory CTCL under the Section 100 (Highly Specialised Drugs Program – Public and Private Hospital) Authority Required (STREAMLINED).

2.6 At its September 2021 meeting, the PBAC recommended methoxsalen for the treatment of patients with treatment refractory cGVHD following its deferral in July 2021 to await the outcome of MSAC's consideration. At its July 2021 meeting, MSAC supported creation of new MBS items for closed system ECP for the treatment of cGVHD (MSAC Application 1651).

3 Requested listing

3.1 The submission requested the following changes to the existing listing. Suggested additions are in italics and deletions are in strikethrough.

3.2 As the submission did not request changes to the restrictions apart from the addition to allow treatment by, or treatment under the supervision of a dermatologist, the full restrictions have not been reproduced here.

Amend existing listing as follows:

Cutaneous T-cell lymphoma

Initial treatment

MEDICINAL PRODUCT medicinal product pack		PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
METHOXSALEN						
methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials		12156T (Public) 12162D (Private)	0.17	2	6	Uvadex
Restriction Summary [10951] / Treatment of Concept: [10985]						
	Category / Program: Section 100 – Highly Specialised Drugs Program Public (Code HB) / Private hospitals (Code HS)					
	Prescriber type: ☒ Medical Practitioners					
	Restriction type: ☒ Authority Required (STREAMLINED)					
	Indication: Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma					
	Treatment phase: Initial treatment					
	Treatment criteria:					
	Must be treated by a haematologist; or					
	Must be treated by a dermatologist; or					
	Must be treated by a medical physician working under the supervision of a haematologist *or dermatologist*					
Abridged version						

Continuing treatment

MEDICINAL PRODUCT medicinal product pack		PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
METHOXSALEN						
methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials		12154Q (Public) 12173Q (Private)	0.08	1	5	Uvadex
Restriction Summary [10950] / Treatment of Concept: [10988]						
	Category / Program: Section 100 – Highly Specialised Drugs Program (Public/Private hospitals)					
	Prescriber type: ☒ Medical Practitioners					
	Restriction type: ☒ Authority Required (STREAMLINED)					
	Indication: Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma					
	Treatment phase: Continuing treatment					
	Treatment criteria:					
	Must be treated by a haematologist; or					
	Must be treated by a dermatologist; or					
	Must be treated by a medical physician working under the supervision of a haematologist *or dermatologist*					
Abridged version						

Chronic graft versus host disease

Initial treatment in a treatment episode

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
METHOXSALEN					
methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials	12876Q (Public) 12855N (Private)	1	12	1	Uvadex
Restriction Summary [12546] / Treatment of Concept: [12546]					
	Category / Program: Section 100 – Highly Specialised Drugs Program (Public/Private hospitals)				
	Prescriber type: ☒ Medical Practitioners				
	Restriction type: ☒ Authority Required (STREAMLINED)				
	Indication: Chronic graft versus host disease				
	Treatment phase: Initial treatment in a treatment episode				
	Treatment criteria:				
	Must be treated by a haematologist; or				
	Must be treated by a dermatologist; or				
	Must be treated by an oncologist with allogeneic bone marrow transplantation experience; or				
	Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types				
Abridged version					

Continuing treatment

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
METHOXSALEN					
methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials	12854M (Public) 12839R (Private)	0.17	2	0	Uvadex
Restriction Summary [12531] / Treatment of Concept: [12531]					
	Category / Program: Section 100 – Highly Specialised Drugs Program (Public/Private hospitals)				
	Prescriber type: ☒ Medical Practitioners				
	Restriction type: ☒ Authority Required (STREAMLINED)				
	Indication: Chronic graft versus host disease				
	Treatment phase: Continuing treatment				
	Treatment criteria:				
	Must be treated by a haematologist; or				
	Must be treated by a dermatologist; or				
	Must be treated by an oncologist with allogeneic bone marrow transplantation experience; or				
	Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types				
Abridged version					

4 Consideration of the evidence

Sponsor hearing

4.1 There was no hearing for this item.

Consumer Inputs

4.2 The PBAC noted that no consumer inputs were received for this item.

Rationale for request

4.3 The submission sought to extend current prescriber restrictions for ECP and methoxsalen to better align with contemporary practice and international standards, where dermatologists are recognised as key contributors in the delivery of ECP.

4.4 The submission claimed the proposed change is small but would improve equity of access for a small, high-need patient population. The submission noted the requested change in the restrictions will not alter the safety, efficacy, and costs previously recommended by the PBAC.

4.5 The submission noted that the current restrictions were informed by clinical practice at the time of the previous submissions. At the time of these submissions, ECP was available at two locations within Australia (the Peter MacCallum Cancer Centre (Victoria) and the Royal Prince Alfred Hospital (New South Wales)) and these units were primarily staffed by haematologists.

4.6 The submission noted that ECP services are currently available at one hospital in each of New South Wales, South Australia, and Queensland, and three hospitals in Victoria. The submission claimed that allowing specialist dermatologists to prescribe methoxsalen as part of ECP delivery would increase patient access and facilitate the establishment of additional sites, improving equity of access for patients with CTCL and cGVHD.

4.7 The submission provided reference to guidelines relevant to the management of CTCL only. The submission noted that in Australia, optimal care pathways for CTCL management produced by the Leukemia Foundation in 2023 identify dermatologists as part of multidisciplinary CTCL teams. The National Comprehensive Cancer Network guidelines for Primary Cutaneous Lymphomas similarly recommend collaboration or co-management with a dermatologist for CTCL (see Table 1).

Table 1: National and international guide supporting multidisciplinary management including dermatologist

Name of guideline	Produced by	Relevant statements and recommendations
Optimal care pathway for people with cutaneous T-cell lymphoma* (National)	Leukaemia Foundation, endorsed by ALLG, ANZTCT, Cancer Australia, Cancer Council, HSANZ, Lymphoma Australia	"For patients with erythrodermic MF or SS, extracorporeal photopheresis (ECP) should be considered where available." (Leukaemia Foundation 2023 p35) "If a clinician diagnoses or considers a high likelihood of MF or SS based on the initial consultation with the patient, referral for diagnosis and ongoing management at a specialist centre with access to a multidisciplinary CTCL team should occur. This multidisciplinary team should include dermatologists, haematologists/oncologists, radiation oncologists, pathologists, nurses and clinical psychologists." (Leukaemia Foundation 2023 p23)
NCCN Guidelines Version 3.2025 Primary Cutaneous Lymphomas (International)	National Comprehensive Cancer Network	"Collaboration with a dermatologist for supportive care is essential." (National Comprehensive Cancer Network 2025 p44) "Co-management with a dermatologist with expertise in skin care and CTCL." (National Comprehensive Cancer Network 2025 p44)
eviQ Clinical resource: Chronic graft versus host disease (cGVHD) (National)	eviQ: NSW Cancer Institute	"Consider referral to organ-specific clinicians with experience in chronic graft versus host disease for surveillance or treatment input (e.g. dermatologists)" (eviQ Clincal resource: Chronic graft versus host disease (cGVHD))
EDF White Book 2020 (International)	European Dermatology Forum	"Extracorporeal phototherapy is provided to patients from transplantation centers to reduce and resolve graft-versus-host disease as a typical complication of transplantation. Collaborative dermatological services may also include diagnosis and general management of predictable complications of treatments instituted for non-dermatological disease, e.g., the increased risk of skin cancer in transplantation patients." (EDF White Book 2020 p54)

Abbreviations: ALLG, Australasian Leukaemia & Lymphoma Group; ANZTCT, Australia and New Zealand Transplant & Cellular Therapies; CTCL, cutaneous T-cell lymphoma; ECP, extracorporeal photopheresis; EDF, European Dermatology Forum; HSANZ, Haematology Society of Australia and New Zealand; MF, mycosis fungoides; NCCN, National Comprehensive Cancer Network; SS, Sézary Syndrome.
**Optimal care pathway is a guide to ensure blood cancer specialists, treating hospitals, GPs, and people diagnosed with blood cancer, can access the same, nationally consistent standards that outline the high-quality care all Australians should expect to receive.*
Source: Submission body pg. 8

4.8 The updated guidelines on the use of ECP (which included cGVHD indication) developed by the European Dermatology Forum (EDF) were provided by the submission upon request. The guidelines do not explicitly address multidisciplinary teams involving dermatologists, however EDF produced a White Book detailing some guidance around GVHD.[1] Notwithstanding this, the Secretariat noted the eviQ guidelines for cGVHD[2] state to 'consider referral to organ-specific clinicians with experience in chronic graft versus host disease for surveillance or treatment input (e.g. dermatologists)' (see Table 1).

4.9 The submission noted a letter was provided from Professor Pablo Fernandez Penas, the Head of the Department of Dermatology at Westmead Hospital supporting the need for dermatologists to access PBS subsidised methoxsalen. The letter claimed that expertise in dermatology is central to management of both indications and ensures optimal timing for initiating therapy with methoxsalen and ECP. Further, it noted historically haematology departments were the main providers of methoxsalen and ECP but a collaborative care model where experts in dermatology driving the clinical management is most appropriate.

4.10 The submission noted it also contacted the Australasian College of Dermatologists (ACD), who advised that while they do not provide letters in support of applications as a matter of principle, they would be willing to comment if approached directly by the Department.

Estimated PBS usage and financial implications

4.11 As a Category 3 submission, the financial implications were not independently evaluated.

4.12 The submission estimated the utilisation and costs of the proposed listing based on a market-share approach.

[1]EDF White Book – Challenges of Skin Diseases in Europe, pg. 54, 2020, 6th Edition https://www.edf.one/pdf-viewer?file=https://www.edf.one/uploads/attachments/cm67vt0gh02mu21jrp0vdg05s-white-book-6th-edition-2020-online-bm.pdf&download=false&print=false&pageArrowsPosition=onPage

[2]Treatment section of Clinical resource: Chronic graft versus host disease (cGVHD) 2024, v.4, eviQ BMT & cellular therapies 3829-Chronic graft versus host disease (cGVHD) | eviQ, https://www.eviq.org.au/clinical-resources/bmt-cellular-therapies/3829-chronic-graft-versus-host-disease-cgvhd#treatment

4.13 The submission noted that expanding the prescribing and supervision restrictions to include specialist or consultant dermatologists will not alter the eligibility criteria or increase the number of eligible patients with CTCL or cGVHD. However it noted the amendment will increase the number of clinicians authorised to supervise ECP, which is expected to support the establishment of additional centres and improve access to the therapy. A 15% increase in utilisation of both the MBS and PBS services was modelled, attributable to the proposed change.

4.14 However, the Secretariat noted the requested changes to methoxsalen do not affect the eligible patient population that was costed when methoxsalen was first listed. The Secretariat considered there will be a nil cost to the PBS/RPBS for the following reasons: no change to size of patient population (market size); no change to the current treatment algorithm (no change in annual packs consumed); and no change to the price per unit of existing medications (no change in total cost). The financial impact to Services Australia will be determined by that agency as part of the post PBAC process.

4.15 The PBAC considered the proposed changes will result in a nil financial impact to the PBS/RPBS.

Quality use of medicines

4.16 The submission stated it provides initial and ongoing education to health care professionals on methoxsalen in accordance with the product information and consumer medicine information.

5 PBAC outcome

5.1 The PBAC recommended extending the current listings for methoxsalen for the treatment of CTCL and cGVHD to allow treatment by a dermatologist (including specialist and consultant) or a medical practitioner working under the supervision of a dermatologist, as part of treatment with integrated, closed system ECP.

5.2 The PBAC considered the clinical claims in the submission to be appropriate.

5.3 The PBAC considered the methodology used to calculate the financial estimates was not appropriate. The submission modelled a 15% increase in utilisation based on the assumption that expanding the number of clinicians authorised to supervise ECP will support the establishment of additional centres and improve access to the therapy. However, the PBAC considered there will be a nil cost to the PBS/RPBS because the requested changes to methoxsalen do not affect the eligible patient population that was costed when methoxsalen was first listed.

5.4 The PBAC noted the current treatment criteria for CTCL and cGVHD and supported extending to allow treatment by a dermatologist or by a medical practitioner working under the supervision of a dermatologist.

5.5 The PBAC considered there to be substantive shared care between specialists for the treatment of CTCL and cGVHD, including consultant or specialist dermatologists and medical practitioners working under the supervision of a dermatologist. The PBAC considered the eligible population for methoxsalen will likely be unchanged by the addition of consultant or specialist dermatologists and medical practitioners working under the supervision of a dermatologist to the list of authorised prescribers.

5.6 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 Amend existing listing as follows:

Cutaneous T-cell lymphoma

Initial treatment

MEDICINAL PRODUCT medicinal product pack		PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
METHOXSALEN						
methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials		12156T (Public) 12162D (Private)	0.17	2	6	Uvadex
Restriction Summary [10951] / Treatment of Concept: [10985]						
	Category / Program: Section 100 – Highly Specialised Drugs Program Public (Code HB) / Private hospitals (Code HS)					
	Prescriber type: ☒ Medical Practitioners					
	Restriction type: ☒ Authority Required (STREAMLINED)					
	Indication: Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma					
	Treatment phase: Initial treatment					
	Treatment criteria:					
	Must be treated by a haematologist; or					
	Must be treated by a dermatologist; or					
	Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.					
Abridged version						

Continuing treatment

MEDICINAL PRODUCT medicinal product pack		PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
METHOXSALEN						
methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials		12154Q (Public) 12173Q (Private)	0.08	1	5	Uvadex
Restriction Summary [10950] / Treatment of Concept: [10988]						
	Category / Program: Section 100 – Highly Specialised Drugs Program (Public/Private hospitals)					
	Prescriber type: ☒ Medical Practitioners					
	Restriction type: ☒ Authority Required (STREAMLINED)					
	Indication: Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma					
	Treatment phase: Continuing treatment					
	Treatment criteria:					
	Must be treated by a haematologist; or					
	Must be treated by a dermatologist; or					
	Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.					
Abridged version						

Chronic graft versus host disease

Initial treatment in a treatment episode

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
METHOXSALEN					
methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials	12876Q (Public) 12855N (Private)	1	12	1	Uvadex
Restriction Summary [12546] / Treatment of Concept: [12546]					
	Category / Program: Section 100 – Highly Specialised Drugs Program (Public/Private hospitals)				
	Prescriber type: ☒ Medical Practitioners				
	Restriction type: ☒ Authority Required (STREAMLINED)				
	Indication: Chronic graft versus host disease				
	Treatment phase: Initial treatment in a treatment episode				
	Treatment criteria:				
	Must be treated by a haematologist; or				
	Must be treated by a dermatologist; or				
	Must be treated by an oncologist with allogeneic bone marrow transplantation experience; or				
	Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types				
Abridged version					

Continuing treatment

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
METHOXSALEN					
methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials	12854M (Public) 12839R (Private)	0.17	2	0	Uvadex
Restriction Summary [12531] / Treatment of Concept: [12531]					
	Category / Program: Section 100 – Highly Specialised Drugs Program (Public/Private hospitals)				
	Prescriber type: ☒ Medical Practitioners				
	Restriction type: ☒ Authority Required (STREAMLINED)				
	Indication: Chronic graft versus host disease				
	Treatment phase: Continuing treatment				
	Treatment criteria:				
	Must be treated by a haematologist; or				
	Must be treated by a dermatologist; or				
	Must be treated by an oncologist with allogeneic bone marrow transplantation experience; or				
	Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types				
Abridged version					

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