MSAC application 1818

MSAC Application for Expansion of specialist supervision criteria for MBS and PBS items for integrated, closed-system, extracorporeal photopheresis and methoxsalen (UVADEX®) for the treatment of Cutaneous T-Cell Lymphoma and chronic Graft Versus Host Disease

Application for MBS eligible service or health technology

HPP Application number:

HPP200369

Application title:

Expansion of specialist supervision criteria for MBS and PBS items for integrated, closed-system, extracorporeal photopheresis and methoxsalen (UVADEX®) for the treatment of Cutaneous T-Cell Lymphoma and chronic Graft Versus Host Disease

Submitting organisation:

HEALTH TECHNOLOGY ANALYSTS PTY LIMITED

Submitting organisation ABN:

13099239442

Application description

Succinct description of the medical condition/s:

Cutaneous T-cell lymphoma (CTCL) is a rare type of cancer that affects T-cells and causes raised, rash-like or itchy patches of skin, skin lumps or ulcers. The disease can be long-lasting and difficult to manage, with symptoms that significantly affect quality of life. People with CTCL commonly experience persistent itching, discomfort and visible skin changes. As the disease progresses, it can spread to lymph nodes, blood, or internal organs, leading to more serious health complications.

Chronic graft versus host disease (cGVHD) is a serious and sometimes life-threatening complication that can occur after a bone marrow or stem cell transplant from a donor. The disease can affect many organs, but most commonly the skin, liver, eyes, mouth, lungs, and gut. Symptoms include rash, tightening of the skin, liver problems, dry eyes and mouth, difficulty swallowing, diarrhoea, and breathing problems. These symptoms often lead to a significant reduction in quality of life and can be fatal.

Succinct description of the service or health technology:

Extracorporeal photopheresis (ECP) is a type of treatment that involves attaching a patient to a machine that removes some of their blood. The machine separates the white blood cells, and the red blood cells and plasma. The white blood cells are

mixed with a drug called methoxsalen, exposed to ultraviolet (UV) light, and then all blood products are put back into the patient. ECP activates the patient's immune system to fight the cancer.

Application contact details

Are you the applicant, or are you a consultant or lobbyist acting on behalf of the applicant?

Consultant

Are you applying on behalf of an organisation, or as an individual?

Organisation

Applicant organisation name:

THERAKOS AUSTRALIA PTY LTD

Application details

Does the implementation of your service or health technology rely on a new listing on the Pharmaceutical Benefits Scheme (PBS) and/or the Prescribed List?

Yes

Which list/schedule will the other health technologies be listed on?

Pharmaceutical Benefits Scheme

Is the application for a new service or health technology, or an amendment to an existing listed service or health technology?

Amendment

What is the nature of the amendment?

Access to an existing item(s) by a different health practitioner group

Justification for amendment:

This submission seeks approval to expand the current prescriber restriction for integrated, closed-system extracorporeal photopheresis (ECP) with methoxsalen (UVADEX®) under the Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS). The amendment is proposed for the treatment of both cutaneous T-cell lymphoma (CTCL) and chronic graft versus host disease (cGVHD)

The existing restrictions specifies that ECP for CTCL must be supervised by a specialist or consultant physician in the field of haematology, and ECP for cGVHD must be supervised by a specialist or consultant physician in the field of haematology or oncology. This application proposes to extend that supervision requirement to include dermatologists. This restriction was informed by clinical practice at the time of the initial MSAC submissions, when ECP was only available at two centres in Australia: The Peter MacCallum Cancer Centre and the Royal Prince Alfred Hospital. Both services operated within apheresis units and were primarily staffed by haematologists. Accordingly, expert consultation for the original application came predominantly from the haematology field. However, this limitation was not a central requirement of the MSAC submission, and this amendment is intended to ensure that the MBS and PBS criteria reflect contemporary clinical practice, improve equity of access, and align Australia's governance of ECP with international standards.

In other jurisdictions, dermatologists are involved in the delivery of ECP. The European Dermatology Forum published clinical guidelines in 2013, which were updated in 2020 (Knobler et al. 2020; Knobler et al. 2014). Developed through consultation both within and outside the field of dermatology, these guidelines currently represent the most comprehensive expert recommendations for the use of ECP, based on published literature and consensus opinion. In the United Kingdom (UK), ECP is formally endorsed by the Joint British Association of Dermatologists for CTCL, and the by the UK Photopheresis Society for both CTCL and cGVHD. ECP services are delivered through specialised NHS centres located in regions throughout the UK. All designated centres assess and manage patients with CTCL and cGVHD, with dermatologists routinely involved in both referral and longitudinal clinical care. In Germany, ECP is predominantly delivered within hospital-based settings, typically with departments of dermatology, haematology, or transfusion medicine. Access is enabled through established procedural codes, allowing dermatologists to initiate, coordinate, and oversee ECP therapy as part of multidisciplinary inpatient services.

More recently in Australia, the optimal care pathways for CTCL and cGVHD management have positioned dermatologists as leading contributors within multidisciplinary care teams (Leukaemia Foundation 2023). Given their recognised expertise in assessing the characteristic cutaneous manifestations of both CTCL and cGVHD, dermatologists play an integral role in the clinical evaluation and coordination of care for these patients. Their established experience with phototherapy and ultraviolet (UV) interventions similarly supports their capacity to supervise light-based therapies such as ECP for the management of these conditions (Tan and GeBauer 2025). While availability of ECP in Australia has expanded since the

initial MSAC submissions, it remains limited, with services currently available at one hospital in each of New South Wales, South Australia, and Queensland, and three hospitals in Victoria. Expert clinical opinion indicates that expanding prescribing rights to dermatologists would facilitate the establishment of additional sites, improving equity of access for these small but high-need patient populations.

In the management of CTCL, MSAC has accepted ECP is likely safer than, and at least as effective as, all four identified comparators for stage T4 M0 CTCL (MSAC Application 1420.1 PSD). Similarly, MSAC considered ECP plus methoxsalen has acceptable safety, superior effectiveness and acceptable cost-effectiveness in the treatment of cGVHD compared with the current standard of care alone for the proposed patient population. MSAC also advised that there was a high unmet clinical need for effective treatments for cGVHD, given that it is not well managed by existing therapies (MSAC Application 1651 PSD).

No other changes are proposed to the MBS and PBS criteria for the listings for ECP or methoxsalen. The expansion to allow supervision by dermatologists is expected to have no impact on the information or cost-effectiveness previously considered by MSAC and the PBAC when listing of the items was recommended.

Relevant MBS items

Please select any relevant MBS items.

MBS item number	Select reason type
13761	Expansion or amendment to existing item
13762	Expansion or amendment to existing item
14247	Expansion or amendment to existing item
14249	Expansion or amendment to existing item

What is the type of service or health technology?

Therapeutic

PICO sets

Application PICO set 1

Integrated, closed-system, extracorporeal photopheresis and methoxsalen (UVADEX®) for chronic graft versus-host-disease, update to MBS and PBS items

Population

Describe the population in which the proposed health technology is intended to be used:

Graft versus host disease (GVHD) is a severe complication that can occur following haematopoietic stem cell transplantation (HSCT). This condition arises when immunocompetent T lymphocytes from the donor graft recognise the recipient's tissues as foreign due to histocompatibility differences and initiate an immune response against them (Ferrara et al. 2009; Welniak et al. 2007). This attack typically leads to tissue damage in various organs, including the skin, gastrointestinal tract, liver, and lungs.

Historically, the distinction between acute GVHD (aGVHD) and chronic GVHD (cGVHD) was based on whether diagnosis occurred before or after 100 days post-transplant. The 2005 National Institutes of Health (NIH) Consensus Conference redefined aGVHD and cGVHD as distinct clinical syndromes without a strict time cutoff (Lee 2017), a definition reaffirmed by the NIH Consensus Conference in 2014 (Jagasia et al. 2015). Under this framework, aGVHD is characterised by the inflammatory involvement of the skin, liver, and gastrointestinal tract, and may occur either before or after 100 days post-transplant. cGVHD instead manifests as an autoimmune-like, multi-organ condition and may arise de novo, evolve from acute GVHD, or develop following its resolution. Clinically, cGVHD is based on organ-specific findings defined in the NIH consensus report (Jagasia et al. 2015). Affected organs include skin, liver, lungs, oral mucosa, and eyes, and symptoms reflect chronic immune dysregulation, often presenting similar to systemic autoimmune disease (van der Wagen et al. 2018; Wood et al. 2013). cGVHD is associated with prolonged immunosuppression, reduced quality of life, and increased non-relapse mortality (Berger et al. 2015; Wood et al. 2013).

ECP is indicated for patients who are steroid-refractory, steroid-dependent, or steroid-intolerant. The supported MBS item descriptor (MSAC Application 1651 PSD p12) defines steroid-refractory or steroid-dependent disease 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 > 0.5 mg/kg/day or 1 mg/kg every day or equivalent other day for at least 4 weeks, OR

• Increase to prednisolone dose to > 0.25 mg/kg/day or equivalent after 2 unsuccessful attempts to taper the dose.

In addition, steroid-intolerance is defined as when patients who are unable to tolerate the side effects of adequate doses of systemic steroids (Das-Gupta et al. 2014).

Select the most applicable Medical condition terminology (SNOMED CT):

cGVHD: 402356004 | Chronic graft versus host disease (disorder)

Intervention

Name of the proposed health technology:

Integrated, closed-system, extracorporeal photopheresis (ECP), Methoxsalen (UVADEX®)

Comparator

Nominate the appropriate comparator(s) for the proposed medical service (i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system). This includes identifying health care resources that are needed to be delivered at the same time as the comparator service:

Not applicable

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:

This submission requests that the current restriction for supervision of ECP be expanded to include dermatologists. This proposed change is not expected to alter the clinical outcomes or cost-effectiveness previously accepted by MSAC and the

PBAC, as it does not modify the treatment indication, delivery method, dosage, or duration of therapy.

Proposed MBS items

Proposed item:

AAAAA

MBS item number (where used as a template for the proposed item):

13761

Category number:

THERAPEUTIC PROCEDURES

Category description:

MISCELLANEOUS THERAPEUTIC PROCEDURES

Proposed item descriptor:

Extracorporeal photopheresis for the treatment of chronic graft-versus-host disease, if: (a) the person is: (i) has received allogeneic haematopoietic stem cell transplantation; and (ii) has been diagnosed with chronic graft versus host disease following the transplantation; and (iii) steroid treatment is clinically unsuitable as the disease is steroid refractory or the person is steroid-dependent or steroid-intolerant; and (b) the person has not previously received extracorporeal photopheresis treatment; and (c) the service is delivered using an integrated, closed extracorporeal photopheresis system; and (d) the service is provided in combination with the use of methoxsalen that is listed on the Pharmaceutical Benefits Scheme; and (e) the service is provided by, or on behalf of, a specialist or consultant physician who: (i) is practising in the speciality of haematology or oncology or dermatology; and (ii) has experience with allogeneic bone marrow transplantation. Applicable once per treatment session

Proposed MBS fee:

$2,139.55

Indicate the overall cost per patient of providing the proposed health technology:

$2,139.55

Please specify any anticipated out of pocket expenses:

$0.00

Provide details and explain:

The application does not propose any change to the MBS fee for ECP services for cGVHD

Proposed item:

BBBBB

MBS item number (where used as a template for the proposed item):

13762

Category number:

THERAPEUTIC PROCEDURES

Category description:

MISCELLANEOUS THERAPEUTIC PROCEDURES

Proposed item descriptor:

Extracorporeal photopheresis for the treatment of chronic graft-versus-host disease, if: (a) the person is: (i) has received allogeneic haematopoietic stem cell transplantation; and (ii) has been diagnosed with chronic graft versus host disease following the transplantation; and (iii) steroid treatment is clinically unsuitable as the disease is steroid refractory or the person is steroid-dependent or steroid-intolerant; and (b) the person has previously received an extracorporeal photopheresis treatment cycle and had a partial or complete response in at least one organ in response to treatment; and (c) the person requires further extracorporeal photopheresis; and (d) the service is delivered using an integrated, closed extracorporeal photopheresis system; and (e) the service is provided in combination with the use of methoxsalen that is listed on the Pharmaceutical Benefits Scheme; and (f) the service is provided by, or on behalf of, a specialist or consultant physician who: (i) is practising in the speciality of haematology or oncology or dermatology; and (ii) has experience with allogeneic bone marrow transplantation. Applicable once per treatment session

Proposed MBS fee:

$2,139.55

Indicate the overall cost per patient of providing the proposed health technology:

$2,139.55

Please specify any anticipated out of pocket expenses:

$0.00

Provide details and explain:

The application does not propose any change to the MBS fee for ECP services for cGVHD

How is the technology / service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):

In July 2021, MSAC supported an application for public funding of extracorporeal photopheresis by the Medicare Benefits Schedule for the treatment of patients with chronic graft versus host disease (cGVHD) who are steroid-dependent and/or steroid-intolerant and/or steroid-refractory. The service is currently funded on the MBS under items 13761 and 13762. Methoxsalen for the treatment of cGVHD is reimbursed on the PBS under items 12839R, 12854M, 12855N, 12876Q.

Claims

In terms of health outcomes (comparative benefits and harms), is the proposed technology claimed to be superior, non-inferior or inferior to the comparator(s)?

Non-inferior

Please state what the overall claim is, and provide a rationale:

The clinical claim is unchanged from the July 2021 submission. The MSAC considered that ECP plus methoxsalen has acceptable safety, superior effectiveness and acceptable cost-effectiveness in the treatment of cGVHD compared with the current standard of care alone for the proposed patient population. Expanding treatment criteria for the service to allow supervision by dermatologists is not expected to affect this claim.

Estimated utilisation

Estimate the prevalence and/or incidence of the proposed population:

Not applicable. The MSAC has previously assessed the population of patients with cGVHD who are eligible for treatment with ECP and accepted that the MBS listing of ECP and PBS listing of methoxsalen resulted in an acceptable budget impact. As described in the PICO set documentation, expanding prescribing rights to dermatologists is expected to facilitate the establishment of additional ECP service sites, improving equity of access. Given that ECP is already listed on the MBS and current MBS usage can be determined, a market share approach will be used to estimate the expected increase in MBS service claims for items 13761 and 13762, reflecting the anticipated impact of amending the treatment criteria to allow these services to be supervised by a specialist or consultant physician in dermatology. Overall, allowing dermatologists to provide ECP is expected to result in a 10–20% increase in utilisation of the relevant MBS items, based on Therakos market data on projected service use.

Provide the percentage uptake of the proposed health technology by the proposed population:

Year 1 estimated uptake (%):

10

Year 2 estimated uptake (%):

10

Year 3 estimated uptake (%):

10

Year 4 estimated uptake (%):

10

Estimate the number of patients who will utilise the proposed technology for the first full year:

196 patients will access item 13761, and 273 will access item 13762, in 2026.

Optionally, provide details:

Medicare item reports for claims made under existing MBS items 13761 and 13762 for ECP in cGVHD provide the best available data on the utilisation of these services. MBS items 13761 and 13762 are claimable once per treatment session.

Limits were established to prevent double claiming, as ECP is typically delivered over two consecutive days with an overnight stay. Treatment protocols can vary depending on individual patient response. According to the Product Information (PI) for UVADEX® methoxsalen 200 µg/10 mL (for extracorporeal circulation via photopheresis). The treatment schedule for cGVHD is: "Three ECP treatments in the first week, followed by two ECP treatments per week for at least 12 weeks, or as clinically indicated."

The explanatory note for item 13762 for cGVHD clarifies that, for administrative purposes, a treatment cycle under item 13761 generally refers to a 12-week period, whereas item 13762 typically refers to a 6-week period. A treatment session is a single attendance for ECP, usually occurring two or three times per week. Patients may therefore make multiple claims under these items within a single year, meaning item numbers represent claims rather than unique patients. Consequently, utilisation reports cannot determine the number of individual patients treated.

The table below summarises total claims made for the relevant MBS items since their introduction. As described in the PICO set documentation, expanding prescribing rights to dermatologists is expected to facilitate the establishment of additional ECP service sites, improving equity of access. Utilisation data for these items were insufficient to calculate a reliable growth rate; therefore, a 10% increase in service utilisation has been assumed to estimate the projected impact of the proposed update. An estimated 196 patients will access item 13761, and 273 will access item 13762, in 2026.

Table 1 Medicare item reports processed for MBS items for extracorporeal photopheresis for the treatment of cGVHD

Year	2021	2022	2023	2024	2025 (YTD)
13761	N/A	10	61	162	190
13762	N/A	13	46	226	329

Source: Medicare item reports for items 13761, and 13762 from date of listing to current.
Abbreviations: cGVHD, chronic graft versus host disease; CTCL, cutaneous T-cell lymphoma; N/A, not applicable; YTD, year to date.

Will the technology be needed more than once per patient?

Yes, multiple times

Over what duration will the health technology or service be provided for a patient? (preferably a number of years):

Not applicable

What frequency will the health technology or service be required by the patient over the duration? (range, preferably on an annual basis):

Not applicable

Application PICO set 2

Integrated, closed-system, extracorporeal photopheresis and methoxsalen (UVADEX®) for cutaneous T-cell lymphoma, update to MBS and PBS items

Population

Describe the population in which the proposed health technology is intended to be used:

Cutaneous T-cell lymphoma (CTCL) is a rare heterogeneous group of diseases comprised of non-Hodgkin lymphomas involving malignant T-cell clones that accumulate in the skin (Knobler et al. 2014; Raphael et al. 2011). CTCL has an annual age-standardised incidence of 0.77 per 100,000 (95% CI 0.74–0.79) in Australia (Campbell et al. 2025) and occurs most commonly in adults of all races aged 40–60 years, with males affected approximately twice as often as females. The two most common CTCL variants are mycosis fungoides (MF) and Sézary Syndrome (SS). MF accounts for around 60% (Knobler et al. 2014) of all CTCL patients and is characterised by clonal T-cells in the cutaneous environment that present early on as plaques and patches on the skin (which can resemble eczema or psoriasis), and eventually result in lesions, pruritus, and tumours (Knobler et al. 2014; Raphael et al. 2011). SS accounts for around 5% (Knobler et al. 2014) of all CTCL and is a leukaemic form of MF, where T-cells circulate in the peripheral blood and affect internal organs such as the spleen and lungs (Knobler et al. 2014; Raphael et al. 2011). The most commonly used staging criteria for CTCL is the International Society for Cutaneous Lymphomas (ISCL) and European Organisation of Research and Treatment of Cancer's (EORTC) revision to the staging of MF and SS. Based on this criterion, MSAC supported listing of ECP for patients with erythrodermic (stage T4 M0) CTCL.

Select the most applicable Medical condition terminology (SNOMED CT):

CTCL: 400122007 | Primary cutaneous T-cell lymphoma (disorder)

Intervention

Name of the proposed health technology:

Integrated, closed-system, extracorporeal photopheresis (ECP), Methoxsalen (UVADEX®)

Comparator

Nominate the appropriate comparator(s) for the proposed medical service (i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system). This includes identifying health care resources that are needed to be delivered at the same time as the comparator service:

Not applicable

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:

This submission requests that the current restriction for supervision of ECP be expanded to include dermatologists. This proposed change is not expected to alter the clinical outcomes or cost-effectiveness previously accepted by MSAC and the PBAC, as it does not modify the treatment indication, delivery method, dosage, or duration of therapy.

Proposed MBS items

Proposed item:

AAAAA

MBS item number (where used as a template for the proposed item):

14247

Category number:

THERAPEUTIC PROCEDURES

Category description:

MISCELLANEOUS THERAPEUTIC PROCEDURES

Proposed item descriptor:

Extracorporeal photopheresis for the treatment of erythrodermic stage III-IVa T4 M0 cutaneous T-cell lymphoma; if the service is provided in the initial six months of treatment; and the service is delivered using an integrated, closed extracorporeal photopheresis system; and the patient is 18 years old or over; and the patient has received prior systemic treatment for this condition and experienced either disease progression or unacceptable toxicity while on this treatment; and the service is provided in combination with the use of Pharmaceutical Benefits Scheme-subsidised methoxsalen; and the service is supervised by a specialist or consultant physician in the speciality of haematology or dermatology. Applicable once per treatment cycle

Proposed MBS fee:

$2,158.85

Indicate the overall cost per patient of providing the proposed health technology:

$2,158.85

Please specify any anticipated out of pocket expenses:

$0.00

Provide details and explain:

The application does not propose any change to the MBS fee for ECP services for CTCL
Proposed item: BBBBB **MBS item number (where used as a template for the proposed item):** 14249 **Category number:** THERAPEUTIC PROCEDURES **Category description:** MISCELLANEOUS THERAPEUTIC PROCEDURES **Proposed item descriptor:** Extracorporeal photopheresis for the continuing treatment of erythrodermic stage III-IVa T4 M0 cutaneous T-cell lymphoma; if in the preceding 6 months:(i) a service to which item 14247 applies has been provided; and(ii) the patient has demonstrated a response to this service; and(iii)the patient requires further treatment; and the service is delivered using an integrated, closed extracorporeal photopheresis system; and the patient is 18 years old or over; and the service is provided in combination with the use of Pharmaceutical Benefits Scheme-subsidised methoxsalen; and the service is supervised by a specialist or consultant physician in the speciality of haematology or dermatology. Applicable once per treatment cycle **Proposed MBS fee:** $2,158.85 **Indicate the overall cost per patient of providing the proposed health technology:** $2,158.85 **Please specify any anticipated out of pocket expenses:** $0.00 **Provide details and explain:**

The application does not propose any change to the MBS fee for ECP services for CTCL

How is the technology / service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):

In April 2020, MSAC supported an application for public funding of ECP by the MBS. The service is currently funded on the MBS under items 14247 and 14249. Methoxsalen is reimbursed on the PBS under items 12154Q, 12156T, 12162D, and 12173Q.

Claims

In terms of health outcomes (comparative benefits and harms), is the proposed technology claimed to be superior, non-inferior or inferior to the comparator(s)?

Non-inferior

Please state what the overall claim is, and provide a rationale:

The clinical claim is unchanged from the April 2020 submission; extracorporeal photopheresis (ECP) has superior safety and at least non-inferior effectiveness compared to its comparators. The Medical Services Advisory Committee (MSAC) accepted the claim of improved comparative safety and confirmed that ECP is associated with fewer adverse events than its comparators (MSAC Application 1420.1 PSD). Regarding comparative effectiveness, MSAC accepted that although the evidence is limited, ECP is at least as effective as the four identified comparators (MSAC Application 1420.1 PSD). Expanding treatment criteria for the service to allow supervision by dermatologists is not expected to affect this claim.

Estimated utilisation

Estimate the prevalence and/or incidence of the proposed population:

Not applicable. The MSAC has previously assessed the population of patients with CTCL who are eligible for treatment with ECP and accepted that the MBS listing of ECP and PBS listing of methoxsalen resulted in an acceptable budget impact. As described in the PICO set documentation, expanding prescribing rights to dermatologists is expected to facilitate the establishment of additional ECP service

sites, improving equity of access. Given that ECP is already listed on the MBS and current MBS usage can be determined, a market share approach will be used to estimate the expected increase in MBS service claims for items 14247 and 14249, reflecting the anticipated impact of amending the treatment criteria to allow these services to be supervised by a specialist or consultant physician in dermatology. Overall, allowing dermatologists to provide ECP is expected to result in a 10–20% increase in utilisation of the relevant MBS items, based on Therakos market data on projected service use.

Provide the percentage uptake of the proposed health technology by the proposed population:

Year 1 estimated uptake (%):

10

Year 2 estimated uptake (%):

10

Year 3 estimated uptake (%):

10

Year 4 estimated uptake (%):

10

Estimate the number of patients who will utilise the proposed technology for the first full year:

143 patients will access item 14247 and 145 patients will access item 14249, in 2026.

Optionally, provide details:

Medicare item reports for claims made under existing MBS items 14247 and 14249 for ECP in CTCL provide the best available data on the utilisation of these services. MBS items 14247 and 14249 are claimable once per treatment cycle.

Limits were established to prevent double claiming, as ECP is typically delivered over two consecutive days with an overnight stay. Treatment protocols can vary depending on individual patient response. According to the Product Information (PI) for UVADEX® methoxsalen 200 µg/10 mL (for extracorporeal circulation via photopheresis), the treatment schedule for CTCL is: “The patient should receive treatment on two successive days each month for six months. Patients who show an

increase in skin scores after eight treatment sessions may have their treatment schedule increased to two successive days every two weeks for the next three months."

CTCL, item 14247 applies to services provided during the first six months of treatment, while item 14249 applies to any services delivered thereafter. Patients may therefore make multiple claims under these items within a single year, meaning item numbers represent claims rather than unique patients. Consequently, utilisation reports cannot determine the number of individual patients treated.

The table below summarises total claims made for the relevant MBS items since their introduction. As described in the PICO set documentation, expanding prescribing rights to dermatologists is expected to facilitate the establishment of additional ECP service sites, improving equity of access. The annual growth rate for ECP items from listing to 2024 was calculated to be 17% for item 14247, and 26% for item 14249. A 10% increase in service utilisation has been assumed to estimate the projected impact of the proposed update. Based on these projections, it is estimated that 143 patients will access item 14247 and 145 patients will access item 14249, in 2026.

Table 2 Medicare item reports processed for MBS items for extracorporeal photopheresis for the treatment of cGVHD

Year	2021	2022	2023	2024	2025 (YTD)
14247	59	212	94	95	23
14249	9	52	82	83	87

Source: Medicare item reports for items 14247, 14249 from date of listing to current.
Abbreviations: cGVHD, chronic graft versus host disease; CTCL, cutaneous T-cell lymphoma; N/A, not applicable; YTD, year to date.

Will the technology be needed more than once per patient?

Yes, multiple times

Over what duration will the health technology or service be provided for a patient? (preferably a number of years):

Not applicable

What frequency will the health technology or service be required by the patient over the duration? (range, preferably on an annual basis):

Not applicable

Consultation

List all entities that are relevant to the proposed service / health technology. The list can include professional bodies / organisations who provide, request, may be impacted by the service/health technology; sponsor(s) and / or manufacturer(s) who produce similar products; patient and consumer advocacy organisations or individuals relevant to the proposed service/health technology.

Entities who provide the health technology/service:

HAEMATOLOGY SOCIETY OF AUSTRALIA AND NEW ZEALAND

THE AUSTRALASIAN COLLEGE OF DERMATOLOGISTS

Entities who may be impacted by the health technology/service:

HAEMATOLOGY SOCIETY OF AUSTRALIA AND NEW ZEALAND

THE AUSTRALASIAN COLLEGE OF DERMATOLOGISTS

Patient and consumer advocacy organisations relevant to the proposed service/health technology:

THE LEUKAEMIA FOUNDATION OF AUSTRALIA LIMITED

Regulatory information

Would the proposed health technology involve the use of a medical device, in-vitro diagnostic test, radioactive tracer or any other type of therapeutic good?

Yes

Has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?

Yes

Is the therapeutic good classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?

No

Please enter all relevant ARTG IDs:

ARTG ID	ARTG name
329260	Therakos Cellex Photopheresis System - Photopheresis system

Is the intended purpose in this application the same as the intended purpose of the ARTG listing(s)?

Yes

Codependent details

Will a submission be made to the Pharmaceutical Benefits Advisory Committee (PBAC)?

Yes

Please provide a rationale for the codependency and indicate how the proposed PBS restriction would reference the intervention(s) proposed for MSAC consideration:

ECP and methoxsalen are co-dependent components of a single therapeutic process. ECP involves the extraction of a patient's white blood cells from whole blood via apheresis, the white blood cells are combined with the photoactive drug methoxsalen and exposed to ultraviolet-A (UVA) light. All blood components, including the treated white blood cells, are returned to the patient to induce an immune-modulatory response. Once re-infused into the patient, the processing of the treated cells induces a systemic immuno-modulatory response, including an increase in anti-inflammatory cytokines, a decrease in pro-inflammatory cytokines, and an increase in regulatory T-cells (Lamioni et al. 2005; Morelli et al. 2003).

The PBS listings for items 12154Q, 12156T, 12162D, 12173Q for CTCL contain treatment criteria that states patients i) must be treated by a haematologist, OR ii) must be treated by a medical physician working under the supervision of a haematologist. The PBS items 12839R, 12854M, 12855N, 12876Q for cGVHD contain treatment criteria which states that patients i) must be treated by a haematologist, OR ii) Must be treated by an oncologist with allogeneic bone marrow transplantation experience, OR iii) must be treated by a medical practitioner working under the direct supervision of one of the above-mentioned specialist types. These criteria will also need to be updated to allow treatment by a dermatologist.

Prior to submitting this application, the sponsor sought advice from the PBAC Secretariat at the Office of Health Technology Assessment and the MSAC Pre-Assessment team contact. The PBAC Secretariat noted that a change to the existing listings to allow dermatologists to be able to prescribe methoxsalen (without a change to the indication/s) may meet the criteria for a Category 3 PBAC submission. Accordingly, the sponsor intends to submit a Category 3 PBAC to address the PBAC component of this request.