

Medical Services Advisory Committee (MSAC) Public Summary Document

Application No. 1818 – 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 (CTCL) and chronic Graft Versus Host Disease (cGVHD)

Applicant: HTAnalysts on behalf of Therakos Australia Pty Ltd

Date of MSAC consideration: 30 July 2026

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, [visit the MSAC website](#)

1. Purpose of application

An application requesting 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 was proposed for the treatment of both cutaneous T-cell lymphoma (CTCL) and chronic graft versus host disease (cGVHD).

2. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness, cost-effectiveness and total cost, MSAC supported the amendment of existing Medicare Benefits Schedule (MBS) items 14247 and 14249 for extracorporeal photopheresis for the treatment of cutaneous T-cell lymphoma and MBS items 13761 and 13762 for extracorporeal photopheresis for the treatment of chronic graft versus host disease, to expand specialist supervision criteria to include dermatologists. MSAC noted that the Pharmaceutical Benefits Advisory Committee (PBAC), at its July 2026 meeting, recommended extending the current Pharmaceutical Benefits Scheme (PBS) listing for methoxsalen (UVADEX®) to allow treatment by a dermatologist, or treatment by a medical physician working under the supervision of a dermatologist. MSAC noted that PBAC considered the eligible population for methoxsalen will likely be unchanged. MSAC considered the addition of dermatologists had no implications for safety of the procedure and the financial impact to the MBS to be cost-neutral. MSAC noted this application focussed only on closed loop extracorporeal photopheresis systems. MSAC also noted feedback on this application and policy advice that open loop extracorporeal photopheresis systems are now included on the Australian Register of Therapeutic Goods and in use within the public hospital system. MSAC supported the policy recommendation for method agnostic item descriptors to enable clinicians to provide extracorporeal photopheresis using the system that is clinically appropriate for their patients and to ensure patients can obtain an MBS rebate for this service.

3. Summary of consideration and rationale for MSAC's advice

MSAC noted that this application from Therakos Australia Pty Ltd was 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 was proposed for the treatment of both cutaneous T-cell lymphoma (CTCL) and chronic graft versus host disease (cGVHD). The relevant MBS items are 14247, 14249, 13761 and 13762.

MSAC noted that the existing PBS restrictions specify 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.

MSAC noted that PBAC recommended amending the current MBS items to allow treatment by a dermatologist, or treatment by a medical physician working under the supervision of a dermatologist, as part of treatment with integrated, closed system ECP. MSAC also noted that PBAC considered the eligible population for methoxsalen will likely be unchanged by amending the treatment criteria and the financial impact would be cost neutral, which MSAC accepted.

MSAC noted that dermatologists already have a role in the diagnosis, staging and ongoing management of CTCL and cutaneous manifestations of cGVHD; that the proposed item descriptors largely reflected existing arrangements; and that this is consistent with established international practice and clinical guidelines. MSAC considered that the addition of dermatology as a supervising specialty would increase access to specialist medical care for this patient population while not increasing the demand for ECP treatment.

MSAC noted that dermatologists involved in the management of CTCL and cGVHD would typically have experience managing patients post-transplant, and that existing governance and credentialling practices would provide appropriate safeguards, without requiring this to be detailed in the items.

MSAC noted the application and current item descriptors included only closed loop ECP systems. MSAC noted the consultation submission from Vencare Medical advising MSAC about the listing of their open loop ECP system on the Australian Register of Therapeutic Goods and requesting that the requirement for an ECP system to be "closed" be removed from the descriptors.

MSAC considered policy advice that the current item descriptors are not method agnostic and therefore are not consistent with the MBS principle that where more than one technique, device or system is available to deliver the same service, the item descriptor should be method agnostic to enable clinicians to utilise any clinically appropriate method for their patient. MSAC reviewed the policy intent to further amend the items to ensure patients are able to access an MBS rebate for an ECP service delivered by any means. MSAC considered previous deliberations had identified the benefits of a closed circuit may be a reduction in contamination, infection and reinfusion errors. MSAC considered policy advice that in an Australian context the requirements for facilities delivering ECP to comply with blood safety standards and accreditation requirements exist regardless of the system used. MSAC agreed with the policy position that existing regulatory frameworks ensure there are practises in place to limit the risks of blood product related external contamination, cross contamination and reinfusion errors and as such no specific safety concerns exist that necessitate limiting the MBS items to only closed loop ECP systems.

MSAC considered the wording of the descriptor could be device-agnostic but that Section 100 access to the drug used for ECP (methoxsalen) meant the drug name must be retained.

In summary MSAC supported the policy proposed item descriptor that:

- expanded the specialist supervision criteria by adding “dermatology” as a specific medical specialty in the relevant MBS items.
- removed the requirement for “experience with allogenic bone marrow transplantation” in the relevant MBS items.
- removed “integrated closed” from the relevant MBS items in relation to the ECP system.
- retained the drug name “methoxsalen” in the relevant MBS items.

Category 3 – Therapeutic procedures Group T1 - Miscellaneous Therapeutic Procedures Subgroup13 - Other Therapeutic Procedures
MBS item 14247 Extracorporeal photopheresis for the treatment of erythrodermic stage III-IVa T4 M0 cutaneous T-cell lymphoma; if (a) the service is provided in the initial six months of treatment; and ~~(b) the service is delivered using an integrated, closed extracorporeal photopheresis system;~~ and (c) the patient is 18 years old or over; and (d) the patient has received prior systemic treatment for this condition and experienced either disease progression or unacceptable toxicity while on this treatment; and (e) the service is provided in combination with the use of Pharmaceutical Benefits Scheme-subsidised methoxsalen; and (f) the service is supervised by a specialist or consultant physician in the speciality of haematology or dermatology. Applicable once per treatment cycle (H)
Fee: \$2,215.00 Benefit: 75% = \$1,661.25

Category 3 – Therapeutic procedures Group T1 - Miscellaneous Therapeutic Procedures Subgroup13 - Other Therapeutic Procedures
MBS item 14249 Extracorporeal photopheresis for the continuing treatment of erythrodermic stage III-IVa T4 MO cutaneous T-cell lymphoma; if (a) 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 ~~(b) the service is delivered using an integrated, closed extracorporeal photopheresis system; and~~ (c) the patient is 18 years old or over; and (d) the service is provided in combination with the use of Pharmaceutical Benefits Scheme-subsidised methoxsalen; and (e) the service is supervised by a specialist or consultant physician in the speciality of haematology or dermatology. Applicable once per treatment cycle (H)
Fee: \$2,215.00 Benefit: 75% = \$1,661.25
Category 3 – Therapeutic procedures Group T1 - Miscellaneous Therapeutic Procedures Subgroup 8 - Haematology
MBS item 13761 Extracorporeal photopheresis for the treatment of chronic graft-versus-host disease, if: (a) the person: (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) 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 dermatology, haematology or oncology; and ~~(ii) has experience with allogeneic bone marrow transplantation.~~ Applicable once per treatment session (H)
Fee: \$2,195.20 Benefit: 75% = \$1,646.40

Category 3 – Therapeutic procedures Group T1 - Miscellaneous Therapeutic Procedures Subgroup 8 - Haematology
MBS item 13762 Extracorporeal photopheresis for the treatment of chronic graft-versus-host disease, if: (a) the person: (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) 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) 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 <i>dermatology</i>, haematology or oncology; ~~and~~ ~~(ii) has experience with allogeneic bone marrow transplantation.~~ Applicable once per treatment session (H)
Fee: \$2,195.20 Benefit: 75% = \$1,646.40

4. Applicant comments on MSAC's Public Summary Document

Therakos Australia welcomes the decision by MSAC to support expanding the MBS items to include dermatologists.

5. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website: [visit the MSAC website](#)