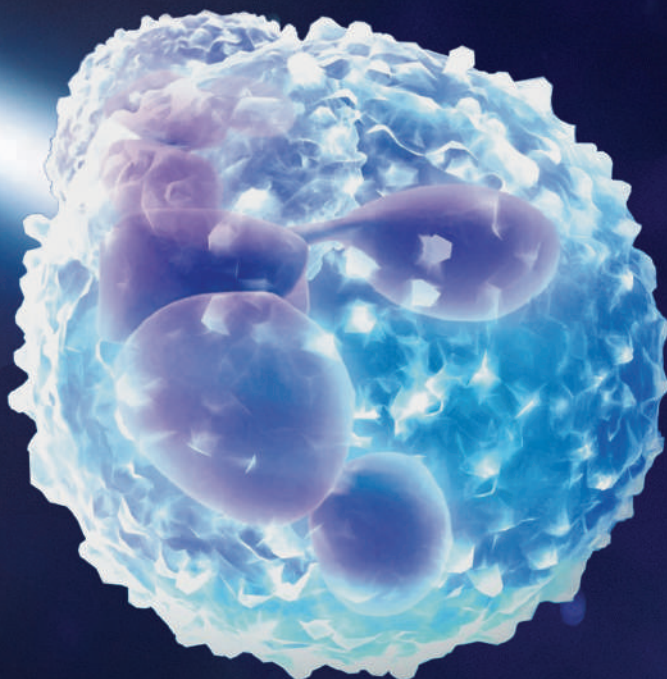


# REIMAGINE IMMUNOTHERAPY<sup>1-3</sup>

Activate the system, target the disease<sup>3,4</sup>



## **INDICATION**

The THERAKOS® CELLEX® Photopheresis System is indicated for use in the ultraviolet-A (UVA) irradiation, in the presence of the photoactive drug 8-methoxypsoralen (8-MOP), of extracorporeally circulating leukocyte-enriched blood, in the palliative treatment of the skin manifestations of cutaneous T-cell lymphoma (CTCL).

Please see the Important Safety Information on pages 17-18.

# Cutaneous T-cell lymphoma (CTCL) is a rare, chronic disease characterized by burdensome skin symptoms<sup>5</sup>

**CTCLs constitute 71% of all primary cutaneous lymphomas<sup>6,7\*</sup>**

The most common types of CTCL are MF (60%) and SS (5%).<sup>5</sup>

## **MYCOSIS FUNGOIDES (MF)**

- Generally a more indolent form of CTCL that usually stays confined to the skin<sup>8,9</sup>
- Characterized by a variety of skin manifestations, including scaly patches, plaques, and nodular lesions<sup>5,9</sup>
- Lesions are often morphologically similar to other inflammatory conditions (eg, eczema, psoriasis) and, together with the slow progression of the disease, can contribute to delayed diagnosis and treatment<sup>9</sup>

## **SÉZARY SYNDROME (SS)**

- Patients typically present with erythroderma (>80% BSA), itching, and enlarged lymph nodes<sup>8</sup>
- Commonly characterized by severe itching<sup>10</sup>
- Tends to progress more rapidly than MF and has a worse prognosis<sup>10</sup>

BSA, body surface area.

\*According to a population-based study conducted in the United States.

# Clinical staging of MF and SS

|                   | Clinical Stage <sup>7,a*</sup>                   |  | TNMB Classification <sup>7*</sup> |                       |              |                       |
|-------------------|--------------------------------------------------|--|-----------------------------------|-----------------------|--------------|-----------------------|
|                   |                                                  |  | Skin (T) <sup>b</sup>             | Node (N) <sup>b</sup> | Visceral (M) | Blood involvement (B) |
| Stage I MF        | IA (Limited skin involvement)                    |  | 1                                 | 0                     | 0            | 0,1                   |
|                   | IB (Skin-only disease)                           |  | 2                                 | 0                     | 0            | 0,1                   |
| Stage II MF       | IIA                                              |  | 1,2                               | 1,2                   | 0            | 0,1                   |
|                   | IIB (Tumour stage disease)                       |  | 3                                 | 0-2                   | 0            | 0,1                   |
| Stage III MF      | IIIA (Erythrodermic disease)                     |  | 4                                 | 0-2                   | 0            | 0                     |
|                   | IIIB (Erythrodermic disease)                     |  | 4                                 | 0-2                   | 0            | 1                     |
| Stage IV MF or SS | IVA <sub>1</sub> (SS <sup>c</sup> )              |  | 1-4                               | 0-2                   | 0            | 2                     |
|                   | IVA <sub>2</sub> (SS <sup>c</sup> or Non-Sézary) |  | 1-4                               | 3                     | 0            | 0-2                   |
| Stage IV MF       | IVB (Visceral disease)                           |  | 1-4                               | 0-3                   | IA or IB     | 0-2                   |

| TNMB Classification <sup>11</sup> | Clinical Descriptions <sup>11</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>T</b>                          | <b>T0:</b> no clinically suspicious lesions<br><b>T1:</b> patches, papules, and/or plaques covering <10% BSA<br><b>T2:</b> patches, papules, and/or plaques covering ≥10% BSA<br><b>T3:</b> 1 or more tumours (≥1 cm in diameter)<br><b>T4:</b> confluence of erythema covering ≥80% BSA                                                                                                                                                                                              |
| <b>N</b>                          | <b>N0:</b> no clinically abnormal lymph node<br><b>N1<sup>d</sup>:</b> no atypical lymphocytes, occasional and isolated atypical lymphocytes (not arranged in clusters), or many atypical lymphocytes or in 3- to 6-cell clusters<br><b>N2<sup>d</sup>:</b> aggregates of atypical lymphocytes; nodal architecture preserved<br><b>N3<sup>d</sup>:</b> partial/complete effacement of nodal architecture by atypical lymphocytes or frankly neoplastic cells                          |
| <b>M</b>                          | <b>M0:</b> no visceral involvement<br><b>M1A (bone marrow only involvement):</b> clone positive and identical to skin or clone negative or indeterminate<br><b>M1B (non-bone marrow visceral involvement):</b> clone positive and identical to skin or clone negative or indeterminate<br><b>MX:</b> visceral involvement is neither confirmed nor refuted by available pathologic or imaging assessment                                                                              |
| <b>B</b>                          | <b>B0:</b> absence of significant blood involvement (B0=250 cells/μL of CD4+/CD26- or CD4+/CD7- cells)<br><b>B1:</b> low blood tumour burden (does not meet B0 or B2 criteria)<br><b>B2:</b> high blood tumour burden (≥1000 cells/μL of Sézary cells, which involve abnormal T-cell subsets including but not limited to CD4+/CD26- or CD4+/CD7- cells). It is expected that patients with B2 blood involvement will have a clone in the blood that is identical to that in the skin |

NCI-VA, National Cancer Institute-Veterans Administration.

\*Adapted with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines<sup>®</sup>) for Primary Cutaneous Lymphoma. V3.2025  
 © 2025 National Comprehensive Cancer Network, Inc. All rights reserved. The NCCN Guidelines<sup>®</sup> and illustrations herein may not be reproduced in any form for any purpose without the express written permission of NCCN. To view the most recent and complete version of the NCCN Guidelines, go online to NCCN.org. The NCCN Guidelines are a work in progress that may be refined as often as new significant data becomes available.

<sup>a</sup>Folliculotropism is a histological feature that can occur irrespective of stage and is associated with higher risk of disease progression. In selected cases or inadequate response, consider primary treatment for stage IIB (tumour-stage disease).<sup>7</sup>

<sup>b</sup>Large-cell transformation is a histologic feature that can occur irrespective of clinical stage and often (but not always) corresponds to a more aggressive growth rate.<sup>7</sup>

<sup>c</sup>A diagnosis of SS requires B2 level of blood involvement.<sup>11</sup>

<sup>d</sup>Per the NCI-VA Lymph Node Classification.<sup>11</sup>

# Treatment selection depends on the stage of disease or occurrence of disease progression<sup>7</sup>



## Early-stage MF (IA-IIA) is often managed with skin-directed treatments<sup>7</sup>

- Topicals
- Local radiation
- Phototherapy
- Total skin electron beam therapy



## Advanced-stage disease (IIB-IVB) is often managed with systemic treatments<sup>7</sup>

- Systemic retinoids
- Histone deacetylase inhibitors
- Chemotherapy
- Photopheresis (excluding tumour stage)
- Targeted immunotherapy
- Other



## Treatment selection may depend on several factors<sup>7,10,12</sup>

### Disease related

- Clinical stage (TNMB)
- Morphologic features
- Localization of malignant cells

### Patient related

- Age
- Comorbidities
- Concomitant medications
- Insurance barriers

### Other considerations

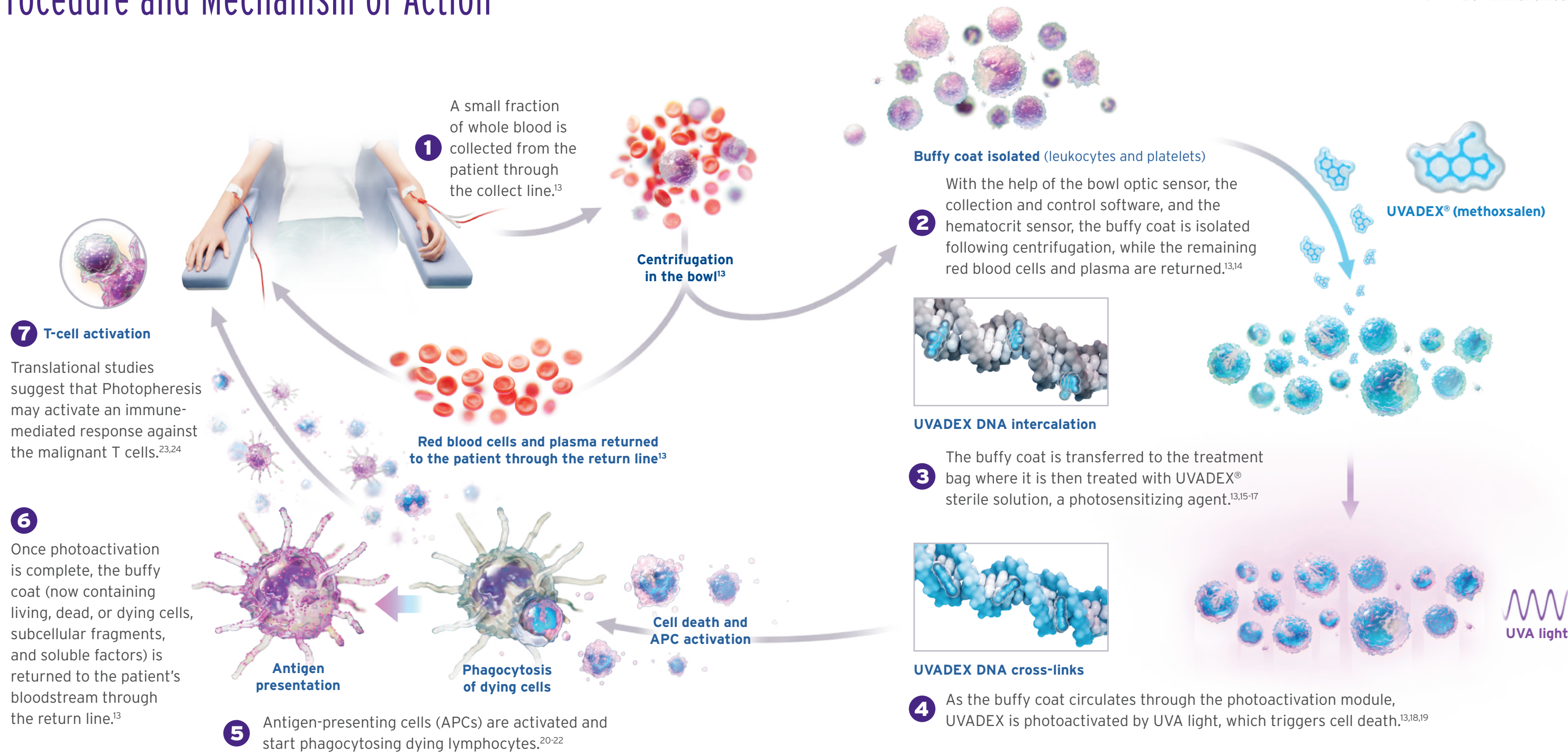
- Recycling treatments
- Maintenance therapy
- NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines<sup>®</sup>)



**When choosing your patient's next treatment, consider its side effect profile and clinical efficacy.<sup>10</sup>**

When patients progress and  
systemic treatment is next,  
consider starting with  
a therapy that is  
immunomodulatory.<sup>10</sup>

THERAKOS® CELLEX® PHOTOPHERESIS SYSTEM:  
Procedure and Mechanism of Action



While much is known about the mechanism of action, the exact mechanism of action is currently being studied.

The procedure pictured above illustrates a patient using double-needle mode.<sup>13</sup>

THERAKOS® CELLEX® PHOTOPHERESIS SYSTEM:

A fully integrated ECP system with a single, closed, and sterile circuit<sup>13</sup>



**ECP is recommended by multiple international guidelines as a treatment option for certain patients with CTCL.<sup>5,7</sup>**



**Scan the QR code to learn how the procedure works**

Versatility to treat CTCL skin symptoms in patients with a range of clinical needs

**SYSTEM IS CUSTOMIZABLE  
BASED ON PATIENT MEDICAL  
CONSIDERATIONS, INCLUDING<sup>13</sup>:**

- Low body weight and hemodynamic instability
- Abnormal plasma conditions
- Medical conditions warranting lower flow rates, including cardiac, renal, or pulmonary insufficiency, diabetes, hypertension, hypotension, edema, or fragile veins
- Venous access conditions (system is also compatible with implantable ports)

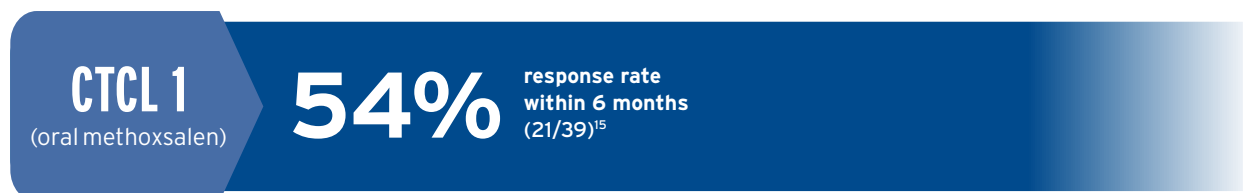


Using double-needle mode, the amount of ECV is reduced, fluid shifts are minimized, and treatment can be completed in as little as 75 minutes.<sup>13,25</sup>

# THERAKOS® Photopheresis delivered a meaningful response in clinical trials<sup>15</sup>

In 3 multicentre, single-arm, open-label trials, efficacy and safety were established in patients (N=147) unresponsive to skin-directed CTCL treatments, including tough-to-treat disease<sup>15,26</sup>

**A SUCCESSFUL TREATMENT RESPONSE WAS DEFINED AS  
A ≥25% REDUCTION IN OVERALL SKIN SCORE FROM BASELINE  
MAINTAINED FOR 4 CONSECUTIVE WEEKS<sup>15</sup>**



Although the response rate with UVADEX in CTCL 3 was similar to oral methoxsalen in CTCL 2, the possibility that UVADEX is inferior in efficacy to oral methoxsalen cannot be excluded due to the design and size of the clinical trials. The higher response rate with oral methoxsalen in CTCL 1 may be partly due to patients receiving more treatments (mean of 64 in CTCL 1, 31 in CTCL 2, and 20 in CTCL 3) and to the administration of systemic steroids in CTCL 1.<sup>15</sup>



Participants were not required to have blood involvement to qualify for the trials, nor were they screened for it if they met inclusion criteria based on another positive criterion.<sup>15,26</sup>

## STUDY DESIGNS

Only patients with patch plaque, extensive plaque, and erythrodermic disease were enrolled in these studies. No patients with disease in the tumour phase were treated.<sup>15</sup>

- **CTCL 1** permitted prednisone up to 10 mg/day in addition to topical steroids<sup>15</sup>
- **CTCL 2** was a 5-year post-approval follow-up to evaluate long-term safety and had no concomitant medication restriction<sup>15</sup>
- **CTCL 3, the clinical trial using UVADEX<sup>15,26,a</sup>**
  - Patients had difficult-to-treat disease<sup>b</sup> and were on an average of 4.3 prior therapies
  - *There are no data available regarding the efficacy of UVADEX in patients with disease in the tumour phase*
  - Patients were only permitted to use topical steroids for the treatment of fissures on the soles of the feet and palms of the hands (all other steroids, topical or systemic, were prohibited)

### In CTCL 3:

- Of the 17 responses, 15 were observed within 6 months and 2 after 6 months<sup>15</sup>
- Clinical experience does not extend beyond this treatment duration, and there is no evidence to show that treatment with UVADEX beyond 6 months, or using a different schedule, provided additional benefit<sup>15</sup>

<sup>a</sup>UVADEX formulation of methoxsalen and the UVAR Photopheresis System. UVAR is no longer manufactured and was replaced by THERAKOS® CELLEX® Photopheresis System.

<sup>b</sup>Defined as exhibiting progressive disease during the prior year.<sup>26</sup>

GIVEN THE CHRONIC NATURE OF CTCL SKIN SYMPTOMS,  
**Safety and tolerability are important  
considerations when choosing treatments<sup>5,7</sup>**



**Please remind patients to wear UVA-absorbing, wraparound sunglasses; cover exposed skin or use a sunblock; and avoid all exposure to sunlight for 24 hours following their Photopheresis treatment.<sup>15</sup>**

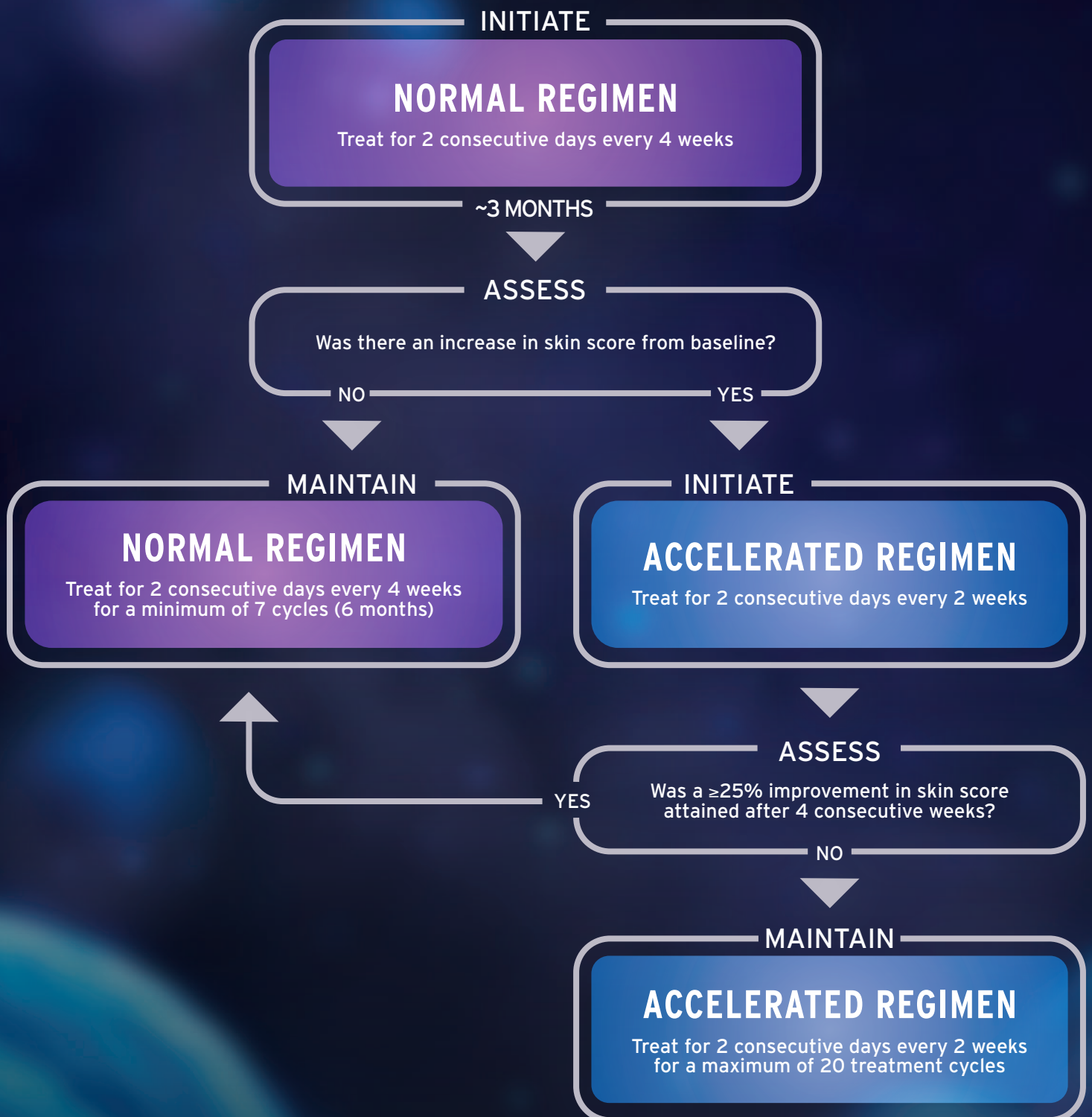
## **THERAKOS® PHOTOPHERESIS HAS BEEN IN THE MARKET FOR 35 YEARS WITH AN ESTABLISHED SAFETY PROFILE<sup>5,15</sup>**

- **Adverse events (AEs)** in clinical trials were primarily related to hypotension secondary to changes in ECV (>1%)
- In the UVADEX® (methoxsalen) clinical trial CTCL 3 (N=51):
  - 6 serious cardiovascular AEs (5 unrelated to Photopheresis) were reported in 5 patients (10%)
  - 6 infections were also reported in 5 patients
    - 2 were Hickman catheter infections in 1 patient
    - 4 infections were not related to Photopheresis
- Adverse reactions reported from postmarketing experience included nausea, dysgeusia, photosensitivity reaction, pyrexia, and hypersensitivity reactions, including anaphylaxis and rash



**Practicing proper infection control is critical to mitigating the potential for infection.**

# THERAKOS® Photopheresis treatment regimen<sup>15</sup>



## Additional dosing considerations<sup>15</sup>

- Patients in the clinical study who were unresponsive to the normal treatment schedule were placed on the accelerated schedule and reassessed for response. The 3-month patient assessment can help inform whether to adjust the treatment schedule if indicated
- Treatment schedule may vary based on individual response and the discretion of the healthcare provider
- There is no evidence to show that treatment with UVADEX beyond 6 months or using a different schedule provided additional benefit, and clinical experience does not extend beyond this treatment frequency

# THERAKOS® Photopheresis is available at centres across Canada

## Independent treatment centres' support teams can complement your care

Based on your referral, treatment centre staff will work with your patient to schedule an intake evaluation and treatments.

THERAKOS Photopheresis is available worldwide at

➤ **300** TREATMENT  
CENTERS in  
➤ **30** COUNTRIES<sup>27</sup>

THERAKOS ECP EDGE

# Access and Funding Information

## Practical tools and guidance to help support access to THERAKOS® ECP

From budget impact models to tailored pricing, Therakos offers custom support for your clinic.



### Directly supporting your funding and reimbursement efforts with:

- Comprehensive business cases and financial impact models
- Transferable budget impact data that may demonstrate cost offsets
- Submission information to support coverage requests



### Flexible pricing plans created with Canadian hospitals in mind:

- Fixed kit pricing based on prior-year volume
- 12-month pricing with discounts defined by volume thresholds
- Pricing options to support predictable budgeting, even as patient needs grow



### Support models designed to fit your environment:

- Four service model options
- Single- and multi-year contracts for added flexibility
- Evaluation program offering a one-year trial of CELLEX® at no additional cost, including full service throughout the trial period



# Important Safety Information

## **INDICATIONS**

UVADEX® (methoxsalen) Sterile Solution is indicated for extracorporeal administration with the THERAKOS® CELLEX® Photopheresis Systems in the palliative treatment of the skin manifestations of Cutaneous T-Cell Lymphoma (CTCL) that is unresponsive to other forms of treatment.

- There is no clinical evidence to show that treatment with UVADEX beyond six months provides additional benefit if the patient has not responded within this timeframe.
- Not authorized for use pediatric or geriatric use.

Read the THERAKOS CELLEX Photopheresis Systems Operator's Manual before administering the treatment.

## **CONTRAINDICATIONS**

UVADEX is contraindicated in patients:

- Hypersensitive to this drug or any ingredient in the formulation
- Possessing a specific history of a light-sensitive disease state, such as lupus erythematosus, porphyria cutanea tarda, erythropoietic protoporphyria, variegate porphyria, xeroderma pigmentosum, and albinism
- With aphakia, because of the significantly increased risk of retinal damage due to the absence of lenses
- With severe cardiac disease, severe anemia, white blood cell count greater than 25,000/mm<sup>3</sup>, previous splenectomy, and coagulation disorders
- With coexisting melanoma, basal cell, or squamous cell skin carcinoma

## **SERIOUS WARNINGS AND PRECAUTIONS**

**Carcinogenicity:** Oral administration of methoxsalen followed by cutaneous UVA exposure (PUVA therapy) is carcinogenic. Because the dose of methoxsalen with UVADEX therapy is about 200 times less than with PUVA and the skin is not exposed to high cumulative doses of UVA light, the risk of developing skin cancer following UVADEX therapy may be lower

**Mutagenicity:** Methoxsalen causes DNA damage, interstrand cross-links, and errors in DNA repair

**Teratogenicity:** Methoxsalen may cause fetal harm when given to a pregnant woman. Both men and women who are being treated with UVADEX should take adequate contraceptive precautions both during and after completion of Photopheresis therapy

**Cataractogenicity:** Patients should be told emphatically to wear UVA-absorbing, wraparound sunglasses for 24 hours after UVADEX treatment. They should wear these glasses any time they are exposed to direct or indirect sunlight, whether they are outdoors or exposed through a window

**Skin Burning:** Serious burns from either UVA or sunlight (even through window glass) can result if the recommended dosage of methoxsalen is exceeded or precautions are not followed. Patients should cover exposed skin or use sunblock (SPF 15 or higher) for 24 hours following treatment with methoxsalen, whether exposed to direct or indirect sunlight outdoors or through a window.

## **FOR MORE INFORMATION**

**See product monograph for UVADEX at [health-products.canada.ca/dpd-bdpp/](http://health-products.canada.ca/dpd-bdpp/) for important information relating to adverse reactions, drug interactions, and dosing information which have not been discussed in this piece, and the appropriate THERAKOS CELLEX Photopheresis System Operator's Manual. The product monograph is also available by calling 1-833-223-4ECP (1-833-223-4327).**

## Important Safety Information for THERAKOS® CELLEX® Photopheresis Procedure

### **INDICATION**

The THERAKOS® CELLEX® Photopheresis System is indicated for use in the ultraviolet-A (UVA) irradiation, in the presence of the photoactive drug 8-methoxypsoralen (8-MOP), of extracorporeally circulating leukocyte-enriched blood, in the palliative treatment of the skin manifestations of cutaneous T-cell lymphoma (CTCL).

### **CONTRAINDICATIONS**

Certain underlying medical conditions contraindicate THERAKOS CELLEX Photopheresis, including:

- Patients who cannot tolerate extracorporeal volume loss during the leukocyte enrichment phase
- Patients exhibiting idiosyncratic or hypersensitivity reactions to 8-methoxypsoralen/psoralen compounds
- Patients with coagulation disorders or who have had previous splenectomy

### **WARNINGS AND PRECAUTIONS**

THERAKOS CELLEX Photopheresis treatments should always be performed in locations where standard medical emergency equipment is available. Volume replacement fluids and/or volume expanders should be readily available throughout the procedure.

- **MR-Unsafe:** Do not expose the device to a magnetic resonance (MR) environment. The device may present a risk of projective injury, and thermal injury and burns may occur. The device may generate artifacts in the MR image, or may not function properly.
- **Thromboembolic Events:** Thromboembolic events, including pulmonary embolism and deep vein thrombosis, have been reported in the treatment of Graft versus Host Disease (GvHD), an indication not approved in Canada. Special attention to adequate anticoagulation is advised when treating patients with GvHD.
- **Concomitant Therapy:** When prescribing and administering THERAKOS CELLEX Photopheresis for patients receiving concomitant therapy, exercise caution when changing treatment schedules to avoid increased disease activity that may be caused by abrupt withdrawal of previous therapy.

### **ADVERSE REACTIONS**

Hypotension may occur during any treatment involving extracorporeal circulation. Monitor the patient closely during the entire treatment.

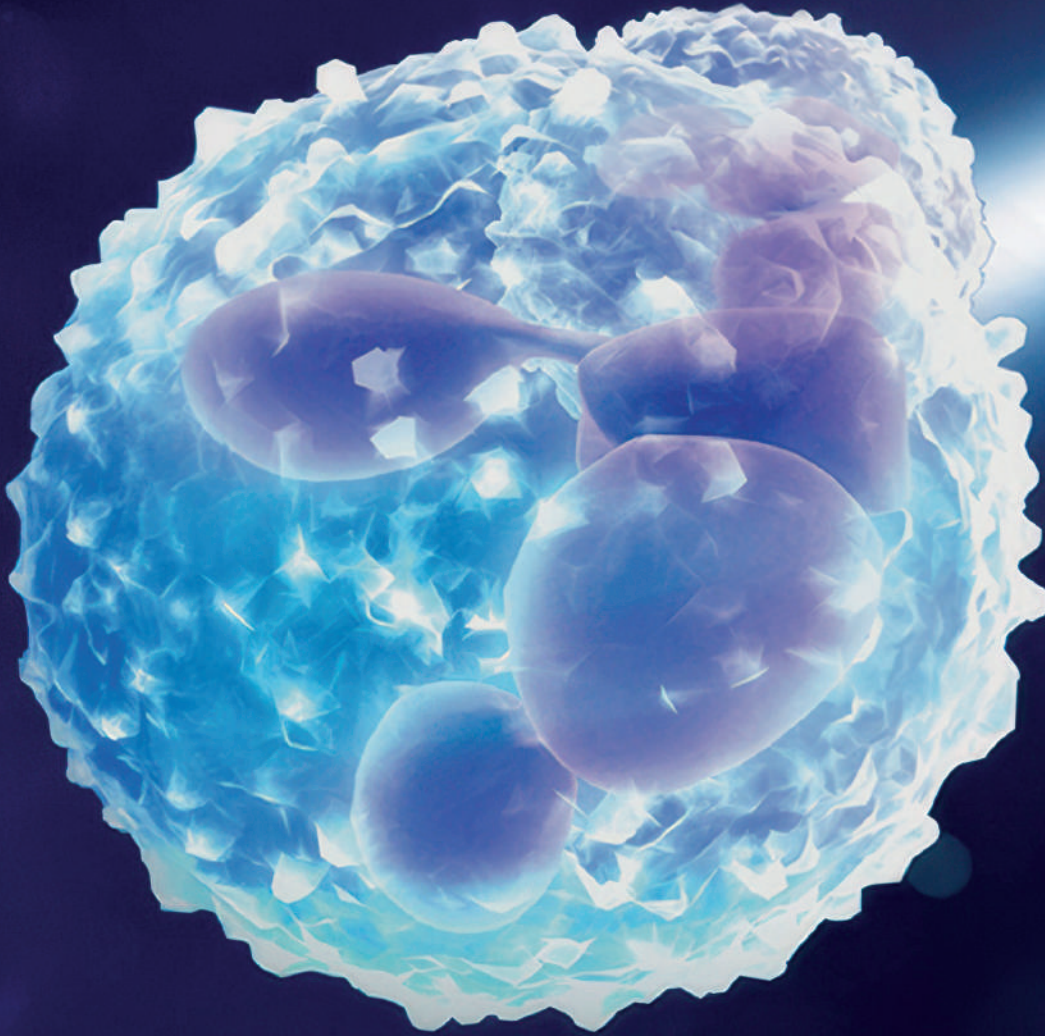
Transient pyretic reactions, 37.7-38.9°C (100-102°F), have been observed in some patients within 6-8 hours of reinfusion of the photoactivated leukocyte-enriched blood. A temporary increase in erythroderma may accompany the pyretic reaction.

Treatment frequency exceeding labeling recommendations may result in anemia.

Venous access carries a small risk of infection and pain.

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# REIMAGINE IMMUNOTHERAPY<sup>1-3</sup>

Activate the system, target the disease<sup>3,4</sup>

- **CTCL is a rare**, chronic disease characterized by burdensome skin symptoms<sup>5</sup>
- THERAKOS<sup>®</sup> Photopheresis is **an ECP system indicated for the treatment of skin symptoms** associated with CTCL that are unresponsive to other forms of treatment<sup>13,15</sup>
- ECP is **recommended by multiple international guidelines** as a treatment option for certain patients with CTCL<sup>5,7</sup>
- THERAKOS Photopheresis has an **established safety profile** and can deliver a meaningful clinical response<sup>15</sup>
- THERAKOS Photopheresis is **widely covered and available at centres across Canada**
- **Information and assistance are available to help support educating your patients** on THERAKOS Photopheresis

Please see the Important Safety Information on pages 17-18

Discover the Therakos Healthcare Professional website

