

POLICY AND PROCEDURE

POLICY NUMBER: *RX.PA.206.E*REVISION DATE: *10/17*

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POLICY TITLE: *Methoxsalen (Oxsorelen, Oxsorolen-Ultra)*
DEPARTMENT: *Clinical Pharmacy Services- Utilization Management*
ORIGINAL DATE: *September 2013 (as adopted from UPMC Health Plan)*

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	<input type="checkbox"/> HMO <input type="checkbox"/> PPO <i>Products:</i> <input type="checkbox"/> Small <i>Exchange:</i> <input type="checkbox"/> Shop <input checked="" type="checkbox"/> All <input type="checkbox"/> Indiv. <input type="checkbox"/> Indiv. <input type="checkbox"/> Large
OTHER	<input checked="" type="checkbox"/> Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Methoxsalen (Oxsorelen, Oxsorolen-Ultra).

Methoxsalen (Oxsorolen-Ultra) soft gelatin capsules are indicated for:

- Symptomatic control of severe, recalcitrant, disabling psoriasis not adequately responsive to other forms of therapy and when the diagnosis has been supported by biopsy
- Methoxsalen is intended to be administered only in conjunction with a schedule of controlled doses of long wave ultraviolet radiation

Methoxsalen (Oxsorelen) 1% topical solution is indicated as a topical repigmenting agent in vitiligo in conjunction with controlled dose of ultraviolet A (320-400nm) or sunlight.

DEFINITIONS

UVAR- a photophoresis system used for treatment of cutaneous T-cell lymphoma

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Methoxsalen (Oxsorelen, Oxsorolen-Ultra), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

1. Psoriasis:

- Must be prescribed by a dermatologist
- Must have a diagnosis of severe, recalcitrant, disabling psoriasis confirmed by biopsy
- Must have an adequate trial of topical treatments with an inadequate response, significant side effects /toxicity, or have a contraindication to these therapies
- Must be used in conjunction with ultraviolet A (UVA) light therapy

2. Cutaneous T-cell lymphoma:

- Must be prescribed by a dermatologist or an oncologist
- Must have a diagnosis of cutaneous T-cell lymphoma
- Must use methoxsalen (8-MOP) hard gelatin capsule dosage formulation with UVAR system

Diagnoses not covered:

- The following diagnosis is considered cosmetic and therefore is not covered:
 - Vitiligo

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 6 months
Reauthorization	Up to 1 year

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. 2. Oxsoalolen-Ultra Capsules [prescribing information]. Aliso Viejo, CA: Valeant Pharmaceuticals. December 2009.
2. 3. Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. *J Am Acad Dermatol.* 2008;58:826-850.
3. 4. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. *J Am Acad Dermatol.* 2008;1-17.
4. 5. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: Case-based presentations and evidence-based conclusions. *J Am Acad Dermatol.* 2011; 65:137-74.

RECORD RETENTION

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Methoxsalen (8-MOP, Oxsorelen, Oxsorolen-Ultra)

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REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
<i>Annual review</i>	<i>02/16, 02/17, 02/18</i>
<i>Removal of 8-MOP</i>	<i>10/17</i>

