

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

## Oxsoralen-Ultra (methoxsalen)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Oxsoralen-Ultra (methoxsalen capsules)

### APPROVAL CRITERIA

Requests for Oxsoralen-Ultra (methoxsalen) may be approved if the following criteria are met:

- I. Individual has a diagnosis of severe, recalcitrant, disabling psoriasis; **AND**
- II. Individual is not adequately responsive to other forms of therapy; **AND**
- III. Methoxsalen is used in conjunction with a schedule of controlled doses of long wave ultraviolet radiation;

#### **OR**

- IV. Individual has a diagnosis of idiopathic vitiligo (AHFS); **AND**
- V. Methoxsalen is used in conjunction with a schedule of controlled doses of long wave ultraviolet radiation or sunlight;

#### **OR**

- VI. Individual has a diagnosis of the skin manifestations of cutaneous T-cell lymphoma, such as but not limited to Mycosis Fungoides and Sezary Syndrome(NCCN 2A); **AND** Methoxsalen is used in conjunction with ultraviolet-A (as a component of PUVA).

#### **Note:**

Methoxsalen has a black box warning that concurrent use with UV radiation should only be used by physicians who have special competence in diagnosis and treatment of psoriasis and vitiligo and who have special training and experience in photochemotherapy. Photochemotherapy should be restricted to individuals with severe, recalcitrant, disabling psoriasis which is not adequately responsive to other forms of therapy, and only when the diagnosis is certain. Risks of therapy include ocular damage, aging of the skin, and skin cancer (including melanoma). The soft gelatin capsules (Oxsoralen-Ultra) should not be used interchangeably with regular hard

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gelatin capsules (8-MOP) due to greater bioavailability and earlier photosensitization onset time of the newer soft gelatin capsule dosage form.

**Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: January 15, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
5. Elmetts CA, Lim HW, Stoff B, et. Al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with phototherapy. *J Am Acad Dermatol*. 2019; 81(3): 775-804.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on January 15, 2020.
  - a. Primary Cutaneous Lymphomas. V1.2020. Revised January 6, 2020.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.