

Market Applicability													
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

Methoxsalen

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
8-MOP (methoxsalen capsules)** Oxsoralen-Ultra (methoxsalen capsules)

**8-MOP was discontinued by the manufacturer as of 11-2016. Criteria will remain active as claims can adjudicate up to 3 years after agent discontinuation.

APPROVAL CRITERIA

Requests for methoxsalen capsules (8-MOP**, Oxsoralen-Ultra) may be approved if the following criteria are met:

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

OR

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

OR

- VII. Individual has a diagnosis of the skin manifestations of cutaneous T-cell lymphoma, such as but not limited to Mycosis Fungoides and Sezary Syndrome^; **AND**
- VIII. Methoxsalen is used in conjunction with photopheresis with the UVAR instrument; **AND**
- IX. Individual has not been responsive to other forms of treatment.

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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.

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Applicable	X	X	NA	NA	X	X	X	X	X	X	NA	NA	X

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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 gelatin capsules (8-MOP) due to greater bioavailability and earlier photosensitization onset time of the newer soft gelatin capsule dosage form. *Indication is FDA-approved for 8-MOP. Accepted off-label (AHFS) indication for Oxsoralen-Ultra.

^Indication is FDA-approved for 8-MOP. Accepted off-label (DrugPoints B IIb) indication for Oxsoralen-Ultra.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. 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, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
5. Menter A, Korman NJ, Elmetts CA, et. al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 5. Guidelines of care for the treatment of psoriasis with phototherapy and photochemotherapy. J Am Acad Dermatol. 2009; 62(1):114-135

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