Market Applicability/Effective Date														
Market	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	NA	NA	X	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**
   A. Not adequately responsive to other forms of therapy; **AND**
   B. The diagnosis has been supported by biopsy; **AND**
   C. Used in conjunction with a schedule of controlled doses of long wave ultraviolet radiation

OR

II. Individual has a diagnosis of idiopathic vitiligo*; **AND**
III. Used in conjunction with a schedule of controlled doses of long wave ultraviolet radiation [AHFS]

OR

IV. 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**
   A. Used in conjunction with photopheresis with the UVAR® instrument; **AND**
   B. Have not been responsive to other forms of treatment [Drug Dex, NCCN]

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

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

*FHK- Florida Healthy Kids

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 (NCCN 2A, DrugPoints BIIb) indication for Oxsoralen-Ultra.

Note: Edit applies to New Starts ONLY

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

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. URL: http://www.clinicalpharmacology.com. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed January 30, 2017.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2017; Updated periodically.