

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

## Isotretinoin Agents

Override(s)	Approval Duration <sup>1</sup>
Prior Authorization Quantity Limit	5 months

Medications	Comments	Quantity Limit
Claravis (isotretinoin)	Preferred	30 day supply per fill
Myorisan (isotretinoin)	Preferred	
Zenatane (isotretinoin)	Preferred	
Absorica (isotretinoin)	Non-Preferred	
Amnesteem (isotretinoin)*	Non-Preferred	

\*Amnesteem was discontinued by the manufacturer as of 03-11-2016. Utilization management clinical programs will remain active as claims can adjudicate up to 3 years after agent discontinuation.

### APPROVAL CRITERIA

Requests for oral isotretinoin agents may be approved if the following criteria are met:

- I. Individual has a diagnosis of severe, recalcitrant, nodular acne; **AND**
- II. Individual has had a prior trial and inadequate response to conventional therapy of at least one topical<sup>2</sup> and one systemic antibiotic<sup>3</sup> acne treatment;

**OR**

- III. Individual has a diagnosis of severe, refractory, papulopustular rosacea (DrugPoints B IIa, Del Rosso et al. 2014);

**OR**

- IV. Individual has a diagnosis of mild-to-moderate acne (DrugPoints A IIa); **AND**
- V. Individual has had a prior trial and inadequate response to conventional therapy of at least one topical<sup>2</sup> and one systemic antibiotic<sup>3</sup> acne treatment;

**OR**

- VI. Individual has a diagnosis of psoriasis(AAD2011, AHFS); **AND**
- VII. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional<sup>4</sup> therapy (AAD 2011); **AND**
- VIII. Individual is using for one of the following:

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- A. To control pustulation and systemic symptoms associated with pustular psoriasis (AHFS); **OR**
- B. In combination with psoralen and UVA light (PUVA therapy) for severe psoriasis (AHFS); **OR**
- C. In combination with a biologic agent for chronic plaque psoriasis (AAD 2011);

**OR**

- IX. Individual has a diagnosis of mycosis fungoides (MF)/Sezary syndrome (SS) (NCCN 2A);

**OR**

- X. Individual is considered high-risk (such as, immunosuppressed) and using as prophylaxis to reduce the development of pre-cancers (such as, actinic keratosis) and non-melanoma skin cancers (such as, basal and squamous cell) (NCCN 2A);

**AND**

- XI. If the request is for Absorica or Amnesteem\*, the following criterion must be met in addition to the above approval criteria for all agents:
  - A. Individual has had a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one preferred agent.

**Note:**

1. Per label, a single course of therapy for 15 to 20 weeks has been shown to result in complete and prolonged remission of disease. If a second course of therapy is needed, it should not be initiated until at least 8 weeks after completion of the first course.
2. Conventional topical acne treatments may include, but not limited to the following: Benzoyl peroxide, salicylic acid, sulfur preparations, clindamycin, erythromycin, retinoids (adapalene, tretinoin, tazarotene), Aczone, Azelex.
3. Conventional systemic antibiotic acne treatments may include, but not limited to the following: Tetracycline, minocycline, and doxycycline,.
4. Conventional psoriasis treatments may include, but not limited to the following: Phototherapy (UVB, UVA), acitretin, cyclosporine, methotrexate, biologic agents (such as TNF antagonists, Stelara, Otezla) (AAD 2011).
5. Oral Isotretinoin products have a black box warning for birth defects. Isotretinoin must not be used by female individuals who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking any amount of isotretinoin. There is an increased risk of spontaneous abortions and premature births. If pregnancy does occur during treatment of a female individual who is

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taking isotretinoin, therapy must be discontinued immediately, and she should be referred to an Obstetrician-Gynecologist experienced in reproductive toxicity for further evaluation and counseling. Because of the risk of teratogenicity, isotretinoin is available only through a special restricted distribution program called iPLEDGE™. The prescriber, individual, and pharmacy must be registered and meet all of the requirements of iPLEDGE™ before distribution.

### **QUANTITY LIMIT**

Major fetal abnormalities have been documented in women using isotretinoin. The FDA requires isotretinoin to be prescribed under the iPLEDGE™ program. Prescribers and individuals complete qualifying forms and tests prior to using isotretinoin.

To help ensure compliance with the iPLEDGE™ program, Anthem’s Pharmacy and Therapeutic committee has approved the following:

- I. Maximum 30 day supply of isotretinoin/fill; **AND**
- II. No refills allowed

The Food and Drug Administration requires the parameters. No over-ride permitted.

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

### **Key References:**

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Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2016. 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>.

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

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2016; Updated periodically.

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