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

Isotretinoin Agents

Override(s)	Approval Duration[1]
Prior Authorization Quantity Limit	5 months

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

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[2] and one systemic antibiotic[3] acne treatment;

OR

III. Individual has a diagnosis of severe, refractory, papulopustular rosacea (DrugPoints B IIa, Del Rosso et al. 2014, Schaller et al. 2016);

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[2] and one systemic antibiotic[3] 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[4] therapy (AAD 2011); **AND**

Market Applicability							
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Applicable	X	X	X	X	X	X	NA

VIII. Individual is using for one of the following:
   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

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, 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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Applicable	X	X	X	X	X	X	NA

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.

Key References:

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

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: http://www.clinicalpharmacology.com. Updated periodically.
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3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. Del Rosso JQ, Thiboutot D, Gallo R, et al. Consensus Recommendations From the American Acne & Rosacea Society on the Management of Rosacea, Part 2: A Status Report on Topical Agents. *Cutis.* 2013; 92: 277-284. Available at: http://www.mdedge.com/cutis/article/79250/rosacea/consensus-recommendations-american-acne-rosacea-society-management/pdf.
6. Del Rosso JQ, Thiboutot D, Gallo R, et al. Consensus Recommendations From the American Acne & Rosacea Society on the Management of Rosacea, Part 5: A Guide on the Management of Rosacea. *Cutis.* 2014; 93: 18-28. Available at: http://www.mdedge.com/cutis/article/80829/rosacea/consensus-recommendations-american-acne-rosacea-society-management/pdf.
7. Del Rosso JQ, Thiboutot D, Gallo R, et al. Consensus Recommendations From the American Acne & Rosacea Society on the Management of Rosacea, Part 3: A Status Report on Systemic Therapies. *Cutis.* 2014; 93: 134-138.
8. Schaller M, Almedia LMC, Bewley A., et.al. Rosacea treatment update: recommendations from the global ROSacea Consensus (ROSCO) PANEL. *British Journal of Dermatology*. 2017; 176: 465-471. Available from: https://onlinelibrary.wiley.com/doi/full/10.1111/bjd.15173.
9. The NCCN Drugs & Biologics Compendium (NCCN Compendium™)© 2018 National Comprehensive Cancer Network, Inc. Available at: NCCN.org. Updated periodically.
10. Zaenglein AL, Pathy AL, Schlosser BJ, Alikhan A, Baldwin HE, Berson DS, et al. Guidelines of care for the management of acne vulgaris. *J Am Acad Dermatol*. 2016; 74:945-73. Available from: https://www.aad.org/practice-tools/quality-care/clinical-guidelines/acne.

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.