



## MEDICATION POLICY

**Generic Name:** Isotretinoin

**Therapeutic Class or Brand Name:** Isotretinoin Products

**Applicable Drugs** (if Therapeutic Class):

Preferred: Amnesteem®, Myorisan™, Zenatane™

Non-Preferred: Absorica®, Claravis™

**Date of Origin:** 2/1/13

**Date Last Reviewed/Revised:** 12/1/17

**GPI Code:** 9005001300

### **Prior Authorization Criteria (may be considered medically necessary when criteria I through VI are met):**

- I. Documented diagnosis of moderate to severe, scarring, and/or refractory acne.
- II. Patient must be registered with and meet all of the requirements of the iPLEDGE program.
- III. History of treatment failure, intolerance, or contraindication with at least two of the following A through D:
  - A. One topical retinoid (i.e. adapalene, tretinoin).
  - B. Benzoyl peroxide.
  - C. One topical antibiotic (i.e. clindamycin, erythromycin).
  - D. One oral antibiotic (i.e. tetracycline, doxycycline, minocycline, erythromycin).
- IV. Prescriber must be a dermatologist and must be registered and activated with the iPLEDGE program.
- V. Minimum age requirement: 12 years old.
- VI. Non-preferred products (Absorica® and Claravis™) also require a history of treatment failure, intolerance, or contraindication to at least two preferred Isotretinoin products.

### **Exclusion Criteria:**

- Pregnancy.

### **Other Criteria:**

- N/A

### **Quantity/Days Supply Restrictions:**

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- Quantities of up to 60 tablets per 30 days.

### Approval Length:

- **Authorization:** 5 months.
- **Re-Authorization:** One additional 5 month approval may be granted after one failure of isotretinoin AND a minimum of at least 8 weeks has passed since the patient completed their first course of isotretinoin therapy.

### Appendix:

N/A

### References:

1. [http://pediatrics.aappublications.org/content/131/Supplement\\_3/S163.full.pdf](http://pediatrics.aappublications.org/content/131/Supplement_3/S163.full.pdf).
2. <http://www.aad.org/File%20Library/Global%20navigation/Education%20and%20quality%20care/Guidelines-Acne-Vulgaris.pdf>.
3. <https://www.aad.org/practicecenter/quality/clinical-guidelines/acne>.
4. [https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Pharmacy%20Resources/PA\\_Notification\\_Absorica.pdf](https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Pharmacy%20Resources/PA_Notification_Absorica.pdf).
5. Medi-Span.
6. <http://dailymed.nlm.nih.gov/dailymed/getFile.cfm?setId=b2cb63c9-f825-4991-9a2c-6260f1bbcc2c>.
7. <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=a31fd109-d0fd-4ab9-ba98-a3d64333c18d>.
8. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=51ff6346-9256-4c01-9f52-417d13f2df05>.
9. <http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=27b3cf26-f22e-5b70-1c24-009933b7c6ee>.
10. [http://absorica.com/pdf/Absorica\\_PI\\_September\\_2015.pdf](http://absorica.com/pdf/Absorica_PI_September_2015.pdf).

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<b>Historical Tracking Of Changes Made To Policy</b>	
12/1/2017	<ol style="list-style-type: none"> <li>1. <b>Changed</b> "I. Documented diagnosis of severe, scarring, and/or refractory acne" to "I. Documented diagnosis of moderate to severe, scarring, and/or refractory acne" <b>under Prior Authorization Criteria.</b></li> <li>2. <b>Added</b> "<a href="https://www.aad.org/practicecenter/quality/clinical-guidelines/acne">https://www.aad.org/practicecenter/quality/clinical-guidelines/acne</a>" <b>under References.</b></li> <li>3. <b>Removed</b> "<a href="https://www.optumrx.com/rxsol/live/PAGDocs/Guideline_7300.pdf">https://www.optumrx.com/rxsol/live/PAGDocs/Guideline_7300.pdf</a>" <b>under References</b> (link no longer valid).</li> <li>4. <b>Updated</b> "<a href="http://absorica.com/Absorica_PI_September_2015.pdf">http://absorica.com/Absorica_PI_September_2015.pdf</a>" to "<a href="http://absorica.com/pdf/Absorica_PI_September_2015.pdf">http://absorica.com/pdf/Absorica_PI_September_2015.pdf</a>" <b>under References.</b></li> </ol>
9/22/2016	<ol style="list-style-type: none"> <li>1. <b>Updated</b> "<a href="https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Pharmacy%20Resources/Notification_Absorica.pdf">https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Pharmacy%20Resources/Notification_Absorica.pdf</a>" to "<a href="https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Pharmacy%20Resources/PA_Notification_Absorica.pdf">https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Pharmacy%20Resources/PA_Notification_Absorica.pdf</a>", "<a href="http://www.akorn.com/documents/catalog/package_inserts/61748-304-13.pdf">http://www.akorn.com/documents/catalog/package_inserts/61748-304-13.pdf</a>" to "<a href="https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=51ff6346-9256-4c01-9f52-417d13f2df05">https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=51ff6346-9256-4c01-9f52-417d13f2df05</a>", <b>and</b> "<a href="http://www.absorica.com/images/absorica_pi.pdf">http://www.absorica.com/images/absorica_pi.pdf</a>" to "<a href="http://absorica.com/Absorica_PI_September_2015.pdf">http://absorica.com/Absorica_PI_September_2015.pdf</a>" <b>under References.</b></li> </ol>
3/6/2015	<ol style="list-style-type: none"> <li>1. <b>Changed</b> "Preferred (branded generics): Amnesteem®, Myorisan™, Zenatane™.; Non-Preferred: Absorica® and Claravis™." to "Preferred: Amnesteem®, Myorisan™, Zenatane™; Non-Preferred: Absorica®, Claravis™" <b>under Applicable Drugs.</b></li> <li>2. <b>Changed</b> "N/A" to "Pregnancy" <b>under Exclusion Criteria.</b></li> <li>3. <b>Updated</b> "<a href="https://www.oxhp.com/secure/policy/absorica_accutane_isotretinoin.pdf">https://www.oxhp.com/secure/policy/absorica_accutane_isotretinoin.pdf</a>" to "<a href="https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Pharmacy%20Resources/Notification_Absorica.pdf">https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Pharmacy%20Resources/Notification_Absorica.pdf</a>", "<a href="http://www.mylanpharms.com/assets/mylan-pharms/pdfs/ISOT-R1.pdf">http://www.mylanpharms.com/assets/mylan-pharms/pdfs/ISOT-R1.pdf</a>" to "<a href="http://dailymed.nlm.nih.gov/dailymed/getFile.cfm?setId=b2cb63c9-f825-4991-9a2c-6260f1bbcc2c">http://dailymed.nlm.nih.gov/dailymed/getFile.cfm?setId=b2cb63c9-f825-4991-9a2c-6260f1bbcc2c</a>", "<a href="https://www.ipledgeprogram.com/Documents/Barr%20Claravis%20Package%20InsertI.pdf">https://www.ipledgeprogram.com/Documents/Barr%20Claravis%20Package%20InsertI.pdf</a>" to "<a href="http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=a31fd109-d0fd-4ab9-ba98-a3d64333c18d">http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=a31fd109-d0fd-4ab9-ba98-a3d64333c18d</a>", "<a href="http://www.versapharm.com/media/productinserts/myorisan_pi.pdf">http://www.versapharm.com/media/productinserts/myorisan_pi.pdf</a>" to "<a href="http://www.akorn.com/documents/catalog/package_inserts/61748-304-13.pdf">http://www.akorn.com/documents/catalog/package_inserts/61748-304-13.pdf</a>", <b>and</b> "<a href="https://www.ipledgeprogram.com/Documents/Zenatane_USPI_FullSizeFont_Jan2013.pdf">https://www.ipledgeprogram.com/Documents/Zenatane_USPI_FullSizeFont_Jan2013.pdf</a>" to "<a href="http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=27b3cf26-f22e-5b70-1c24-009933b7c6ee">http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=27b3cf26-f22e-5b70-1c24-009933b7c6ee</a>" <b>under References.</b></li> <li>4. <b>Removed</b> "<a href="https://www.ipledgeprogram.com/Documents/Ranbaxy%20Sotret%20Package%20InsertI.pdf">https://www.ipledgeprogram.com/Documents/Ranbaxy%20Sotret%20Package%20InsertI.pdf</a>" <b>from References.</b></li> </ol>

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### *Historical Tracking Of Changes Made To Policy*

2/11/2014	<ol style="list-style-type: none"><li>1. <b>Adapted policy to new format.</b></li><li>2. <b>Added</b> “Absorica”, “Myorisan”, and “Zenatane” <b>to Applicable Drugs.</b> Listed “Absorica” and “Claravis” under “Non-preferred”, and listed all other products under “Preferred (branded generics)”.</li><li>3. <b>Removed</b> “Sotret” <b>under Applicable Drugs.</b></li><li>4. <b>Added GPI code.</b></li><li>5. <b>Changed covered diagnosis from:</b> “severe recalcitrant nodular acne” <b>to</b> “severe, scarring, and/or refractory acne”.</li><li>6. <b>Changed wording under criterion III from:</b> “Documented trial and failure of, or contraindication to, at least two of the following” <b>to</b> “History of treatment failure, intolerance, or contraindication with at least two of the following”.</li><li>7. <b>Added</b> “Non-preferred products (Absorica® and Claravis™) also require a history of treatment failure, intolerance, or contraindication to at least two preferred Isotretinoin products” <b>requirement.</b></li><li>8. <b>Changed wording under “Re-Authorization” from:</b> “An additional 5 month approval...” <b>to</b> “One additional 5 month approval...”.</li><li>9. <b>Updated references</b> to include evidence-based guidelines, current policy, Medi-Span, and package inserts for all Isotretinoin Products.</li></ol>
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