

Generic Name: Isotretinoin

Therapeutic Class or Brand Name:

Amnesteem®, Myorisan™ Zenatane™,
Absorica®, Claravis™

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 9005001300

Preferred: Isotretinoin

Non-preferred: Absorica®, Claravis™,
Amnesteem®, Myorisan™ Zenatane™

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 1/16/2020

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

- Quantities of up to 60 capsules 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.
2. <https://www.aad.org/practicecenter/quality/clinical-guidelines/acne>.
3. Medi-Span.
4. <http://dailymed.nlm.nih.gov/dailymed/getFile.cfm?setId=b2cb63c9-f825-4991-9a2c-6260f1bbcc2c>.
5. <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=a31fd109-d0fd-4ab9-ba98-a3d64333c18d>.
6. <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=51ff6346-9256-4c01-9f52-417d13f2df05>.
7. <http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=27b3cf26-f22e-5b70-1c24-009933b7c6ee>.
8. http://absorica.com/pdf/Absorica_PI_September_2015.pdf.

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
1/16/2020	<ol style="list-style-type: none"> 1. Changed preferred product to "Isotretinoin" and moved "Amnesteem®, Myorisan™ Zenatane™" Non-Preferred. 2. Deleted "https://www.uhcprovider.com/content/provider/en/viewer.html?file=%2Fcontent%2Fdam%2Fprovider%2Fdocs%2Fpublic%2Fprior-auth%2Fdrugs-pharmacy%2Fcommercial%2Fa-g%2FCOMM-PA-Notification-Absorica.pdf." Under References.
8/13/2018	<ol style="list-style-type: none"> 1. Deleted "http://www.aad.org/File%20Library/Global%20navigation/Education%20and%20quality%20care/Guidelines-Acne-Vulgaris.pdf." due to invalid link and Added https://www.aad.org/practicecenter/quality/clinical-guidelines/acne." And Deleted "https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Pharmacy%20Resources/PA_Notification_Absorica.pdf" (no longer valid) and Added https://www.uhcprovider.com/content/provider/en/viewer.html?file=%2Fcontent%2Fdam%2Fprovider%2Fdocs%2Fpublic%2Fprior-auth%2Fdrugs-pharmacy%2Fcommercial%2Fa-g%2FCOMM-PA-Notification-Absorica.pdf
12/1/2017	<ol style="list-style-type: none"> 1. Changed "I. Documented diagnosis of severe, scarring, and/or refractory acne" to "I. Documented diagnosis of moderate to severe, scarring, and/or refractory acne" under Prior Authorization Criteria. 2. Added "https://www.aad.org/practicecenter/quality/clinical-guidelines/acne" under References. 3. Removed "https://www.optumrx.com/rxsol/live/PAGDocs/Guideline_7300.pdf" under References (link no longer valid). 4. Updated "http://absorica.com/Absorica_PI_September_2015.pdf" to "http://absorica.com/pdf/Absorica_PI_September_2015.pdf" under References
9/22/2016	<ol style="list-style-type: none"> 1. Updated "https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Pharmacy%20Resources/Notification_Absorica.pdf" to "https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Pharmacy%20Resources/PA_Notification_Absorica.pdf", "http://www.akorn.com/documents/catalog/package_inserts/61748-304-13.pdf" to "https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=51ff6346-9256-

	<p>4c01-9f52-417d13f2df05", and "http://www.absorica.com/images/absorica_pi.pdf" to "http://absorica.com/Absorica_PI_September_2015.pdf" under References.</p>
<p>3/6/2015</p>	<ol style="list-style-type: none"> 1. Changed "Preferred (branded generics): Amnesteem®, Myorisan™, Zenatane™.; Non-Preferred: Absorica® and Claravis™." to "Preferred: Amnesteem®, Myorisan™, Zenatane™; Non-Preferred: Absorica®, Claravis™" under Applicable Drugs. 2. Changed "N/A" to "Pregnancy" under Exclusion Criteria. 3. Updated "https://www.oxhp.com/secure/policy/absorica_accutane_isotretinoin.pdf" to "https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Parmacy%20Resources/Notification_Absorica.pdf ", "http://www.mylanpharms.com/assets/mylan-pharms/pdfs/ISOT-R1.pdf" to "http://dailymed.nlm.nih.gov/dailymed/getFile.cfm?setId=b2cb63c9-f825-4991-9a2c-6260f1bbcc2c", "https://www.ipledgeprogram.com/Documents/Barr%20Claravis%20Package%20InsertI.pdf" to "http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=a31fd109-d0fd-4ab9-ba98-a3d64333c18d", "http://www.versapharm.com/media/productinserts/myorisan_pi.pdf" to "http://www.akorn.com/documents/catalog/package_inserts/61748-304-13.pdf", and "https://www.ipledgeprogram.com/Documents/Zenatane_USPI_FullSizeFont_Jan2013.pdf" to "http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=27b3cf26-f22e-5b70-1c24-009933b7c6ee" under References. 4. Removed "https://www.ipledgeprogram.com/Documents/Ranbaxy%20Sotret%20Package%20InsertI.pdf" from References.
<p>2/11/2014</p>	<ol style="list-style-type: none"> 1. Adapted policy to new format. 2. Added "Absorica", "Myorisan", and "Zenatane" to Applicable Drugs. Listed "Absorica" and "Claravis" under "Non-preferred", and listed all other products under "Preferred (branded generics)". 3. Removed "Sotret" under Applicable Drugs. 4. Added GPI code. 5. Changed covered diagnosis from: "severe recalcitrant nodular acne" to "severe, scarring, and/or refractory acne". 6. Changed wording under criterion III from: "Documented trial and failure of, or contraindication to, at least two of the following" to "History of treatment failure, intolerance, or contraindication with at least two of the following" 7. Added "Non-preferred products (Absorica® and Claravis™) also require a history of treatment failure, intolerance, or contraindication to at least two preferred Isotretinoin products" requirement. 8. Changed wording under "Re-Authorization" from: "An additional 5 month approval..." to "One additional 5 month approval..."

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| | <p>9. Updated references to include evidence-based guidelines, current policy, Medi-Span, and package inserts for all Isotretinoin Products.</p> |
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