ABSORICA LD™
isotretinoin capsules
8mg • 16mg • 24mg • 32mg

Authorization & Appeals Kit

Supporting Patient Access to ABSORICA LD™ (isotretinoin) oral capsules

Sun Pharmaceutical Industries, Inc. cannot guarantee insurance coverage or reimbursement. Coverage or reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the health care provider to ensure the accuracy of all statements made in seeking coverage and reimbursement for an individual patient.

INDICATIONS AND USAGE

ABSORICA LD (isotretinoin) capsules is indicated for the treatment of severe recalcitrant nodular acne in non-pregnant patients 12 years of age and older with multiple inflammatory nodules with a diameter of 5 mm or greater. Because of significant adverse reactions associated with its use, ABSORICA LD is reserved for patients with severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics.

Limitations of Use:

If a second course of ABSORICA LD therapy is needed, it is not recommended before a two-month waiting period because the patient's acne may continue to improve following a 15 to 20-week course of therapy.

SELECTED IMPORTANT SAFETY INFORMATION

WARNING: EMBRYO-FETAL TOXICITY – CONTRAINDICATED IN PREGNANCY

ABSORICA LD can cause severe life-threatening birth defects and is contraindicated in pregnancy. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking any amount of ABSORICA LD even for short periods of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining prenatally whether an exposed fetus has been affected. If pregnancy occurs, discontinue ABSORICA LD immediately and refer the patient to an Obstetrician-Gynecologist experienced in reproductive toxicity for further evaluation and counseling.

Because of the risk of embryo-fetal toxicity, ABSORICA LD is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the iPLEDGE® REMS.

Please see additional Important Safety Information throughout and full Prescribing Information for Boxed Warning, Contraindications, and other important Warnings and Precautions.

Resource Overview

This kit has been created to provide information and sample letters that can be used to help you communicate with health plans about prior authorization (PA) or appeal issues related to ABSORICA LD™.

This kit includes:

Checklists to help ensure you have provided all needed information

Sample letters with information that will usually be required

Please see additional Important Safety Information throughout and full Prescribing Information for Boxed Warning, Contraindications, and other important Warnings and Precautions.

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Table of Contents

Clinical Considerations for ABSORICA LD™

Long-Lasting Clearance 2 Years Post-Treatment[1,2*†]

95%

required NO retreatment with isotretinoin[1,2*†]

82%

required NO retreatment with any OTC or prescription acne medication[1,2*†]

***ABSORICA LD™ was approved by the FDA based on ABSORICA® (isotretinoin) clinical data. Please see full Clinical Statement below.**

†Phase IV trial analyzing efficacy of ABSORICA® based on per protocol population, N=166; N=119 patients completed the post-treatment period.[2]

Study Design: A single-arm, open-label study of ABSORICA® was conducted to investigate the treatment efficacy, frequency of relapse once treatment has been discontinued, and quality of life during the active treatment and during a 2-year post-treatment period. An initial 20-week, open-label, active-treatment-period (ATP) of lidose-isotretinoin was followed by a 104-week follow-up post-treatment period (PTP), in which endpoints included monitoring of retreatment. The total study duration was 124 weeks, excluding a screening period. During the PTP, the first visit took place at Week 24, followed by visits at weeks 32, 46, 72, 98, and 124. Of the 201 enrolled patients, 166 fit the protocol to start treatment. 4.2%, or 7 patients, required retreatment with isotretinoin. In addition, 82.5%, or 137 patients, did not need retreatment with any acne medication (OTC or prescription) during this period. Efficacy analyses were assessed using the per-protocol population (166). However, only 119 patients completed the post-treatment period; those who withdrew or were otherwise lost to follow-up were assumed to not need treatment.[2]

***ABSORICA®/ABSORICA LD™ CLINICAL STATEMENT: The effectiveness of ABSORICA/ABSORICA LD for the treatment of severe recalcitrant nodular acne in patients 12 years of age and older has been established and is based on a double-blind, randomized, parallel group trial in subjects with severe recalcitrant nodular acne who received ABSORICA or another isotretinoin capsule product under fed conditions.**

ABSORICA LD was approved by the FDA based on ABSORICA clinical data.

FDA, US Food and Drug Administration; OTC, over the counter.

SELECTED IMPORTANT SAFETY INFORMATION (CONT'D)

CONTRAINDICATIONS

Pregnancy: ABSORICA LD is contraindicated in pregnancy.

Hypersensitivity: ABSORICA LD is contraindicated in patients with hypersensitivity to isotretinoin (or Vitamin A, given the chemical similarity to isotretinoin) or to any of its components (anaphylaxis and other allergic reactions have occurred).

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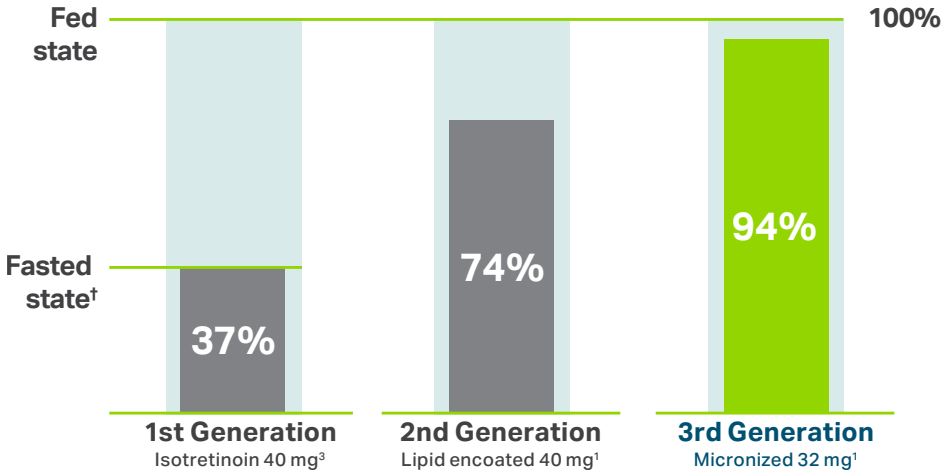
Clinical Considerations for ABSORICA LD™ (cont'd)

ABSORICA LD Provides Maximal Peak Plasma Concentration Regardless of Meals[1,3]*

ABSORPTION IS CRITICAL TO REACHING A THERAPEUTIC DOSE AND LOWER RATES OF RELAPSE[2]

ABSORICA LD delivers predictable absorption in a fasted state[1,4]*



†C_{max} values (ng/mL) in a fasted state expressed as a percentage of C_{max} values in a fed state for each product.

Study Design: Two open-label, crossover studies compared the bioavailability of micronized-isotretinoin 32 mg and lidose-isotretinoin 40 mg in fed and fasted state in healthy adults. ABSORICA LD demonstrated twice the plasma concentrations than ABSORICA in a fasted state. When administered in a fed state, plasma concentrations were bioequivalent between ABSORICA and ABSORICA LD.[4]

ABSORICA LD DEMONSTRATED

2X MORE ABSORPTION

in a fasted state compared to ABSORICA® (isotretinoin)[4]

Enhanced absorption gives patients the possibility of achieving[1,2,5-7]

Visible Results	Clearer Skin	Long-Lasting Clearance
1 Month	5 Months	2 Years

FEWER RETREATMENTS & LESS SCARRING

Most common adverse reactions (incidence ≥ 5%) are: dry lips, dry skin, back pain, dry eye, arthralgia, epistaxis, headache, nasopharyngitis, chapped lips, dermatitis, increased creatine kinase, cheilitis, musculoskeletal discomfort, upper respiratory tract infection, reduced visual acuity.[1]

***ABSORICA®/ABSORICA LD™ CLINICAL STATEMENT: The effectiveness of ABSORICA/ABSORICA LD for the treatment of severe recalcitrant nodular acne in patients 12 years of age and older has been established and is based on a double-blind, randomized, parallel group trial in subjects with severe recalcitrant nodular acne who received ABSORICA or another isotretinoin capsule product under fed conditions.**

ABSORICA LD was approved by the FDA based on ABSORICA clinical data.

SELECTED IMPORTANT SAFETY INFORMATION (CONT'D)

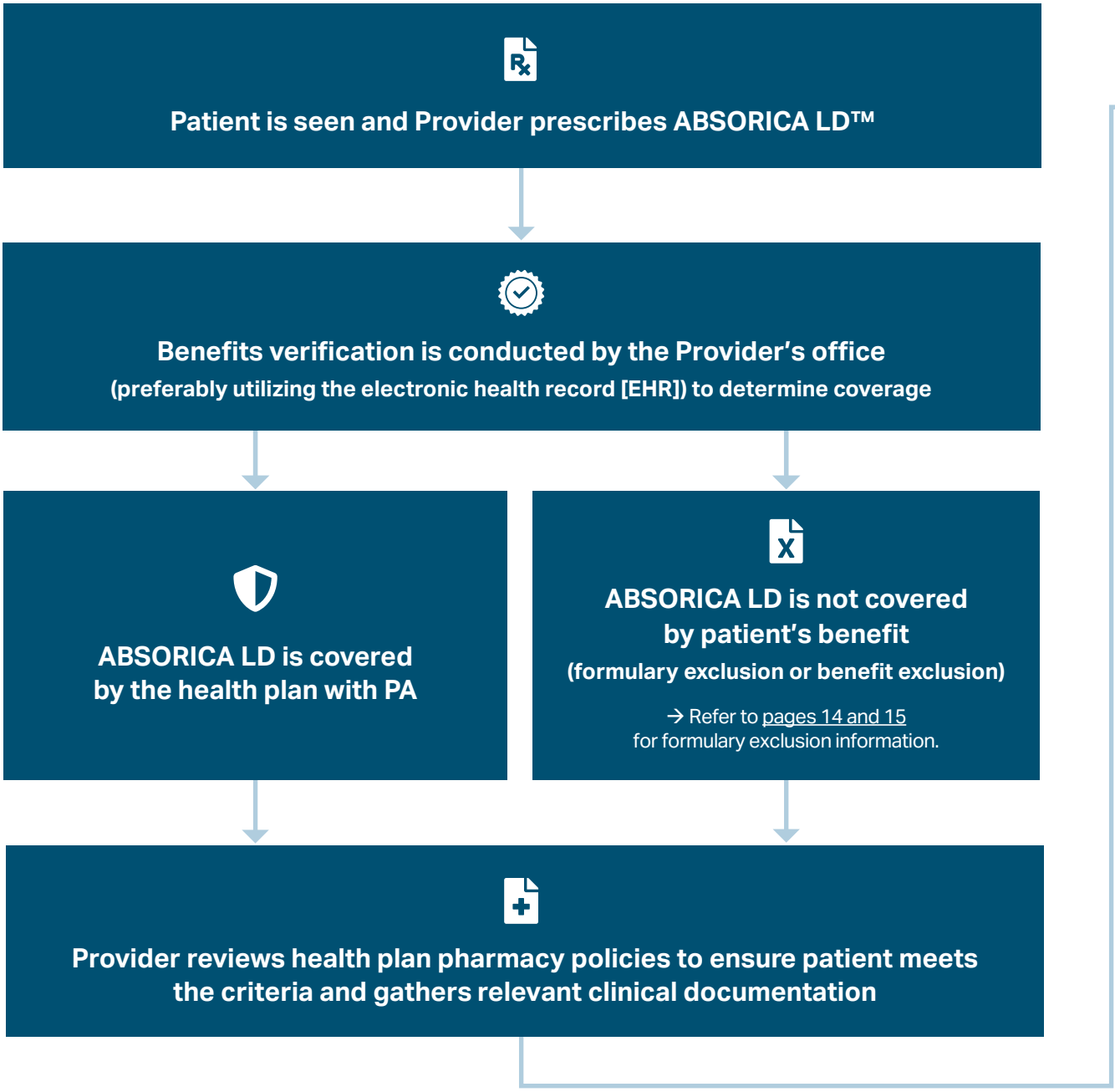
WARNINGS AND PRECAUTIONS

ABSORICA and ABSORICA LD are Not Substitutable: The bioavailability and the recommended dosage of ABSORICA and ABSORICA LD are different. For example, while ABSORICA and ABSORICA LD both have a 20 mg strength, these strengths have different bioavailability and are not substitutable.

Please see additional Important Safety Information throughout and full Prescribing Information for Boxed Warning, Contraindications, and other important Warnings and Precautions.

ABSORICA LD™ isotretinoin capsules 8mg • 16mg • 24mg • 32mg

Prior Authorization Process Overview



SELECTED IMPORTANT SAFETY INFORMATION (CONT'D)

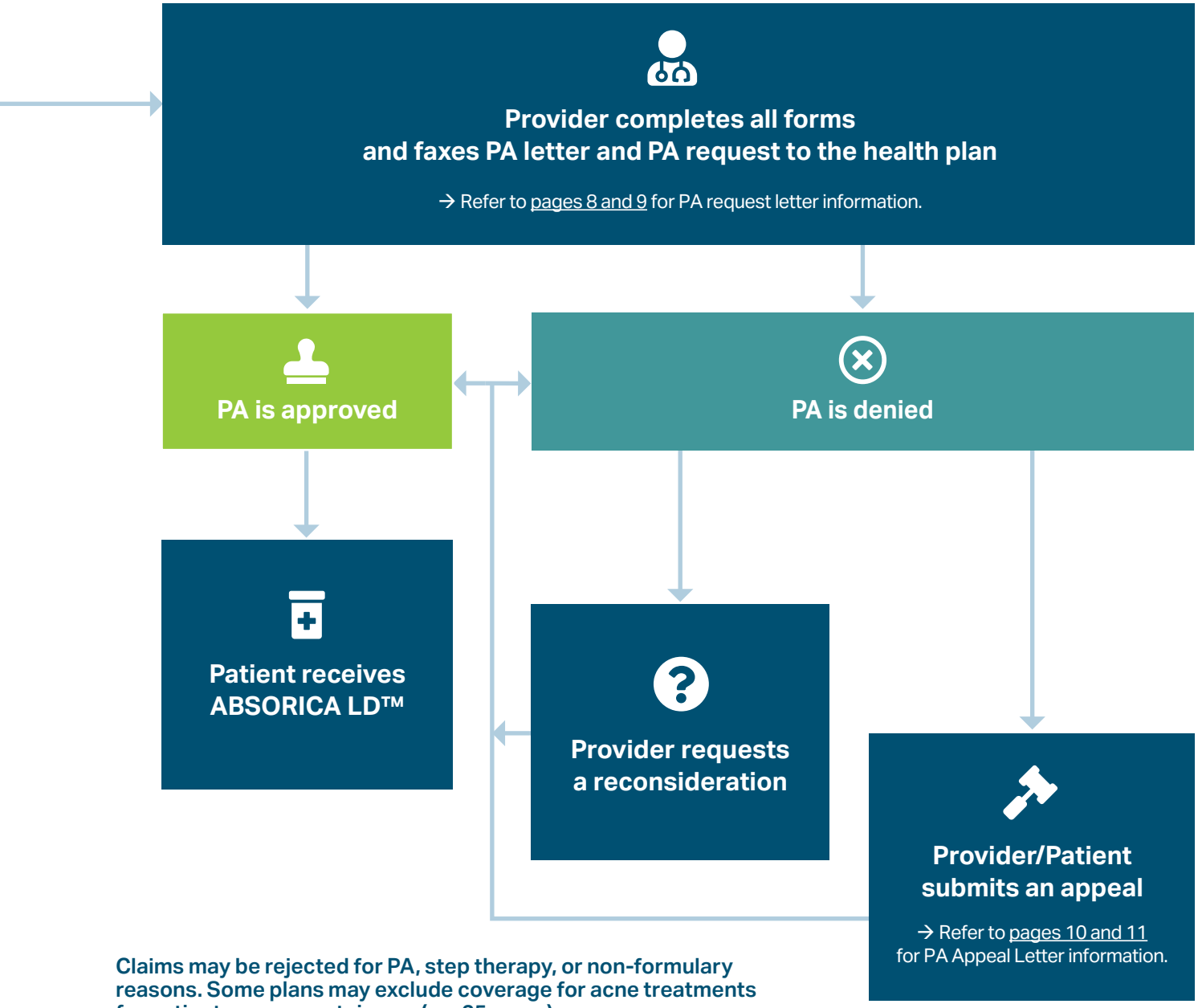
WARNINGS AND PRECAUTIONS (CONT'D)

Psychiatric Disorders: ABSORICA LD may cause depression, psychosis and, rarely, suicidal ideation, suicide attempts, suicide, and aggressive and/or violent behaviors. Prior to and during therapy, assess for these conditions.

Patients should immediately stop ABSORICA LD and promptly contact their prescriber if they develop depression, mood disturbance, psychosis, or aggression. Discontinuation of ABSORICA LD may be insufficient; further evaluation may be necessary such as a referral to a mental healthcare professional.

Please see additional Important Safety Information throughout and full Prescribing Information for Boxed Warning, Contraindications, and other important Warnings and Precautions.

Prior Authorization Process Overview (cont'd)



Claims may be rejected for PA, step therapy, or non-formulary reasons. Some plans may exclude coverage for acne treatments for patients over a certain age (eg, 25 years).

Many payers will allow up to 3 levels of appeals for PA denials. A third level of appeal may include an external review.*

Formulary exclusions may be appealed while appeals for benefit exclusions are generally not available.

*An external review can also be requested at any point when there are extenuating circumstances.

SELECTED IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Intracranial Hypertension (Pseudotumor Cerebri): Isotretinoin use has been associated with cases of intracranial hypertension (pseudotumor cerebri), some of which involved concomitant use of tetracyclines. Concomitant treatment with tetracyclines should therefore be avoided with ABSORICA LD use.

Please see additional Important Safety Information throughout and full Prescribing Information for Boxed Warning, Contraindications, and other important Warnings and Precautions.

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Suggestions for a PA Request Letter

All PA forms should be completed and submitted to the plan by your office. Benefits verifications performed by the customer service center of the patient's plan can identify PA requirements, step therapies, and form requirements.

A PA letter comes from the patient and/or the physician. Fax the PA request to the health plan. Many payers will allow up to 3 levels of appeals for PA denials. Refer to pages 10 and 11 for PA Appeal Letter information.

Checklist

- ☐ Use the health plan's website to locate their PA form
- ☐ Include the patient's information: name, DOB, sex, policy information
- ☐ List previous therapies, if applicable
  - Explain why each therapy was discontinued and give the duration of therapy for each agent
- ☐ Document that all PA requirements of the plan have been met, if applicable

  Provide evidence that the patient is an appropriate candidate for ABSORICA LD™, including but not limited to:
  - Diagnosis of severe recalcitrant nodular acne unresponsive to conventional therapy, including systemic antibiotics
  - Non-pregnant patients 12 years of age and older
  - Multiple inflammatory nodules with a diameter of 5 mm or greater
- ☐ Provide rationale and clinical support for your recommendation.

  Information can include:
  - Efficacy and safety data for ABSORICA LD
  - Adverse events/contraindications with other treatment options
  - Applicable treatment guidelines (American Academy of Dermatology)
- ☐ Review sample letter format on the next page for additional information

PA Process Overview

SELECTED IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Serious Skin Reactions: There have been postmarketing reports of erythema multiforme and severe skin reactions [e.g., Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN)] associated with isotretinoin use. These reactions may be serious and result in death, life-threatening events, hospitalization, or disability. Patients should be monitored closely for severe skin reactions, and ABSORICA LD should be discontinued if they occur.

Please see additional Important Safety Information throughout and full Prescribing Information for Boxed Warning, Contraindications, and other important Warnings and Precautions.

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Sample PA Request Letter for ABSORICA LD™

[Date]
[Claims department]
[Name of health plan]
[Mailing address]

RE: [Patient name]
Policy number: [Policy number]
Claim number: [Claim number]
Subject: Coverage Request for ABSORICA LD™ (isotretinoin) capsules

Dear [Medical director],

This letter is sent on behalf of [patient's name] to request coverage for ABSORICA LD (isotretinoin) capsules for the treatment of [insert patient diagnosis].

[Patient's name] is [a/an] [age]-year-old [male/female] who was diagnosed with [insert patient diagnosis] on [date]. [Patient's name] has been in my care since [date] and has previously tried and failed on multiple other treatments including [list any previous treatments].

[Patient's name] meets your prior authorization criteria of: [Insert rationale]

[Provide any other information that in your professional medical judgment is relevant, including but not limited to a brief summary of the patient's history and current condition, contraindications to other treatments, and what factors led you to recommend the use of ABSORICA LD.]

I am attesting that my patient has agreed to the iPLEDGE® program requirements and is an appropriate patient for treatment with ABSORICA LD.

ABSORICA LD [was/will be] prescribed to [patient's name] for the treatment of [insert patient diagnosis]. Enclosed you will find other relevant supporting documentation.

Please contact my office by calling [phone number] for any additional information you may require. I look forward to your timely approval.

Sincerely,
[Physician signature]
[Insert name]

Suggested enclosures:
Package insert for ABSORICA LD
Copy of patient medical records
Other supporting documentation

Suggestions for a PA Appeal Letter

This type of letter can be used when a PA request for ABSORICA LD™ has been denied. There can be multiple levels of appeals. Please refer to the plan's specific appeal guidelines.

This letter comes from the patient and the physician. It should be submitted along with a copy of the patient's relevant medical records and a Letter of Medical Necessity (see pages 12 and 13). Many payers will allow up to 3 levels of appeals for PA denials.

Checklist

- ☐ Include the patient's information: name, DOB, sex, policy information
- ☐ Acknowledge that you are familiar with the company's policy and state the reason for the denial
- ☐ Document that all PA requirements of the plan have been met, if applicable
  - Diagnosis of severe recalcitrant nodular acne unresponsive to conventional therapy, including systemic antibiotics
  - Non-pregnant patients 12 years of age and older
  - Multiple inflammatory nodules with a diameter of 5 mm or greater
- ☐ List previous therapies, if applicable
  - Explain why each therapy was discontinued and give the duration of therapy for each agent
- ☐ If other agents/treatments are not appropriate for this patient, explain why not (if they have not already been listed as previous therapies)
- ☐ Provide rationale and clinical support for your recommendation. Information can include:
  - Efficacy and safety data for ABSORICA LD
  - Adverse events or contraindications with other treatment options
  - Applicable treatment guidelines (American Academy of Dermatology)
- ☐ Attach a Letter of Medical Necessity (see pages 10 and 11)

For second- and third-level appeals, it may be helpful to include:

- ☐ The original letter of denial
- ☐ Specific medical notes in response to the denial
  - A third level of appeal may include review by an independent noninsurance-affiliated external review board or hearing

PA Process Overview

SELECTED IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Acute Pancreatitis: Acute pancreatitis has been reported with isotretinoin use in patients with either elevated or normal serum triglyceride levels. In rare instances, fatal hemorrhagic pancreatitis has been reported. If symptoms of pancreatitis occur, the patient should discontinue ABSORICA LD and seek medical attention.

Please see additional Important Safety Information throughout and full Prescribing Information for Boxed Warning, Contraindications, and other important Warnings and Precautions.

Sample Letter of Appeal for ABSORICA LD™

[Date]
[Appeals department]
[Name of health plan]
[Mailing address]

RE: [Patient name]
Policy number: [Policy number]
Treatment requested: ABSORICA LD™ (isotretinoin) capsules

Subject: Appeal of denial for ABSORICA LD™ (isotretinoin) capsules

This letter is sent on behalf of [patient's name] to request an appeal of a denied prior authorization for ABSORICA LD (isotretinoin) capsules. According to the denial letter, [name of health plan] denied this prior authorization because [reason from denial letter]. I am asking that you reconsider your denial of coverage for ABSORICA LD for the treatment of [insert patient diagnosis] for [patient's name].

The rationale for this appeal is as follows:
[Insert rationale]

Please contact my office by calling [phone number] for any additional information you may require in support of this appeal. I look forward to your timely approval.

Enclosures [List additional documents, which may include: denial letter, letter of medical necessity, Prescribing Information, clinical notes/medical records, or clinical practice guidelines.]

Sincerely,
[Physician signature]
[Insert name]

Suggestions for a Letter of Medical Necessity

Some plans require that a Letter of Medical Necessity be submitted along with a PA Appeal Letter (see pages 10 and 11) to support the choice of ABSORICA LD™ over agents that are on formulary.

The information provided below and the sample letter on the next page may be helpful to consider as you prepare the letter.

A Letter of Medical Necessity should also accompany a Formulary Exception Request Letter (see pages 14 and 15).

Checklist

- ☐ Include the patient's information: name, DOB, sex, policy information
- ☐ Include specific diagnosis code for severe recalcitrant nodular acne where appropriate
- ☐ Clearly state the rationale for treatment with ABSORICA LD and why it is appropriate for your patient
- ☐ Be sure to include all the listed documents with the letter when you send it to your patient's insurance provider
- ☐ List previous therapies, if applicable
  - Explain why each therapy was discontinued and give the duration of therapy for each agent
- ☐ Explain why formulary-preferred agents are not appropriate if they have not already been listed as previous therapy
- ☐ Provide rationale and clinical support for your recommendation. Information can include:
  - Efficacy and safety data for ABSORICA LD
  - Adverse events/contraindications with other treatment options
  - Applicable treatment guidelines (American Academy of Dermatology)
- ☐ To close the letter, summarize your recommendation, and provide a phone number should any additional information be required

PA Process Overview

SELECT IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Lipid Abnormalities: Elevations of serum triglycerides above 800 mg/dL have been reported with isotretinoin use. These lipid changes were reversible upon isotretinoin capsule cessation. Some patients have been able to reverse triglyceride elevation by reduction in weight and restriction of dietary fat and alcohol while continuing isotretinoin or through dosage reduction. The cardiovascular consequences of hypertriglyceridemia associated with isotretinoin are unknown.

Please see additional Important Safety Information throughout and full Prescribing Information for Boxed Warning, Contraindications, and other important Warnings and Precautions.

Sample Letter of Medical Necessity for ABSORICA LD™

[Date]
[Claims department]
[Name of health plan]
[Mailing address]

RE: [Patient name]
Policy number: [Policy number]
Claim number: [Claim number]
Subject: Supporting Coverage of ABSORICA LD™ (isotretinoin) capsules

Dear [Medical director],

This letter is sent on behalf of [patient's name] to document that [he/she] has been diagnosed with [insert patient diagnosis] and requires treatment with ABSORICA LD (isotretinoin) capsules. I am writing to document my patient's medical history and diagnosis and summarize my treatment rationale. Treatment with ABSORICA LD [dose, frequency] is medically appropriate and necessary for this patient.

[Patient's name] is [a/an] [age]-year-old [male/female] who was diagnosed with [insert patient diagnosis] on [date]. [Patient's name] has been in my care since [date] and has previously tried, and failed on multiple other treatments including [list any previous treatments].

[Provide any other information that in your professional medical judgment is relevant, including but not limited to a brief summary of the patient's history and current condition, contraindications to other treatments, and what factors led you to recommend the use of ABSORICA LD.]

I am attesting that my patient has agreed to the iPLEDGE® program requirements and is an appropriate patient for treatment with ABSORICA LD.

ABSORICA LD [was/will be] prescribed to [patient's name] for the treatment of [insert patient diagnosis]. Enclosed you will find other relevant supporting documentation.

Please contact my office by calling [phone number] for any additional information you may require. I look forward to your timely approval.

Sincerely,
[Physician signature]
[Insert name]

Suggested enclosures:
Package insert for ABSORICA LD
Copy of patient medical records
Other supporting documentation

Suggestions for a Formulary Exception Request Letter

This type of letter can be used when ABSORICA LD™ is not listed on a formulary or if it has an NDC block. While the plan may provide a form on its website that can be used to apply for an exception, you can refer to the information in this kit to see what is typically required.

This letter is written and sent by the patient, with the help of their physician. The letter should also be signed by the physician. It should be submitted along with a copy of the patient's relevant medical records and a Letter of Medical Necessity (see pages 12 and 13).

The following is an example outline for information that should be included within the Formulary Exception Request Letter. If your patient is requesting an exception to the formulary to fill their prescription for ABSORICA LD, ensure they include the following information:

- ☐ Patient's name, DOB, sex, and policy information
- ☐ The patient is requesting an exception to your formulary to fill [his/her] prescription for ABSORICA LD
- ☐ Patient has been diagnosed with severe recalcitrant nodular acne
- ☐ Past treatments include [list previous treatments and drugs]. Enclosed are medical records and a Letter of Medical Necessity from [physician name] supporting the request for the formulary exception approval of ABSORICA LD

(Note: Medical records should include the records from the date ABSORICA LD was first prescribed to the patient.)

- ☐ The main reasons for requesting this exception are [main medical necessity points]
- ☐ [Physician name] can be contacted at [phone number] to answer any additional questions or to participate in a peer-to-peer review discussing the necessity of providing a formulary exception for the use of ABSORICA LD for this patient
- ☐ Include physician and patient signature at the bottom of the letter
- ☐ If this is a second- or third-level appeal for formulary exception, include level of appeal, letter of denial, and medical notes in response to denial

PA Process Overview

NDC, National Drug Code.

SELECTED IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Hearing Impairment: Impaired hearing has been reported in patients taking isotretinoin; in some cases, the impairment has been reported to persist after therapy has been discontinued. Mechanism(s) and causality for this reaction have not been established. Patients who experience tinnitus or hearing impairment should discontinue ABSORICA LD treatment and be referred for specialized care for further evaluation.

Please see additional Important Safety Information throughout and full Prescribing Information for Boxed Warning, Contraindications, and other important Warnings and Precautions.

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Sample Formulary Exception Request Letter for ABSORICA LD™

[Date]
[Claims department]
[Name of health plan]
[Mailing address]

RE: [Patient name]
Policy number: [Policy number]
Claim number: [Claim number]

Subject: Exception Request for Coverage of ABSORICA LD™ (isotretinoin) capsules

Dear [Medical director],

This letter is sent on behalf of [patient's name] to request an exception to your formulary for ABSORICA LD (isotretinoin) capsules. [Patient's name] is [a/an] [age]-year-old [male/female] who was diagnosed with [insert patient diagnosis] on [date]. I am writing to document my patient's medical history and diagnosis and summarize my treatment rationale. Treatment with ABSORICA LD [dose, frequency] is medically appropriate and necessary for this patient.

[Provide any other information that in your professional medical judgment is relevant, including but not limited to a brief summary of the patient's medical history and current condition, contraindications to other treatments, what factors led you to recommend the use of ABSORICA LD, and reasons for requesting this exception.]

I am attesting that my patient has agreed to the iPLEDGE® program requirements and is an appropriate patient for treatment with ABSORICA LD.

I hope you will agree ABSORICA LD is appropriate and medically necessary to treat [patient's name] and will support this request for a formulary exception. Enclosed you will find other relevant documentation that supports this request.

Please contact my office by calling [phone number] for any additional information you may require or to participate in a peer-to-peer review discussing the necessity of providing a formulary exception for the use of ABSORICA LD for this patient. I look forward to your timely approval.

Sincerely,
[Physician signature]
[Insert name]

Suggested enclosures:
Package insert for ABSORICA LD
Letter of medical necessity
Copy of patient medical records
Other supporting documentation

covermymeds®

PA Determinations, Faster.

PA SUPPORT IS AVAILABLE FOR ABSORICA LD™ THROUGH COVERMYMEDS.

Through an online platform and integrations with 75% of EHRs, more than 750,000 providers use CoverMyMeds® to electronically submit PA requests to every health plan.

- Submit requests for any medication and all plans
- Receive faster PA determinations, often in real time
- Automatically renew previously submitted PA requests
- Use the solution at no cost

HOW TO INITIATE A PA REQUEST AT THE PROVIDER OFFICE:

01 **Create an account with CoverMyMeds**, or log into your existing account at covermymeds.com.

02 **Shorten time to therapy by creating a PA request** required for treatment.

03 Fill in medical details and then **click one button to electronically submit the request** to any plan for determination.

HOW TO COMPLETE A PHARMACY INITIATED REQUEST:

01 **Create an account with CoverMyMeds**, or log into your existing account at covermymeds.com.

02 On your CoverMyMeds dashboard, click **"Enter Key."**

03 Enter the access key, as well as **your patient's last name and DOB,** as indicated on the fax. You'll see that most of the request is already completed.

04 Fill in any remaining fields and click **"Send to Plan."**

05 **Mark determinations directly** in your CoverMyMeds account. Once it's determined by the plan, the pharmacy will be notified of the outcome.

Questions? CoverMyMeds can help.

Live support: call 1-866-452-5017 or chat at covermymeds.com
FAQ and webinar registration: go.covermymeds.com/help

Please see additional Important Safety Information throughout and full Prescribing Information for Boxed Warning, Contraindications, and other important Warnings and Precautions.

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scripthero™

AFFORDABILITY OPTIONS FOR ALL COMMERCIALLY INSURED PATIENTS

Only Sun Pharma offers PA support services and ABSORICA LD™ Non-Covered Pricing through ScriptHero™ powered by CoverMyMeds®. With Non-Covered Pricing, communication is directly with the patient.

If PA is APPROVED:

Commercially insured patients will be emailed or texted with relevant affordability options where they could pay as little as **$0 for their ABSORICA LD prescription each month.***

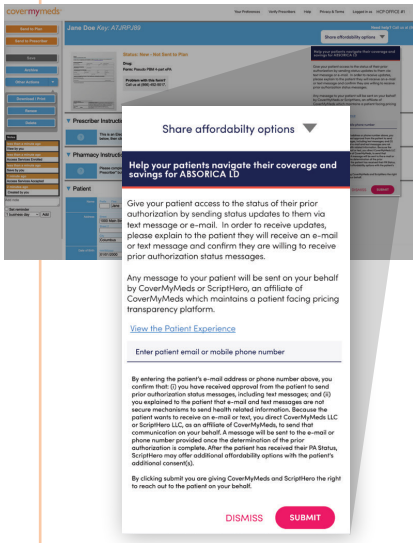
If PA is DENIED:

Eligible commercially insured patients can enroll in **ABSORICA LD Non-Covered Pricing**, lowering the cost to **only $350 (per 60 capsules).†**

THREE EASY STEPS TO ABSORICA LD SAVINGS FOR COMMERCIALLY INSURED PATIENTS

01 Your office submits a PA

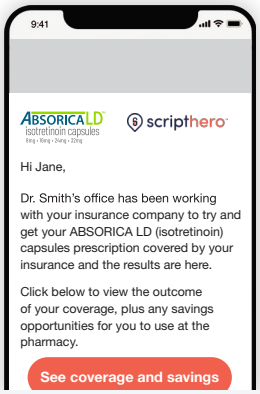
Ensure that you **enter the patient's email address or phone number in the "affordability" box** before submitting through **CoverMyMeds®**.



02 Patient receives PA status

Your patient will be notified of their PA status by email or text, along with affordability options. There is a companion piece for patients with step-by-step instructions for their reference.

(If your patient doesn't receive their email or text within 3 business days, call **1-866-747-4276**, M–F, 9 AM to 5 PM EST, or email questions to **help@scripthero.com**.)



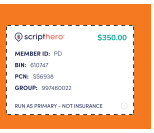
03 PA status determines savings

APPROVED PA*:
ABSORICA LD Copay Card

If the PA is approved, your patient will have the opportunity to sign up for an ABSORICA LD Copay Card and get their prescription for as little as **$0 each month.***

Patient directions are at **ABSORICALD.com/support.**

DENIED PA†:
ABSORICA LD Non-Covered Pricing



If the PA is denied, your patient will have the opportunity to enroll in ABSORICA LD Non-Covered Pricing. They'll show their ABSORICA LD Non-Covered Pricing card to the pharmacist and get their prescription for **$350 (per 60 capsules).†**

Learn more about ScriptHero powered by CoverMyMeds at scripthero.com/providers/absoricald.

*Patients are not eligible if prescriptions are paid in part or full by any state or federally funded program, including but not limited to Medicare or Medicaid, Medigap, VA, DOD, or Tricare, and where prohibited by law. See full terms and conditions at ABSORICALD.com/support.

†ABSORICA LD Non-Covered Pricing is available to people with commercial insurance.

Please see additional Important Safety Information throughout and full Prescribing Information for Boxed Warning, Contraindications, and other important Warnings and Precautions.

ABSORICA LD™
isotretinoin capsules
8mg • 16mg • 24mg • 32mg

INDICATIONS AND USAGE

ABSORICA LD™ (isotretinoin) capsules is indicated for the treatment of severe recalcitrant nodular acne in non-pregnant patients 12 years of age and older with multiple inflammatory nodules with a diameter of 5 mm or greater. Because of significant adverse reactions associated with its use, ABSORICA LD is reserved for patients with severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics.

Limitations of Use:

If a second course of ABSORICA LD therapy is needed, it is not recommended before a two-month waiting period because the patient's acne may continue to improve following a 15 to 20-week course of therapy.

IMPORTANT SAFETY INFORMATION

WARNING: EMBRYO-FETAL TOXICITY – CONTRAINDICATED IN PREGNANCY

ABSORICA LD can cause severe life-threatening birth defects and is contraindicated in pregnancy. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking any amount of ABSORICA LD even for short periods of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining prenatally whether an exposed fetus has been affected. If pregnancy occurs, discontinue ABSORICA LD immediately and refer the patient to an Obstetrician-Gynecologist experienced in reproductive toxicity for further evaluation and counseling.

Because of the risk of embryo-fetal toxicity, ABSORICA LD is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the iPLEDGE® REMS.

CONTRAINDICATIONS

Pregnancy: ABSORICA LD is contraindicated in pregnancy.

Hypersensitivity: ABSORICA LD is contraindicated in patients with hypersensitivity to isotretinoin (or Vitamin A, given the chemical similarity to isotretinoin) or to any of its components (anaphylaxis and other allergic reactions have occurred).

WARNINGS AND PRECAUTIONS

ABSORICA and ABSORICA LD are Not Substitutable: The bioavailability and the recommended dosage of ABSORICA and ABSORICA LD are different. For example, while ABSORICA and ABSORICA LD both have a 20 mg strength, these strengths have different bioavailability and are not substitutable.

Psychiatric Disorders: ABSORICA LD may cause depression, psychosis and, rarely, suicidal ideation, suicide attempts, suicide, and aggressive and/or violent behaviors. Prior to and during therapy, assess for these conditions.

Patients should immediately stop ABSORICA LD and promptly contact their prescriber if they develop depression, mood disturbance, psychosis, or aggression. Discontinuation of ABSORICA LD may be insufficient; further evaluation may be necessary such as a referral to a mental healthcare professional.

Intracranial Hypertension (Pseudotumor Cerebri): Isotretinoin use has been associated with cases of intracranial hypertension (pseudotumor cerebri), some of which involved concomitant use of tetracyclines. Concomitant treatment with tetracyclines should therefore be avoided with ABSORICA LD use.

Serious Skin Reactions: There have been postmarketing reports of erythema multiforme and severe skin reactions [e.g., Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN)] associated with isotretinoin use. These reactions may be serious and result in death, life-threatening events, hospitalization, or disability. Patients should be monitored closely for severe skin reactions, and ABSORICA LD should be discontinued if they occur.

Acute Pancreatitis: Acute pancreatitis has been reported with isotretinoin use in patients with either elevated or normal serum triglyceride levels. In rare instances, fatal hemorrhagic pancreatitis has been reported. If symptoms of pancreatitis occur, the patient should discontinue ABSORICA LD and seek medical attention.

Lipid Abnormalities: Elevations of serum triglycerides above 800 mg/dL have been reported with isotretinoin use. These lipid changes were reversible upon isotretinoin capsule cessation. Some patients have been able to reverse triglyceride elevation by reduction in weight and restriction of dietary fat and alcohol while continuing isotretinoin or through dosage reduction. The cardiovascular consequences of hypertriglyceridemia associated with isotretinoin are unknown.

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IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Hearing Impairment: Impaired hearing has been reported in patients taking isotretinoin; in some cases, the impairment has been reported to persist after therapy has been discontinued. Mechanism(s) and causality for this reaction have not been established. Patients who experience tinnitus or hearing impairment should discontinue ABSORICA LD™ treatment and be referred for specialized care for further evaluation.

Hepatotoxicity: Clinical hepatitis has been reported with isotretinoin use. Additionally, mild to moderate elevations of liver enzymes have been observed in approximately 15% of individuals treated during clinical trials with isotretinoin capsules, some of which normalized with dosage reduction or continued administration of the drug. If normalization does not readily occur or if hepatitis is suspected during treatment, ABSORICA LD should be discontinued.

Inflammatory Bowel Disease: Isotretinoin has been associated with inflammatory bowel disease (including regional ileitis) in patients without a prior history of intestinal disorders. In some instances, symptoms have been reported to persist after isotretinoin treatment has been stopped. Patients experiencing abdominal pain, rectal bleeding or severe diarrhea should discontinue ABSORICA LD immediately.

Musculoskeletal Abnormalities: Effects of multiple courses of isotretinoin on the developing musculoskeletal system are unknown. There is some evidence that long-term, high-dose, or multiple courses of therapy with isotretinoin have more of an effect than a single course of therapy on the musculoskeletal system. It is important that ABSORICA LD be given at the recommended dose for no longer than the recommended duration.

Ocular Abnormalities: Visual problems should be carefully monitored. If visual difficulties occur, the patient should discontinue ABSORICA LD treatment and obtain an ophthalmological examination.

ADVERSE REACTIONS

Most common adverse reactions (incidence ≥ 5%) are: dry lips, dry skin, back pain, dry eye, arthralgia, epistaxis, headache, nasopharyngitis, chapped lips, dermatitis, increased creatine kinase, cheilitis, musculoskeletal discomfort, upper respiratory tract infection, reduced visual acuity.

DRUG INTERACTIONS

Vitamin A: ABSORICA LD is closely related to vitamin A. Therefore, the use of both vitamin A and ABSORICA LD at the same time may lead to vitamin A related adverse reactions. Patients treated with ABSORICA LD should be advised against taking supplements containing Vitamin A to avoid additive toxic effects.

Tetracyclines: Concomitant treatment with ABSORICA LD and tetracyclines should be avoided because isotretinoin use has been associated with a number of cases of intracranial hypertension (pseudotumor cerebri), some of which involved concomitant use of tetracyclines.

USE IN SPECIFIC POPULATIONS

There are no data on the presence of isotretinoin in either animal or human milk, the effects on the breastfed infant, or the effects on milk production. Because of the potential for serious adverse reactions in nursing infants from isotretinoin, advise patients that breastfeeding is not recommended during treatment with ABSORICA LD, and for at least 8 days after the last dose of ABSORICA LD.

These are not all of the possible side effects of ABSORICA LD. You may report side effects to FDA at **1-800-FDA-1088** or Sun Pharmaceutical Industries, Inc. at **1-800-818-4555.**

Please see full Prescribing Information for Boxed Warning, Contraindications, and other important Warnings and Precautions.

References: 1. ABSORICA/ABSORICA LD [prescribing Information]. Sun Pharmaceutical Industries, Inc.; November 2019. **2.** Del Rosso JQ, Stein Gold L, Segal J, Zaenglein AL. An open-label, phase IV study evaluating lidose-isotretinoin administered without food in patients with severe recalcitrant nodular acne: low relapse rates observed over the 104-week post-treatment period. *J Clin Aesthet Dermatol.* 2019;12(11):13-18. **3.** Webster GF, Leyden JJ, Gross JA. Comparative pharmacokinetic profiles of a novel isotretinoin formulation (isotretinoin-lidose) and the innovator isotretinoin formulation: A randomized, 4-treatment, crossover study. *J Am Acad Dermatol.* 2013;69(5):762-767. **4.** Madan S, Kumar S, Segal J. Comparative pharmacokinetic profiles of a novel low-dose micronized isotretinoin 32 mg formulation and lidose-isotretinoin 40 mg in fed and fasted conditions: two open-label, randomized, crossover studies in healthy adult participants. *Acta Derm Venereol.* 2020;100(1-4):1-7. **5.** Layton AM, Henderson CA, Cunliffe WJ. A clinical evaluation of acne scarring and its incidence. *Clin Exp Dermatol.* 1994;19(4):303-308. **6.** Zaenglein AL, Pathy AL, Schlosser BJ, et al. Guidelines of care for the management of acne vulgaris. *J Am Acad Dermatol.* 2016;74(5):945-973. **7.** Webster GF, Leyden JJ, Gross JA. Results of a phase III, double-blind, randomized, parallel-group, non-inferiority study evaluating the safety and efficacy of isotretinoin-lidose in patients with severe recalcitrant nodular acne. *J Drugs Dermatol.* 2014;13(6):665-670.

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