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5.90.048

Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Topical Products	**Original Policy Date:**	April 2, 2021
Subject:	Isotretinoins	**Page:**	1 of 4

Last Review Date: September 6, 2024

Isotretinoins

Description

Absorica, Absorica LD* (isotretinoin)

*Prior authorization for this formulation applies only to formulary exceptions due to being a non-covered medication

Background
Isotretinoin is a retinoid medication that inhibits sebaceous gland function and keratinization. Clinical improvement in nodular acne patients occurs in association with a reduction in sebum secretion. The decrease in sebum secretion is temporary and is related to the dose and duration of treatment with Isotretinoin and reflects a reduction in sebaceous gland size and an inhibition of sebaceous gland differentiation (1).

Regulatory Status
FDA-approved indication: Isotretinoin products are indicated for the treatment of severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics (1).

Isotretinoins have a boxed warning regarding embryo-fetal toxicity. Isotretinoin can cause 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 Isotretinoin in any amount, even for short periods of time. Pregnancy testing should occur prior to isotretinoin being prescribed, each month during therapy, end of therapy, and one month after discontinuation. Isotretinoin is available only through a restricted program called the iPLEDGE REMS (1).

The safety and effectiveness of isotretinoin in pediatric patients less than 12 years of age have not been established (1).

Related policies
Tazarotene, Tretinoin

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Isotretinoin may be considered **medically necessary** if the conditions indicated below are met.

Isotretinoin may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 12 years of age or older

Diagnosis

Patient must have the following**:**

1. Severe nodular acne
   a. Patient has multiple nodules with a diameter of 5 mm or greater
   b. Patient has had an inadequate treatment response, intolerance, or contraindication to systemic antibiotics (e.g., doxycycline, tetracycline, minocycline, erythromycin, trimethoprim-sulfamethoxazole, trimethoprim, azithromycin)
   c. Patient has had an inadequate treatment response, intolerance, or contraindication to a generic isotretinoin product

AND the following:

1. Patient and prescriber are enrolled in the iPLEDGE REMS program

Prior – Approval *Renewal* Requirements

Age 12 years of age or older

Diagnosis

Patient must have the following**:**

1. Severe nodular acne
   a. Patient has been off of Isotretinoin therapy for at least 2 months

AND the following:

1. Patient and prescriber are enrolled in the iPLEDGE REMS program

Policy Guidelines

Pre – PA Allowance

None

Prior - Approval Limits

Duration 6 months

Prior – Approval *Renewal* Limits

Duration 6 months (**ONE** renewal **ONLY**)

Rationale

Summary

Isotretinoin is a retinoid medication that inhibits sebaceous gland function and keratinization. Clinical improvement in nodular acne patients occurs in association with a reduction in sebum secretion. The decrease in sebum secretion is temporary and is related to the dose and duration of treatment with Isotretinoin and reflects a reduction in sebaceous gland size and an inhibition of sebaceous gland differentiation. The safety and effectiveness of Isotretinoin in pediatric patients less than 12 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of isotretinoin while maintaining optimal therapeutic outcomes.

References

1. Absorica/Absorica LD [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; November 2019.

Policy History

Date	Action
April 2021	Addition to PA per MQA
June 2021	Annual review
December 2021	Annual review
June 2022	Annual review and reference update
June 2023	Annual review. Changed policy number to 5.90.048
June 2024	Annual review
September 2024	Annual review. Per SME, removed negative pregnancy testing requirement as it's already covered in iPLEDGE requirement

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.