

ISOTRETINOINS**Absorica, Absorica LD* (isotretinoin)**

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

RATIONALE FOR INCLUSION IN PA PROGRAM**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).

Isotretinoin has 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).

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).



Federal Employee Program.

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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.