

DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Estrogens (Topical) – Estradiol Gel Drug Quantity Management Policy – Per Rx

- Divigel® (estradiol 0.1% topical gel – Vertical, generic)

REVIEW DATE: 10/12/2022

OVERVIEW

Estradiol gel (Divigel, generic) is indicated for the treatment of moderate to severe **vasomotor symptoms due to menopause**.¹

Dosing

The recommended initial dose of estradiol gel for the treatment of moderate to severe vasomotor symptoms associated with menopause is 0.25 g applied once daily on the skin of either the right or left upper thigh.¹ The dose may be adjusted up to a maximum of 1.25 g as needed based on patient response.

Availability

Estradiol 0.1% gel is supplied in unit dose packets available in five different sizes: 0.25 g, 0.5 g, 0.75 g, 1 g and 1.25 g, which correspond to 0.25 mg, 0.5 mg, 0.75 mg, 1 mg, and 1.25 mg of estradiol per packet, respectively.¹ The packets are supplied in cartons containing 30 packets each. When administered, the entire contents of a unit dose packet should be applied each day.

Off-Label Use

Estradiol gel has been used off-label in protocols for assisted reproductive technology procedures.² Estrogens are used for the preparation of the endometrium in these protocols; a higher dose of estrogen is usually prescribed. Generally, transdermal estrogens are preferred over oral estrogens due to the bypass of the first-pass metabolism by the liver. This allows administration of estrogen at lower doses to possibly reduce the risk of adverse events.

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of estradiol gel (Divigel, generic). If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year unless otherwise noted below.

Automation: None.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Divigel® (estradiol 0.1% gel, generic)	0.25 g unit dose packets	30 packets	90 packets
	0.5 g unit dose packets	30 packets	90 packets
	0.75 g unit dose packets	30 packets	90 packets
	1 g unit dose packets	30 packets	90 packets
	1.25 g unit dose packets	30 packets	90 packets

CRITERIA

10/12/2022

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Estradiol 0.1% gel 0.75 g (Divigel, generic) unit dose packets

1. If the patient is applying 1.5 g once daily, approve the requested quantity, not to exceed 60 packets per dispensing at retail or 180 packets per dispensing at home delivery.

Estradiol 0.1% gel 1 g (Divigel, generic) unit dose packets

1. If the patient is applying 2 g once daily, approve the requested quantity, not to exceed 60 packets per dispensing at retail or 180 packets at home delivery.

Estradiol 0.1% gel (Divigel, generic) unit dose packets (all strengths)

1. If the patient is using estradiol gel (Divigel, generic) in a protocol for Assisted Reproductive Technology procedures (e.g., *in vitro* fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer) AND infertility is a covered benefit, approve the requested quantity for a 30-day supply per dispensing at retail or a 90-day supply per dispensing at home delivery for 1 year.

REFERENCES

1. Divigel® packets [prescribing information]. Bridgewater, NJ: Vertical; December 2019.
2. Vartanyan E, Tsaturova K, Devyatova E, et al. Thin endometrium problem in IVF programs. *Gynecol Endocrinol.* 2020;36(sup1):24-27.