



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: 10/16/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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.

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

Estrogens (Topical) – Estradiol Gel Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

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.

REFERENCES

1. Divigel® packets [prescribing information]. Bridgewater, NJ: Vertical; May 2023.
2. Vartanyan E, Tsaturova K, Devyatova E, et al. Thin endometrium problem in IVF programs. *Gynecol Endocrinol.* 2020;36(sup1):24-27.

HISTORY

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	<p>Policy updated to reflect the availability of generic estradiol 0.1% topical gel.</p> <p>Policy name was changed to "Estrogens (Topical) – Estradiol Gel Drug Quantity Management Policy – Per Rx". Previously, the policy was named "Estrogens (Topical) – Divigel Drug Quantity Management Policy – Per Rx".</p> <p>Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery.</p>	10/12/2022
Annual Revision	No criteria changes.	10/16/2023

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