

MEDICAL POLICY

POLICY TITLE	LASER TREATMENT FOR VULVOVAGINAL ATROPHY AND VAGINAL REJUVENATION
POLICY NUMBER	MP 4.047

CLINICAL BENEFIT	<input type="checkbox"/> MINIMIZE SAFETY RISK OR CONCERN. <input type="checkbox"/> MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. <input checked="" type="checkbox"/> ASSURE APPROPRIATE LEVEL OF CARE. <input type="checkbox"/> ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. <input type="checkbox"/> ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. <input type="checkbox"/> ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	3/1/2024

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I. POLICY

Treatment of vulvovaginal atrophy with the use of a fractional laser or fractional carbon dioxide (CO2) laser treatment(s) is considered **investigational** for all indications. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Vaginal rejuvenation and vaginal tightening procedures to improve appearance or enhance sexual performance using fractional lasers or fractional carbon dioxide (CO2) lasers are considered **cosmetic**.

Cross-reference

MP 1.004 Cosmetic and Reconstructive Surgery

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital BlueCross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: <https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>.

III. DESCRIPTION/BACKGROUND

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Vulvovaginal Atrophy

Vulvovaginal atrophy also known as vaginal atrophy, urogenital atrophy, or atrophic vaginitis results from estrogen loss and is often associated with vulvovaginal complaints (eg, dryness, burning, dyspareunia) in menopausal women. Estrogen loss from surviving cancer/radiation,

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certain medications, and prolonged breast feeding can also cause vaginal atrophy. Tissues near the vagina can become dry, thin, and inflamed. Other symptoms include dyspareunia, burning, itching, dryness and laxity. Urinary frequency and recurrent bladder infections may also occur.

The treatment options for atrophy due to menopause typically involve hormone therapy.

Vaginal Relaxation Syndrome

Vaginal relaxation syndrome (VRS) is defined as laxity of the vaginal wall. It can result in loss of friction and sexual satisfaction for both a woman and her partner. This condition is quite common and usually associated with vaginal childbirth as well as natural aging.

Fractional carbon dioxide (CO2) lasers (e.g. MonaLisa Touch®, CO2RE Intima) and fractional lasers have been proposed as non-surgical treatment for vulvovaginal atrophy, vaginal rejuvenation, and vaginal tightening. The lasers provide a photo thermal heating effect on collagen in the vaginal walls which may cause restructuring and regrowth of the collagen. This results in thickening and tightening of the vaginal walls to improve atrophy. Laser therapy typically consists of three laser treatment sessions over a specified time period (usually one session every four to six weeks). The procedure is performed in a physician's office.

Potential complications of vaginal laser treatment procedures include infection, loss of sensation or altered sensations, pain in the area, or pain during intercourse, adhesions, and scarring.

IV. RATIONALE

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Available published peer reviewed medical literature for the safety and effectiveness of these devices for the treatment of vulvovaginal atrophy, vaginal rejuvenation, and vaginal tightening cannot be established. The evidence is insufficient as currently there are no published studies that assess the clinical utility, long-term outcomes, safety and complication rates of these procedures. Further randomized controlled trials with long term follow up and comparative effectiveness to established procedures and treatments are necessary to evaluate the efficacy of these technologies. The evidence is insufficient to determine the effects of the technology on net health outcomes.

PRACTICE GUIDELINES AND POSITION STATEMENTS

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS (ACOG)

In 2020 ACOG issued a Committee Opinion (number 795) regarding Elective Female Genital Cosmetic Surgery. Obstetrician–gynecologists may receive requests from adolescents and adults for cosmetic genital surgery. For those choosing to provide cosmetic services, patient counseling (including definitions of normal range of anatomy and sexual function), shared decision making, and informed consent are paramount. Patients should be made aware that surgery or procedures to alter sexual appearance or function (excluding procedures performed for clinical indications, such as clinically diagnosed female sexual dysfunction, pain with intercourse, interference in athletic activities, previous obstetric or straddle injury, reversing female genital cutting, vaginal prolapse, incontinence, or gender affirmation surgery) are not

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medically indicated, pose substantial risk, and their safety and effectiveness have not been established.

V. DEFINITIONS

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N/A

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Treatment of vulvovaginal atrophy with fractional laser or fractional carbon dioxide (CO2) laser is considered investigational, and vaginal rejuvenation and tightening procedures are considered cosmetic; therefore, these procedures are non-covered services:

Procedure Codes							
58999							

IX. REFERENCES

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1. *The American College of Obstetricians and Gynecologists (ACOG), Committee Opinion Number 795, Elective Female Genital Cosmetic Surgery December 19, 2019*

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2. *The American College of Obstetricians and Gynecologists (ACOG), Fractional Laser Treatment of Vulvovaginal Atrophy and U.S. Food and Drug Administration Clearance Position Statement. May 2016 (Reaffirmed July 2018)*
3. *Bachman, G. Genitourinary syndrome of menopause (vulvovaginal atrophy): Treatment) In: UpToDate Online Journal [serial online]. Waltham, MA: UpToDate; updated November 8, 2023.*
4. *Clinical Study of the CO2RE Laser Device Performance for Vaginal Atrophy Treatments. Last updated June 14, 2018*
5. *Salvatore S, Nappi RE, Zerbinati N, et. al. A 12-week treatment with fractional CO2 laser for vulvovaginal atrophy: a pilot study. Climacteric 2014 Aug;17(4):363-9. PMID 24605832*
6. *Salvatore S, Nappi RE, Parma M, et.al. Sexual function after fractional microablative CO2 laser in women with vulvovaginal atrophy. Climacteric 2015 Apr;18(2):219-25. PMID 25333211*
7. *U.S. Food and Drug Administration. FDA Warns Against use of Energy-Based Devices to Perform Vaginal “Rejuvenation” or Vaginal Cosmetic: FDA Safety Communication Procedures. 30 July 2018*

X. POLICY HISTORY

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MP 4.047	5/14/18 New policy. Treatment of vulvovaginal atrophy through the use of either a fractional laser or fractional CO2 laser is considered investigational. Vaginal rejuvenation and vaginal tightening procedures to improve appearance or enhance sexual performance using fractional lasers or fractional carbon dioxide (CO2) laser are considered cosmetic. Coding reviewed.
	3/29/19 Consensus review. Policy statement unchanged. References updated.
	4/10/20 Consensus Review. Policy statement unchanged. References updated. Rationale updated to include the updated reference.
	3/5/2021 Consensus review. Policy statement unchanged. References updated.
	1/21/2022 Consensus review. No change to policy statement. References reviewed and updated. Product Variations updated. No coding changes.
	12/1/2023 Consensus review. No change to policy statement. Policy Guidelines removed. References updated.

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