Policy Number	**SUR717.016**
Policy Effective Date	**04/01/2025**
Policy End Date	**12/31/2025**

Laser Treatment of Vulvovaginal Atrophy (VVA)

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

This medical policy has become inactive as of the end date above. See medical policy ADM1001.028 for dates of service 01/01/2026 and after.

Treatment of vulvovaginal atrophy (VVA) with the use of a fractional laser or fractional carbon dioxide (CO_2) laser treatment(s) **is considered experimental, investigational and/or unproven** for all indications.

Policy Guidelines

None.

Description

Vulvovaginal Atrophy

Vulvovaginal atrophy (VVA), also known as vaginal atrophy, atrophic vaginitis, and/or urogenital atrophy, is a condition which causes the vaginal tissue to become dry, thin and inflamed due to a reduction of the hormone estrogen. Common conditions that are known to cause VVA include:

- Medications that decrease estrogen levels for conditions such as uterine fibroids or endometriosis (e.g., anti-estrogen drugs to prevent cancer recurrence and prolonged use of birth control);
- Menopause or perimenopause;
- Oophorectomy (surgical removal of the ovaries) prior to the age of natural menopause;
- Prolonged breastfeeding;
- Radiation treatments for ovarian cancer;
- Surviving cancer/radiation (as a result of ovarian failure).

Patients may exhibit symptoms of VVA including but not limited to, vaginal dryness and itching, vaginal burning, dyspareunia (painful intercourse) and post-coital bleeding. Urinary symptoms including urge incontinence, frequency dysuria and stress incontinence have also been reported. Traditionally, mild symptoms can be managed with over the counter non-hormonal moisturizers and lubricants. If these treatments are ineffective, the patient may be prescribed low-dose estrogen in the form of a cream, tablet, or vaginal ring to improve symptoms. (1) Currently, fractional carbon dioxide (CO_2) lasers are actively marketed as a non-surgical treatment option for VVA. This micro-ablative procedure is performed in the physician's office with local anesthetic. The premise of these energy-based devices is to promote blood flow to the vagina to stimulate healthy tissue growth. (2)

Regulatory Status

On July 30, 2018, the United States (U.S.) Food and Drug Administration (FDA) issued a warning regarding energy-based devices that are used to treat vaginal conditions and symptoms related to menopause, urinary incontinence, or sexual function. Currently, no vaginal laser device or procedure is cleared or approved by the FDA for any of these vaginal issues. (2)

Examples of fractional CO_2 lasers include but are not limited to the following devices:

- DEKA SmartXide2 Laser System (MonaLisa Touch; [3])
- Alma Laser Pixel CO_2 laser system (4); and
- Syneron CO_2RE laser system (5).

There are a variety of lasers which are being used for the treatment of VVA. Refer to <https://fda.gov> for a comprehensive list of CO_2 lasers. Product code GEX.

Rationale

This policy was created in July 2019 and is based on a PubMed search of published scientific literature through February 6, 2024.

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

In 2014, Salvatore et al. (6) performed a pilot study to assess the efficacy and feasibility of the fractional carbon dioxide (CO_2) laser in the treatment of vulvovaginal atrophy (VVA) in postmenopausal women. Symptoms were assessed before and after 3 applications of laser over 12 weeks in 50 women (age 59.6 ± 5.8 years) dissatisfied with prior local estrogen therapies. Subjective visual analog scale (VAS) and objective (Vaginal Health Index [VHI] Score) measures were used to assess VVA. Fractional CO_2 laser treatment was effective to improve VVA symptoms (vaginal dryness, vaginal burning, vaginal itching, dyspareunia, dysuria; $p < 0.001$) at 12-week follow-up, as well as the VHI score (13.1 ± 2.5 at baseline versus [vs.] 23.1 ± 1.9; $p < 0.001$). Both physical and mental scores of quality of life (QOL) were significantly improved in comparison with baseline ($p < 0.001$). Satisfaction with the laser procedure was reported by 42 women (84%) and minimal discomfort was experienced at the first laser application. Finally, the technique was easy to perform in all women starting from the second application at week 4 and no adverse events were recorded during the trial period. The authors concluded that a 12-week treatment with the fractional CO_2 laser was feasible and induced a significant improvement of VVA symptoms by ameliorating vaginal health in post-menopausal women and that further controlled studies should be performed to confirm data and assess the long-term effects of the laser procedure on vaginal tissues. There were several limitations to this study: 1) Several authors performing the study disclosed conflicts of interests; and 2) The study had a small sample size and short duration, without any long-term follow-up of the patients; and 3) The sham laser or active comparator groups were lacking. (7)

In another study published by Salvatore and associates (2015) 77 women with VVA were evaluated by assessing their sexual function and QOL after fractional micro-ablative CO_2 laser using the Female Sexual Function Index (FSFI) and the Short Form-12 patient survey. (7, 8)

Patients were assessed at baseline and 12 weeks. Patients were advised to avoid coital activity for at least 3 days post-laser application. The researchers reported that 2 patients could not be treated. VAS was used to measure overall patient satisfaction and the intensity of VVA symptoms (e.g., vaginal burning, vaginal itching, vaginal dryness, dyspareunia, and dysuria) prior to and after the study period. Researchers noted improvement in the total FSFI score and the scores in each domain at 12 weeks compared with baseline. Seventeen out of 20 women (85%) who were not sexually active because of VVA severity at baseline regained a normal sexual life at the 12-week follow-up. There were limitations of this small study including absence of a control arm with a sham laser procedure (given the high placebo response reported in interventional trials on female sexual dysfunction) or with hormone treatment. This open-label study precluded an effective control of potential serious confounding factors (e.g., higher motivation for coitus) and selection bias (women who were distressed and more motivated for improvement in their sexual lives). In addition, the authors report that the short follow-up precludes the comprehensive understanding of the duration of the laser effect. Another limitation of this study is that the potential risk of long-term complications, such as scarring, was not addressed. Patients were not monitored for concurrent use of intravaginal products or systemic medications that could also affect vaginal/vulvar health. Over the counter moisturizers, lubricants, prescribed local estrogen products, or systemic hormones could have contributed to the observed improvement with laser treatment. In addition, one author performing the study disclosed a financial conflict of interest.

In 2017, Arroyo (9) investigated the use of the fractional CO_2 laser for the treatment of symptoms associated with VVA in perimenopausal women. Twenty-one perimenopausal women (mean age 45±7 years) were treated 3 times by CO_2 laser resurfacing with coagulation of the vaginal canal tissue and mucosal tissue of the introitus. VHI scores were computed at baseline and follow-ups. Sexual function, patient satisfaction, and symptom improvement with treatment were assessed. VAS was used to measure discomfort with treatment. Vaginal health and subjective assessment of vaginal symptoms improved with successive treatments. At 12 weeks following the third treatment, 82% of the patients showed a statistically significant improvement in VHI ($p<0.05$). Additionally, 81% of patients reported improvement in sexual fulfillment, 94% reported improvement in vaginal rejuvenation, and 100% reported satisfaction with treatment. VHI improvement remained significant at 6-8 months after treatments ($P<0.01$). Most patients (97%) reported no to mild discomfort with treatment. Responses were mild and transient following treatment, with itching being the most commonly reported (20%) side effect. In this study, fractional CO_2 laser treatment was associated with improved vaginal health and in VVA symptoms which resulted in improved sexual function in perimenopausal women. Treatment time was quick, and there was minimal discomfort associated with treatment. The author concluded that investigation of clinical outcomes in a larger study population is warranted.

In 2017, Arunkalaivanan et al. (10) conducted a systematic review on the use of laser therapy for the relief of genitourinary syndrome of menopause (GSM) symptoms. Six electronic databases were searched, and conference abstracts were searched manually. Of the 165 articles identified, none was a randomized controlled trial (RCT). As a result, 3 observational

studies without a control group and 1 case-control study that met inclusion criteria were included in the review. A total of 4 studies included 220 patients. The collated data suggest that laser therapy may be valuable as a non-hormonal therapeutic modality in the management of GSM. The authors suggest that higher quality evidence from RCTs are needed to establish efficacy of laser treatment in the management of GSM symptoms.

In 2017, Pieralli et al. (11) sought to evaluate the long-term effects of the fractional CO_2 laser for the treatment of VVA symptoms. Women presenting with VVA symptoms and meeting inclusion criterion were enrolled to receive fractional CO_2 laser therapy. Patient's satisfaction was measured on a 5-point Likert scale at 4 weeks and 6, 12, 18, 24 months after treatment by interview and clinical examination. A total of 184 patients constituted the final study group: 128 women were spontaneous menopause and 56 were oncological menopause. One hundred seventeen women were nulliparous and 36 had previous hysterectomy. 95.4% (172/184) of the patients declared that they were satisfied or very satisfied with the procedure at 4 weeks post treatment. At 6 months, 92% (170/184) patients were satisfied; at 12 months, 72% (118/162) were satisfied; at 18 months, 63% (60/94) were satisfied; at 24 months, 25% (4/16) of patients answered they were still satisfied. The authors observed a decline in patient's satisfaction between 18- and 24-months post laser therapy. Data showed that the time interval from onset of menopause was a statistically significant factor ($p < 0.05$) for treatment satisfaction in the oncological group. The authors noted that data demonstrated that the improvement of vaginal health may continue up to 24 months after fractional CO_2 laser treatment although between 18- and 24-months benefits decline, and approximately 80% of women decide to start a new treatment cycle of laser applications.

In 2018, Cruz et al. (12) compared fractional CO_2 laser with topical estriol in the treatment of vaginal atrophy in 45 postmenopausal women. Patients were randomized to laser, estriol (E), or laser + estriol (LE) groups. Assessments were performed at baseline, 8 and 20 weeks using VHI, VAS for VVA symptoms, FSFI, and maturation value (MV) of Meisels. Three women were lost to follow-up. VHI average score was significantly higher at weeks 8 and 20 in all study arms. At week 20, the LE arm showed incremental improvement of VHI score ($p = 0.01$). Laser and LE groups showed a significant improvement of dyspareunia, burning, and dryness, and the E arm only of dryness ($P < 0.001$). LE group presented significant improvement of total FSFI score ($P = 0.02$) and individual domains of pain, desire, and lubrication. In contrast, the laser group showed significant worsening of pain domain in FSFI ($P = 0.04$), but FSFI total scores were comparable in all treatment arms at week 20. The authors concluded that CO_2 vaginal laser alone or in combination with topical estriol is a good treatment option for VVA symptoms although sexual-related pain with the use of vaginal laser treatment might be of concern.

In 2023, Page et al. conducted a randomized, double-blind, sham-controlled, single-center study to examine if CO_2 laser treatment is more effective than sham application in relieving the most bothersome symptom (MBS) in women with genitourinary syndrome of menopause (GSM). (13) The trial included a total of 60 women with moderate-to-severe GSM symptoms. All participants eventually received 3 consecutive laser and 3 consecutive sham applications, either 1st laser followed by sham, or conversely. The primary outcome was the

participant-reported change in severity of the most bothersome syndrome (MBS) at 12 weeks. Secondary outcomes included subjective (patient satisfaction, sexual function, urinary function) and objective (pH, vaginal health index [VHI] score, in-vivo microscopy) measurements examining the short-term effect and the longevity of treatment effects at 18 months after commencement of the therapy; adverse events (AEs) were reported at every visit. The MBS severity score decreased from 2.86 ± 0.35 to 2.17 ± 0.93 (-23.60 %; 95 % CI: -36.10 % to -11.10 %) in women treated with laser compared with 2.90 ± 0.31 to 2.52 ± 0.78 (-13.20 %; 95 % CI: -22.70 % to -3.73 %) in those receiving sham applications (p = 0.13). There were no serious AEs reported up to 18 months. The authors concluded that in women with GSM, the treatment response 12 weeks following laser application was comparable to that of sham applications. There were no obvious differences for secondary outcomes and no serious AEs were reported.

In 2023, UpToDate reviewed vulvovaginal atrophy (VVA) treatment and stated that: "Laser or energy-based devices have not been cleared or approved by the FDA for the treatment of vulvovaginal atrophy. In July 2018, the FDA issued a safety communication warning patients about the risks associated with use of these devices, which include vaginal burns, scarring, pain during sexual intercourse, and recurring/chronic pain. In August 2018, the American College of Obstetricians and Gynecologists advised that additional data from randomized trials are needed to further assess the efficacy and safety of this procedure. A 2020 clinical consensus statement by the American Urogynecologic Society concluded that, while energy-based therapies had shown treatment promise, long-term outcomes were not yet understood." (15)

Summary of Evidence

Published literature related to the use of fractional carbon dioxide (CO_2) laser treatment for the management of vulvovaginal atrophy (VVA) have small sample sizes or short duration to follow-up (up to 24 months). The available published literature is primarily from review articles and/or observational studies. There is a lack of randomized controlled trials (RCTs) and comparative studies. Additional RCTs or comparative trials with long term follow up which compare CO_2 laser treatments to established treatments are necessary to evaluate the effectiveness of this technology. Currently, the evidence is insufficient to determine the effects of the technology on net health outcomes, therefore the use of fractional carbon dioxide (CO_2) laser treatment for the management of VVA is considered experimental, investigational, and/or unproven.

Professional Guidelines and Position Statement

<u>The North American Menopause Society (NAMS)</u>

In 2015, the NAMS published guidance which concluded (7):

"Although laser technology may hold promise for the future of VVA treatment, further long-term efficacy and safety data should be collected before fully embracing this expensive new technology. In addition, the laser has a broad indication; therefore, further research is required before advocating its use in multiple, random gynecologic conditions."

The 2020 NAMS position statement on the management of symptomatic VVA (14) does not support fractional laser or fractional CO_2 laser as a treatment option for VVA. Several RCTs

evaluating the efficacy of energy-based devices in the treatment of genitourinary syndrome of menopause (GSM) are in progress. The NAMS provided the following recommendations:

- First-line therapies for women with symptomatic VVA include non-hormonal lubricants with sexual activity and regular use of long-acting vaginal moisturizers. (Level A: supported by sufficient, consistent scientific evidence).
- For women with moderate to severe GSM and those who do not respond to lubricants and moisturizers, several safe and effective options are available:
    - Low-dose vaginal estrogen therapy (ET) (Level A: supported by sufficient, consistent scientific evidence),
    - Vaginal dehydroepiandrosterone (DHEA) (Level A),
    - Ospemifene (Level A), and
    - Systemic ET (when vasomotor symptoms [VMS] are also present) (Level A).

In 2020 the NAMS published further guidance which stated (14): "Energy-based therapies, including vaginal laser and radiofrequency devices, require long-term, sham-controlled safety and efficacy studies before their routine use can be recommended."

American College of Obstetricians and Gynecologists (ACOG)

In December 2021, ACOG published a clinical consensus on the treatment of urogenital symptoms stating that laser therapy is neither FDA-approved nor FDA-cleared for the treatment of symptoms related to menopause. (16) Safety concerns raised include, citing a potential for adverse events including vaginal burns, scarring, pain during sexual intercourse and recurring or chronic pain. Additional research is warranted before recommending laser therapy. Current available data is based on largely observational studies with either small number of participants or limited follow-up. Efficacy has also not been compared with other treatment options.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in February 2024 identified the following ongoing and unpublished trials that would likely influence this medical policy.

NCT No.	Study Name	Number of Participants	Date of Completion
Ongoing			
NCT04657536	Randomized Multicenter Clinical Trial for Evaluating the Efficacy of Temperature-controlled Radiofrequency Compared With Topical Estriol in the Treatment of Vulvovaginal Atrophy in Postmenopausal Women	200	December 2021 (unknown status)
NCT03628092	Laser Therapy for Vulvovaginal Symptoms in Breast Cancer Patients.	70	October 2021 (unknown status)

NCT04081805	LASER and Radiofrequency as Alternative Treatment of Vaginal Vulvar Atrophy in Women Treated for Breast Cancer	195	September 2025 (recruiting)
NCT04045379	LASER and Radiofrequency and Genitourinary Syndrome of Menopause (EPMLARF-arm1)	195	August 2025 (enrolling by invitation)
NCT05305209	Laser Therapy for Treatment of Genitourinary Syndrome of Menopause (GSM) in Postmenopausal Women (LASER_2022)	189	December 15, 2022 (no results posted)

Table Key: No: number; NCT: National Clinical Trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	58999
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
12/31/2025	Document became inactive.
04/01/2025	Reviewed. No changes.
04/01/2024	Document updated with literature review. Coverage unchanged. Reference 1 and 13 added; others updated.
06/01/2023	Reviewed. No changes.
01/15/2023	Document updated with literature review. Coverage unchanged. Reference 15 updated.
02/01/2022	Reviewed. No changes.
09/15/2021	Document updated with literature review. Coverage unchanged. Reference 13 updated and reference 15 added.
10/15/2020	Reviewed. No changes.
12/15/2019	New medical document. Treatment of vulvovaginal atrophy (VVA) with the use of a fractional laser or fractional carbon dioxide (CO2) laser treatment(s) is considered experimental, investigational and/or unproven for all indications.