SCHOOL OF MEDICINE
DEPARTMENT OF OBSTETRICS & GYNECOLOGY

STANDARD OPERATING PROCEDURE- GUIDELINE

FRACTIONATED CO2 LASER USE IN GYNECOLOGY

SCOPE/APPLICABILITY:

This policy applies to licensed practitioners in the Department of Obstetrics and Gynecology who are caring for non-pregnant women who present with genitourinary syndrome of menopause (GSM), lichen sclerosis, and/or stress urinary incontinence (SUI) who are considering CO2 fractionated laser treatment of the vulva and/or vagina to treat these conditions.

SUMMARY:

- Fractionated CO2 laser therapy of the vulva and/or vagina may be offered to non-pregnant, adult women with an established clinical diagnosis of genitourinary syndrome of menopause (GSM) only if they have distinct contraindications to, intolerance of, or failure to respond to adequate vaginal estrogen therapy AND they have either failed a reasonable trial of a non-hormonal alternative (such as a plant-based oil or moisturizer) OR symptoms are causing morbid medical illness (e.g. recurrent UTI, vulvar stenosis, etc.).

- Fractionated CO2 laser therapy of the vulva may be offered to non-pregnant, adult women with an established diagnosis of lichen sclerosis with the goal of relief of symptoms, improvement in quality of life, and improvement in genital appearance to clinical eye.
    - People with lichen sclerosis should not be offered CO2 fractionated laser treatment to improve tissue histopathological appearance or to alter the risk of development or progression of vulvar cancer.

- Fractionated CO2 laser should NOT be offered as a first-line treatment of SUI symptoms.

BACKGROUND:

Pelvic floor complaints are common in women. Vaginal or vulvar complaints such as genitourinary syndrome of menopause (GSM), lichen sclerosis of the vulva, or stress urinary incontinence (SUI) can be highly bothersome and, at times, refractory to first or second-line therapy.

CO2 fractionated laser use has been approved by the US Food and Drug Administration (FDA) for treatment of abnormal or precancerous vulvar or vaginal tissues and condylomas.(1) Approval has not been sought for other common gynecologic complaints such as urinary incontinence, GSM, sexual dysfunction, or vaginal rejuvenation. However, many gynecologic clinics offer CO2 fractionated laser treatment of the vulvar and/or vagina for these and a variety

of other gynecologic complaints. The evidence for use in certain gynecologic disorders is growing, but many gaps in the literature still exist. Many gynecologic indications still lack robust trials to support use of the fractionated CO2 laser.(2)

Therefore, this document was created to provide guidance on considerations for fractionated CO2 laser treatment of GSM, lichen sclerosis, and other possible indications for fractionated CO2 laser treatment of the vulva and/or vagina. This document is based on the information available at the time it was written and is not intended to be a comprehensive guide. Clinicians should make decisions on patient treatment according to the best available clinical and evidence-based information, the needs and goals of the patient, and, if necessary, in consultation with other physicians.

PURPOSE:
To describe possible indications for the use of fractionated CO2 laser treatment of the vulva and/or vagina in women presenting with gynecologic complaints, and summarize the evidence for use in such indications.

DEFINITIONS:

Definitions of relevant conditions:
Lichen sclerosis:* Lichen sclerosis is a chronic, inflammatory skin condition, usually affecting the genital and peri-anal epithelium, that creates patches of thin, friable, pale-appearing skin and is characterized by specific pathologic changes in the dermis and epidermis. An established diagnosis of lichen sclerosis should include tissue confirmation by biopsy or strong clinical suspicion with appropriate ruling out of alternative vulvar diagnoses.

Genitourinary syndrome of menopause (GSM):** GSM is defined as a collection of symptoms and signs associated with a decrease in estrogen and other sex steroids involving changes to the labia majora/minora, clitoris, vestibule/introitus, vagina, urethra, and bladder. The syndrome may include but is not limited to genital symptoms of dryness, burning, and irritation; sexual symptoms of lack of lubrication, discomfort or pain, and impaired function; and urinary symptoms of urgency, dysuria, and recurrent urinary tract infections. Women may present with some or all of the signs and symptoms, which must be bothersome and should not be better accounted for by another diagnosis.(3)

Stress urinary incontinence (SUI):*** SUI is involuntary loss or leakage of urine with activities or reflexes that increase intra-abdominal pressure such as coughing, laughing, sneezing, physical exertion, etc. A clinical diagnosis of SUI should include careful review of patient symptoms as well as a genitourinary exam with cough stress test, evaluation of urethral mobility, evaluation for urinary infection, evaluation of bladder emptying, and evaluation for concurrent or complicating issues such as vaginal prolapse, fistula, accessory urinary tracts, etc.

EVIDENCE REGARDING FRACTIONATED C02 LASER USE

See Appendix 1

PROCEDURES:

Provider criteria:
Fractionated CO2 laser for any of the following possible indications considered valid by our clinics must be administered by providers that have had training in the relevant anatomy and demonstrated clinical competence, judgment, and experience in the full range of treatments of the intended conditions, in accordance with the American Urogynecologic Society (AUGS) Clinical Consensus Statement on vaginal-based devices.(4)

Workup and contraindications:
Absolute contraindications for treatment with fractionated CO2 laser include current pelvic malignancy, recent pelvic surgery, or an active infection(4).

Patients considering treatment with vulvar or vaginal fractionated CO2 laser should have the following appropriate workup prior to proceeding with treatment per the AUGS Clinical Consensus Statement:

- Malignant vulvar, vaginal, or cervical pathology should be excluded.
- Patients should have a gynecologic examination within the preceding year by a qualified gynecologic provider before initiating energy-based device therapy.

Clinical Indications:

The AUGS Clinical Consensus committee unanimously decided that potential indications for energy-based devices included inability to use vaginal estrogen treatment for menopausal dyspareunia, GSM, or vaginal dryness(4). The same consensus committee also reached 80% agreement that energy-based devices may be effective for treatment of lichen sclerosis, as at the time of the writing more recent randomized, controlled trials verifying its efficacy were not yet available.(4–6)

Based on the most current evidence (See Appendix 1), the following are recommendations for appropriate patient populations and indications for which to offer CO2 fractionated laser therapy of the vulva and/or vagina in adult, non-pregnant women seeking treatment for the following disorders:

- Lichen sclerosis
  - Non-pregnant, adult women with an established diagnosis of lichen sclerosis* may be offered CO2 fractionated laser treatment of the vulva

for vulvar lichen sclerosis with the goal of relief of symptoms, improvement in quality of life, and improvement in genital appearance to clinical eye (Level of Recommendation: A, Level of Evidence: I)

- CO2 fractionated laser treatment of the vulva should not be utilized with the goal of improving tissue histopathological appearance (Level of Recommendation: C, Level of Evidence: I)
- CO2 fractionated laser treatment of the vulva should not be used to alter risk of development or progression of vulvar cancer (Level of Recommendation: L, Level of Evidence: III)

- Non-pregnant, adult women with an established diagnosis of lichen sclerosis* may be offered rescue CO2 fractionated laser therapy if they have failed topical medical therapy with steroids, either in conjunction with ongoing topical steroids or in place of steroids, depending on patient preference. (Level of Recommendation: B, Level of Evidence: II-3)
- Non-pregnant, adult women with an established diagnosis of lichen sclerosis* may be offered rescue CO2 fractionated laser therapy if they are either unable to tolerate topical steroid therapy or have contraindications or inability to use this therapy (Level of Recommendation: A, Level of Evidence: I)
- It is safe and reasonable to offer women participation in regulated, IRB-approved **clinical trials** of laser therapy for the indication of lichen sclerosis

- Genitourinary syndrome of menopause (GSM)
  - Fractional CO2 laser therapy of the vulva/vaginal should NOT be utilized in the primary treatment of genitourinary syndrome of menopause (GSM) in women that can undergo usual standard treatments such as vaginal topical therapy with moisturizers and/or topical estrogen (Level of Recommendation: A; Level of Evidence: I)
  - Adult women wanting to engage in fractionated CO2 laser therapy of the vulvar and/or vagina for the indication of GSM should be counseled that there is evidence for profound sham effects on clinical and sexual outcomes with this treatment. (Level of Recommendation: A; Level of Evidence: I)
  - Non-pregnant, adult women with an established clinical diagnosis of GSM** may be offered CO2 fractionated laser therapy of the vulva and/or vagina if they have distinct contraindications to, intolerance of, or failure to respond to adequate vaginal estrogen therapy AND they have either failed a reasonable trial of a non-hormonal alternative (such as a plant-based oil or moisturizer) OR symptoms are causing morbid medical illness

(e.g. recurrent UTI, vulvar stenosis, etc.) (Level of Recommendation: B; Level of Evidence: I)
        - Non-pregnant, adult women with an established clinical diagnosis of GSM** may be offered CO2 fractionated laser therapy of the vulva and/or vagina if they are survivors of cancers that would be contraindications to vaginal hormone therapy AND they have either failed a reasonable trial of a non-hormonal alternative (such as a plant-based oil or non-hormonal moisturizers) OR symptoms are causing morbid medical illness (e.g. recurrent UTI, vulvar stenosis, etc.) (Level of Recommendation: B; Level of Evidence: II-2)
    - Stress Urinary Incontinence (SUI)
        - Fractionated CO2 laser should NOT be offered as a first-line treatment of SUI symptoms (Level of Recommendation: C; Level of Evidence: III)
        - Non-pregnant, adult women with an established clinical diagnosis of SUI*** can be offered fractionated CO2 laser therapy if they have failed other SUI treatments such as pelvic floor physical therapy, pessary use, and mid-urethral sling (Level of Recommendation: B; Level of Evidence: III)

Treatment Timing/Settings:

The following are established fractionated CO2 laser treatment courses in the literature according to indication, although needs of patients may vary based on co-existent indication(s), cost, or logistical factors. The body of literature on this topic has a wide variety of treatment timing and frequency, machine settings, and devices used, making a universal recommendation for all patients and all indications not feasible (Level of Recommendation C; Level of Evidence: III).

- Genitourinary syndrome of menopause (GSM)(7,8)
    - Probe in vagina
    - 3 treatments spaced 6 weeks apart
- Lichen sclerosis(6)
    - Probe on vulva
    - 3 treatments 4-6 weeks apart
    - Delay for 2 weeks following vulvar biopsy if indicated/recent
- SUI symptoms(9,10)
    - Probe in vagina
    - 2-3 sessions at monthly intervals
- Local anesthetic applied for 20-30 min prior to procedure, then wiped off prior to procedure

I: Evidence obtained from at least one properly randomized controlled trial
II-1: Evidence from well-designed controlled trials without randomization

II-2: Evidence from well-designed cohort (prospective or retrospective) or case-control studies, preferably from more than one center or research group.
II-3: Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940's) could also be included in this category.
III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.
A: There is good evidence to recommend the clinical preventive action
B: There is fair evidence to recommend the clinical preventive action
C: The existing evidence is conflicting and does not allow to make a recommendation for or against use of the clinical preventive action; however, other factors may influence decision-making
D: There is fair evidence to recommend against the clinical preventive action
E: There is good evidence to recommend against the clinical preventive action
L: There is insufficient evidence (in quantity or quality) to make a recommendation: however, other factors may influence decision making.

REFERENCES:

1. Fractional Laser Treatment of Vulvovaginal Atrophy and U.S. Food and Drug Administration Clearance | ACOG [Internet]. [cited 2021 Nov 14]. Available from: https://www.acog.org/clinical-information/policy-and-position-statements/position-statements/2018/fractional-laser-treatment-of-vulvovaginal-atrophy-and-us-food-and-drug-administration-clearance
2. Shobeiri SA, Kerkhof MH, Minassian VA, Bazi T, IUGA Research and Development Committee. IUGA committee opinion: laser-based vaginal devices for treatment of stress urinary incontinence, genitourinary syndrome of menopause, and vaginal laxity. Int Urogynecol J. 2019 Mar;30(3):371–376.
3. Portman DJ, Gass MLS, Vulvovaginal Atrophy Terminology Consensus Conference Panel. Genitourinary syndrome of menopause: new terminology for vulvovaginal atrophy from the International Society for the Study of Women's Sexual Health and the North American Menopause Society. J Sex Med. 2014 Dec;11(12):2865–2872.
4. Alshiek J, Garcia B, Minassian V, Iglesia CB, Clark A, Sokol ER, et al. Clinical Consensus Statement: Vaginal Energy-Based Devices. Urogynecology (Hagerstown). 2022 Oct 1;28(10):633–648.
5. Mitchell L, Goldstein AT, Heller D, Mautz T, Thorne C, Joyce Kong SY, et al. Fractionated carbon dioxide laser for the treatment of vulvar lichen sclerosus: A randomized controlled trial. Obstet Gynecol. 2021 Jun 1;137(6):979–987.
6. Burkett LS, Siddique M, Zeymo A, Brunn EA, Gutman RE, Park AJ, et al. Clobetasol compared with fractionated carbon dioxide laser for lichen sclerosus: A randomized controlled trial. Obstet Gynecol. 2021 Jun 1;137(6):968–978.
7. Sokol ER, Karram MM. Use of a novel fractional CO2 laser for the treatment of genitourinary syndrome of menopause: 1-year outcomes. Menopause. 2017 Jul;24(7):810–814.
8. Paraiso MFR, Ferrando CA, Sokol ER, Rardin CR, Matthews CA, Karram MM, et al. A randomized clinical trial comparing vaginal laser therapy to vaginal estrogen therapy in women with genitourinary syndrome of menopause: The VeLVET Trial. Menopause. 2020 Jan;27(1):50–56.

This information is a guideline and should not be considered as inclusive of all proper treatments or methods of care or as a statement of the standard of care.

9. Palacios S, Ramirez M. Efficacy of the use of fractional CO2RE intima laser treatment in stress and mixed urinary incontinence. Eur J Obstet Gynecol Reprod Biol. 2020 Jan;244:95–100.
10. Dabaja H, Lauterbach R, Matanes E, Gruenwald I, Lowenstein L. The safety and efficacy of CO2 laser in the treatment of stress urinary incontinence. Int Urogynecol J. 2020 Aug;31(8):1691–1696.

APPROVALS:

SOP Owner:	Kate Meriwether, MD	Date: 4/20/23
Chair Approval:		Date: 4/24/2023
Effective Date:	April 24, 2023	