Molina Clinical Policy
Fractional CO2 Laser Treatment for Traumatic and Burn Scars: Policy No. 443

Last Approval: 10/12/2023
Next Review Due By: October 2024

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Hypertrophic scars are pathological scars resulting from chronic inflammation and excessive collagen production in the healing phase of wounds that penetrate the dermis. Risk factors for hypertrophic scarring include mechanical stretching forces around the wound bed, inflammation, dysregulated wound healing process, genetics, age, and hypertension (Ogawa 2022). The most common injuries that result in hypertrophic scars are burns, traumatic wounds, and surgical sites. Burn injuries alone account for approximately 40,000 hospitalized patients and 486,000 patients seeking medical attention annually in the United States (van Baar 2020). Hypertrophic scars stay confined to the original wound's borders, unlike keloid scars that extend beyond the original wound bed. Hypertrophic scars are raised, firm, erythematous, and can feel painful, itchy, and tight. Fragile scar tissue can be susceptible to tears and blisters, increasing the risk of infection; and the decreased pliability and/or elasticity in the skin can result in contractures that reduce range of motion and mobility, leading to functional impairment. Scarring can also cause permanent disfigurement which, in addition to functional impairment, can greatly decrease a person's quality of life.

Conventional noninvasive scar treatment consists of topical or injectable corticosteroids, compression therapy, and silicone dioxide or non-silicone gel sheeting. These treatments target small non-contractured hypertrophic scars and are employed with the goal to reduce inflammation and tension on the scar tissue; however, compression therapy and gel sheeting have limited high quality evidence attesting to their efficacy (Ogawa 2022). Surgical techniques such as Z- plasty, W-plasty, skin grafts, or local skin flaps are employed when contractures develop, however, these techniques are associated with high recurrence rates and morbidity (Peprah and McCormack 2019).

Fractional Carbon Dioxide Laser Treatment (FCO_2LT) is a dermatological surgical procedure utilizing a laser that targets microscopic columns of the skin in the epidermal and dermal layers to induce therapeutic thermal injury, which stimulates wound healing and collagen remodeling. The skin surrounding these microscopic columns is spared and acts as an anchor to aid in the healing process. This laser treatment can be ablative, in which the epidermal layer is removed, or non-ablative where collagen remodeling is stimulated in the dermal layer with the epidermis remaining intact. The procedure is administered in the outpatient setting and utilizes local anesthetic if anesthetic is necessary at all. Healing time takes one to three weeks post treatment, and multiple treatments are typically necessary to see substantial results.

Regulation Status

The FDA has approved several fractional lasers through the 510(k) Premarket process under product codes GEX for powered laser surgical instruments, and ONG for powered laser surgical instruments with microbeam/fractional output. There are various types of lasers used, either ablative or non-ablative. Examples of lasers used in fractional carbon dioxide laser therapy are UltraPulse® Encore CO2 [Lumenis Ltd., Yokneam, Israel; Lumenis Inc. USA, San Jose, CA], Fraxel Repair [Solta Medical], and Syneron CO2RE System [Syneron-Candela Corp].

COVERAGE POLICY

Ablative or non-ablative Fractional Carbon Dioxide Laser Treatment for the treatment of hypertrophic trauma and burn scars **may be considered medically necessary** when **ALL** the following criteria are met:

1. Member has a permanent hypertrophic scar resulting from trauma or a burn; **AND**
2. Documented evidence that the hypertrophic scar results in functional impairment; **AND**
3. Member has employed at least one conventional noninvasive scar treatment method (including, but not limited to, silicone dioxide or non-silicone gel sheeting, pressure garments, and/or steroid injections) without satisfactory results; **AND**
4. Member is free from **ALL** the following contraindications:
    a. Open wounds and/or active acne lesions at or around treatment site
    b. Active infection at or around the treatment site
    c. Prior radiation therapy to treatment site

Limitations and Exclusions

1. The following indications for fractional laser treatment are considered **experimental, investigational, or unproven** based on insufficient evidence:
    a. Erbium:YAG and Nd:YAG lasers for the treatment of hypertrophic trauma and burn scars with functional impairment
    b. Fractional laser treatment for the treatment of keloid scars
    c. Scar revision in the absence of functional impairment
    d. Cosmetic procedures, including but not limited to, acne management, skin rejuvenation, and/or tattoo removal

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Won et al. (2023) conducted a prospective randomized split scar trial to assess the safety and efficacy of low energy fractional carbon dioxide laser treatment (FCO_2LT) on early-stage pediatric hypertrophic scars. Twenty participants under the age of 12 completed the study. Each participant's scar was split into three zones: one edge was the treatment zone, the middle of the scar was a transition zone and was not included in the results, and the other edge was the control zone that did not receive laser therapy. The primary outcome was a reduction in the Patient and Observer Scar Assessment Scale (POSAS), with a secondary outcome of procedure pain evaluation using the Visual Analogue Scale. The participants underwent three laser therapy treatments at 1-month intervals. The total POSAS score at the 6-month follow-up was significantly lower for the treated site (44.95 for the treated group vs. 64.85 for the control group, $p < 0.0001$). No significant difference was found in patient score of irregularity. The average pain rating on the Visual Analogue Scale was 3.5 ± 1.43 out of 10 after each procedure. The results led the authors to conclude low energy FCO_2LT is a viable therapy in pediatric hypertrophic scars, as it improves scar outcomes with less procedural pain than higher energy laser treatments.

Buhalog et al (2021) conducted a systematic review on FCO_2LT in the treatment of hypertrophic burn scars. While 23 studies met inclusion criteria, 15 of these reported on adverse effects and were thus the studies analyzed. Within the 15 studies, 681 subjects received a cumulative total of 1969 treatments, with 50 minor adverse events noted resulting in an adverse event rate of 2.54% per treatment. The most common adverse events, which often resolved by final follow up, were skin discoloration (20 subjects, 40% of complications), pain and swelling (10 subjects, 20% of complications), and erythema (6 subjects, 12% of complications). The authors reported significant heterogenicity among the studies and stated it is due to the difficulty of performing controlled studies.

Choi et al. (2021) conducted a systematic review on the efficacy of FCO_2LT in the treatment of burn scars. A total of 15 articles, which comprised of 3 RCTs (randomized controlled studies) and 12 observational studies, from the years 2012 to 2019. Sample sizes ranged from 10 to 320 for a combined 778 subjects. All studies analyzed used ablative FCO_2LT with a median of 2.5 (IQR 4.3) treatments per subject, with a range of 1 to 3 months between treatments. The data was subjective with participants self-reporting a 97% satisfaction with FCO_2LT in two studies, and a 76% self-reported resolution in scar pain and pruritis. There was a 95% reported improvement in scar thickness and pliability. The authors concluded that FCO_2LT is a safe and effective procedure in the outpatient setting to improve burn scar symptoms.

Peng et al. (2021) conducted a meta-analysis on the safety and efficacy of FCO_2LT in the treatment of burn scars. Twenty articles were included and weighted mean difference was conducted to combine the results, a random – effect model was used to pool the results, and publication bias was estimated with Begg and Egger's regression asymmetry test. The analysis revealed side effects from FCO_2LT were mild and tolerable, with no major morbidity or mortality related to the procedure documented. The results also uncovered FCO_2LT significantly improved the Vancouver Scar Scale (VSS) score (WMD = -3.24, 95%CI: -4.30, -2.18; P < 0.001), and reduced (POSAS)-patient (WMD = -14.05, 95%CI: -22.44, -5.65; P = 0.001) and Observer (WMD = -6.31, 95%CI: -8.48, -4.15; P < 0.001) scores as well. Upon ultrasonography measurement scar thickness was significantly reduced (WMD = -0.54, 95%CI: -0.97, -0.10; P < 0.001). Only the cutometer measure R2 (scar elasticity) (WMD = -0.06, 95%CI: -0.10, -0.01; P = 0.023) was significantly improved with the laser therapy, but cutometer measures R0 (scar firmness) (WMD = 0.03, 95%CI: -0.04, 0.09; P = 0.482) was not. In conclusion FCO_2LT significantly improved burn scar symptoms, however, the authors noted more large-scale, well designed randomized controlled trials are needed to confirm these findings.

Radmanesh et al (2021) conducted a comparison study to evaluate the efficacy of pulsed dye laser (PDL) versus FCO_2LT in the treatment of hypertrophic scars. Thirty–five participants were enrolled in the study. Depending on scar size and shape, either one hypertrophic scar was treated with PDL on one side and FCO_2LT on the other, or two similar scars were chosen with PDL utilized on one scar and FCO_2LT on the other. The settings used for FCO_2LT were power = 30 W, pulse energy = 50 mJ, density = 200 spots/cm2 for three passes with coagulated tissue was wiped out before the next pass. The settings for pulsed dye laser therapy were 585 nm PDL were 9 J/cm2 with 5 mm spot size for two superimposed passes. Both procedures were repeated every month for 4 months. At the conclusion of the four sessions both sides showed remarkable improvement, but no meaningful difference was detected between two areas that were treated with PDL versus FCO_2LT ($p > .05$). The mean VSS was 7.31 ± 1.93 in the beginning, and the final scores one month after the final session were 4.26 ± 1.48 for FCO_2LT and 4.33 ± 1.70 for PDL.

Zhang et al. (2021) conducted a meta-analysis on the efficacy of FCO_2LT for burn scars. A total of 14 studies were included and the outcomes compiled to analyze scar improvement were the POSAS and VSS. The results revealed scars treated with FCO_2LT significantly improved VSS score (MD -3.01 [95% confidence interval (CI) -3.79, -2.22]; $p < .00001$), and reduced the POSAS score: POSAS Patient (MD -14.38 [95% CI -17.62, -11.13]; $p < .000010$; POSAS - Observer (MD -8.81 [9% CI -11.60, -6.02]; $p < .00001$) especially with regards to pigmentation, vascularity, pliability, and height of scar. Scar thickness measured with ultrasonography decreased non-significantly (MD -0.48 [95% CI -1.04, 0.09]; $p = .1$) whereas cutometer measures, R0 (scar firmness) and R2 (scar elasticity) did not change meaningfully. Patients also reported a reduction in scar pain and pruritis, leading the authors to conclude FCO_2LT is a valuable tool in burn scar severity reduction.

Issler-Fisher et al. (2017) conducted a prospective study on ablative FCO_2LT for burn scar reconstruction. Objective factors analyzed were the VSS, POSAS, and ultrasound measurements of scar thickness. Subjective factors analyzed were quality of life assessed via the Burns Specific Health Scale, neuropathic pain, and pruritus. For treatment effect analysis, patients were stratified according to scar maturation status (> or <2 years after injury). A total of 47 patients with 118 burn scars were included in this short-term study and all completed at least one treatment cycle. At a median of 55 days (IQR 32-74) post treatment all objective parameters decreased significantly: scar thickness decreased from a median of 2.4mm to 1.9mm ($p<0.001$) in addition to a reduction in the VSS score (from a median of 7 to 6 ($p<0.001$), and the POSAS observer score (POSAS-O; maximal score 60) decreased from a median of 29.0 to 21.0 ($p<0.001$, 47 individuals, 118 scars). Participants reported neuropathic pain and pruritis reduction, as well as a 15-point increase (median 120 to 135; $p<0.001$) on the Burns Specific Health Scale which correlates to a rise in quality of life. The results were equally significant across all scars, regardless of their maturity.

SUPPLEMENTAL INFORMATION

Vancouver Scar Scale (VSS): Total Score Ranges from 0 – 13. Points assigned within parentheses.

1. Vascularity: Normal (0) Pink (1) Red (2) Purple (3)
2. Pigmentation: Normal (0) Hypopigmentation (1) Hyperpigmentation (2)
3. Pliability: Normal (0) Supple (1) Yielding (2) Firm (3) Ropes (4) Contracture (5)
4. Height (mm): Flat (0) < 2 (1) 2-5 (2) > 5 (3)

Patient and Observer Scar Assessment Scale (POSAS) is a two-part scoring system that incorporates both patient and observer scores. Each item is scored on a 10-point scale, with the score of 10 being the largest variation from normal skin. Both scores are added together to assign the scar a rating from 6 – 60 points.

1. Patient Scoring Categories: Pain, Thickness, Stiffness, Itch, Color, Irregularity
2. Observer Scoring Categories: Vascularity, Texture, Pliability, Pigmentation, Thickness, Surface Area

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes

CPT	Description
0479T	Fractional ablative laser fenestration of burn and traumatic scars for functional improvement; first 100 cm2 or part thereof, or 1% of body surface area of infants and children
0480T	Fractional ablative laser fenestration of burn and traumatic scars for functional improvement; each additional 100 cm2, or each additional 1% of body surface area of infants and children, or part thereof (List separately in addition to code for primary procedure)

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

10/12/2023 New Policy. IRO Peer Reviewed by a practicing physician board certified in dermatology October 2023.

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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*