

## CO2 (Carbon Dioxide) Fractional Ablative Laser Treatment for Burn and Hypertrophic Scars

**Policy MP-060**

**Origination Date:** 08/26/2020

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### **Disclaimer:**

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial, CHIP, Healthy U (Medicaid) and Health Choice Utah (Medicaid) plans. Refer to the "Policy" section for more information.
3. Services requiring prior-authorization may not be covered, if prior-authorization is not obtained.
4. **This Medical Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.**

### **Description:**

Scars may be considered as a natural part of the healing process associated with cutaneous injuries as a result of disturbed collagen production. Generally, scars are often asymptomatic and do not result in a functional impairment, therefore, do not require any intervention.

Hypertrophic scars remain within the borders of the original incision or area of trauma. They occur in common areas subject to increased tension or movement or in areas with slow wound healing and appear as red, raised, nodular areas of tissue. The hypertrophic scar may be associated with itching and dysesthesias. Most hypertrophic scars spontaneously return to normal.

Contracture scars are commonly found in patients who have experienced burn injuries. They are considered the most severe form of a scar and cause permanent disfiguring problems. Contractures form when the full-thickness edges of skin overlying a joint pull together, affecting the underlying tissues, resulting in constriction of normal movement. The most common method of correcting contractures involves excising the scar and replacing it with additional tissue (i.e., graft or flap) or redirecting the tension lines with techniques such as W-plasty or Z-plasty.

A newer technique, developed in 1964, using carbon dioxide, nitrogen, and helium to treat scars is the fractional ablative carbon dioxide (CO<sub>2</sub>) laser. This is a laser technique used to treat

mature hypertrophic and contracted burn or traumatic scars that result in significant symptoms (such as pain) or physical functional impairment. The laser uses fenestration to relax the tension on scar tissue and improve the pain, burning and itching that can occur. It produces a mid-infrared wavelength (10,600 nm). The CO2 laser is excellent as a cutting instrument because scattering is minimal, absorption in water is excellent, soft tissue vaporization is rapid, and the surrounding tissue damage is negligible. The CO2 laser permits the coagulation of blood vessels smaller than 0.5 mm in diameter.

## **Policy Statement and Criteria**

### **1. Commercial Plans/CHIP**

**U of U Health Plans covers CO2 (Carbon Dioxide) fractional ablative laser procedures for treatment of symptomatic burn scars, in limited circumstances, to correct functional impairment.**

#### **Coverage Criteria for CO2 Fractional ablative Laser Therapy (ALL must be met):**

- A. Member documentation demonstrates laser therapy is intended to treat functional impairment related to severe third degree burns;
- B. Member documentation demonstrates member has attempted and failed conservative therapy;
- C. Member documentation describes location and size of the area to be treated.

**U of U Health Plans covers fractional carbon dioxide laser for the treatment of hypertrophic burn scars, traumatic scars, and surgical scars when conventional therapies (e.g., compression garments, corticosteroid injections, and silicone gel/sheeting) have failed.**

### **2. Medicaid Plans**

**U of U Health Plans Medicaid plans covers CO2 (Carbon Dioxide) fractional ablative laser procedures for treatment of symptomatic burn scars, in limited circumstances, to correct functional impairment.**

#### **Coverage Criteria for CO2 Fractional ablative Laser Therapy (ALL must be met):**

- A. Member documentation demonstrates laser therapy is intended to treat functional impairment related to severe third degree burns;
- B. Member documentation demonstrates member has attempted and failed conservative therapy;
- C. Member documentation describes location and size of the area to be treated.

**U of U Health Plans Medicaid plans covers fractional carbon dioxide laser for the treatment of hypertrophic burn scars, traumatic scars, and surgical scars when conventional therapies (e.g., compression garments, corticosteroid injections, and silicone gel/sheeting) have failed.**

## **Clinical Rationale**

International guideline recommendations on scar management state that “ablative and non-ablative fractional lasers are focus of much current research and that the evidence is generally favorable in scientific literature for preventative and treatment applications”.

In 2023, Hayes released a new health tech assessment for fractional laser treatment (FLT) of burn and traumatic scars for functional improvement. The authors found that most studies were non-comparative and did not report safety-related outcomes. One single study compared FLT plus conservative scar therapy with conventional scar therapy in patients with hypertrophic burn scars and found similar to superior improvement across functional outcomes. There is an overall low-quality body of evidence suggesting that ablative FLT with a carbon dioxide (CO<sub>2</sub>) laser appears reasonably safe and may result in statistically significant improvements in function in patients with functional impairment caused by hypertrophic scarring from burns and/or trauma. The authors concluded that there is insufficient evidence to evaluate the effectiveness and safety of ablative FLT for keloid scars due to burn or trauma and for laser media other than CO<sub>2</sub> lasers. Because it is unclear whether FLT consistently leads to clinically important improvements or whether it provides benefits beyond conventional scar care, further, more robust studies are needed.

In a 2014 uncontrolled, prospective study, Connolly et al reported that fractional CO<sub>2</sub> laser has recently emerged as a promising therapeutic modality to improve the texture and appearance of burn scars. An issue in many burn scars is persistent erythema, which traditionally has been treated with vascular lasers. Fractional CO<sub>2</sub> lasers have been shown to improve the appearance of burn scars, including erythema, but no mechanism has been proposed for this change. The study evaluated the histopathological changes in vasculature of 10 patients with mature burn scars treated with fractionated CO<sub>2</sub> laser, and described the mechanism behind reduced erythema following treatment. Biopsy specimens were obtained before and 2 months after 3 treatment sessions. Anti-CD31 immuno-staining was performed to highlight vascular patterns in biopsy specimens. In histological analysis, an increase in vascular density, particularly of small caliber vessels, was seen following treatment, with an 82.6% average increase in vasculature ( $p = 0.028$ ). This increase in vascularity correlated with a decrease in clinical erythema and vascularity scores, measured using the Vancouver Scar Scale (VSS). The study concluded, mature hypertrophic burn scars treated with a fractional CO<sub>2</sub> laser showed a statistically significant increase in vascular density in the superficial dermis. However, there was a non-statistical decrease in clinically perceived erythema and improvement of overall appearance.

In 2015, El-Zawahry et al analyzed the clinical and histopathological effects of fractional CO<sub>2</sub> laser on thermal burns. A total of 15 patients (11 with hypertrophic and 4 with keloid scars) received 3 CO<sub>2</sub> fractional laser sessions every 4 to 6 weeks; 50% of the scar was untreated as a control. Clinical evaluation by VSS, Patient and Observer Scar Assessment Scale (POSAS) scores, and photography before, monthly, and 3 months after the last laser session was performed; 10 patients were evaluated histopathologically by standard H&E, Masson trichrome, and Elastica von Gieson special stains. Hypertrophic scars (HTSs) showed textural improvement and a significant decrease of VSS, POSAS, and patient scores by the end of follow-up period in the laser-treated area ( $p = 0.011$ ,  $0.017$  and  $0.018$ , respectively) unlike keloid scars. Histopathology revealed significant decrease in scar thickness in HTSs

only ( $p < 0.001$ ) as well as a significant decrease in collagen bundle thickness and density in the upper dermis in both types of scars. The authors concluded that fractional CO<sub>2</sub> laser is a possible safe and effective modality for the treatment of hypertrophic burn scars with improvement achieved both clinically and histopathologically.

In 2016, Levi et al conducted a retrospective study of the use of fractional CO<sub>2</sub> laser for the treatment of symptomatic burn scars and skin grafts. Burn injury and laser treatment demographics, as well as complications, were reported. A questionnaire was administered to all patients and included patient-reported outcome measures aimed at understanding the patient experience and their subjective response to treatment. A total of 387 CO<sub>2</sub> laser procedures were performed on 131 patients for the treatment of symptomatic burn scars and skin grafts between October 1, 2011, and May 1, 2014 (average of 2.95 procedures/patient; range of 1 to 11). Average time between injury and first laser was 597.35 days (range of 60 to 13,475). Average time between laser treatments (when multiple) was 117.73 days (range of 22 to 514). There were no infections requiring treatment with oral antibiotics. Overall patient satisfaction with laser therapy was 96.7%. Patients reported reductions in neuropathic pain, contracture, and pruritus (54.0, 50.6, and 49.0%, respectively). Patient satisfaction with this procedure is high, and complications were low. The authors found that fractional photothermolysis utilizing the CO<sub>2</sub> laser is a safe and effective modality for the treatment of symptomatic burn scars, donor sites, and skin grafts. Significant improvements in scar appearance, pliability, tightness, neuropathic pain, and pruritus were commonly reported. Although, a major drawback from this single-center study were its retrospective design.

A 2016 observational study (Zadkowski et al) reported on children with hypertrophic burn scars treated with fractional ablative CO<sub>2</sub> laser fenestration. From March to April of 2013, a group of 47 patients aged 6 to 16 years underwent 57 laser surgery treatments. The average time from accident was 7.5 years. The results of treatment were investigated in 114 areas. The assessed areas were divided into 2 groups: (i) 9-cm area 1, where the thickness of the scar measured by physician was the lowest, and (ii) 9-cm area 2, where the thickness of the scar was the biggest. 1.9-cm area 1, where the thickness of the scar measured by physician was the lowest, and 2.9-cm area 2, where the thickness of the scar was the biggest. The results were considered on the VSS independently by the surgeon and by parents 1, 4, and 8 months after the procedure. The biggest change in total VSS score in area 1 in the evaluation of the investigator was obtained at follow-up after the 1st month of treatment (average of 7.23 points before and 5.18 points after the 1st month after surgery; a difference of 2.05 points). In the ultrasound assessment, the improvement was statistically significant, more frequently for both minimum and maximum thickness of the scars (B-mode measures) ( $p < 0.05$ ). The main drawback of this study was that these investigators included only the patients with hypertrophic scars, not all the children with burn scars because response to keloids treatment results would be worse, and if they mixed all the scars, results would potentially not be clinically meaningful. Another drawback was excluding patients with parents who do not pay enough attention to their children: in order to achieve good long-term outcomes, strict control of the healing process after the procedure is necessary. There is no guidance on which type of laser or energy dose should be used or the frequency of repeated treatments. This is connected with the high volatility of scars, their different location, and morphology. They concluded, the use of a CO<sub>2</sub> laser in the treatment of hypertrophic scars in children is a safe and effective method and results obtained in this work are very promising.

Several studies published in 2017 also supported the potential efficacy and safety of CO<sub>2</sub> ablative laser therapy for scar treatment. The first study was a non-controlled, open-label, clinical trial (El-Hoshy et al) looked at the efficacy of fractional CO<sub>2</sub> laser in the treatment of mature burn scars. A total of 20 patients with mature burn scars were included in the study. Three fractional CO<sub>2</sub> laser sessions were

given, 4 to 8 weeks apart. Primary outcome was measured using 2 scar scales, the VSS and the POSAS. Secondary outcomes included evaluation of collagen and elastic fibers using routine hematoxylin and eosin, Masson's trichrome, and orcein stains. Outcomes were measured 2 months after the last laser session. Both VSS and POSAS showed significant reduction following treatment ( $p < 0.001$ ). Scar relief and pliability improved most followed by vascularity. Pigmentation improved the least. Percent improvement in POSAS patients' overall assessment was 44.44%. The pattern and arrangement of collagen and elastic fibers showed significant improvement ( $p < 0.001$ ,  $p = 0.001$ , respectively), together with significant improvement in their amounts ( $p = 0.020$ ,  $p < 0.001$ , respectively). No significant correlation existed between clinical and histopathological/histochemical scores. Side effects and complications were mild and tolerable. It was concluded that fractional CO<sub>2</sub> laser can be a safe and effective modality in the treatment of post-burn scars. Although, limitations of this study included its small sample size ( $n = 20$ ) and the relatively short follow-up period (2 months).

Another study in 2017, was a prospective study (Poetschke et al) which evaluated the effects of a single treatment session of fractional ablative CO<sub>2</sub> laser fenestration in 10 adults (average age,  $39.3 \pm 15.3$  years) with widespread hypertrophic burn scars older than 1.5 years. The mean scar age was  $12.45 (\pm 17.18)$  years with a range of 2.5 to 56 years. A total of 60% of participants had previously undergone other forms of scar therapy including scar gels and sheets, microneedling, massages, pressure garments, intralesional corticosteroid injections, and surgery. Two similarly scarred skin areas of approximately 10 cm by 10 cm were defined with one area treated and the other area left untreated as a control. Treatment effects, including scarring, quality of life, and treatment progress were evaluated using the VSS, POSAS, and Dermatology Life Quality Index (DLQI) clinical questionnaires. Measurements of skin relief and pliability in the treated and untreated scars were taken once before treatment, and at 1, 3, and 6 months after a single treatment using a noninvasive high-resolution imaging system and other noninvasive measurement devices. Over the course of 6 months after treatment, VSS and POSAS scores showed significant improvement in the rating of scar parameters, as did the quality of life rating according to the DLQI. The overall VSS score decreased from an initial rating of 6.8 to 2.2 at 6 months ( $p < 0.0001$ ). Pliability improved with a pretreatment VSS of 3.2 to 1.3 at 6 months ( $p = 0.004$ ). The POSAS Observer Scale and Overall Opinion scores dropped from pretreatment to 6 months following treatment (23.60 to 13.30 [ $p = 0.0144$ ] and 5.2 to 2.60 [ $p = 0.0032$ ], respectively), with the largest changes observed in the categories pliability (4.6 to 2.6;  $p = 0.0115$ ), surface area (3.8 to 1.8;  $p = 0.0129$ ), and thickness (3.9 to 2.2;  $p = 0.0192$ ). Objective clinical measurement of scar surface irregularities indicated significant improvement in treated scars over the course of 6 months, with the most improvement occurring 1 to 3 months postoperatively. Throughout the study, none of the participants experienced severe side effects after receiving laser treatment. Treatment pain was reduced with use of local topical anesthesia. The authors concluded that fractional ablative CO<sub>2</sub> laser treatment appears to be a safe and efficacious option for the treatment of hypertrophic burn scars. However, further studies are required with more treatment sessions to see satisfying results.

The final 2017 study was a prospective study (Issler-Fisher et al) that assessed the safety of fractional ablative CO<sub>2</sub> laser treatment in severe burn scars with structural changes. A total of 47 individuals (ages 16-80) with 118 severe burn scars completed laser treatment in the Active FX and Deep FX modes, with ( $n = 6$ ) or without ( $n = 41$ ) other simultaneously performed surgical reconstructive procedures (such as contracture release with Z-plasty). Subjective parameters collected included assessment of neuropathic pain, pruritus, and quality of life using the Burns Specific Health Scale (BSHS-B). For treatment effect analysis, individuals were stratified according to scar maturation status ( $>$  or  $<$  2 years after injury). At a median follow-up of 55 days after laser treatment, all analyzed objective parameters decreased significantly, including intra-patient normalized scar thickness decreasing from a median of 2.4 mm to 1.9 mm ( $p < 0.001$ ), with a concomitant drop in VSS score from a median of 7 to 6 ( $p < 0.001$ ). The

Observer Scar Assessment Score of the POSAS (POSAS-O; maximal score 60) decreased from a median of 29.0 to 21.0 ( $p < 0.001$ , 47 individuals, 118 scars), and the overall POSAS-O (maximal score 10) decreased from 5.0 to 4.0 ( $p < 0.001$ , 46 individuals, 116 scars). All of the identified changes following laser treatment remained significant irrespective of scar maturation status. Quality of life increased significantly by 15 points (median 120 to 135;  $p < 0.001$ ). A significant reduction was reported in both pain and pruritus. No wound infections occurred following laser treatment. The study conclusion was that the preliminary results have shown improvement in thickness, texture, color, and symptoms following treatment. However, larger studies are needed to show further efficacy with CO2 laser treatments.

Finally, a 2019 randomized control trial (Douglas, et al) investigated the effect of ablative fractional CO2 lasers on 20 adult patient's burn scars appearance and dermal architecture at 6 weeks and up to 3-years post-treatment. Inclusion criteria were a minimum scar area of 10x10cm and VSS score of  $>5$  and  $>=6$  months since the time of injury. The region of scar was randomized to treatment/control zones. Treatment zones received 3 standardized laser treatments at 4- to 6-week intervals. All areas of scar received standard scar care. Outcome measures were recorded at baseline, 6-weeks post final treatment and up to 3 years post-treatment. Measures included blinded assessor VSS, Patient Scar Assessment Scale and histological tissue analysis. Nineteen and nine patients completed the short- and long-term studies, respectively. Clinical results revealed improvement in all scar areas over time. There was a statistically significant improvement in pain and itch in the treatment zone compared to the control zone at 6 weeks. Histological data revealed a significant increase in medium-sized collagen fibers at 6 weeks relative to the control site. Sub-group analysis according to scar age revealed greater histological improvement following laser treatment in immature scars relative to more mature scar. The conclusion reached by the study was, that 3 treatments of CO2 laser significantly improve scar pain, itch and dermal architecture at 6 weeks post-treatment. However, histological results suggest greater potential in treating immature scars, therefore, further investigation into the timing of laser treatment could help assist treatment protocols.

## **Applicable Coding**

### **CPT Codes**

- 0479T** Fractional ablative laser fenestration of burn and traumatic scars for functional improvement; first 100 cm<sup>2</sup> or part thereof, or 1% of body surface area of infants and children
- 0480T** ; each additional 100 cm<sup>2</sup>, or each additional 1% of body surface area of infants and children, or part thereof (List separately in addition to code for primary procedure)

### **HCPCS Codes**

No applicable codes

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