

**DRAFT Medical Coverage Policy | Fractional Carbon Dioxide (CO<sub>2</sub>) Laser Ablation Treatment of Hypertrophic Scars or Keloids for Functional Improvement**



**EFFECTIVE DATE:** 07|01|2024

**POLICY LAST REVIEWED:** 03|20|2024

## OVERVIEW

Hypertrophic scars and keloids are cutaneous lesions resulting from abnormal wound healing. There is no gold standard therapy for hypertrophic scars and keloids, and treatment frequently involves multiple techniques including pharmacotherapy, compression, surgery, radiation, and light sources. For scars and keloids impairing function, fractional carbon dioxide (CO<sub>2</sub>) ablative laser treatment is proposed to improve abnormal texture, thickness, and stiffness of scars by ablative destruction and resurfacing. The treatment may be used as monotherapy or in combination with other therapies (e.g., sequential treatment with other lasers, sequential treatment with other therapies, or laser-assisted drug delivery).

## MEDICAL CRITERIA

Not applicable

## PRIOR AUTHORIZATION

Not applicable

## POLICY STATEMENT

### Medicare Advantage Plans

Carbon dioxide (CO<sub>2</sub>) fractional laser ablation treatment of hypertrophic scars or keloids for functional improvement is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

### Commercial Products

Carbon dioxide (CO<sub>2</sub>) fractional laser ablation treatment of hypertrophic scars or keloids for functional improvement is not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

## COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate section of the Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable physician administered drug benefits/coverage.

## BACKGROUND

### Hypertrophic Scars and Keloids

Hypertrophic scars and keloids are cutaneous lesions resulting from abnormal wound healing. Hypertrophic scars present as raised lesions that do not exceed the limits of the original skin injury. They tend to regress spontaneously within 1 year. Keloids present as raised, firm lesions that extend beyond the margins of original injury. Keloids do not regress spontaneously, are often refractory to treatment, and have a high probability of recurrence after excision. The highest prevalence of keloids is in people of color, with an incidence of up to 16% in Black Africans. Keloids can occur months or years after injury.

Consensus-based clinical recommendations published in 2014 endorsed the use of a scar classification system first developed in 2002.4, In this system, hypertrophic scars are classified as linear (e.g., surgical, traumatic) or

widespread (e.g., burn). Keloids are classified as minor or major. Minor keloids are focally raised, itchy scars extending over normal tissue. Major keloids are large, raised (>0.5 cm) scars, possibly painful or pruritic, and extending over normal tissue. Major keloids are often refractory to treatment and have a high probability of recurrence after excision. Mature scars are light-colored and flat. Immature scars are slightly elevated in the process of remodeling and may be painful or itchy. Immature hypertrophic scars (red, slightly raised) may develop into hypertrophic scars; if they persist for longer than 1 month, the guidelines recommend treating them as a linear hypertrophic scar.

There is no gold standard therapy for hypertrophic scars and keloids, and treatment frequently involves multiple techniques including pharmacotherapy, compression, surgery, radiation, and light sources.

#### Laser Therapy for Scar Treatment

Carbon dioxide (CO<sub>2</sub>) fractional laser treatment was initially developed for cosmetic purposes (e.g., photoaging, acne scarring). Fractional CO<sub>2</sub> laser ablation works by creating microscopic thermal wounds, resulting in tissue vaporization and coagulation of surrounding extracellular proteins. The technique has the advantage of reaching the dermis by ablating the epidermis, while avoiding complications associated with nonfractional ablative lasers (no longer in use), such as postoperative pain and infection. For scars and keloids impairing function, CO<sub>2</sub> fractional ablative laser treatment is proposed to improve abnormal texture, thickness, and stiffness of scars by ablative destruction and resurfacing. The treatment may be used as monotherapy or in combination with other therapies (e.g., sequential treatment with other lasers, sequential treatment with other therapies, or laser-assisted drug delivery).

This review focuses on CO<sub>2</sub> fractional ablative laser treatment for functional improvement. Other types of lasers used for hypertrophic scars and keloids include pulsed dye laser and intense pulse light.

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For individuals with hypertrophic scars who receive fractional CO<sub>2</sub> ablative laser treatment as monotherapy for functional improvement, the evidence includes randomized controlled trials (RCTs), nonrandomized studies, and systematic reviews of these studies. Relevant outcomes are functional improvement, quality of life, and adverse effects of treatment. A Cochrane systematic review included 3 RCTs of CO<sub>2</sub> fractional therapy as monotherapy compared to no treatment. None evaluated functional outcomes. For all outcomes reported, the review authors graded the overall evidence as very low certainty, downgraded for very serious imprecision and serious risk of bias. The reviewers concluded that it was unclear whether fractional CO<sub>2</sub> laser impacts scar severity compared with no treatment as measured by commonly used scar scales. Conclusions were limited by study heterogeneity and lack of functional outcome measures. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with keloids who receive fractional CO<sub>2</sub> ablative laser treatment as monotherapy for functional improvement, the evidence includes RCTs, nonrandomized studies, and systematic reviews of these studies. Relevant outcomes are functional improvement, quality of life, and adverse effects of treatment. One RCT included in a Cochrane review evaluated CO<sub>2</sub> fractional laser therapy monotherapy for keloids compared to no treatment. The review authors concluded that it is uncertain whether fractional CO<sub>2</sub> impacts on keloid scar severity compared to no treatment after up to 6 months, downgrading the evidence for very serious imprecision and serious risk of bias. Adverse events and function were not assessed. Scar pain and pruritus outcomes were not presented by treatment arm. Another systematic review included 1 RCT of CO<sub>2</sub>

fractional laser monotherapy compared to intralesional triamcinolone and found no significant differences between keloid response but faster improvement in the intralesional triamcinolone group. Functional outcomes were not evaluated. Conclusions were limited by study heterogeneity and lack of functional outcome measures. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with hypertrophic scars who receive fractional CO2 ablative laser treatment as adjunctive therapy for functional improvement, the evidence includes a RCT, nonrandomized studies, and systematic reviews of these studies. Relevant outcomes are functional improvement, quality of life, and adverse effects of treatment. A systematic review included a 3-arm RCT that compared combination therapy with CO2 laser plus IPL laser, CO2 monotherapy, or no therapy in 23 individuals with hypertrophic scars. Statistically significant improvements were found on commonly used scar scales for both CO2 plus IPL laser and for CO2 alone. The reviewers determined the trial was at unclear risk of bias for unclear adequacy of allocation concealment and blinding. Functional outcomes were not evaluated, and adverse events were not reported. Conclusions were limited by study heterogeneity and lack of functional outcome measures. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with keloids who receive fractional CO2 ablative laser treatment as adjunctive therapy for functional improvement, the evidence includes a RCT, nonrandomized studies, and systematic reviews of these studies. Relevant outcomes are functional improvement, quality of life, and adverse effects of treatment. One RCT included in 2 systematic reviews compared CO2 laser plus intralesional triamcinolone to cryosurgery plus triamcinolone. Of 60 individuals enrolled, 23 were lost to follow-up and not assessed. Scar severity ratings favored the laser therapy group at 12 months, but certainty of the evidence was downgraded due to very serious imprecision and serious risk of bias. Pain not related to treatment favored the CO2 group, but there was no difference in pruritus score. There were more frequent early adverse effects in the CO2 laser group. At 12 months, there was a recurrence of 6 keloid scars (16.7%), all of which were in the CO2 laser group. Conclusions were limited by heterogeneity of subject characteristics and study outcomes measures, small sample sizes, and inconsistent study designs. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## **CODING**

### **Medicare Advantage Plans and Commercial Products**

The following CPT code(s) is not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

- 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** Fractional ablative laser fenestration of burn and traumatic scars for functional improvement; each additional 100 cm<sup>2</sup>, or each additional 1% of body surface area of infants and children, or part thereof

## **RELATED POLICIES**

N/A

## **PUBLISHED**

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## **REFERENCES**

1. Leszczynski R, da Silva CA, Pinto ACPN, et al. Laser therapy for treating hypertrophic and keloid scars. *Cochrane Database Syst Rev*. Sep 26 2022; 9(9): CD011642. PMID 36161591
2. Walsh LA, Wu E, Pontes D, et al. Keloid treatments: an evidence-based systematic review of recent advances. *Syst Rev*. Mar 14 2023; 12(1): 42. PMID 36918908

3. UpToDate. Laser Therapy for Hypertrophic Scars and Keloids. 2023. <http://tinyurl.com/5x5d4tkr>. Accessed November 20, 2023.
4. Gold MH, McGuire M, Mustoe TA, et al. Updated international clinical recommendations on scar management: part 2--algorithms for scar prevention and treatment. *Dermatol Surg*. Aug 2014; 40(8): 825-31. PMID 25068544
5. Gold MH, Berman B, Clementoni MT, et al. Updated international clinical recommendations on scar management: part 1--evaluating the evidence. *Dermatol Surg*. Aug 2014; 40(8): 817-24. PMID 25068543
6. Seago M, Shumaker PR, Spring LK, et al. Laser Treatment of Traumatic Scars and Contractures: 2020 International Consensus Recommendations. *Lasers Surg Med*. Feb 2020; 52(2): 96-116. PMID 31820478
7. Buhalog B, Moustafa F, Arkin L, et al. Ablative fractional laser treatment of hypertrophic burn and traumatic scars: a systematic review of the literature. *Arch Dermatol Res*. Jul 2021; 313(5): 301-317. PMID 32926192
8. Annabathula A, Sekar CS, Srinivas CR. Fractional Carbon Dioxide, Long Pulse Nd:YAG and Pulsed Dye Laser in the Management of Keloids. *J Cutan Aesthet Surg*. 2017; 10(2): 76-80. PMID 28852292
9. Azzam OA, Bassiouny DA, El-Hawary MS, et al. Treatment of hypertrophic scars and keloids by fractional carbon dioxide laser: a clinical, histological, and immunohistochemical study. *Lasers Med Sci*. Jan 2016; 31(1): 9-18. PMID 26498451
10. Behera B, Kumari R, Thappa DM, et al. Therapeutic Efficacy of Intralesional Steroid With Carbon Dioxide Laser Versus With Cryotherapy in Treatment of Keloids: A Randomized Controlled Trial. *Dermatol Surg*. Oct 2016; 42(10): 1188-98. PMID 27661432
11. Blome-Eberwein S, Gogal C, Weiss MJ, et al. Prospective Evaluation of Fractional CO<sub>2</sub> Laser Treatment of Mature Burn Scars. *J Burn Care Res*. 2016; 37(6): 379-387. PMID 27828835
12. Daoud AA, Gianatasio C, Rudnick A, et al. Efficacy of Combined Intense Pulsed Light (IPL) With Fractional CO<sub>2</sub> -Laser Ablation in the Treatment of Large Hypertrophic Scars: A Prospective, Randomized Control Trial. *Lasers Surg Med*. Oct 2019; 51(8): 678-685. PMID 31090087
13. Garg GA, Sao PP, Khopkar US. Effect of carbon dioxide laser ablation followed by intralesional steroids on keloids. *J Cutan Aesthet Surg*. Jan 2011; 4(1): 2-6. PMID 21572673
14. Maari C (2017). Randomized, controlled, within-patient, single-blinded pilot study to evaluate the efficacy of the ablative fractional CO<sub>2</sub> laser in the treatment of hypertrophic scars in adult burn patients. *J Am Acad Dermatol* 76:AB212.
15. Majid I, Imran S. Fractional Carbon Dioxide Laser Resurfacing in Combination With Potent Topical Corticosteroids for Hypertrophic Burn Scars in the Pediatric Age Group: An Open Label Study. *Dermatol Surg*. Aug 2018; 44(8): 1102-1108. PMID 30045141
16. Makboul M, Makboul R, Abdelhafez AH, et al. Evaluation of the effect of fractional CO<sub>2</sub> laser on histopathological picture and TGF- $\beta$ 1 expression in hypertrophic scar. *J Cosmet Dermatol*. Sep 2014; 13(3): 169-79. PMID 25196683
17. Srivastava S, Kumari H, Singh A. Comparison of Fractional CO<sub>2</sub> Laser, Verapamil, and Triamcinolone for the Treatment of Keloid. *Adv Wound Care (New Rochelle)*. Jan 01 2019; 8(1): 7-13. PMID 30705785
18. Wang J, Wu J, Xu M, et al. Combination therapy of refractory keloid with ultrapulse fractional carbon dioxide (CO<sub>2</sub>) laser and topical triamcinolone in Asians-long-term prevention of keloid recurrence. *Dermatol Ther*. Nov 2020; 33(6): e14359. PMID 33002270
19. Zuccaro J, Muser I, Singh M, et al. Laser Therapy for Pediatric Burn Scars: Focusing on a Combined Treatment Approach. *J Burn Care Res*. Apr 20 2018; 39(3): 457-462. PMID 29897540

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