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MEDICAL POLICY – 2.01.107

Fractional Carbon Dioxide (CO2) Laser Ablation Treatment of Hypertrophic Scars or Keloids for Functional Improvement

BCBSA Ref. Policy:	2.01.107	
Effective Date:	April 1, 2024	RELATED MEDICAL POLICIES:
Last Revised:	Mar. 12, 2024	2.01.57 Electrostimulation and Electromagnetic Therapy for Treating Wounds
Replaces:	N/A	

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

Fractional carbon dioxide laser ablation is a minimally invasive procedure used to treat skin conditions such as hypertrophic scars or keloids. This treatment involves using a specialized laser to remove layers of scar tissue, promoting the growth of new, healthier skin cells. By targeting specific areas of the scar, the laser helps to improve the appearance and flexibility of the scar tissue, leading to functional improvement.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Treatment	Investigational
Carbon dioxide (CO2) fractional laser ablation treatment of hypertrophic scars or keloids	**Carbon dioxide (CO2) fractional laser ablation treatment of hypertrophic scars or keloids for functional improvement is considered investigational.**

Coding

Code	Description
CPT	
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

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Related Information

N/A

Evidence Review

Description

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 (CO2) 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).

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 one year.[1] 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.[2] Keloids can occur months or years after injury.[3]

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.[5]

Laser Therapy for Scar Treatment

Carbon dioxide (CO2) fractional laser treatment was initially developed for cosmetic purposes (e.g., photoaging, acne scarring). Fractional CO2 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, CO2 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 CO2 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.

Summary of Evidence

For individuals with hypertrophic scars who receive fractional CO2 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 CO2 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 CO2 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 CO2 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 CO2 fractional laser therapy monotherapy for keloids compared to no treatment. The review authors concluded that it is uncertain whether fractional CO2 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 the treatment arm. Another systematic review included 1 RCT of CO2 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 an 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 an 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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this review are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04736251	A Prospective Intra-patient Single-blinded Randomised Trial to Examine the Mechanistic Basis of fractiOnal Ablative carbOn Dioxide Laser Therapy in Treating Adult Burns and/or Trauma Patients With Hypertrophic Scarring (SMOOTH)	60	Aug 2023
NCT04567537	Ablative Fractional Laser Treatment for the Improvement of Hypertrophic Scars and Scleroderma: a Prospective Cohort Study	20	May 2024
NCT03692273	A Within-Scar, Randomized Control Trial Comparing Fractional Ablative Carbon Dioxide Laser to Non-Energy-Based, Mechanical Tissue Extraction and No Treatment	120	Dec 2024
NCT04364217	Evaluating the Mechanism of Pain and Itch Reduction in Burn Scars Following Fractional Ablative CO2 Laser Treatment	28	Jul 2025

NCT: national clinical trial.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

International Advisory Panel on Scar Management

In 2014, Gold et al published updated international clinical recommendations on scar management.[4] Although they were not informed by a systematic review and strength of evidence ratings were not provided, the recommendations are frequently cited and were accompanied by a narrative review of the literature.[5] The recommendation document notes that,

where clinical evidence was lacking, management recommendations were based on advisory panel member consensus.

Specific recommendations on laser therapy include the following, according to scar classification:

- Immature or Erythmatous Hypertrophic Scars

  "In the case of persistent erythema for more than a month despite preventative efforts, management should transition to that of a linear hypertrophic scar or alternatively, pulsed-dye laser therapy may be applied once monthly for 2 to 3 months. If the scar is unresponsive to the pulsed-dye laser, fractional laser therapy or treatment as a linear hypertrophic scar may be instituted."

- Linear Hypertrophic Scars Arising from Surgery or Trauma

  "Pulsed-dye or fractional laser therapy are second-line and, often, first -line options for linear hypertrophic scars."

- Widespread Burn Hypertrophic Scars

  "Positive data for fractional lasers support their use for burn scar treatment. Ablative fractional lasers offer the advantage of fewer treatment sessions compared with nonablative options."

- Minor Keloids

  If improvement with conservative therapy is not observed within 8 to 12 weeks, 5-FU in combination with intralesional corticosteroids and, ultimately, laser therapy or surgical excision may be considered. Although data from published clinical trials are lacking, some advisory panel members suggest the use of ablative fractional lasers over other types of laser therapy for the treatment of refractory keloids."

- Major Keloids

  "Secondary management options for refractory keloids include laser treatment and surgical excision with appropriate prophylactic therapy."

Consensus Recommendations

In 2020, Seago et al published consensus recommendations on laser treatment of scars and contractures.[6] The recommendations were developed by a panel of 26 dermatologists and plastic and reconstructive surgeons from 13 countries between March 2018 and March 2019. The panel used a modified Delphi method consisting of 2 rounds of email questionnaires and supplementary face-to-face meetings. The threshold for consensus recommendations was at least 80% concurrence among the panel members. The recommendations were not informed by a systematic review and do not include strength of evidence ratings.

Specific recommendation statements on laser therapy include the following:

- "The panel members are unanimous in their view that lasers are a first-line therapy in the management of traumatic scars and contractures."
- "The potential indications for laser treatment are determined based on clinical findings (i.e., erythema, hypopigmentation, hyperpigmentation, atrophy, hypertrophy, degree of epithelialization, pliability, and restriction) as well as subjective symptoms including pain and pruritus."
- "The fractional lasers, especially AFL, have the most potential to treat the entire range of clinical issues as a single modality. The optimal treatment routinely includes multiple laser types in concurrent or alternating treatment sessions to suit varying clinical presentations and treatment goals in a particular location at a particular time. Effective comprehensive traumatic scar management frequently incorporates surgical evaluation, ongoing conservative measures (i.e., compression, massage, and silicone gels and sheets); physical and occupational therapy; medical management such as corticosteroids and antimetabolites; and mental health evaluation where appropriate."

The document also includes recommendations on device application and settings but notes, "Optimal wavelengths and settings for traumatic scar management have not yet been fully elaborated in the literature and settings will vary depending on the characteristics of the particular device chosen by the operator, the clinical findings on the day of the visit (e.g., degree of erythema, presence of a tan, etc.), and issues specific to the individual (e.g., pain tolerance, approximate downtime, etc.)."

In its recommendations on scar assessment, the panel noted, "Continuing research is vital to determining the optimal laser devices, timing, combinations, and settings in the management of traumatic scars," and "Given the greater range of scar response to current laser techniques such as AFL, future scar assessment should incorporate evaluation of function, symptom relief, and overall quality of life to a greater extent."

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

Multiple fractional CO2 laser systems have been approved by FDA through the 510(k) program. These devices have broad indications for dermatological procedures requiring ablation, resurfacing, and coagulation of soft tissue.

FDA Product Codes GEX, ONG.

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History

Date	Comments
04/01/24	New policy, approved March 12, 2024, Policy created with literature review through November 30, 2023. CO2 fractional laser ablation treatment for hypertrophic scars and keloids to improve function is considered investigational. Added CPT codes 0479T and 0480T.

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