Clinical Policy Title: Laser treatments for hypertrophic scars

Clinical Policy Number: CCP.1304

Effective Date: June 1, 2017
Initial Review Date: May 19, 2017
Most Recent Review Date: May 7, 2019
Next Review Date: May 2020

Policy contains:
- Hypertrophic scars.
- Keloids.
- Pulsed dye laser therapy.

Related policies:
None.

ABOUT THIS POLICY: AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas’ clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas’ clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas’ clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas’ clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas considers the use of laser treatments for hypertrophic scars for therapeutic and preventive purposes to be clinically proven, and therefore, medically necessary if there is documentation of physical impairment caused by the scar, for members who have not responded to conservative treatments (Gold, 2014; Monstrey, 2014).

Limitations:

AmeriHealth Caritas considers all other uses of laser treatments for hypertrophic scars to be investigational, and therefore, not medically necessary, including cases when the procedure is for cosmetic purposes.

Alternative covered services:
- Excision/closing of wound.
- Corticosteroid injections.
- Silicone elastomer sheeting.
- Pressure dressings or garments.
- Injection of intralesional triamcinolone acetate.

**Background**

Hypertrophic scars are skin conditions resulting from the over-production and deposits of collagen. The scar occurs after burns, cuts, wounds, traumatic injuries, infections, and piercings, and occur most often in the shoulders, neck, presternum, knees, and ankles. The scar often is red in color (sometimes pink or purple). It is slightly raised above the skin, and is thick, itchy, and sometimes painful.

High incidence occurs after surgery (40 percent to 70 percent) and burns (90 percent) (Gauglitz, 2011). There is a genetic predisposition to developing raised skin scars such as hypertrophic scars, most likely due to the interaction of several gene pathways plus environmental factors (Brown, 2009).

Hypertrophic scars will appear within a month after a traumatic event. Collagen deposition develops in stages: inflammation during day 3 – 10, proliferation during day 11 – 24, and maturation beginning day 24 and lasting months. Keloids, which are more elevated and firm than hypertrophic scars, are somewhat similar, but have some clinical, histological, and epidemiological differences (Juckett, 2009; Gauglitz, 2011).

The majority of hypertrophic scars will become paler and flatten after 1 – 2 years, without any treatment. However, some cases require intervention. A simple excision is a common means of treatment if the scar is accessible, and steroid injections may be appropriate as well. Recurrence after these treatments is rare. Persons under age 30 often have a longer progression of scar maturation than do those over age 55 (Bond, 2008).

One review listed pressure therapy (preferred), topical silicone gel sheeting, and flavonoids in scar creams as prophylactic therapies, with imiquimod five percent cream and intradermal avotermorph (TGF-B3) as emerging approaches. It also cited intra-lesional corticosteroid injections, cryotherapy, surgical manipulation/scar revision (preferred), radiotherapy (X-rays, electron beams, and brachytherapy), and laser therapy as current treatments. It reviewed interferon injections, bleomycin sulfate injections, and 5-Fluorouracil injections as emerging therapies for hypertrophic scars (Gauglitz, 2011).

Lasers, including the pulsed dye laser and laser-assisted skin healing, have been used to accelerate and improve the healing process in surgical scars since 1983. Hypertropic scars is one of the conditions for which lasers have been applied (Leclere, 2010).

The most popular laser therapy has been the 585 nanometer pulsed-dye laser; other commonly-used methods are the 595 nanometer pulsed-dye laser and laser-assisted skin healing 810 nanometer
(Leclere, 2010). Laser therapy is administered as 2 – 6 treatments for each patient with hypertrophic scars. This treatment is believed to induce neocollagenesis and decrease fibroblast proliferation, as well as release histamine that influences fibroblast activity. The most common side effect of laser therapy is post-operative purpura, which can persist for 7 – 10 days. Other adverse events include transient hyper- or hypo-pigmentation and blistering, along with hyperpigmentation (Gauglitz, 2011).

**Searches**

AmeriHealth Caritas searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality.
- The Centers for Medicare & Medicaid Services.
- Cochrane reviews.

We conducted searches on March 15, 2019. Search terms were: “hypertrophic scar,” “laser therapy,” and “pulsed dye laser.”

We included:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

In 2014, a set of recommendations for scar prevention and management were released by the International Advisory Panel on Scar Management. The panel cited growing evidence supporting a place in therapy for newer agents in scar management, including pulsed-dye and fractional laser therapy. Authors state that pulsed-dye or fractional laser therapy are second-line and often first-line treatments for hypertrophic scars. They note that positive data support the use of ablative fractional lasers for widespread burn hypertrophic scars (Gold, 2014).

Another guideline for hypertrophic scar therapy mentions several useful modalities, including laser treatments (Gupta, 2011). Another guideline is based on an international and multi-specialty panel of 24 European experts. The panel states that while various therapies can be used to reduce hypertrophic scars, silicone sheeting or gel is considered as the first line low-intensity intervention for prevention and treatment (Monstrey, 2014). The German Society of Dermatology guidelines recommended pulsed dye
laser as the primary treatment for reducing erythema, and that it also should be considered for severe pruritus (Nast, 2012).

Guidelines for treating hypertropic scars for pediatric cases are limited. One review stated that pulsed dye laser is effective in treating hypertropic scars, but that evidence is limited and that outcomes are modest for large scars (Krakowski, 2016).

Currently, there is no universally accepted set of standards for treatment of hypertrophic scars (Lumenta, 2014). Moreover, a review of 29 studies found that of 18 rating scales, only one received a high quality rating, but only in the area of reliability for total scores and the subscale vascularity, making it difficult to evaluate effectiveness of treatments (Tyack, 2012). Clear algorithms for preventing and treating hypertrophic scars and keloids are limited (Ogawa, 2010). Some analyses do not make the distinction between hypertrophic scars and keloids, limiting ability to assess efficacy (Atiyeh, 2007).

A review listed approaches considered effective for hypertrophic scars, including cryotherapy (as a first-line approach); corticosteroid injections (first-line); silicone elastomer sheeting (first-line for prevention and treatment); pressure dressings or garments (prevention); and combined surgery, silicone sheeting, and corticosteroid injection (second-line). Other less-studied methods with no demonstrated effectiveness include intrallesional verapamil, fluororacil, bleomycin, interferon alfa-2b injections, topical iniquumod percent cream, and onion extract topical gel, and topical vitamin E. Pulsed dye laser was only addressed as a treatment for keloids (Juckett, 2009).

A literature review determined that pulsed-dye laser had low efficacy for the prevention of hypertrophic scars, but pulsed-dye and CO2 laser combined had high efficacy for the treatment of existing scars (Khansa, 2016).

Perhaps the first meta-analysis to confirm safety and efficacy of laser therapy included 28 trials (n = 919), including both hypertrophic scars and keloids. The response rate was 71 percent for scar prevention, 68 percent for hypertrophic scars, and 72 percent for keloid treatment. Studies showed improvement in Vancouver Scar Scale scores, scar height, and scar erythema of hypertrophic scars. Optimal treatment was 5 – 6 weeks (Jin, 2013).

A systematic review of eight randomized controlled trials found pulsed dye laser therapy for hypertrophic scars and keloids were superior to conventional means in improving scar appearance, but there was no difference when scar parameters were evaluated separately (de las Alas, 2012). Another systematic review determined that laser treatment efficacy has been largely anecdotal, with no consensus of optimal wave length or amount of energy used (Kim, 2013).

Another systematic review of 13 articles evaluated seven lasers for efficacy in treating hypertrophic scars. The often-used pulsed dye laser 585 nanometers was included in eight studies, but was considered to have low efficacy in treatment. The other six laser treatments showed more promising
results, but most were included in only one or two studies, and authors recommended more research (Vrijman, 2011).

A systematic review of 12 studies by Canadian researchers on effectiveness of laser therapy for hypertrophic burn scars found insufficient scientific evidence to determine effectiveness of this treatment. Authors state that more randomized controlled trials are needed (Zuccaro, 2017).

A systematic review of 38 studies determined the evidence is strongest for intralesional 5-fluoracil in treating keloids, hypertrophic scars, and keratoacanthomas (the procedure can be administered topically, intralesionally, or assisted by lasers) (Prince, 2018).

In a study of 95 patients with hypertrophic scars undergoing 163 laser treatment sessions (71 percent with pulsed dye laser), adverse events were found in 43 percent (41 of 95) of cases. Pain (37 percent of patients with adverse events), mild blistering (27 percent), hypopigmentation (12 percent), and fever (10 percent) accounted for most events. Pulsed dye laser patients had significantly lower rate of hypopigmentation, compared to those undergoing CO2 laser. However, most adverse events were mild (Clayton, 2013).

One study found that improvement in Vancouver scar scale after treatment of post-surgical scars with 585 nm pulsed dye laser was relatively equal for short- and long-pulse uses (92 and 89 percent), with both being significantly greater than the 67 percent improvement at the control site (Nouri, 2010). Another study of post-surgical scar treatment found that 585 nm was more effective than the 595 nm mode in normalizing the height, vascularity, and pliability of scars (Nouri, 2009); superiority of the 585 nm has been confirmed in other studies (Gauglitz, 2013).

In a systematic review of three randomized controlled trials investigating efficacy of intralesional injections of triamcinolone, 5-Fluorouracil combined triamcinolone and additional irradiation with a 585 nm pulsed-dye laser to treat hypertrophic scars. Results showed this approach to be superior to others – if the pulsed-dye laser is not used (Kafka, 2017).

The 1064-nm Neodym: YAG laser, which reaches greater depths than a pulsed dye laser, has shown potential to improve keloids and hypertrophic scars. Its ability to treat thick keloids may be limited since its efficacy decreases with the thickness of the scar (Akaishi, 2012).

Policy updates:

A total of one guideline/other and two peer-reviewed references were added to, and six peer-reviewed references were removed from, this policy in March, 2019.

The policy number was changed from #CD17.02.07 to CCP.1304 in March, 2019.

References
**Professional society guidelines/other:**


**Peer-reviewed references:**


**Centers for Medicare & Medicaid National Coverage Determinations:**

No National Coverage Determinations identified as of the writing of this policy.

**Local Coverage Determinations:**

No Local Coverage Determinations identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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