Clinical Policy Title: Laser treatments for hypertrophic scars

Clinical Policy Number: 17.02.07

Effective Date: June 1, 2017
Initial Review Date: May 19, 2017
Most Recent Review Date: April 10, 2018
Next Review Date: April 2019

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

Related policies:
None.

ABOUT THIS POLICY: Select Health of South Carolina has developed clinical policies to assist with making coverage determinations. Select Health of South Carolina’s 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 Select Health of South Carolina 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. Select Health of South Carolina’s 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. Select Health of South Carolina’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Select Health of South Carolina will update its clinical policies as necessary. Select Health of South Carolina’s clinical policies are not guarantees of payment.

Coverage policy

Select Health of South Carolina 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 (Gold, 2014; Monstrey, 2014).

Limitations:

All other uses of laser treatments for hypertrophic scars are considered investigational/experimental, 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 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 (Gauglitz, 2011; Juckett, 2009).

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 avoterin (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 (5-FU) injections as emerging therapies for hypertrophic scars (Gauglitz, 2011).

The most popular laser therapy has been the 585 nanometer (nm) pulsed-dye laser; other commonly-used methods are the 595 nm pulsed-dye laser and laser-assisted skin healing 810 nm (Leclere, 2010). Laser therapy is administered as 2 – 6 treatments for each patient with hypertrophic scars. This treatment is believed to induce neocollagensesis 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).

More research on laser therapy is recommended, i.e., a prospective randomized, controlled study using the 595 nm pulsed dye laser, in preventing scars with less than six months duration (Brewin, 2014).
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).

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).

**Searches**

Select Health of South Carolina searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on February 14, 2018. Search terms were: “hypertrophic scar,” “laser therapy,” and “585 nm 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**

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 intralesional 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 nm 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 20 articles on hypertrophic scar treatment rated laser therapy “favorable” but this was based on just two trials on laser therapy, with a total of only 58 subjects (Friedstat, 2014).

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).

A study of 203 patients with bilateral reduction mammoplasty or median sternotomy incision found 60 percent developed a hypertrophic scar within one year, nearly all within three months, of the operation. Half of the scars that occurred within three months regressed by month 12. Non-smoking and young persons had an elevated risk for scars (Mahdavaian, 2012).

A 2013 review of 147 burn patients with hypertrophic scars used pulsed dye laser or CO2 therapy. Treatments occurred 16 and 48 months after burn injury. Significant decreases were observed in both Vancouver Scar Scale and UNC Scar Scale, suggesting the treatments were effective (Hultman, 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 (5-FU) 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).

A study of 56 randomly-divided patients assessed the effect treating immature red hypertrophic scars with an adjustable pulse width Pulsed Dye Laser, with versus without fractional CO2 laser. The total score of the Vancouver Scar Scale, and score of the melanin, height, vascularity, and pliability in the group without CO2 laser decreased more (p<.05), and thus combining the two types of lasers was more beneficial. (Ouyang, 2018).

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 five peer-reviewed references were added to, and two peer-reviewed references were removed from, this policy in February 2018.

**Summary of clinical evidence:**
<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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| **Key points:**     | Meta-analysis of 28 studies (n=919)  
|                     | Response rate for laser therapy was 71% for scar prevention, 68% for hypertrophic scars, 72% for keloids  
|                     | Optimal treatment interval was 5 to 6 weeks  
|                     | Best responses from 585/595 nm pulsed-dye and 532-nm lasers  
| Clayton (2013)      | Rate of adverse events from laser therapies for treatment of hypertrophic burn scars |
| **Key points:**     | Descriptive study over 6 months of 95 burn patients with 163 laser treatments  
|                     | 71% received pulse dye laser, 22% received CO2 laser, 7% received other lasers  
|                     | Total of 41 adverse effects recorded (43%)  
|                     | Most common were pain (37%), mild blistering (27%), hypopigmentation (12%), fever (10%), and all other (14%)  
|                     | Major effects were exceedingly rare, and improved in all patients  
| Tyack (2012)        | Rating burn scars using various scales |
| **Key points:**     | Systematic review of 29 studies, with data for 18 scar rating scales  
|                     | 17 of 18 scales had a low quality rating, or an indeterminate rating due to methodological issues  
|                     | Other scale (Patient and Observer Scar Assessment Scale) only had high quality rating in area of reliability for total score and vascularity  
|                     | Heterogeneity of scales make it difficult to evaluate efficacy of types of scar treatment  
| Vrijman (2011)      | Comparison of efficacy of seven types of lasers for hypertrophic scars |
| **Key points:**     | Systematic review of 8 studies evaluating types of lasers for hypertrophic scar therapy  
|                     | Pulsed dye laser 585 nm was reviewed in all 8 studies, but showed low efficacy  
|                     | Pulsed dye laser 595 nm shows promise, but more research needed  
|                     | Other lasers had better results, but most were only included in 1 trial  
| Nouri (2010)        | Comparison in improvement in 585 vs. 595 nm pulsed dye laser treatment |
| **Key points:**     | Prospective study of 20 patients with postoperative linear scars >2.1 cm, given 585 nm pulsed dye laser treatment, 595 nm pulsed dye laser treatment, or control field  
|                     | Patients treated immediately after wound sutures removed, then monthly for 3 months  
|                     | 585 and 595 nm pulsed dye treatments were equally successful (92% and 89%) in improving Vancouver scar scale  
|                     | Both treatments significantly more effective than control (67%)  
|                     | No differences detected in efficacy of short- and long-pulse dye laser treatment  

**References**

Professional society guidelines/other:


**Peer-reviewed references:**


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCDs):**

No LCDs 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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<tr>
<td>17111</td>
<td>Destruction (eg, laser surgery, electrocautery, cryosurgery, chemosurgery, surgical curettage) of benign lesions other than skin tags or curaneous vascular proliferative lesions; 15 or more lesions</td>
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