Anthem

Clinical UM Guideline

Subject: Treatment of Keloids and Scar Revision
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Description

This document describes the medically necessary and reconstructive indications for the treatment of keloids and scar revision.

Note: Please see the following related documents for additional information:

- ANC.00007 Cosmetic and Reconstructive Services: Skin Related
- ANC.00008 Cosmetic and Reconstructive Services of the Head and Neck
- MED.00110 Silver-based Products for Wound and Soft Tissue Applications
- SURG.00011 Allogeneic, Xenographic, Synthetic, Bioengineered, and Composite Products for Wound Healing and Soft Tissue Grafting

Medically Necessary: In this document, procedures are considered medically necessary if there is a significant functional impairment AND the procedure can be reasonably expected to improve the functional impairment.

Reconstructive: In this document, procedures are considered reconstructive when intended to address a significant variation from normal related to accidental injury, disease, trauma, treatment of a disease or a congenital defect.

Note: Not all benefit contracts/certificates include benefits for reconstructive services as defined by this document. Benefit language supersedes this document.

Cosmetic: In this document, procedures are considered cosmetic when intended to change a physical appearance that would be considered within normal human anatomic variation. Cosmetic services are often described as those that are primarily intended to preserve or improve appearance.

Clinical Indications

I. Treatment of Keloids

Medically Necessary:

Treatment of a keloid is considered **medically necessary** when there is documented evidence of significant functional impairment related to the keloid **and** the treatment can be reasonably expected to improve the functional impairment.

Treatment of a keloid with radiation therapy (up to 3 fractions) is considered **medically necessary** as adjunct therapy following surgical excision (initiated within 3 days) when the medically necessary criteria for keloid removal are met.

Reconstructive:

Treatment of a keloid is **reconstructive** when the keloid results in a significant variation from normal related to accidental injury, disease, trauma, or treatment of a disease.

Treatment of a keloid with radiation therapy (up to 3 fractions) is considered **medically necessary** as adjunct therapy following surgical excision (initiated within 3 days) when the reconstructive criteria for keloid removal are met.

Cosmetic and Not Medically Necessary:

Treatment of keloids is considered **cosmetic and not medically necessary** when performed in the absence of a significant functional impairment, is not reconstructive, and is intended to change a physical appearance that would be considered within normal human anatomic variation.

II. Scar Revision

Medically Necessary:

Scar revision is considered **medically necessary** when there is documented evidence of significant functional impairment related to the scar **and** the treatment can be reasonably expected to improve the functional impairment.

Fractional ablative carbon dioxide laser fenestration of a burn scar or traumatic scar is considered **medically necessary** when there is documented evidence of significant functional impairment related to the scar (that is, limited movement) **and** the treatment can be reasonably expected to improve the functional impairment **and** the individual has tried at least one other scar revision intervention (for example, silicone gel or sheeting, or pressure garments).

Reconstructive:

Scar revision is considered **reconstructive** when there is significant variation from normal related to accidental injury, disease, trauma, or treatment of a disease or congenital defect.

Cosmetic and Not Medically Necessary:

Scar revision is considered **cosmetic and not medically necessary** when performed in the absence of a significant functional impairment, is not reconstructive, and is intended to change a physical appearance that would be considered within normal human anatomic variation.

Fractional ablative carbon dioxide laser fenestration is considered **cosmetic and not medically necessary** when performed in the absence of a significant functional impairment and is intended to change a physical appearance that would be considered within normal human anatomic variation. (For example: enhance the appearance of the upper layer of the skin as a result of acne, acne scars, uneven pigmentation or wrinkles).

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary or Reconstructive when criteria are met:

CPT	
11400-11446	Excision benign lesions [includes codes 11400, 11401, 11402, 11403, 11404, 11406, 11420, 11421, 11422, 11423, 11424, 11426, 11440, 11441, 11442, 11443, 11444, 11446]
12031-13153	Repair, intermediate complex [includes codes 12031, 12032, 12034, 12035, 12036, 12037, 12041, 12042, 12044, 12045, 12046, 12047, 12051, 12052, 12053, 12054, 12055, 12056, 12057, 13100, 13101, 13102, 13120, 13121, 13122, 13131, 13132, 13133, 13151, 13152, 13153]
14000-14302	Adjacent tissue transfer or rearrangement [includes codes 14000, 14001, 14020, 14021, 14040, 14041, 14060, 14061, 14301, 14302]
0479T	Fractional ablative laser fenestration of burn and traumatic scars for functional improvement; first 100 cm^2 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^2, or each additional 1% of body surface area of infants and children, or part thereof

ICD-10 Procedure	
0HN0XZZ-0HNNXZZ	Release, skin, external approach [by body area; includes codes 0HN0XZZ, 0HN1XZZ, 0HN2XZZ, 0HN3XZZ, 0HN4XZZ, 0HN5XZZ, 0HN6XZZ, 0HN7XZZ, 0HN8XZZ, 0HN9XZZ, 0HNAXZZ, 0HNBXZZ, 0HNCXZZ, 0HNDXZZ, 0HNEXZZ, 0HNFXZZ, 0HNGXZZ, 0HNHXZZ, 0HNJXZZ, 0HNKXZZ, 0HNLXZZ, 0HNMXZZ, 0HNNXZZ]

ICD-10 Diagnosis	
L73.0	Acne keloid
L90.5	Scar conditions and fibrosis of skin
L91.0	Hypertrophic scar (keloid)

When services are Cosmetic and Not Medically Necessary:
For the procedure and diagnosis codes listed above when medically necessary or reconstructive criteria are not met, or when the code describes a procedure designated in the Clinical Indications section as cosmetic and not medically necessary.

When services may also be Medically Necessary or Reconstructive for adjunct keloid treatment when criteria are met:

CPT	
77261	Therapeutic radiology treatment planning; simple
77290	Therapeutic radiology treatment planning; intermediate
77300	Basic radiation dosimetry calculation, central axis depth dose calculation, TDF, NSD, gap calculation, off axis factor, tissue inhomogeneity factors, calculation of non-ionizing radiation surface and depth dose, as required during course of treatment, only when prescribed by the treating physician
77332	Treatment devices, design and construction; simple (simple block, simple bolus)
77334	Treatment devices, design and construction; complex (irregular blocks, special shields, compensators, wedges, molds or casts)
77401	Radiation treatment delivery, superficial and/or ortho voltage, per day
77402	Radiation treatment delivery; > 1 MeV; simple
77407	Radiation treatment delivery; > 1 MeV; intermediate
77412	Radiation treatment delivery; > 1 MeV; complex
77431	Radiation therapy management with complete course of therapy consisting of 1 or 2 fractions only

ICD-10 Diagnosis	
L73.0	Acne keloid
L91.0	Hypertrophic scar (keloid)

When services are Cosmetic and Not Medically Necessary:
For the procedure and diagnosis codes listed above when medically necessary or reconstructive criteria are not met, or when the code describes a procedure designated in the Clinical Indications section as cosmetic and not medically necessary.

Discussion/General Information

Concepts of Medical Necessity, Reconstructive, and Cosmetic

The coverage eligibility of medical and surgical therapies to treat skin conditions is often based on a determination of whether treatment is considered medically necessary, reconstructive, or cosmetic in nature.

Description of the Condition

Keloids

Keloids are an overgrowth of scar tissue in response to skin injury causing a raised, hardened section of skin. Similar to hypertrophic scars, keloids are bulkier and extend beyond the borders of the original site of injury. Keloids occur as a result of acne, burns, chicken pox, skin injuries such as surgical incisions, traumatic wounds, vaccination sites, ear piercings, or even minor scratches. Keloids can occur on any part of the body, but typically occur on the ear lobes, shoulders, chest, and back. Some keloids cause symptoms of pain and pruritus, redness, unusual sensations at the site, and may result in hyperpigmentation and disfigurement (Lee, 2015). In some

individuals, keloids can cause a high degree of symptoms which affects their ability to perform normal activities (for example, interferes with sleep). Suboptimal tissue healing can result in impaired function. The recurrence rate of keloids after excision alone has been reported at 45% to 100%. Additionally, the peer-reviewed medical literature notes that keloids may become larger in size after treatment.

Scars

Scar formation may result from healed wounds, lesions from diseases, surgical operations, or trauma. The amount of scarring may be determined by the size, depth, and location of the wound, the age of the person, heredity, and skin characteristics including pigmentation. Scar tissue may be associated with symptoms of discomfort, become hypertrophic, or breakdown. Hypertrophic scarring typically occurs within 4 to 8 weeks following wound infection, wound closure with excess tension or other traumatic skin injury, and has a rapid growth phase for up to 6 months. Hypertrophic scarring may gradually regress over a period of a few years, eventually leading to flat scars with no further symptoms (Gauglitz, 2011). A contracture is a severe form of a scar and is commonly associated with thermal injuries. Surgical scar revision is a procedure intended to remove scar tissue by cutting it out (excising) and closing the area in a new configuration that restores function and corrects skin changes or disfigurement. The revisions may involve redirecting the tension lines with techniques such as W-plasty or Z-plasty. Some scar revision may involve more complex reconstruction using skin flaps and grafts.

Hypertrophic burn or traumatic scars are cutaneous lesions resulting from an excessive tissue response to dermal injury characterized by local fibroblast proliferation and overproduction of abnormal collagen. Gangemi and colleagues (2008) report that up to 77% of burn injuries develop pathological scarring, and of these, 44% result in hypertrophic scarring and 28% in both hypertrophic scarring and contractures; contractures alone are present in 5% of individuals with burns. Associated symptoms include pain, pruritus, restricted movement, decreased overall function, and disfigurement.

Generally accepted prophylactic and therapeutic treatments that may be effective and performed as monotherapy or in combination with other therapeutic regimens for keloids or hypertrophic scar tissue that cause significant pain or result in a significant functional impairment include, but are not limited to, intralesional corticosteroid injections (with or without 5-fluorouracil) (Asilian, 2006; Manuskiatti, 2002; Nanda, 2004), ablative and non-ablative laser therapy and laser resurfacing with carbon dioxide (CO2) (Oosterhoff, 2021; Shin, 2019), potassium-titanyl-phosphate (KTP), pulsed-dye, or Yttrium-Aluminum Garnet (YAG) lasers (Alster, 2003; Alster, 2007; Asilian, 2006; Azzam, 2016; Bouzari, 2007; de las Alas, 2012; El-Zawahry, 2015; Hultman, 2013; Kwon, 2000; Mamalis, 2014; Manuskiatti, 2002; Tanzi, 2002), radiation therapy, and surgical excision or revision procedures (for example, W-plasty, Z-plasty, or small-wave incisions, with or without skin flap/grafting) (Atiyeh, 2007; Bermueller, 2010; Ellis, 2020; Gauglitz; 2011; Mofikoya, 2007; Watson, 2012). Additional treatments are available but are not considered in accordance with generally accepted standards of medical practice, these include, but are not limited to, growth factors, magnetic therapy, photodynamic therapy, and radiofrequency therapy.

Fractional Ablative CO2 Lasers and Laser Fenestration for Burn or Traumatic Scars

The optimal approach for treatment of hypertrophic burn scars depends on the degree of tension on the burn wound margin and involved surface area. Laser therapy can produce microscopic patterns of thermal injury in the dermis, which stimulates the complex process of tissue remodeling in scar management. Ablative (and nonablative) fractional lasers produce numerous nonselective, microscopic vertical zones of thermal damage, referred to as microscopic thermal zones (MTZs), throughout the epidermis and dermis. Fractional ablative lasers (including CO2 lasers) create zones of ablation at variable depths of the skin with subsequent induction of wound healing and collagen remodeling (Waibel, 2013). The surrounding undamaged skin adjacent to a MTZ acts as a reservoir of viable tissue, allowing the rapid repopulation of the epidermis. A skin tightening effect also occurs following treatment with fractional ablative lasers; both immediate and delayed collagen contraction and collagen remodeling may contribute to improvement in skin laxity.

Fractional ablative CO2 laser fenestration is a type of laser technique used to treat mature hypertrophic and contracted burn or traumatic scars that result in significant symptoms (such as pain) or functional impairment (Anderson, 2014). The efficacy and safety of fractional ablative CO2 laser fenestration in the management of hypertrophic burn or traumatic scars has been evaluated in an observation study, uncontrolled prospective studies, and numerous retrospective case series (Qu, 2012; Shumaker, 2012; Waibel, 2013).

Buhalog and colleagues (2021) conducted a systematic review to retrieve literature pertaining to AFL treatment of hypertrophic burn scars. Only studies with five or more subjects with hypertrophic scars obtained from burns and related trauma were considered. The authors selected 23 studies that involved 859 subjects who underwent 2433 laser treatments. The review included 4 RCTs and the remaining 19 were nonrandomized controlled trials. The presence or absence of adverse effects was reported in 15 studies. Within the 15 studies, 681 subjects received a cumulative total of 1969 treatments. The authors noted 50 minor adverse effects occurred yielding an overall rate of 1 adverse event per 40 treatments (2.54%). Three of the most common adverse effects reported were skin discoloration (20 subjects, 40% of complications), pain and swelling (10 subjects, 20% of complications) and, erythema (6 subjects, 12% of complications). The researchers indicated the majority of the complications had resolved by the last follow-up visit. The authors reported significant heterogenicity among the studies and stated it was a cause in the difficulty of performing controlled studies. It was also indicated that due to the public awareness of the procedure, the authors had problems recruiting subjects for studies with a no treatment arm which would normally be included in a standard controlled prospective study.

Choi and colleagues (2021) conducted a systematic review and meta-analysis to determine the efficacy of fractional CO2 lasers in treating burn scars. A total of 15 articles, which comprised of 3 RCTs and 12 observational studies, were included. Publication years for the articles ranged from 2012 to 2019. There were a total of 778 subjects and sample sizes ranged from 10 to 320, with a median of 22 (interquartile range [IQR] 36.5). Gender was reported in 93% (n=14) of studies with a higher proportion of women (52%, n=235) than men (48%, n=213). The median age reported was 22 years (IQR 36.5). All studies used ablative fractional CO2 lasers (AFL-CO2) with a median of 2.5 (IQR 4.3) treatments per subject, with a range of 1 to 3 months between treatments. “Patient self-report” was used in 2 studies and reported 97% satisfaction with laser therapy, 95% reported improvement in scar thickness and pliability, and 76% reported resolution of pruitus and pain. After review, the authors concluded that fractional CO2 laser therapy is a safe and efficacious procedure in the outpatient setting to improve stable burn scars.

Issler-Fisher and colleagues (2021) conducted a study to determine the effectiveness and safety of one treatment with AFL-CO2 compared to a standard burn treatment. A total of 187 individuals were included with 167 in the AFL-CO2 group and 20 in the control cohort. The individuals in the cohort group were assessed in the scar clinic and their treatment had been deferred due to lack of availability of operating theater capacity. Baseline demographics and scar characteristics demonstrated no significant differences between the groups. Individuals in the treatment group had to have completed their first treatment with the AFL-CO2 and their first follow-up visit. The control group received conventional scar management such as pressure garments, silicone treatments and physiotherapy. The researchers noted that the scar thickness showed a significant reduction in the AFL-CO2 treatment group (3.2µm (IQR 2.3-4.5) to 2.6µm (IQR 1.9-3.4), $p<0.001$), and a non-significant decrease in the control group (3.1µm (IQR 2.4-4.0) to 2.3µm (IQR 1.9-3.8), $p=0.47$). However, it was reported there was no difference in scar thickness between the AFL-CO2 case versus control

group. In regards to the pain scores, there was a significant improvement in the treatment group whereas the control group indicated the same scores in their initial assessments and follow-ups. The authors concluded that burn scars can be effectively and safely treated with AFL-CO2 and that objective and subjective outcomes improved significantly following just one treatment with AFL-CO2 compared to individuals who receive traditional treatment.

Poetschke and colleagues (2017) prospectively studied the effects of a single treatment session of fractional ablative CO2 laser fenestration in 10 adults (average age, 39.3 ± 15.3 years) with widespread hypertrophic burn scars older than 1.5 years. The mean scar age was 12.45 (± 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. Similarly scarred skin areas were assessed, and 2 were selected of approximately 10 cm by 10 cm with 1 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 Vancouver Scar Scale (VSS), Patient and Observer Scar Assessment Scale (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=0.014] and 5.2 to 2.60 [p=0.003], 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=0.013), and thickness (3.9 to 2.2; p=0.019). Objective clinical measurement of scar surface irregularities (through the parameters S_{max} and S_z) 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.

Issler-Fisher and colleagues (2017) prospectively evaluated the efficacy and safety of fractional ablative CO2 laser treatment in severe burn scars with structural changes (that is, atrophic, hypertrophic, and keloid scars). A total of 47 individuals (ages 16-80) with 118 severe burn scars completed one UltraPulse® Encore CO2 (Lumenis Ltd., Yokneam, Israel; Lumenis Inc. USA, San Jose, CA) 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-subject 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.

Zadowski and colleagues (2016) conducted an observational study of 47 children (ages 6 to 16 years; mean age, 10.5 years) with hypertrophic burn scars treated with fractional ablative CO2 laser fenestration. The average time from initial burn to treatment was 7.5 ± 2 years. The average burned total body surface area was 8.8% with a minimum VSS score of 4 points. A total of 57 laser sessions were performed; 10 children with extensive burn scars were treated twice. Treatment outcomes were reported as changes in VSS score at 1, 4, and 8 months post treatment and ultrasound evaluation of scar thickness before and after treatment. The greatest change in total VSS score in area 1 by physician evaluation was obtained at 1 month following treatment (2.05 points difference; average 7.23 points before to 5.18 points 1 month post treatment). Improvement in 3 of 4 VSS parameters was observed, including pigmentation (81% of assessed area 1 and no worsening), height (88% of assessed areas; p<0.05), and pliability of scarring (98%; p<0.05). The most common adverse effect was erythema at 1 and 4 months post treatment.

Hultman and colleagues (2013) performed a prospective study at a single center evaluating 147 individuals with hypertrophic burn scars involving a mean body surface area of 16%. Procedures were performed more than 6 months after burn injury and repeated monthly. The overall treatment algorithm included four laser treatment modalities: pulsed dye laser (PDL), fractional ablative CO2 laser (UltraPulse in Active FX and Deep FX modes to treat abnormal texture, thickness, and stiffness of the more mature scar), intense pulsed light (IPL)/neodymium-doped:YAG (Nd:YAG) laser, and Alexandrite laser procedures. A total of more than 415 sessions (2.8 sessions/individual), including PDL (n=327) and CO2 laser treatments (n=139) were administered to flame burns (n=75), scald injury (n=37), and other burns (n=35). Treatments occurred 16 months (median) and 48 months (mean) after burn injury. Functional outcomes were assessed at baseline, immediately before the first session, and 4 to 6 weeks later (at the time of the next session) with the VSS and a subjective, self-reported University of North Carolina (UNC) designed “4P”(UNC4P) Scar Scale which assessed 4 components of the burn scar: pruritus, paresthesias, pain, and pliability. The range of scores for the UNC4P was 0 to 12, with higher scores associated with more morbidity. Mean length of follow-up was 4.7 months. Outcomes were reported as a significant decrease in VSS score from 10.4 to 5.2 (p<0.0001). The participant-reported UNC4P Scar Scale score decreased from 5.4 to 2.1 (p<0.0001). The largest decline in both VSS and UNC4P scores occurred after the first laser session. VSS and UNC4P scores decreased significantly after 1 session from 10.43 to 6.67 and 5.40 to 2.89, respectively (p<0.0001). Subsequent sessions, were reported (in composite) as yielding statistically significant reductions in scar scores. Adverse events or outcomes representing 12.9% of participants, 4.6% of sessions, and 3.9% of all treatments included hypopigmentation (n=8), moderate to severe blistering (n=4), post-inflammatory hyperpigmentation (n=3), intraoperative arrhythmia (n=1), postoperative cellulitis of concurrent adjacent tissue rearrangement (n=1), superficial yeast infection of burn scar (n=1), and oral herpes simplex infection (n=1). Hultman and colleagues (2014) reported on long-term follow-up (mean, 30.7 months) of the original study participants from 2011. Using only data from participants seen in 2013 (n=35), the long-term cohort had significant improvement in VSS (10.28 to 5.31, p<0.001) and UNC4P scores (5.18 to 1.93, p<0.001) at 5-month follow-up. At 30-month follow-up, provider-rated VSS scores continued to drop to 3.29 (p<0.001), while UNC4P remained stable at 1.74 (no significant change). In summary, long-term follow-up participants with hypertrophic burn scars who underwent laser treatments had both early and late improvement in VSS and UNC4P scores, but also had more treatments than the cohort with only short-term follow-up.

Other Considerations

A consensus report published by eight independent, self-selected academic and military dermatology and plastic surgery physicians with extensive experience in the use of lasers for scar treatment (Anderson, 2014) concluded:

> Ablative fractional lasers typically produce the greatest improvement for hypertrophic and contracted scars, with or without the addition of intralesional or topical medications (eg, corticosteroids or antimetabolites)…Current ablative fractional laser (AFL) devices have a significantly greater potential depth of thermal injury compared with non-ablative fractional laser (NAFL) devices (approximately 4.0 and 1.8 mm, respectively). Therefore, the AFL may

prove more effective for thicker scars and for scars associated with restriction. Our consensus is that an appropriate degree of surrounding thermal coagulation around the ablated column appears to facilitate the subsequent remodeling response.

The optimal time to begin fractional laser treatment is undetermined. A minimum treatment interval of 1 to 3 months between fractional laser treatments is suggested, and the treatments are continued until a therapeutic plateau or treatment goals are achieved.

International guidelines for the prevention and treatment of pathologic scarring based upon expert consensus (Gold, 2014) include the following recommendations:

- Immature or linear hypertrophic erythematous scars resulting from surgery or trauma that present with persistent erythema for more than 1 month despite preventive treatment with silicone gel or sheeting, hypoallergenic paper tape, or onion extract preparations may be treated with pulsed dye laser (PDL) once monthly for 2 to 3 months. Fractional laser therapy is reserved for scars that are refractory to PDL.
- Widespread hypertrophic burn scars that failed to improve with treatment with silicone gel or sheeting, pressure garments, and/or onion extract preparations for 8 to 12 weeks may be treated with fractional laser therapy.

The optimal interval between different laser treatments has not been established (Anderson, 2014). Intervals ranging from 4 weeks to 2 to 3 months have been used, with most studies suggesting 6 weeks as the optimal interval.

Fractional ablative lasers have a reported improved adverse effect profile compared with nonfractional ablative devices, however, delayed wound healing, post-inflammatory hyperpigmentation, scarring, and ulceration, particularly in areas of thinner skin and decreased adnexal structures such as the neck, have been reported (Lee, 2011; Ozog, 2013). Relative contraindications to fractional ablative laser treatment include fresh healing wounds with unstable epidermal coverage in the first 1 to 3 months after injury and active infection (Anderson, 2014). In addition, a history of herpes simplex virus infection should prompt prophylactic antiviral treatment before offering laser therapy.

Jin and colleagues (2013) performed a meta-analysis of 28 clinical trials with 919 subjects evaluating the response rate of various laser therapy in hypertrophic scar and keloid management. The overall response rate for laser therapy was 71% for scar prevention, 68% for hypertrophic scar treatment, and 72% for keloid treatment. The 585/595-nm pulsed-dye laser and 532-nm laser subgroups yielded the best responses among all laser systems. Recurrence or progression of treated scars was not reported in any of the included trials, further trials that record this data are needed.

Radiation Therapy

Low- or high-dose radiation therapy (superficial [external beam] or interstitial [brachytherapy]) following excisional surgery has been reported to have higher response rates and lower recurrence rates for treatment-resistant keloids. Low-dose rate (LDR) and high-dose rate (HDR) brachytherapy for the treatment of keloids involves the placement of radioactive seeds or strands placed into a plastic tube that is sutured into the wound site after the keloid is surgically removed. In HDR, the total dosage is divided into lower-dosed sessions and administered over hours (that is, left in for seconds to minutes at a time) instead of over days. LDR implants are left in for 2 to 3 days and then removed. The tubes are removed after therapy and the wound is closed. External beam radiation therapy (EBRT) for treatment of keloids is administered after surgical excision by low-voltage photon X-ray or high-energy (voltage) electrons delivered by linear accelerator in divided doses, once or twice daily for up to a total treatment dose.

Ekstein and colleagues (2021) conducted a systematic review of 100 articles to investigate updates regarding keloid incidence and treatment. It was indicated that keloid management remained a multimodal approach and there is no gold standard of treatment. The authors reviewed a study that involved radiation based treatments involving 72 studies and 9048 keloids. The data in the study demonstrated that post excisional radiotherapy was more effective in preventing recurrence than radiotherapy alone (22% and 37% recurrence rates respectively, P = 0.005). In comparing radiation modalities, postoperative brachytherapy had the lowest reoccurrence rate of 15% compared to 23% recurrence rate for x-ray and 23% recurrence rate for electron beam radiation. After review of the literature, the authors concluded that there is a need for randomized studies with large sample sizes and longer follow-up timeframe. In addition, future studies could demonstrate the efficacy of novel treatment modalities for management of keloids.

Bijlard and colleagues (2018) treated 238 keloids with HDR brachytherapy after keloid excision to determine the optimal brachytherapy dose and fractionation scheme for keloid treatment. Subjects from 3 centers treated with keloid excision followed by 2 fractions of 9 Gy, 3 fractions of 6 Gy, or 2 fractions of 6 Gy HDR brachytherapy were compared using logistic regression analyses for recurrence rates (after at least 12 months' follow-up) and complications (after at least 1 month's follow-up). At 2 treatment centers, a 6-Gy fraction was applied within 3 hours following surgery; the next day 1 (center 3) or 2 (center 2) additional fractions of 6 Gy were given separated by at least 6 hours. An overall full recurrence rate of 8.3% was found. No statistically significant differences in recurrence rates between fractionation schemes were identified after correction for confounding factors such as sex, skin color, keloid location, and keloid duration. There were 29 (12.8%) major complications including severe infection (n=4) and chronic wounds (> 3 months) (n=23) and 45.6% (n=103) minor complications (including hyper- and hypopigmentation and dermatitis grade 2) with no significant differences found in recurrence rates and complications between treatment with 2 fractions of 9 Gy and 3 fractions of 6 Gy; however, there were significantly fewer complications after 2 fractions of 6 Gy compared with 2 fractions of 9 Gy (odds ratio, 0.35; p=0.015). A total of 106 (46.9%) individuals did not experience a treatment-related complication. Keloids of the upper trunk had an increased risk of complications (odds ratio, 2.5; p=0.032) and ear keloids had the least risk of complications (odds ratio, 0.43; p=0.05). Based on low recurrence and complication rates, the authors recommended a BED of approximately 20 Gy HDR brachytherapy after surgical excision of treatment-resistant keloids.

Lee and Park (2015) retrospectively evaluated a case series of 37 keloids to determine the appropriate time for initiating external beam (electron) radiation therapy following surgical excision. Radiation therapy was initiated within 24 hours in 24 lesions, between 24 and 72 hours in 6 lesions, and after more than 72 hours in 7 lesions. The median follow-up period was 27.4 months. There were 7 lesions which recurred, including 5 lesions reoccurring in high stretch-tension regions (p=0.010); initial treatments in these lesions were administered within 24 hours in 1 lesion and more than 72 hours after surgical excision in 6 lesions (p<0.0001). This study demonstrates that initiating radiotherapy of the keloid site within 72 hours of surgical excision, during the proliferation phase of healing, may suppress fibroblast proliferation as well as inhibit collagen synthesis.

Gupta and Sharma (2011) reported on standard guidelines of care for keloids in a review article evaluating the evidence in the peer-reviewed medical literature for the type of radiation used, timing of treatment, and dosage of radiation used in the treatment of keloids, stating:

- Combination of surgery followed 24 hours later by radiotherapy is considered to be the most effective approach for the management of extensive…keloids which causes significant morbidity/limitation of movement/contracture, with a recurrence rate varying from 9 to 72% (Level B), which generally depends on the total dose of radiation and duration of follow-up.
- A relatively high dose must be applied in a short overall treatment time (Level B). A scheme with a Biologically Effective Dose

(BED) of 30-40 Gy seems to be sufficient to prevent recurrences of keloid after surgical excision (Level B).
- Electron beam irradiation is considered the most effective; however, strontium 90 brachytherapy has also shown low recurrence rate (Level C).

As early as 1994, Klumpar and colleagues reported that radiation therapy following post-surgical excision of keloids resulted in high control rates of 72% to 92%. In a large, single-institution case-control retrospective study, Hoang and colleagues (2017) reported on the 10-year effects of surgical excision and adjuvant brachytherapy versus external beam radiation for the treatment of keloids, stating:

> …surgically excised keloids reportedly recur at a rate of > 45%. Post-excision radiation (RT) has been delivered via external beam radiotherapy (EBRT) or interstitial high dose rate (HDR) brachytherapy. Despite historical data showing 10% to 20% keloid recurrences with post-excision RT, there is a paucity of high-quality evidence comparing keloid recurrences between the two RT modalities.

A total of 128 individuals with 264 keloid lesions were treated by excision alone (n=28), post-excision EBRT (n=197), or post-excision HDR brachytherapy (n=39). Participant and keloid recurrence data were analyzed using mixed effect Cox regression modeling (statistical threshold, $p<0.05$). A total of 54% of keloids recurred after surgical excision alone (9-month median follow-up); 19% of keloids recurred with post-excision EBRT (42-month median follow-up); 23% of keloids recurred with post-excision brachytherapy (12-month median follow-up). Adjuvant EBRT and brachytherapy each showed significant control of keloid recurrence compared to excision alone ($p<0.01$). EBRT significantly delayed the time of keloid recurrence over brachytherapy by a mean difference of 2.5 years ($p<0.01$).

In a review article, Kal and Veen (2005) state that a relatively high-dose radiation must be applied in a short overall treatment time for successful prevention of recurrence of keloids after surgical excision. The optimal treatment may be a radiation strategy resulting in a BED value of at least 30 Gy. A BED value of 30 Gy can be obtained with, for instance, 1 single acute dose of 13 Gy, 2 fractions of 8 Gy, or 3 fractions of 6 Gy, or 1 single dose of 27 Gy at low-dose rate. The authors recommend that radiation treatment should be administered within 2 days following surgery. In follow-up, Kal and colleagues (2009) performed a retrospective review of the literature on the relationship of dose-effect and incidences of recurrence after post-surgical radiotherapy. Based on this study's finding, the BED of 30 Gy or greater, resulted in a keloid recurrence rate of less than 10%.

Additional comparative studies (Emad, 2010; Sclafani, 1996), a prospective study (van Leeuven, 2014); retrospective case studies (Carvajal, 2016; De Cicco, 2014; Guix, 2001; Jiang, 2018; Kim, 2015; Kuribayashi, 2011; Ogawa, 2003; Ogawa, 2007; Shen, 2015), a systematic review and meta-analysis (Shin, 2016), and other systematic reviews (Flickinger, 2011; van Leeuven, 2015) suggest that keloids are effectively treated with a combination of surgical excision and radiation therapy (including EBRT or brachytherapy) in the immediate postoperative period.

Adverse reactions of radiation therapy at the surgically removed keloid site may include skin redness, skin peeling, telangiectasia and permanent skin color changes (generally hypopigmentation) (Gupta and Sharma, 2011). In a systematic review and examination of evidence-based opinions of radiation oncologists regarding the acceptability of using radiation to treat keloids, Ogawa and colleagues (2009) concluded the "risk of carcinogenesis attributable to keloid radiation therapy is very low when surrounding tissues, including the thyroid and mammary glands, especially in children and infants, are adequately protected, and that radiation therapy is acceptable as a keloid treatment modality." In a retrospective analysis of control and toxicity rates in 116 individuals with keloids who underwent postoperative brachytherapy and electron beam radiation, Duan and colleagues (2015) reported no definitive evidence was found for an association between radiotherapy and the occurrence of cancer during the follow-up period (median observation period: 46.5 months [range, 10.0-120.0 months] for all participants).

Definitions

Brachytherapy: A type of radiation treatment given by placing radioactive material directly into the target area; also known as internal or interstitial radiation therapy.

External beam radiation therapy (EBRT): A type of low-dose radiation treatment used in combination (adjunctive) with surgical excision for the treatment of keloids. EBRT uses highly focused beams of light called superficial X-rays to destroy collagen-producing cells and limit the growth of new cells.

Hypertrophic scar: An elevated scar that is typically raised, erythematous (red, pink, or purple) and stiffer than the surrounding skin. Hypertrophic scars are more commonly found in areas of high skin tension, or on people with darker skin tones.

Keloid: A condition where a scar becomes raised above the flat surface of normal skin, has a hardened texture, and may grow beyond the boundaries of the scar.

Patient and Observer Scar Assessment Scale (POSAS): A numeric rating scale used in the clinical evaluation of scar areas. The POSAS consists of two parts: the Patient Scar Assessment Scale and the Observer Scar Assessment Scale, completed by the patient and the observer, respectively. The Observer Scale consists of six items: vascularity, pigmentation, thickness, relief, pliability and surface area. All items are scored on a scale ranging from 1 ('like normal skin') to 10 ('worst scar imaginable'). The sum of the six items results in a total score of the POSAS observer scale (Draaijers, 2004).

Scar: A mark left in the skin by the healing of a wound, sore, or injury because of the replacement by connective tissue of the injured issues.

Vancouver Scar Scale (VSS): A widely used rating scale to assess hypertrophic burn scars by evaluating their rate of development and measuring outcomes of therapy or resolution. The VSS assesses four scar characteristics, with normal skin scoring 0 and an increasing score (total score of 13) assigned to a greater pathologic condition (Sullivan, 1990):

1. Vascularity: 0-3 (Normal, Pink, Red, Purple);
2. Height/thickness: 0-3 (Flat, <2 mm, 2-5 mm, >5 mm);
3. Pliability: 0-5 (Normal, Supple, Yielding, Firm, Ropes, Contracture);
4. Pigmentation: 0-2 (Normal, Hypopigmentation, Hyperpigmentation).

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Revised	05/11/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised Cosmetic and NMN statement. Added Websites for Additional Information section. Updated Discussion/General Information and References section.
Reviewed	05/12/2022	MPTAC review. Updated Discussion/General Information and References section.
Revised	05/13/2021	MPTAC review. Removed the word “physical” from “physical functional impairment” in Clinical Indications. Updated Discussion/General Information, Definitions, and References sections.
	04/07/2021	Revised MN definition text in the Description section.
Reviewed	08/13/2020	MPTAC review. Updated Description, Discussion/General Information and References sections. Reformatted Coding section.
Reviewed	08/22/2019	MPTAC review. Updated References sections.
Reviewed	11/08/2018	MPTAC review. Updated Discussion/General Information and References sections.

Revised	03/22/2018	MPTAC review. Added a MN statement for fractional ablative CO2 laser fenestration of a burn scar or traumatic scar when criteria are met. Added a Cosmetic and NMN statement for fractional ablative CO2 laser fenestration of a burn scar or traumatic scar when criteria are not met. Added Index section. Updated Description, Discussion, Definitions and References sections. Updated Coding section to add 0479T and 0480T.
Revised	11/02/2017	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Added MN and Reconstructive statements for treatment of a keloid with radiation therapy (up to 3 fractions) as adjunct therapy following surgical excision (initiated within 3 days) when the medically necessary or reconstructive criteria for keloid removal are met. Minor clarification to the Cosmetic and NMN statement. Updated Discussion, Definitions, Coding, and References sections. Removed Websites for Additional Information section.
Reviewed	02/02/2017	MPTAC review. Updated Discussion/General Information, References, and Websites for Additional Information sections.
Reviewed	02/04/2016	MPTAC review. Updated Websites for Additional Information section. Removed ICD-9 codes from Coding section.
Reviewed	02/05/2015	MPTAC review. Updated Discussion, References, and Websites for Additional Information sections.
Reviewed	02/13/2014	MPTAC review. Updated Discussion, References, and Websites for Additional Information sections.
Reviewed	02/14/2013	MPTAC review. Updated Web Sites for Additional Information. Removed the Index.
New	02/16/2012	MPTAC review. Initial document development. Transferred and rephrased contents and coding that address the treatment of keloids and scar revision from ANC.00007 Cosmetic and Reconstructive Services: Skin Related.
