Radiation Treatment for Selected Nononcologic Indications

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.

Aetna considers low-dose or high-dose radiation (superficial or interstitial) medically necessary as an adjunctive therapy immediately following excisional surgery (within 7 days) in the treatment of keloids where medical necessity criteria for keloid removal are met. See CPB 0031 - Cosmetic Surgery (.//1_99/0031.html) for medically necessary indications for keloid removal.

Aetna considers radiation therapy medically necessary for preventing heterotopic ossification in persons identified as being at high risk (previous heterotopic ossification, ankylosing spondylitis, diffuse idiopathic skeletal hyperostosis or spinal stenosis, unlimited hip motion preoperatively, and head injury).

Aetna considers use of beta irradiation medically necessary for prevention of primary or recurrent pterygium in cases that cannot be managed medically.
Aetna considers the TRASER (Total Reflection Amplification of Spontaneous Emission Radiation) device experimental and investigational for the treatment of nasal telangiectasias because its effectiveness has not been established.

See also: CPB 0083 - Stereotactic Radiosurgery (. /1_99/0083.html); CPB 0231 - Grenz Ray Therapy for Skin Disorders (. /200_299/0231.html); CPB 0374 - Trigeminal Neuralgia: Treatments (. /300_399/0374.html); CPB 0419 - Graves' Ophthalmopathy Treatments (. /400_499/0419.html); CPB 0491 - Coronary Artery Brachytherapy and Other Adjuncts to Coronary Interventions (. /400_499/0491.html), CPB 0756 - Epiretinal Radiation Therapy (. /700_799/0756.html); and CPB 0800 - Dupuytren Contracture: Treatments (. /800_899/0800.html).

**Background**

Keloids are benign fibrous growths that arise from proliferation of dermal tissue following skin injury. Conventional treatment options for keloids are occlusive dressings (including silicone-based materials), compression therapy, intra-lesional injections of corticosteroid, cryosurgery, and excision surgery. Newer modalities include the carbon dioxide laser, Nd:YAG laser, argon laser, pulsed dye laser, intra-lesional interferon-gamma and interferon-alfa 2b, and cultured epithelial autografts. In general, laser excision results in similar recurrence rates as conventional surgery. However, the incidence of recurrence is high following conventional forms of treatment. In particular, the recurrence rate of keloids after excision alone has been reported to be between 45% and 100%. It has also been reported that the recurrence rate following excision is higher with keloids forming at infected sites and in patients with a family history of keloids. The likelihood of recurrence does not appear to be affected by the person's age, sex, or ethnicity; keloid size or location; individual keloid history; or prior therapy.

Post-operative radiation therapy has been shown to be safe and effective in reducing recurrence of keloids after excision surgery. In addition, it has been reported that post-operative radiation therapy is a simpler treatment modality with better patient compliance than post-operative corticosteroid injections.

Kal and Veen (2005) stated that for successful prevention of
recurrence of keloids after surgical excision, a relatively high-dose must be applied in a short overall treatment time. The optimal treatment probably is an irradiation scheme resulting in a biologically effective dose (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 radiation treatment should be administered within 2 days following surgery.

Ogawa and colleagues (2009) noted that keloids are best treated by a combination of surgery and post-operative radiation therapy, although randomized controlled trials testing this are still lacking. However, plastic surgeons tend to avoid radiation therapy for keloids for fear of inducing malignant tumors. Thus, the authors searched for previous reports of associations between carcinogenesis and keloid radiation therapy, and examined the evidence-based opinions of radiation oncologists regarding the acceptability of using radiation to treat keloids. A computerized literature search was carried out using PubMed that included citations from Medline and PubMed Central between 1901 and March of 2009. The following search terms were used: "keloid(s)," "hypertrophic scar(s)," "radiation," "radiation therapy," "radiotherapy," "carcinogenesis," "carcinoma," "cancer," "complications," and "side effects." Moreover, the references for each report were also retrieved. The authors located 5 cases of carcinogenesis (i.e., fibrosarcoma, basal cell carcinoma, thyroid carcinoma, and breast carcinoma) that were associated with radiation therapy for keloids. However, it was unclear if an appropriate dose of radiation was used and whether sufficient protection of surrounding tissues was provided. Moreover, a questionnaire study of radiation oncologists around the world revealed that approximately 80 % considered radiation to be acceptable for treating keloids. The authors concluded that 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.

Heterotopic ossification (HO) is an overgrowth of bone that
frequently occurs after a bone fracture (break). It commonly occurs in patients who have fractured bones of the spine, hip, or elbow. It causes pain and disability. Radiation therapy is a local treatment modality that works by damaging the DNA of cells.

Based on the clinical evidence, preoperative or postoperative radiation therapy has been proven to be effective in preventing heterotopic ossification for patients identified as being at risk (previous heterotopic ossification, ankylosing spondylitis, diffuse idiopathic skeletal hyperostosis or spinal stenosis, unlimited hip motion preoperatively, and head injury).

Grenfell and Borg (2014) stated that palmar and plantar fascial fibromatoses are benign hyper-proliferative disorders of the deep fascia of the palm and sole. These researchers examined the role of radiotherapy in the management of fascial fibromatosis. A total of 6 consecutive cases of early-stage fascial fibromatosis treated with radiotherapy between July 2008 and May 2011 were analyzed. The results of the case series were compared with a systematic review of the literature. All 6 cases regressed or showed a reduction of symptoms following radiotherapy. Treatment was well-tolerated with minor toxicities. Median follow-up for the case series was 38.5 months. The systematic review identified 7 studies describing the use of radiotherapy as primary treatment for fascial fibromatosis between 1946 and 2013. The literature indicated that radiotherapy can prevent disease progression and improve symptoms for early-stage disease, with low likelihood of significant toxicities. The authors concluded that early results from this case series were consistent with the literature, showing that radiotherapy can provide an effective management option for patients with early-stage fascial fibromatosis, and justified consideration of radiotherapy as a primary treatment for early-stage disease. These preliminary findings need to be validated by well-designed studies.

Nakamatsu et al (2011) noted that postoperative adjuvant treatment with strontium-90 radiation therapy (RT) is a proven technique for reducing the recurrence of pterygium. The authors conducted a single institutional randomized trial to evaluate whether a total dose of 40 Gy provides a better local control rate
than a total dose of 30 Gy for surgically resected pterygia. Between 1999 and 2003, 74 pterygia in 71 patients were randomly allocated to 30 Gy/3 fractions/15 days (arm A) or to 40 Gy/4 fractions/22 days (arm B) and only primary pterygia cases for which RT could be started within 3 days of surgical resection were included. Postoperative RT was given by a strontium-90 eye applicator with a dose of 10 Gy per fraction delivered in weekly fractions (day 1, 8, 15, 22). The investigators found that of the 74 pterygia treated, 73 in 70 patients were analyzed and among these cases of pterygia, 41 were allocated to arm A, and the remaining 32 to arm B. The 2-year local control rates for arm A and arm B were 85% and 75%, respectively, without significant difference. No serious acute and late complications were noted in either arm. The authors concluded that their new standard fractionation for postoperative RT for pterygia is 30 Gy/3 fractions.

Qin et al (2012) studied the long term effects of low dosage strontium-90 in 120 eyes from 104 patients with primary or recurrent pterygia who had been treated with surgery. Dosage was three times every other day at a total combined dosage of 2000 cGy to 3000 cGy and corneal topography was used to evaluate ocular surface regularity before and after treatment. Patient follow-up was performed for 10 years after surgery and no recurrence of pterygium was observed in any study participants. Obvious cataract progression was observed in 6 eyes, which the investigators hypothesized may be due to aging. During follow-up studies, only one eye was reported with dryness and foreign-body sensation. The authors concluded that Sr90 irradiation is effective in preventing the recurrence of primary and recurrent pterygia and that delivering a total combined dosage of 2000 cGy to 3000 cGy of Sr90 irradiation administered in three batches every other day starting from the sixth day after surgery is recommended.

Viani et al (2012a) conducted a prospective, randomized, single-center study to evaluate the effectiveness and safety of postoperative low single-dose of beta-irradiation (β-RT) in pterygium. The study compared conjunctival autograft (CAG) surgery with CAG plus adjuvant β-R with surgery performed in all cases according to the CAG technique. One hundred and eight
pterygia cases were postoperatively to deliver 10 Gy to the sclera surface at a dose rate of between 200 and 250 cGy/min. One hundred and sixteen eyes with primary pterygium were operated on between February 2008 and September 2008 according to the trial protocol. In the 54 eyes randomized to receive CAG + β-RT, 5 relapses occurred compared with 12 recurrences in the 54 eyes in CAG. A crude control rate of 90.8 % vs. 78%; p = 0.032, respectively was seen at a mean follow-up of 18 months (range, 8-33). Treatment complications, including hyperemia, total dehiscence of the autograft and dellen, were significantly more frequent in the CAG group (p < 0.05). The β-RT group experienced better cosmetic results and improves of symptoms than CAG. The investigators concluded that a low single-dose of β-RT of 10 Gy after CAG surgery was a simple, effective, and safe treatment that reduced the risk of primary pterygium recurrence, improved symptoms after surgery and resulted in a better cosmetic effect than CAG alone.

Viani et al (2012b) conducted a randomized trial of 200 patients (216 ptergium). The purpose of this trial was to evaluate a technique for reducing the recurrence of pterygium by using a low fractionation dose of 2 Gy (within 10 fractions) that would provide local control similar to that after a high fractionation dose of 5 Gy (within 7 fractions) for surgically resected pterygium. Only patients with fresh pterygium resected using a bare sclera method and given RT within 3 days were included. Postoperative RT was delivered using a strontium-90 eye applicator. The pterygia were randomly treated using either 5 Gy within 7 fractions (Group 1) or 2 Gy within 10 fractions (Group 2) with the local control rate calculated from the date of surgery. Implementation of this study included randomization of the 216 pterygia, of which 112 were allocated to Group 1 and 104 to Group 2. The 3-year local control rates for Groups 1 and 2 was 93.8% and 92.3%, respectively (p = .616) and a statistically significant difference for cosmetic effect (p = .034), photophobia (p = .02), irritation (p = .001), and scleromalacia (p = .017) was noted in favor of Group 2. The authors concluded that no better local control rate for postoperative pterygium was obtained using high-dose fractionation vs. low-dose fractionation, but a low-dose fractionation schedule produced better cosmetic effects and
resulted in fewer symptoms than high-dose fractionation. The authors further noted that pterygia can be safely treated in terms of local recurrence using RT schedules with a biologic effective dose of 24-52.5 Gy(10).

Guix et al (2001) analyzed the results obtained in a prospective group of patients with keloid scars treated by high-dose-rate (HDR) brachytherapy with or without surgery. A total of 169 patients (134 females and 35 males) with keloid scars were treated with HDR brachytherapy between December 1991 and December 1998. The distribution of keloid scars was as follows: face, 77; trunk, 73; and extremities, 19. The mean length was 4.2 cm (range of 2 to 22 cm), and the mean width 1.8 cm (range of 1.0 to 2.8 cm). In 147 patients, keloid tissues were removed before HDR brachytherapy; and in 22 HDR brachytherapy was used as definitive treatment. In patients who underwent prior surgery, a flexible plastic tube was put in place during the surgical procedure. Bottoms were used to fix the plastic tubes, and the surgical wound was repaired by absorbable suture. High-dose-rate brachytherapy was administered within 30 to 60 mins of surgery. A total dose of 12 Gy (at 1 cm from the center of the catheter) was given in 4 fractions of 300 cGy in 24 hrs (at 09.00 am, 15.00 pm, 21.00 pm, and 09.00 am next day). Treatment was optimized using standard geometric optimization. In patients who did not undergo surgery, standard brachytherapy was performed, and plastic tubes were placed through the skin to cover the whole scar. Local anesthesia was used in all procedures. In these patients a total dose of 18 Gy was given in 6 fractions of 300 cGy in 1 and a half days (at 9.00 am, 3.00 pm, and 9.1 pm; and at 9.00 am, 3.00 pm, and 9.00 pm next day). No further treatment was given to any patient. Patients were seen in follow-up visits every 3 months during the first year, every 6 months in the second year, and yearly thereafter. No patient was lost to follow-up. Particular attention was paid to keloid recurrence, late skin effects, and cosmetic results. All patients completed the treatment. After a follow-up of 7 years, 8 patients (4.7 %) had keloid recurrences; 5 of these had undergone prior surgery (local failure rate 3.4 %), and 3 had received only HDR brachytherapy (local persistence rate 13.6 %). Cosmetic results were considered to be good or excellent in 130/147 patients.
treated with prior surgery and in 17/22 patients without surgery. Skin pigmentation changes were observed in 10 patients, and telangiectasias in 12 patients. No late effects such as skin atrophy or skin fibrosis were observed during the 7 years of follow-up. The authors concluded that HDR brachytherapy is an effective treatment for keloid scars. It was well-tolerated and did not present significant side effects. The brachytherapy results were more successful in patients who underwent previous surgical excision of keloid scar than in patients without surgery. These investigators favored HDR brachytherapy rather than superficial X-rays or low energy electron beams in keloid scars, because HDR provided a better selective deposit of radiation in tissues and a lower degree of normal tissue irradiation. Other advantages of HDR brachytherapy over low-dose-rate (LDR) brachytherapy included its low cost, the fact that it can be performed on an outpatient basis, its excellent radiation protection, and the better dose distribution obtained. From the clinical perspective, the technique provides a high local control rate without significant sequelae or complications.

De Cicco et al (2014) reported their experience on the adjuvant LDR and HDR interstitial brachytherapy. These investigators analyzed data on 70 consecutive patients treated after complete keloid surgical excision. First 38 patients and 46 keloids were treated with adjuvant LDR brachytherapy and the following 39 patients and 50 keloids underwent HDR treatment. Median delivered dose of LDR therapy was 16 Gy; HDR median dose was 12 Gy. A total of 64 keloids (66.7 %) were symptomatic at diagnosis with pain, itching, or stress. Fourteen relapses over 46 treated keloids (30.4 %) were observed in the LDR group and 19 of 50 keloids (38 %) in the HDR group (p = 0.521). Recurrence rate was significantly higher in males (p = 0.009), in patients younger than 44 years (p < 0.0001), for arms, neck, and chest wall anatomic sites (p = 0.0001) and for symptomatic keloids (p = 0.017). Aesthetic outcome was better in case of larger keloids (greater than 8 cm) (p = 0.064). Symptomatic relief was achieved in 92 % of HDR patients and only 68 % of LDR patients (p = 0.032). The authors concluded that post-operative brachytherapy is an effective treatment for keloids. In this study, LDR and HDR treatments resulted in similar recurrence rate. Better
Radiation) generally or that hypertrophic scars were forming the main issue. Surgical excision with adjuvant radiotherapy is considered the most effective treatment. At their institution, the authors have been treating keloids with a HDR brachytherapy procedure for over 10 years, using a protocol with the lowest total radiation dosage known in the literature. This prospective study included 43 patients of all Fitzpatrick skin types, with 67 keloids in total. After extra-lesional excision, a radiation scheme of $2 \times 6$ Gy was administered in 2 fractions: the first within 4 hours after surgery and the second within 24 hours. Scars were measured and recurrence was judged. Scar appearance was evaluated using the Patient and Observer Scar Assessment Scale. The recurrence rate was 3.1% at a mean follow-up of 33.6 months. A significant average scar surface decrease of 56.7% was measured ($p = 0.01$); complaints of pain and pruritus decreased by 82.9 and 87.2%, respectively. Patients were satisfied with the treatment in 88.6% of the cases and with the cosmetic result in 77.1%. Pigmentation problems were seen in 21.4% of the patients, mostly in Fitzpatrick type V and VI/African American individuals. The authors concluded that the results of this prospective study showed a good cosmetic outcome with a low recurrence rate. The unique radiation schedule proved the safety and effectiveness of HDR brachytherapy and suggested the importance of immediate post-operative irradiation. In addition, only 1 out-patient treatment was needed following surgery, enhancing patient convenience.

Furthermore, an UpToDate review on “Management of keloid and hypertrophic scars following burn injuries” (Gauglitz, 2015) states that “Radiotherapy -- Superficial x-rays, electron beam and low- or high-dose-rate brachytherapy have been employed with generally overall good results in terms of reduced recurrence”.

**TRASER (Total Reflection Amplification of Spontaneous Emission Radiation) for the Treatment of Nasal Telangiectasias:**
Friedman and colleagues (2017) stated that destruction of blood vessels by selective photo-thermolysis has been successfully achieved using a number of different laser and light systems, none of which provided significant independent variation in parameters such as wavelength. These researchers evaluated the safety and effectiveness of a novel configurable device in the treatment of nasal telangiectasias. A total of 15 subjects aged 42 to 73 years with Fitzpatrick skin types I and II were treated for nasal telangiectasias of various sizes; effectiveness was measured by blinded analysis of pre- and post-images and self-assessment by the subjects. The primary end-point was a 2-point improvement of telangiectasia based on a 5-point Telangiectasia Scale comparing the pre-treatment photograph to the post-treatment photograph at 30 days post final treatment by an independent reviewer. Treatment completion was defined as greater than 75% vessel clearance. The TRASER (Total Reflection Amplification of Spontaneous Emission Radiation) was configured to produce a narrow spectral output, peaking at 541 ± 5 nm, with 20 to 40 millisecond pulses over an energy density range of 15 to 40 J/cm² utilizing a 12-mm spot size were delivered with contact sapphire cooling tip at approximately 10°C. All 13 subjects (100%) in the efficacy population achieved procedure success at the end of the final treatment, that is a 2-point improvement of telangiectasis on the telangiectasia scale (pre- versus post-treatment). A single treatment was effective in greater than 75% of patients with at least a 75% reduction in blood vessels. Larger vessels responded well to longer pulse durations (40 milliseconds) while smaller vessels responded best to shorter pulse durations (25 milliseconds). No serious adverse events (SAEs) were recorded. The authors concluded that the TRASER device is a safe and effective option for treatment of nasal telangiectasias with all subjects meeting primary end-point success at the end of treatment and the majority of subjects demonstrating clearance after only 1 treatment; these treatments were well-tolerated and provided high patient satisfaction. The main drawbacks of this study were its small sample size (n = 13) as well as short-term follow-up (1 month). These preliminary findings need to be validated by well-designed studies.
CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

### CPT codes covered if selection criteria are met:

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<th>Code(s)</th>
<th>Description</th>
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<tr>
<td>77401</td>
<td>Radiation treatment delivery [includes beta irradiation]</td>
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<td>77417</td>
<td></td>
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<tr>
<td>77767</td>
<td>Remote afterloading high dose rate radionuclide skin surface brachytherapy, includes basic dosimetry, when performed</td>
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<tr>
<td>77772</td>
<td></td>
</tr>
<tr>
<td>77778</td>
<td>Interstitial radiation source application, complex, includes supervision, handling, loading of radiation source, when performed</td>
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### ICD-10 codes covered if selection criteria are met:

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<th>Description</th>
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<td>Hypertrophic scar [keloid]</td>
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<tr>
<td>M08.1.</td>
<td>Ankylosing spondylitis</td>
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<td>M45.0</td>
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<td>Ankylosing spondylitis</td>
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<td>M48.00</td>
<td>Spinal stenosis</td>
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<td>M48.08</td>
<td>Spinal stenosis</td>
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<td>S06.0x0+</td>
<td>Intracranial injury</td>
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<td>S06. 9x9+</td>
<td>Intracranial injury</td>
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### ICD-10 codes related if selection criteria are met:

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<th>Description</th>
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<tr>
<td>M96.89</td>
<td>Other intraoperative and postprocedural complications and disorders of the musculoskeletal system [postoperative heterotopic calcification]</td>
</tr>
</tbody>
</table>

The above policy is based on the following references:

Radiation Therapy for Keloids

3. Ogawa R, Mitsuhashi K, Hyakusoku H, Miyashita T.


27. Gaulitz GG. Management of keloid and hypertrophic scars following burn injuries. UpToDate Inc., Waltham, MA. Last reviewed April 2015.

**Radiation Therapy for Heterotopic Ossification**


**Beta Irradiation for Pterygium**


2. Qin XJ, Chen HM, Guo L, Guo YY. Low-dose strontium-90


Radiation Therapy for Miscellaneous Indications


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Amendment to
Aetna Clinical Policy Bulletin Number: 0551 Radiation Treatment for Selected Nononcologic Indications

There are no amendments for Medicaid.