Clinical Policy Bulletin: Radiation Treatment for Selected Nononcologic Indications

Revised April 2014

Number: 0551

Policy

Aetna considers low-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 for medically necessary indications for keloid removal.

Radiation therapy is considered 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.

See also: CPB 0800 - Dupuytren Contracture: Treatments; CPB 0231 - Grenz Ray Therapy for Skin Disorders; CPB 0756 - Epiretinal Radiation Therapy; CPB 83 - Stereotactic Radiosurgery; CPB 419 - Graves' Ophthalmopathy Treatments; and CPB 0491 - Coronary Artery Brachytherapy and Other Adjuncts to Coronary Interventions.

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 post operative 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 pterygium 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 pterygium 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 pterygium). 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).
Radiation Treatment for Selected Nononcologic Indications

CPT Codes / HCPCS Codes / ICD-9 Codes

CPT codes covered if selection criteria are met:

77401
77776
77777
77778

ICD-9 codes covered if selection criteria are met:

701.4       Keloid scar
720.0       Ankylosing spondylitis
723.0, 724.00  Spinal stenosis
             - 724.09
851.00 - 854.19  Cerebral laceration and contusion, subarachnoid, subdural, and extradural hemorrhage, following injury, other and unspecified intracranial hemorrhage following injury, and intracranial injury of other and unspecified nature

ICD-9 codes related if selection criteria are met:

728.13       Postoperative heterotopic calcification

The above policy is based on the following references:

Radiation Therapy for Keloids


Radiation Therapy for Heterotopic Ossification


**Beta Irradiation for Pterygium**


**Radiation Therapy for Miscellaneous Indications**


http://qawww.aetna.com/cpb/medical/data/500_599/0551_draft.html

12/08/2014