Clinical Policy: Radiation Therapy for Dupuytren’s Contracture
Reference Number: HNCA.CP.MP.618

Last Review Date: 09/19

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Dupuytren’s contracture is caused by a progressive fibroproliferative disorder of the fascia in the hands that can cause permanent flexion contracture of the digits. Treatment includes noninvasive measures such as stretching, heat and ultrasound, and invasive procedures such as local cortisone injection, collagen injections and surgery. Radiation therapy has been proposed as a noninvasive treatment option.

Policy/Criteria
It is the policy of Health Net of California that photon or external radiation therapy may be considered as a treatment option to prevent disease progression in early-stage (N, N/1) Dupuytren’s disease of the hand.

Background
Dupuytren's disease is disorder of unknown origin in which the facia of the palm progressively thickens over time and causes permanent flexion of the fingers. It usually affects the 4th and 5th fingers and limits extension of the metacarpophalangeal (MCP) or proximal interphalangeal (PIP) joint. Initial presentation are small pitted nodule(s) in the palm of the hand that may stay at that stage for months or years, however it may progress to form longitudinal cords of thick fibrous tissue that cause contracture and loss of function. Risk factors for developing this disease include older age, male sex, northern European descent, family history of Dupuytren’s disease, and diabetes mellitus.

Most symptoms are mild and do not require treatment. It has been reported that 10% of individuals will regress but, without treatment, about 50% of patients experience progressive disease. When contracture degree increases and hand function becomes more compromised, more invasive procedures are considered, though all have various degrees of effectiveness, risks and potential complications. Injections of steroids or collagenase can be administered. Needle aponeurotomy is performed under local anesthesia where small needles are inserted into the thickened cord percutaneously, in an attempt to release the contracture. Surgical procedures include fasciotomy where the fibrous cords of tissue are divided but not removed, and the subtotal palmar fasciectomy in which the abnormal tissue and cord are actually excised. This is a more complex and invasive procedure and usually requires wound care and physical therapy and a longer recovery time.

Prophylactic external beam radiation therapy has been evaluated as an alternative treatment for early Dupuytren’s disease. According to UptoDate (2019), radiation therapy can prevent progression and can provide symptomatic benefit in patients with mild to moderate flexion deformities; however, no controlled studies have been published.
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In 2017, Kadhum et al systematically reviewed the evidence on the use of radiotherapy in Dupuytren's disease. Only six articles met a minimum set standard, five of which were retrospective cohort studies and one a randomized controlled study. A total of 770 Dupuytren's hands, nearly all with Tubiana stage 0-1 disease, were irradiated with an average 30 Gy. Disease regression ranged from 0%-56%, stability from 14%-98% and progression from 2%-86%. Salvage surgery was successful in all cases of disease progression post-radiotherapy. There were no reports of adverse wound healing problems associated with such surgery or radiotherapy-associated malignancy. The authors noted radiotherapy should be considered an unproven treatment for early Dupuytren's disease due to a scarce evidence base and unknown long-term adverse effects and that well-designed randomized controlled studies are needed to confirm the benefits of radiotherapy treatment.

In 2001, Seegenschmiedt et al published a study involving 129 patients (67 males; 62 females) with Dupuytrens contracture (DC): 69 had bilateral and 60 uni-lateral involvement of DC accounting for 198 irradiated hands. According to Tubiana's classification, 73 hands had Stage N (nodules/cords, no extension deficit = flexion deformity), 61 had Stage N/I (<or = 10 degrees deficit), 59 had Stage I (11-45 degrees deficit), and 5 had Stage II (46-90 degrees deficit) DC. Prophylactic RT was randomly delivered; in Group A, 63 patients (95 hands) received 10 x 3 Gy (total dose, 30 Gy) in 2 series (5 x 3Gy) separated by 8 weeks; in Group B, 66 patients (103 hands) received 7 x 3 Gy (total dose, 21 Gy) in 1 series within 2 weeks. Orthovoltage RT (120 kV) was applied using standard cones and individual shielding of uninvolved areas of the palm. Relevant patient and disease parameters were equally distributed in both groups. Evaluation (toxicity, efficacy) was performed at 3 and 12 months after RT. Subjective (patient's opinion) and objective parameters (palpation, measurements, and comparative photographs) were applied to assess treatment response. Minimum follow-up (FU) was 1 year.

Study results indicated that acute toxicity was minimal, but slightly more pronounced in Group B. Seventy-six (38%) hands developed skin reactions CTC 1 degrees (A, 30; B, 46); and 12 (6%) had skin reactions CTC 2 degrees (A, 4; B, 8). Chronic side effects were limited to dryness, desquamation, skin atrophy, and change of sensation (LENT 1 degrees ) in 9 (5%) sites without differences between the two groups. At 3 and 12 months after RT, subjective and objective reduction of symptoms, nodules, and cords occurred in both groups (p<0.01) with no differences between the groups: in Group A, 55 (56%) sites regressed, 35 (37%) remained stable, and 7 (7%) progressed, whereas in Group B, 55 (53%) regressed, 39 (38%) remained stable, and 9 (9%) progressed at 12 months FU (NS). Overall and mean number of nodules, cords, and skin changes decreased at 3 and 12 months. The "treatment failure" rate at 1 year was 16 of 198 (8%), but only 4 (2%) sites required hand surgery for disease progression. Seven of 60 patients with unilateral DC received prophylactic RT for the initially uninvolved, contralateral hand due to progression of DC.
The authors concluded that both prophylactic RT concepts have been well accepted and tolerated by patients. Within the first year, they were equally effective to prevent further disease progression of DC and obtain considerable symptomatic improvement. Although 1-year results suggest similar response rates for both treatment groups, long-term FU of > 5 years has to be awaited for final assessment and recommendation of an optimized RT treatment schedule.

Betz et al (2010) reported a retrospective analysis of radiotherapy to prevent disease progression with respect to long-term outcome and late toxicity of this treatment. Between 12/1982 and 02/2006, 135 patients (208 hands) were irradiated with orthovoltage (120 kV; 20 mA; 4-mm Al filter), in two courses with five daily fractions of 3.0 Gy to a total dose of 30 Gy; separated by a 6- to 8-week interval. The extent of disease was described according to a modified classification of Tubiana et al. Long-term outcome was analyzed at last follow-up between 02/2008 and 05/2008 with a median follow-up of 13 years (range, 2-25 years). Late treatment toxicity and objective reduction of symptoms as change in stage and numbers of nodules and cords were evaluated and used as evidence to assess treatment response. Results of the analysis were reported according to the individual stages. 123 cases (59%) remained stable, 20 (10%) improved, and 65 (31%) progressed. In stage N 87% and in stage N/I 70% remained stable or even regressed. In more advanced stages, the rate of disease progression increased to 62% (stage I) or 86% (stage II). 66% of the patients showed a long-term relief of symptoms (i.e., burning sensations, itching and scratching, pressure and tension). Radiotherapy did not increase the complication rate after surgery in case of disease progression and only minor late toxicity (skin atrophy, dry desquamation) could be observed in 32% of the patients. There was no evidence for a second malignancy induced by radiotherapy. The authors concluded that after a mean follow-up of 13 years, radiotherapy is effective in prevention of disease progression and improves patients' symptoms in early-stage Dupuytren's contracture (stage N, N/I). In case of disease progression after radiotherapy, a "salvage" operation is still feasible.

Guidelines from the National Institute for Health and Care Excellence (NICE, 2016) state that “..the evidence on radiation therapy for early Dupuytren's disease raises no major safety concerns. Current evidence on its efficacy is inadequate in quantity and quality, and is difficult to interpret because of uncertainty about the natural history of Dupuytren's disease.”

**Coding Implications**

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<th>CPT® Codes</th>
<th>Description</th>
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<tr>
<td>77401</td>
<td>Radiation treatment delivery, superficial and/or ortho voltage, per day</td>
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ICD-10-CM Diagnosis Codes that Support Coverage Criteria

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<td>M72.0</td>
<td>Palmar fascial fibromatosis (Dupuytren)</td>
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Reviews, Revisions, and Approvals

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<td>Policy developed.</td>
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References


Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health
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Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.

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