

Non-Malignant Conditions Policy

Purpose

To describe the CVS Health Radiation Oncology Policy for non-malignant conditions.

Scope

The scope of this document applies to CVS Health® clients who have signed up for the CVS Radiation Oncology program under CVS Health Solutions. This document includes the policy details for the non-malignant conditions policy, effective 10/9/24.

Policy

CVS Health considers radiation therapy medically necessary for the treatment of many clinical situations where the primary diagnosis is benign, non-malignant, or non-cancerous and the established medical or surgical treatment is insufficient in the treatment of the disorder:

- A. High-risk heterotopic ossification
- B. Keloids delivered via superficial radiation or interstitial brachytherapy
- C. Castleman's disease
- D. Ledderhose disease (plantar fibromatosis)
- E. Neurofibromas, angiofibromas, and papillomas
- F. Orbital pseudotumor
- G. Pterygium
- H. Osteoarthritis
 - a. CVS Health considers radiation therapy for osteoarthritis medically necessary when the following criteria are met^{1,2}:
 - i. Patient is at least 60 years of age AND
 - ii. Patient has had an inadequate response to non-pharmacologic therapies (eg, physical therapies)
 - iii. AND one of the following criteria:
 - 1. Patient has had an inadequate response, intolerable adverse event, or contraindication to pharmacologic therapies (eg, topical and systemic analgesics, intra-articular glucocorticoids) OR
 - 2. Patient has had a consultation/evaluation completed by an orthopedic surgeon and was considered to have disease advanced enough for joint replacement, but was deemed to be medically inoperable.

CVS Health considers radiation therapy experimental and investigational in the treatment of many non-malignant conditions, including but not limited to the following disorders:

- A. Cardiac radioablation

- B. Rheumatoid arthritis and psoriatic arthritis
- C. Infection
- D. Other non-malignant conditions

Related CMS Coverage Guidance

This Clinical Policy Bulletin (CPB) supplements but does not replace, modify, or supersede existing Medicare Regulations or applicable National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). The supplemental medical necessity criteria in this CPB further define those indications for services that are proven safe and effective where those indications are not fully established in applicable NCDs and LCDs. These supplemental medical necessity criteria are based upon evidence-based guidelines and clinical studies in the peer-reviewed published medical literature. The background section of this CPB includes an explanation of the rationale that supports adoption of the medical necessity criteria and a summary of evidence that was considered during the development of the CPB; the reference section includes a list of the sources of such evidence. While there is a possible risk of reduced or delayed care with any coverage criteria, Aetna believes that the benefits of these criteria – ensuring patients receive services that are appropriate, safe, and effective – substantially outweigh any clinical harms.

Code of Federal Regulations (CFR):

42 CFR 417; 42 CFR 422; 42 CFR 423.

Internet-Only Manual (IOM) Citations:

CMS IOM Publication 100-02, Medicare Benefit Policy Manual; CMS IOM Publication 100-03 Medicare National Coverage Determination Manual.

Medicare Coverage Determinations:

Centers for Medicare & Medicaid Services (CMS), Medicare Coverage Database [Internet]. Baltimore, MD: CMS; updated periodically. Available at: Medicare Coverage Center. Accessed November 7, 2023.

References

The Non-Malignant conditions policy is based on the following references:

1. Yu J, Grew D, et al. Radiation Therapy for the Treatment of Osteoarthritis. *Pract Radiat Oncol*. 2024; 15(1): 19-24.
2. Dove A, Cmelak A, et al. The Use of Low-Dose Radiation Therapy in Osteoarthritis: A Review. *Int J Radiation Oncol Biol Phys*. 2022; 114(2): 203-220.