Coverage Summary

Radiologic Therapeutic Procedures

Policy Number: R-003  Products: UnitedHealthcare Medicare Advantage Plans  Original Approval Date: 04/02/2008
Approved by: UnitedHealthcare Medicare Benefit Interpretation Committee  Last Review Date: 11/19/2019

Related Medicare Advantage Policy Guidelines:

- Delivery of IMRT/SRS/SBRT
- Tumor Treatment Field Therapy

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The benefit information in this Coverage Summary is based on existing national coverage policy, however, Local Coverage Determinations (LCDs) may exist and compliance with these policies are required where applicable.

There are instances where this document may direct readers to a UnitedHealthcare Commercial Medical Policy, Medical Benefit Drug Policy, and/or Coverage Determination Guideline (CDG). In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

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I. COVERAGE

Coverage Statement: Therapeutic radiologic procedures are covered when Medicare criteria are met.
Guidelines/Notes:
Therapeutic radiological services (inpatient or outpatient) used the treatment of disease, are covered when such services are determined to be reasonable and necessary. Examples include, but are not limited to:

1. **Percutaneous Transluminal Coronary Interventions (Interventional Cardiology)**
   - Medicare does not have a National Coverage Determination (NCD) for transluminal coronary interventions (interventional cardiology).
   - Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist for all 50 states and compliance with these policies is required where applicable. For state-specific LCDs/LCAs, refer to the LCD/LCA Availability Grid (Attachment A).
   - Committee approval date: November 19, 2019
   - Accessed January 6, 2020

2. **Proton Beam Therapy (PBT)**
   - Medicare does not have a National Coverage Determination (NCD) for PBT.
   - Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For state-specific LCDs/LCAs, refer to the LCD/LCA Availability Grid (Attachment B).
   - For states with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Policy for Proton Beam Radiation Therapy with individual consideration for following diagnoses:
     - Malignant lesions of the head and neck when the intent of treatment is to be curative
     - Pancreatic and adrenal tumors
     - Unresectable retroperitoneal sarcoma
     - Cancers of the lung and upper abdominal/peri-diaphragmatic cancers
     - Unresectable malignant lesions of the liver, biliary tract, anal canal and rectum
     - Skin cancer with macroscopic perineural/cranial nerve invasion of skull base
     - Advanced stage, unresectable pelvic tumors including those with peri-aortic nodes or malignant lesions of the cervix
     - Prostate Cancer, non-metastatic
     - Unresectable breast tumors in proximity to the heart
     - Acoustic neuromas
     - Pituitary neoplasms
     - Unresectable benign or malignant central nervous system tumors to include but not be limited to primary and variant forms of astrocytoma, glioblastoma, medulloblastoma, craniopharyngioma, benign and atypical meningiomas, pineal gland tumors
   - IMPORTANT NOTE: After checking the LCD/LCA Availability Grid and searching the Medicare Coverage Database, if no state LCD/LCA is found, then use the above referenced policy.
   - Committee approval date: November 19, 2019
   - Accessed January 6, 2020

3. **Intensity Modulated Radiation Therapy (IMRT)**
   - Medicare does not have a National Coverage Determination (NCD) for IMRT.
   - Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For state-specific LCDs/LCAs, refer to the LCD/LCA Availability Grid (Attachment C).
   - For states with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Policy for Intensity-Modulated Radiation Therapy for coverage guidelines.
   - IMPORTANT NOTE: After checking the LCD/LCA Availability Grid and searching the Medicare Coverage Database, if no state LCD/LCA is found, then use the above referenced policy.
4. Combined use of Proton Beam Therapy (PBT) and Intensity-Modulated Radiation Therapy (IMRT)
   - Medicare does not have a National Coverage Determination (NCD) for combined use of PBT and IMRT.
   - Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) do not exist at this time.
     (IMPORTANT NOTE: After searching the Medicare Coverage Database, if no state LCD/LCA is found, then use the above referenced policies.)

5. Stereotactic Radiosurgery (SRS)/Stereotactic Body Radiation Therapy (SBRT)
   - Medicare does not have a National Coverage Determination (NCD) for SRS/SBRT.
   - Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For state-specific LCDs/LCAs, refer to the LCD/LCA Availability Grid (Attachment D).
   - For states with no LCDs/LCAs, refer to the MCG™ Care Guidelines, 23rd edition, 2019, for Stereotactic Radiosurgery ACG: A-0423 (AC) and Stereotactic Body Radiotherapy ACG: A-0694 (AC) and Stereotactic Radiosurgery for coverage guidelines or information regarding medical necessity with individual consideration for following diagnoses for SBRT:
     - primary or metastatic pancreatic cancer
     - primary or metastatic renal cancer
     - primary or metastatic adrenal gland cancer
     - primary central nervous system malignancies, generally under 5 cm
     - relapse in a previously irradiated cranial or spinal field where the additional stereotactic precision is required
     - Click here to view the MCG™ Care Guidelines.
     (IMPORTANT NOTE: After checking the LCD/LCA Availability Grid and searching the Medicare Coverage Database, if no state LCD/LCA is found, then use the above referenced policies.)

6. Local Hyperthermia
   Local hyperthermia is covered when used in connection with radiation therapy for the treatment of primary or metastatic cutaneous or subcutaneous superficial malignancies. It is not covered when used alone or in connection with chemotherapy. See the NCD for Hyperthermia for Treatment of Cancer (110.1). (Accessed November 4, 2019)

   - Medicare does not have an NCD for computer-assisted surgical navigation for musculoskeletal procedures.
• Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For state-specific LCDs/LCAs, refer to the LCD Availability Grid (Attachment E).

• For states with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Policy for Computer-Assisted Surgical Navigation for Musculoskeletal Procedures for coverage guidelines.

(IMPORTANT NOTE: After checking the LCD/LCA Availability Grid and searching the Medicare Coverage Database, if no state LCD/LCA is found, then use the above referenced policy.)

• Committee approval date: November 19, 2019
• Accessed January 6, 2020

8. Tumor Treatment Field Therapy (TTFT) (CPT codes A4555 and E0766)
   • Medicare does not have an NCD for TTFT.
   • Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist for all 50 states and compliance with these policies is required where applicable. Refer to the DME MAC LCD for Tumor Treatment Field Therapy (TTFT) (L34823) for coverage guidelines.

• Committee approval date: November 19, 2019
• Accessed January 6, 2020

9. Magnetic Resonance Image Guided High Intensity Focused Ultrasound (MRgFUS) (CPT Code 0398T)
   • Medicare does not have a National Coverage Determination (NCD) for MRgFUS.
   • Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist for all 50 states and compliance with these policies is required where applicable. For state-specific LCDs/LCAs, refer to the LCD/LCA Availability Grid (Attachment F).

• Committee approval date: November 19, 2019
• Accessed January 6, 2020

II. DEFINITIONS

Proton Beam Therapy (PBT): PBT is a technology for delivering conformal external beam radiation with positively charged atomic particles to a well-defined treatment volume. PBT is approved by the U.S. Food and Drug Administration.

Due to its unique dose deposition characteristics, PBT can, in certain situations, deliver the prescribed target dose while giving a lower dose to normal tissues as compared to photon-based forms of external beam radiotherapy.

Photon beams deposit their greatest amount of energy beneath the patient's surface with a gradual reduction in energy deposition along the beam path as photons pass through the target and then through an exit point out of the body. In contrast, the physical profile of a beam of proton particles allows for the majority of its energy to be deposited over a very narrow range of tissue at a depth largely determined by the energy of the proton beam. A proton beam deposits relatively less radiation energy upon entering the body compared to a photon beam. The energy deposition of the proton beam then rapidly increases over a narrow range of tissue at a desired depth to produce an intense dose distribution pattern called the Bragg peak. Beyond the Bragg peak, energy and dose deposition rapidly decrease, resulting in the absence of any significant exit dose deposited in normal tissue beyond the target. National Government Services, Inc. LCD for Proton Beam Therapy (L35075). (Accessed January 6, 2020)

Stereotactic Radiosurgery (SRS): The adjective “Stereotactic” describes a procedure during which
a target lesion is localized relative to a fixed three dimensional reference system, such as a rigid head frame (61800) affixed to a patient, fixed bony landmarks, a system of implanted fiducial markers, or other similar system. This type of localization procedure allows physicians to perform image-guided procedures with a high degree of anatomic accuracy and precision.

Stereotactic radiation therapy (SRT) couples this anatomic accuracy and reproducibility with very high doses of highly precise, externally generated, ionizing radiation, thereby maximizing the ablative effect on the target(s) while minimizing collateral damage to adjacent tissues. SRT requires computer-assisted, three-dimensional planning and delivery with stereotactic and convergent-beam technologies, including, but not limited to, multiple convergent cobalt sources (e.g., Gamma Knife®), protons, multiple, coplanar or non-coplanar photon arcs or angles (e.g., XKnife®), fixed photon arcs or image-directed robotic devices (e.g., CyberKnife®) that meet the criteria.

SRS is a distinct discipline that utilizes externally generated ionizing radiation in certain cases to inactivate or eradicate a defined target(s) in the head or spine without the need to make an incision. The target is defined by high-resolution stereotactic imaging. To assure quality of patient care the procedure involves a multidisciplinary team consisting of a neurosurgeon, radiation oncologist, and medical physicist. SRS typically is performed in a single session, using a rigidly attached stereotactic guiding device, other immobilization technology and/or a stereotactic-guidance system, but can be performed in a limited number of sessions, up to a maximum of five. Technologies that are used to perform SRS include linear accelerators, particle beam accelerators, and multisource Cobalt 60 units. In order to enhance precision, various devices may incorporate robotics and real time imaging. *LCD for Stereotactic Radiation Therapy: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) (L34151). (Accessed January 6, 2020)*

**Stereotactic Body Radiation Therapy (SBT):** A treatment that couples a high degree of anatomic targeting accuracy and reproducibility with very high doses of extremely precise, externally generated, ionizing radiation, thereby maximizing the cell-killing effect on the target(s) while minimizing radiation-related injury in adjacent normal tissues.

The adjective “stereotactic” describes a procedure during which a target lesion is localized relative to a known three dimensional reference system that allows for a high degree of anatomic accuracy and precision. Examples of devices used in SBRT for stereotactic guidance may include a body frame with external reference markers in which a patient is positioned securely, a system of implanted fiducial markers that can be visualized with low-energy (kV) x-rays, and CT imaging-based systems used to confirm the location of a tumor immediately prior to treatment.

All SBRT is performed with at least one form of image guidance to confirm proper patient positioning and tumor localization. To minimize intra-treatment tumor motion associated with respiration or other motion, some form of motion control or “gating” may be used. SBRT may be fractionated (up to 5 fractions). Each fraction requires an identical degree of precision, localization and image guidance.

Since the goal of SBRT is to intensify the potency of the radiotherapy by completing an entire course of treatment within an extremely accelerated time frame, any course of radiation treatment extending beyond five fractions is not considered SBRT and is not to be billed using these codes. *LCD for Stereotactic Radiation Therapy: Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) (L34151). (Accessed January 6, 2020)*

**Transluminal Interventions:** Encompass balloon dilatation, a variety of atherectomy devices as well as approved stents for coronary placement. Complementing medical therapy and aortocoronary bypass, transluminal interventions have emerged as a third therapeutic option for the management of patients with chronic angina, acute coronary insufficiency and evolving myocardial infarction. *LCD*
III. REFERENCES

See above

IV. REVISION HISTORY

12/04/2019  • Added reference link to MCG™ Care Guidelines
11/19/2019  Guideline 5 [Stereotactic Radiosurgery (SRS)/Stereotactic Body Radiation Therapy (SBRT)]
  • Revised language pertaining to states with no Local Coverage Determinations (LCDs):
    o Updated list of diagnoses for SRS/SBRT requiring individual consideration when referring to MCG™ Care Guidelines, 23rd edition, 2019, Stereotactic Radiosurgery ACG: A-0423 (AC) and Stereotactic Body Radiotherapy ACG: A-0694 (AC) and Stereotactic Radiosurgery for applicable coverage guidelines; added:
      ▪ Primary central nervous system malignancies, generally under 5 cm
      ▪ Relapse in a previously irradiated cranial or spinal field where the additional stereotactic precision is required

Attachments
  • Updated LCD Availability Grids to reflect the most current reference links

V. ATTACHMENTS

Attachment A - LCD/LCA Availability Grid
Interventional Cardiology/Percutaneous Transluminal Coronary Interventions
CMS website accessed January 6, 2020

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End of Attachment A

Attachment B - LCD/LCA Availability Grid
Proton Beam Therapy/Proton Beam Radiotherapy
CMS website accessed January 6, 2020

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UHC MA Coverage Summary: Radiologic Therapeutic Procedures
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### Attachment B - LCD/LCA Availability Grid
#### Proton Beam Therapy/Proton Beam Radiotherapy
CMS website accessed January 6, 2020

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### Attachment C - LCD/LCA Availability Grid
#### Intensity Modulated Radiation Therapy (IMRT)
CMS website accessed January 6, 2020

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### Attachment D - LCD/LCA Availability Grid
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### Attachment E - LCD/LCA Availability Grid

**Computer-Assisted Surgical Navigation for Musculoskeletal Procedures**
(CPT code 20985)

CMS website accessed January 6, 2020

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*End of Attachment E*

### Attachment F - LCD/LCA Availability Grid

**Magnetic Resonance Image Guided High Intensity Focused Ultrasound (MRgFUS) (CPT Code 0398T)**

CMS website accessed January 6, 2020

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### Magnetic Resonance Image Guided High Intensity Focused Ultrasound (MRgFUS) (CPT Code 0398T)

**Attachment F - LCD/LCA Availability Grid**

CMS website accessed January 6, 2020

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End of Attachment F