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OVERVIEW

Radiotherapy (RT) is an integral component in the treatment of many brain tumors, both benign and malignant. Intensity-modulated radiotherapy (IMRT) has been proposed as a method of RT that allows adequate RT to the tumor while minimizing the radiation dose to surrounding normal tissues and critical structures.

MEDICAL CRITERIA

BlueCHiP for Medicare and Commercial Products

Intensity-modulated radiotherapy (IMRT) may be considered medically necessary when the criteria below is met:

- For the treatment of tumors of the central nervous system (CNS) when the tumor is in close proximity to organs at risk including;
 - Brain stem
 - Spinal Cord
 - Cochlea and eye structures including optic nerve and chiasm, lens and retina, and;
- Use of conventional radiation dosage will result in damage and complications for normal surrounding tissue.

Intensity-modulated radiotherapy (IMRT) is considered not medically necessary for the treatment of tumors of the CNS for all indications not meeting the criteria above.

PRIOR AUTHORIZATION

Prior authorization is recommended and obtained via the online tool for participating providers.

POLICY STATEMENT

BlueCHiP for Medicare and Commercial Products

Intensity-modulated radiotherapy (IMRT) may be considered medically necessary for the treatment of tumors of the central nervous system (CNS) when the criteria above is met.

IMRT is considered not medically necessary for the treatment of tumors of the CNS for all indications not listed above, as there is insufficient peer-reviewed literature that demonstrates that the procedure/service is effective.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement, or Benefit Booklet for radiology benefit/coverage.

BACKGROUND

The standard approach to the treatment of brain tumors depends on the type and location of tumor. For glioblastoma multiforme, a malignant high-grade tumor, treatment is multimodal, with surgical resection followed by adjuvant RT and chemotherapy. For benign and low-grade brain tumors, gross total resection remains the primary goal. However, RT may be used in selected cases. Some examples are when total resection is not possible, when a more conservative surgical approach may be necessary to achieve long-term treatment goals, and with atypical tumors that may need RT even after gross total resection to reduce the risk of local recurrence. Therefore, RT, either definitive or in the postoperative adjuvant setting, remains an

integral component in the management of residual, recurrent, and/or progressive benign and low-grade brain tumors for maximizing local control. Brain metastases occur in up to 40% of adults with cancer and can shorten survival and detract from quality of life. Many patients who develop brain metastases will eventually die of progressive intracranial disease. Among patients with good performance status, controlled extracranial disease, favorable prognostic features, and a solitary brain metastasis, randomized studies have shown that surgical excision followed by whole-brain radiotherapy (WBRT) prolongs survival. Stereotactic radiosurgery (SRS) may be able to replace surgery in certain circumstances, delivering obliteratively high single doses to discrete metastases. For bulky cerebral metastases, level 1 evidence has also shown that delivering a higher radiation dose with an SRS boost is beneficial in addition to standard WBRT. The use of a concomitant boost with IMRT during WBRT has been attempted to improve overall local tumor control without the use of SRS to avoid additional planned radiation after WBRT (“phase II” or SRS) and its additional labor and expense. Another indication for use of IMRT in WBRT is to avoid radiation exposure to the hippocampus. It is thought that avoiding the hippocampus may minimize cognitive decline that has been associated with WBRT.

Radiation Techniques Conventional External Beam Radiotherapy

Over the past several decades, methods to plan and deliver RT have evolved in ways that permit more precise targeting of tumors with complex geometries. Most early trials used 2-dimensional treatment planning based on flat images and radiation beams with cross-sections of uniform intensity that were sequentially aimed at the tumor along 2 or 3 intersecting axes. Collectively, these methods are termed “conventional external beam RT.

Three-dimensional conformal radiotherapy treatment planning evolved by using 3-dimensional images, usually from computed tomography (CT) scans, to delineate the boundaries of the tumor and discriminate tumor tissue from adjacent normal tissue and nearby organs at risk for radiation damage. Computer algorithms were developed to estimate cumulative radiation dose delivered to each volume of interest by summing the contribution from each shaped beam. Methods also were developed to position the patient and the radiation portal reproducibly for each fraction and immobilize the patient, thus maintaining consistent beam axes across treatment sessions. Collectively, these methods are termed 3-dimensional conformal radiotherapy.

IMRT, which uses computer software and CT and magnetic resonance imaging (MRI) images, offers better conformality than 3D-CRT, as it is able to modulate the intensity of the overlapping radiation beams projected on the target and to use multiple shaped treatment fields.

Treatment planning and delivery are more complex, time consuming, and labor intensive for IMRT than for 3D-CRT. The technique uses a multileaf collimator (MLC) which when coupled with a computer algorithm, allows for “inverse” treatment planning. The radiation oncologist delineates the target on each slice of a CT scan and specifies the target’s prescribed radiation dose, acceptable limits of dose heterogeneity within the target volume, adjacent normal tissue volumes to avoid, and acceptable dose limits within the normal tissues. Based on these parameters and a digitally reconstructed radiographic image of the tumor, surrounding tissues, and organs at risk, computer software optimizes the location, shape, and intensities of the beams ports to achieve the treatment plan’s goals. Based on these parameters and a digitally reconstructed radiographic image of the tumor and surrounding tissues and organs at risk, computer software optimizes the location, shape and intensities of the beams ports, to achieve the treatment plan’s goals.

Increased conformality may permit escalated tumor doses without increasing normal tissue toxicity and thus may improve local tumor control, with decreased exposure to surrounding, normal tissues, potentially reducing acute and late radiation toxicities. Better dose homogeneity within the target may also improve local tumor control by avoiding underdosing within the tumor and may decrease toxicity by avoiding overdosing.

Technologic development has produced advanced techniques which may further improve RT treatment by improving dose distribution. These techniques are considered variations of IMRT. Volumetric modulated arc therapy (VMAT) involves delivery of radiation from a continuous rotation of the radiation source. The

principal advantage of VMAT is greater efficiency in treatment delivery time, reducing radiation exposure and improving target radiation delivery due to less patient motion. Image-guided RT involves the incorporation of imaging before and/or during treatment to more precisely deliver RT to the target volume.

Methodologic Issues With IMRT Studies

Multiple-dose planning studies generate 3D-CRT and IMRT treatment plans from the same scans, and then compare predicted dose distributions within the target area and adjacent organs. Results of such planning studies show that IMRT improves on 3D-CRT with respect to conformality to, and dose homogeneity within, the target. They also demonstrate less radiation exposure to nontarget areas. Dosimetry studies using stationary targets generally confirms these predictions. However, because patients move during treatment, dosimetry with stationary targets only approximate actual radiation doses received. Based on these dosimetry studies, radiation oncologists expect IMRT to improve treatment outcomes compared with those of 3D-CRT. However, these types of studies offer only indirect evidence on treatment benefit from IMRT, and it is difficult to relate results of dosing studies to actual effects on health outcomes.

Comparative studies of radiation-induced adverse effects from IMRT versus alternative radiation delivery would constitute definitive evidence in establishing the benefit of IMRT. Single-arm series of IMRT can give some insights into the potential for benefit, particularly if an adverse effect that is expected to occur at high rates is shown to decrease by a large amount. Studies of treatment benefit are also important to establish that IMRT is at least as good as other types of delivery, but in the absence of such comparative trials, it is likely that benefit from IMRT is at least as good as with other types of delivery.

Practice Guidelines and Position Statements

National Comprehensive Cancer Network Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines on central nervous system cancers state that: when radiation is given to patients with low-grade gliomas, it is administered with restricted margins. Every attempt should be made to decrease the radiation dose outside the target volume. This can be achieved with 3-dimensional planning or IMRT.

NCCN guidelines do not address the use of IMRT in high-grade tumors or metastases of the CNS.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

CODING

BlueCHiP for Medicare and Commercial Products

A4648 Tissue marker, implantable, any type, each (Note: This code is not separately reimbursed for institutional providers.)

Note: To ensure correct pricing of HCPCS code **A4648** for the Calypso 4D localization system, the procedure/clinical notes and the invoice must be submitted.

The following codes are covered for BlueCHiP for Medicare and commercial products when the criteria above is met.

77301 Intensity modulated radiotherapy plan, Including dose volume histograms for target and critical structure partial tolerance specification

77338 Multi-leaf collimator (MLC) device(s) for intensity modulated radiotherapy (IMRT), design and construction per IMRT plan

- 77385:** Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple; (Institutional Providers)
- 77386:** Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex; (Institutional Providers)
- G6015** Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session; (Professional Providers)
- G6016** Compensator-based beam modulation treatment delivery of inverse planned treatment using 3 or more high-resolution (milled or cast) compensator, convergent beam modulated fields, per treatment session; (Professional Providers)

RELATED POLICIES

Preauthorization via Web-Based Tool for Procedures

PUBLISHED

Provider Update, November 2016

Provider Update, February 2016

Provider Update, October 2015

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