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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 obliterated 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.

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 (2D) 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 (3D-CRT) treatment planning evolved by using 3-dimensional (3D) 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. It uses a device (a multileaf collimator [MLC]) which, coupled to 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 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. Because most tumors move as patients breathe, dosimetry with stationary targets may not accurately reflect doses delivered within target volumes and adjacent tissues in patients. Furthermore, treatment planning and delivery are more complex, time consuming, and labor intensive for IMRT than for 3D-CRT. Thus, clinical studies must test whether IMRT improves tumor control or reduces acute and late toxicities when compared with 3D-CRT.

Methodologic Issues With IMRT Studies

Multiple-dose planning studies have generated 3D-CRT and IMRT treatment plans from the same scans, then compared predicted dose distributions within the target and in adjacent organs at risk. Results of such planning studies show that IMRT improves on 3D-CRT with respect to conformality to, and dose homogeneity within, the target. Dosimetry using stationary targets generally confirms these predictions. Thus, radiation oncologists hypothesized that IMRT may improve treatment outcomes compared with those of 3D-CRT. However, these types of studies offer 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 are probably the most important type of evidence in establishing the benefit of IMRT. Such studies would answer the question of whether the theoretical benefit of IMRT in sparing normal tissue translates into real health outcomes. 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.

The body of evidence available to evaluate IMRT in the treatment of CNS tumors consists of dose planning studies and case series. The case series are limited by small numbers, heterogeneous patient populations, and different types of tumors. No randomized trials have been reported that compare results using IMRT with other CRT modalities, nor do any of the reported case series using IMRT include concurrently treated control groups.

In general, the limited evidence suggests that IMRT provides tumor control and survival outcomes comparable with existing radiotherapy techniques. The evidence from treatment planning studies has shown that the use of IMRT decreases radiation doses delivered to critical CNS structures (e.g., optic chiasm, brainstem) and normal tissue adjacent to the tumor. This potentially lowers the risk of adverse events (acute and late effects of radiation toxicity), although the clinical benefit of reducing the radiation dose to critical structures and surrounding normal tissue using IMRT is theoretical. Determination of whether adverse event rates are reduced with IMRT is further complicated by a lack of high-quality literature defining the adverse effects using 3D-CRT therapy for the CNS, the main comparator with IMRT. The single-arm case series are of limited usefulness in determining the benefits of IMRT over other conformal radiation modalities.

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

77338

77385: Use alternate procedure code (G6015)

77386: Use alternate procedure code (G6015)

G6015 Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session

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

RELATED POLICIES

None

PUBLISHED

Provider Update, February 2016

Provider Update, October 2015

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