White Paper: Stereotactic Body Radiation Therapy (SBRT): When is SBRT Medically Necessary?

For Health Plans, Medical Management Organizations and TPAs

SBRT: An Overview

SBRT, which is also known as stereotactic ablative radiotherapy (SABR), refers to the use of stereotactic radiotherapy (SRT) at any extracranial site. SRT delivers multiple smaller fractionated doses, usually two to five, of radiation, potentially allowing for higher doses. Unlike tumors within the central nervous system, tumors and organs throughout the body can potentially move with breathing and other factors while undergoing SBRT. Therefore, SBRT requires accurate and custom mapping for each individual patient’s anatomy and organ motion in order to optimally target the tumor while sparing the surrounding normal tissue. Some lesions require fiducial marker placement for improved image-guided accuracy.

Targets for SBRT include localized tumors up to 6 to 7 cm, and up to three to five tumors throughout the whole body. Palliative use of SBRT may be considered for patients with lung or liver cancer, or cancer of the spine. In addition, curative use of SBRT has been proven for stage I non-small cell lung cancer (NSCLC).

Clinical Application of SBRT

SBRT is clinically indicated for primary cancer when the patient’s general medical condition justifies aggressive treatment. It is also indicated for metastatic disease when the patient’s general medical condition justifies aggressive local therapy to one or more discrete deposits of cancer within the context of efforts to achieve total clearance or clinically beneficial reduction in the patient’s overall burden of systemic disease. Another requirement for SBRT is that the tumor burden can be completely targeted with acceptable risk to critical normal structures.

Common sites for SBRT are the lungs, spine, and liver. SBRT is also used for prostate cancer and bone metastases, as well as for tumors of any type arising in or near previously irradiated regions (when a high level of precision and accuracy is needed to minimize the risk of injury to surrounding normal tissues), and in cases where a high dose per fraction treatment is indicated.

Potential Complications Associated With SBRT

SBRT is generally associated with fewer side effects than conventional radiation therapy. Side effects vary from person to person, depending on the type of radiation and dosage, and the location of the cancer. Some patients may not experience side effects at all. General side effects of radiation therapy, which are usually temporary, include fatigue, skin changes, hair loss, and loss of appetite, as well as specific side effects associated with the area of the body being treated. Long-term side effects, which occur months or years following treatment and are often permanent, can include infertility, joint changes, lymphedema, and secondary cancer.

Potential complications of chest SBRT include decrease in pulmonary reserve and radiation pneumonitis, skin toxicities, collapse of airway, rib fracture/chest wall pain, and brachial plexopathy. Radiation myelopathy and radiculopathy, vertebral fracture, and pain flare are complications commonly seen with spinal SBRT, and radiation-induced liver disease and other liver toxicities and gastric duodenal injury are associated with abdominal SBRT.
Guidelines for the Use of SBRT

Lung Cancer
The National Comprehensive Cancer Network (NCCN) guidelines on NSCLC include the use of SBRT, stating that the use of more advanced technologies (for example, SABR) is appropriate when needed to deliver adequate tumor doses while respecting normal tissue dose constraints. SABR is also recommended for early-stage NSCLC patients who are medically inoperable, older patients, or those who refuse surgery, and it can also be used for patients with limited lung metastasis and for palliative therapy.

Recommendations developed by the American Society for Therapeutic Radiology and Oncology (ASTRO) state that SBRT is an accepted treatment option for stage I-II NSCLC in the medically inoperable setting. In the operable setting, more study and longer follow-up are necessary to ensure that results are equivalent to those of surgery.

Hepatobiliary Cancers
According to the NCCN guidelines on hepatobiliary cancers, all hepatocellular carcinoma tumors (regardless of location) may be amenable to SBRT or external beam conformal radiation. SBRT is often used for one to three tumors with a cumulative diameter under 6 cm. The guidelines also suggest that SBRT can be considered for larger lesions if there is at least 800 cm³ of uninvolved liver, and liver radiation tolerance can be respected.

Palliative Radiotherapy for Bone Metastases
For palliative radiotherapy for bone metastases, the ASTRO evidence-based guideline states that SBRT is a technology that delivers high doses to metastatic spine disease with a steep dose gradient that may allow superior sparing of the adjacent neural structures, including the spinal cord and cauda equina. Given that the complexities of dosing and target delineation for SBRT have yet to be fully defined, ASTRO strongly suggests that these patients be treated only on available clinical trials. In addition, SBRT should not be the primary treatment of vertebral bone lesions causing spinal cord compression.

Prostate Cancer
With regard to the use of SBRT for prostate cancer, the NCCN states that further investigation of its long-term effects and toxicity is warranted. ASTRO guidelines note that preliminary results, primarily available only in abstract form and consisting of reports of clinical experiences from single institutions, show that SBRT for the prostate is technically feasible, with little reported acute morbidity. ASTRO also notes that very early results, of limited statistical power, suggest that treatment will induce an initial prostate-specific antigen response of a magnitude equivalent to that seen with conventionally fractionated radiotherapy.

Determining Medical Necessity of SBRT
The complexity and accuracy of radiation therapy have increased significantly due to rapid advances in radiation oncology. This has resulted in specialization in the types of technology used for different cancer sites, complicating the process of establishing evidence-based criteria for practice guidelines and reimbursement for new procedures. Clinicians may try to justify using a new technology by citing studies that are too small and lack statistical power. Education on clinical guidelines and new technologies and applications may play a key role in curbing overutilization.
Many health plans cover SBRT when very specific conditions are met. For example, SBRT may be considered medically necessary when used in the treatment of the following:

- Primary or recurrent tumors within the spine, OR metastases to the spine from other primary sites, that are BOTH:
  - Not amenable to surgery; and.
  - Not amenable to conventional radiation therapy.
- Early-stage (T1 or T2) NSCLC in an individual who is not a surgical candidate or refuses surgery.
- Symptomatic pulmonary metastasis in an individual with good performance status and controlled systemic disease.
- Low- to intermediate-risk, localized prostate cancer.

SBRT is often considered experimental, investigational, or unproven for: behavioral health disorders, breast cancer, epilepsy, glioma, and pancreatic cancer. In addition, SBRT is not considered medically necessary when treatment is unlikely to result in clinical cancer control and/or functional improvement and when the tumor burden cannot be completely targeted with acceptable risk to critical normal structures.

An independent medical review, which is normally used by healthcare payers, looks at whether or not a specific procedure is medically necessary, in an unbiased, timely manner. It allows ready access to a range of board-certified specialists, which healthcare plans may lack internally, and facilitates effective treatment of patients through the use of specialists who keep up-to-date with the latest medical research literature and standard of care. This is especially important in oncology, which utilizes continually evolving technology.

Board-certified oncologists understand the emerging data on the radiation treatment planning process, remain current on available technologies as they are studied more extensively and potentially accepted into clinical guidelines, and make proactive decisions based on the true needs of the patient. Independent medical review also avoids conflicts of interest, which can relate to economics, lack of specialists to review cases, or having the same doctor who denied a case review an appeal.

**Conclusion**

Advances in imaging techniques and computer software have led to significant improvements in the accuracy of radiation therapy, allowing more accurate targeting of tumors. These advances have improved outcomes and quality of life for patients with cancer, but they have also led to the overutilization of new technologies.

Ongoing innovations in radiation therapy present the challenge for healthcare policy-makers and providers to develop the most effective, efficient, and safe treatments for patients, as well as to integrate these innovations into routine practice, guidelines, and coverage. Keeping up-to-date on clinical guidelines and new technologies and applications may play a key role in reducing overutilization.
Bibliography


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