# MEDICAL POLICY

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| MEDICAL POLICY DETAILS | |
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| **Product Disclaimer** | *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.*<br>*If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.*<br>*If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.*<br>*If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.*<br>*If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.* |

## POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, *stereotactic radiosurgery* (SRS) has been medically proven to be effective and, therefore, is considered **medically appropriate** for the following indications:

A. **Benign conditions:**
1. Arteriovenous malformations;
2. Acoustic neuromas;
3. Pituitary adenomas;
4. Nonresectable, residual, or recurrent meningiomas;
5. Craniopharyngiomas;
6. Glomus tumors;
7. Hemangioblastoma;
8. Pineocytoma;
9. Schwannoma;
10. Cavernous malformations.

B. **Brain:**
1. Primary tumors of the brain that have been previously irradiated.
2. Reirradiation of recurrent inoperable malignant gliomas in individuals with an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2.
3. Intact brain metastases with no history of surgical intervention under the following conditions:
   a. All lesions can be encompassed in a single treatment plan; and
   b. The patient has a ECOG performance status of 0-2; and
   c. Systemic disease is limited and under control or good options for systemic treatment are available; and
   d. There is no leptomeningeal disease; or the primary histology is not germ cell, small cell, or lymphoma; and

e. The total volume of treated lesions should be considered safe to deliver SRS in alignment with current guidelines from the American Society for Therapeutic Radiation Oncology (ASTRO); and
f. The total number of treated brain metastases is less than or equal to four; and
   i. Diameter for each lesion is less than four cm; or
   ii. Diameter for each lesion is between four cm and less than or equal to six cm when:
      a) Individual is not a candidate for surgery; and
      b) There is no presence of a mass effect; and
      c) Documentation is provided demonstrating neurosurgery input;

   **OR**
g. The total number of treated brain metastases is greater than or equal to five and less than or equal to ten when:
   i. Individual is not a candidate for surgery; and
   ii. There is no presence of a mass effect; and
   iii. Documentation is provided demonstrating neurosurgery input.

4. Prior treatment with whole brain irradiation (WBRT):
   a. Total number of brain metastases is less than or equal to four; and
   b. The patient has a ECOG performance status of 0-2; and
   c. Systemic disease is under control; and
   d. The patient's life expectancy is greater than three months.
5. Prior treatment with SRS:
   a. Total number of brain metastases is less than or equal to four; and
   b. The patient has a ECOG performance status of 0-2; and
   c. The patient's systemic disease is under control; and
   d. New lesions are present (no lesion is greater than four cm; and
   e. The patient has not been treated with more than two episodes of radiosurgery in the past nine months.
6. Recurrent brain lesions and no prior treatment with WBRT:
   a. Recurrence involves one to four lesions; and
   b. More than six months have elapsed since RT; and
   c. The patient has a ECOG performance status of 0-2; and
   d. Systemic disease is under control.
7. Post-operative SRS after surgical debulking:
   a. The patient has a combination of up to four resected and unresected lesions, each of which, individually, is less than four cm in size.

C. **For indications that are refractory to medical management and/or invasive neurosurgical treatment**:
   1. Trigeminal neuralgia;
   2. Movement disorders (e.g., epilepsy, Parkinson's disease, essential tremor, or familial tremor classifications with major systemic disease).

II. Based upon our criteria and assessment of the peer-reviewed literature, *stereotactic body radiation therapy* (SBRT) has been medically proven to be effective and, therefore, is considered **medically appropriate** for the following indications:

A. **Nasopharyngeal Carcinoma:**
   1. Recurrent or residual carcinoma at primary site; and
   2. when radiation therapy treatments such as three-dimensional conformal or Intensity-modulated radiation therapy (IMRT) cannot be utilized;

B. **Spinal or Vertebral Body Tumors:**
   1. Site has been previously irradiated; or
   2. Presence of compression or intractable pain; or
   3. Tumor is radioresistant (e.g., sarcoma, melanoma, hepatocellular carcinoma, or renal cell carcinoma); and
      a. Tumor ablation is a goal of treatment; and
      b. Life expectancy is greater than or equal to 3 months.

C. **Non-Small Cell Lung Cancer (NSCLC):**
   1. Tumor is stage I or stage II; and
   2. Inoperable.

D. **Pancreatic Cancer:**
   1. Locally advanced disease in individuals who have an ECOG status of 0-1; and
      a. are not candidates for induction chemotherapy or combination systemic treatment and are without systemic metastases; or
      b. with disease progression where chemoradiation was not previously given and primary site is the sole site of progression; or
      c. presents with poorly controlled pain or local invasion with bleeding; or
   2. Preoperative (neoadjuvant) treatment of borderline resectable cases; and
      a. following chemotherapy and restaging; and
      b. no evidence of tumor progression; or
      c. For neoadjuvant treatment, *refer to Policy Statement IV.H.*

SBRT should not be used if direct invasion of the bowel or stomach is observed on imaging.

E. **Primary Liver Cancer (Hepatocellular Carcinoma [HCC]):**
   1. in the definitive setting; and
   2. concurrent treatment of one (1) or more tumors, and
   3. there is evidence of the ability to protect an adequate volume of uninvolved liver.

F. **Intrahepatic Bile Duct Cancer (Cholangiocarcinoma):**
   1. unresectable; and
   2. localized; and
   3. for definitive treatment; or
   4. for extrahepatic bile duct cancer, *refer to Policy Statement IV.D.*

G. **Prostate cancer:**
   1. disease is clinically localized; and
   2. when used as definitive treatment; and
   3. when not treating pelvic lymph nodes.

The use of a biodegradable perirectal spacer (e.g., SpaceOar system) is considered **medically appropriate** for the treatment of prostate cancer when disease is clinically localized.

H. **Soft tissue sarcoma:**
   1. recurrent; and
   2. is within a previously irradiated area.

I. **Head and neck cancer:**
   1. for retreatment of individuals who have no evidence of metastatic disease.

J. **Cervical cancer**:
   1. when there is a history of previous radiation to the same or abutting region; and
   2. an inability to deliver therapeutic doses of radiation with other techniques.

K. **Small Cell Lung Cancer:**
   1. Limited Stage I; or
   2. node-negative stage IIA.

III. Based upon our criteria and assessment of the peer-reviewed literature, *stereotactic body radiation therapy* (SBRT) has been medically proven to be effective and, therefore, is considered **medically appropriate** for extracranial oligometastatic disease for:

A. **Synchronous disease when:**
   1. Less than six (6) months interval between oligometastatic disease and primary cancer diagnosis; and
   2. Any of the following neoplasms presenting with one (1) to five (5) metastases when local control of the primary tumor is expected, and treatment of the metastases may result in an increased disease-free interval and possible survival:

a. For an individual with non-small cell lung cancer who has had or will undergo curative treatment of the primary tumor (based on T and N stage)
b. For an individual with colorectal cancer who:
   i. has had or will undergo curative treatment of the primary tumor; and
   ii. whose metastases are in the lung or liver; and
   iii. for whom surgical resection is not possible.

B. **Metachronous/metachronous oligorecurrent disease when:**
1. Greater than or equal to six (6) months have elapsed between oligometastastic disease and the primary cancer diagnosis); and
2. Clinical presentation of one to five (5) metastases to the adrenal gland, lung, liver, or bone when the following criteria are met:
   a. the histology is non-small cell lung, colorectal, prostate, breast, sarcoma, renal cell or melanoma; and
   b. there is no prior evidence of metastatic disease (cranial or extracranial); and
   c. the primary tumor received curative local and/or systemic therapy and is controlled; and
   d. there has been a systemic therapy-free interval of time prior to the diagnosis of metachronous disease; and
   e. all metastatic lesions present on imaging will be treated concurrently in a single episode.

IV. Based upon our criteria and assessment of the peer-reviewed literature, SBRT does not improve patient outcomes and therefore, is considered **not medically necessary** for **ALL** of the following indications:
A. Metachronous Oligoprogressive Disease (greater than six [6] months have elapsed since primary diagnosis and individual is under treatment with active systemic therapy when new oligometastatic disease is detected); or
B. Extracranial Repeat Oligometastatic Disease (history of oligometastic disease, local and systemic treatment has failed, disease has not progressed to polymetastatic), including repeat oligoprogression and repeat oligopersistent disease; or
C. Extracranial Induced Oligometastatic Disease (history of polymetastatic disease, has been treated with partially effective systemic treatment) including induced oligorecurrence, induced oligoprogression and induced oligopersistent disease; or
D. Extrahepatic bile duct cancer (cholangiocarcinoma); or
E. Gallbladder cancer; or
F. Chronic pain; or
G. The adjuvant (post-operative) curative treatment of primary adrenocortical carcinoma; or
H. Planned neoadjuvant treatment of pancreatic cancer when:
   1. the primary tumor is otherwise fully resectable; or
   2. the postoperative setting; or
   3. the palliative setting.

V. Based upon our criteria and assessment of the peer-reviewed literature, SBRT has not been medically proven to be effective and, therefore, is considered **investigational** for ALL of the following indications:
A. as an alternative to brachytherapy for the treatment of cervical cancer; or
B. to induce abscopal effects; or
C. as a boost for prostate cancer.

*Refer to Corporate Medical Policy #6.01.11 Proton Beam Radiation*

*Refer to Corporate Medical Policy #6.01.24 Intensity Modulated Radiation Therapy (IMRT)*

*Refer to Corporate Medical Policy #7.01.23 Deep Brain Stimulation*

*Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services*

## POLICY GUIDELINE

SBRT, as a complete course of therapy, must be completed in five fractions or less within a single episode of care.

## DESCRIPTION

Stereotactic Radiosurgery (SRS)

SRS or fractionated radiosurgery is a method of delivering high doses of ionizing radiation to small intracranial targets. This technique differs from conventional radiotherapy, which involves exposing large areas of tissue to relatively broad fields of radiation over a number of sessions. SRS entails delivering highly focused convergent beams in a single session so that only the desired target is radiated, sparing adjacent structures.

Stereotactic Body Radiation therapy (SBRT)

SBRT is often referred to as stereotactic ablative radiotherapy (or SABR) in the literature. As stated in the guideline developed by the American College of Radiology (ACR) and the American Society for Therapeutic Radiation Oncology (ASTRO) (2019), stereotactic body radiation therapy (SBRT) is an external beam radiation therapy method used to deliver, very precisely, a high dose of radiation to an extracranial target within the body, in five fractions or less. Specialized treatment planning results in high target dose and steep dose gradients beyond the target. The ability to deliver a single or a few fractions of high-dose ionizing radiation with high targeting accuracy and rapid dose falloff gradients encompassing tumors within a patient provides the basis for the development of SBRT. SBRT can be applied using noninvasive or minimally invasive stereotactic localization and radiation delivery techniques. It requires significantly improved delivery precision over that required for conventional radiotherapy. Specialized imaging techniques may be required, either to limit or to compensate for target movement during treatment planning and delivery

Perirectal Hydrogel Spacer Use

SpaceOAR (Spacing Organs At Risk (OAR)) (Augmenix, Inc, Waltham, MA), is one example of a polyethylene glycol-based hydrogel spacer. It received FDA approval in 2015. The spacer is injected into the perirectal space, temporarily positioning the rectum further away from the radiation field reducing the dose of radiation outside of the designated treatment area and proposes to improve patient's quality of life by reducing potential toxicities. The hydrogel remains in place for three months after which, it is then absorbed, and excreted through the patient's urine.

ECOG Performance Status

| Performance Status | Description |
|---|---|
| 0 | Fully active; no performance restrictions |
| 1 | Strenuous physical activity restricted; fully ambulatory and able to carry out light work |
| 2 | Capable of all self-care but unable to carry out any work activities Up and about > 50% of waking hours. |
| 3 | Capable of only limited self-care; confined to bed or chair >50% of waking hours |
| 4 | Completely disabled; cannot carry out any self-care; totally confined to bed or chair |

## RATIONALE

Radiosurgery has been known to improve health outcomes by providing local tumor control and increasing survival rates but can be associated with complications such as radionecrosis or central nervous system toxicity.

SRS for Benign Conditions

Literature regarding SRS as first-line treatment of meningioma consists of prospective and retrospective case series, which conclude that SRS provides high rates of tumor growth control or regression in patients with benign meningiomas with low-risk, and in patients with cavernous sinus meningioma.

SRS performed on inoperable arteriovenous malformations (AVM's) with diameters less than 4 cm have been found to have obliteration rates up to 94%.

SRS for the treatment of acoustic neuroma increases the preservation of facial nerve function and decreases hearing loss associated with alternative treatments. A single-institution study reported outcomes of single fractions versus fractionated LINAC-based SRS in 129 patients with acoustic neuromas. With an average follow-up of 33 months, there was no difference in outcome in terms of local tumor control, facial nerve preservation, and hearing preservation.

SRS of the Brain and Spine

Guidelines from ASTRO released in 2022 provided strong recommendations for safe treatment of brain metastases using SRS, including the number and size of lesions. The consensus is that up to four intact brain metastases can be safely treated in patients with reasonable performance status. The guidelines state that optimal treatment for patients with five or more metastases remains controversial due to the lack of published prospectively randomized data, and therefore, conditionally recommends SRS to patients with five to ten intact brain metastases who have a ECOG performance status of two or better. Treatment of lesions that measure less than 2 cm in diameter comes with a strong recommendation for SRS. Lesions that are >2 cm and ≤ 3 cm have a conditional recommendation for single-fraction SRS, patients with lesions ≥ 3 cm to ≤4 cm are conditionally recommended for multi-fraction SRS. The task force identifies that for tumors exerting mass effect and/or are ≥4 cm in size, that multidisciplinary discussion with neurosurgery to consider surgical resection is suggested, and that due to limited evidence, SRS for tumor size greater than 6 cm is discouraged.

NCCN guidelines (v1.2023) for principles of central nervous system cancers includes guidelines addressing the treatment of both extensive and limited brain metastases and that multiple phase III randomized trials comparing SRS alone to SRS plus whole brain radiation therapy have demonstrated similar overall survival and even superior cognitive preservation and quality of life with SRS alone versus SRS with WBRT.

In reference to treatment of the spine, the NCCN guidelines also state that "SRS or SBRT for spinal cases may be preferred for patients with life expectancy ≥3 months where tumor ablation is a goal of treatment, in tumors considered radioresistant (e.g., renal cell, melanoma, sarcoma, hepatocellular, some colorectal and non-small cell lung cancer, and in select patients for optimal pain relief", and that "stereotactic radiation approaches may also be preferred in the setting of tumor recurrence after prior radiation as a strategy to limit radiation dose to the spinal cord or other critical structures. Careful adherence to consensus guidelines for radiosurgery planning and delivery is recommended."

Trigeminal Neuralgia

SRS for trigeminal neuralgia refractory to medical management has similar outcomes compared to alternative treatments (e.g., microvascular decompression), is the least invasive non-pharmacologic treatment, and is associated with less complications (facial paresis, pain recurrence) than alternative treatments.

Refractory Movement Disorders

Gamma knife radiosurgery is a form of SRS. Small case series examined the role of gamma knife radiosurgery in the treatment of refractory movement disorders, although radiofrequency ablation or deep brain stimulation would be considered the gold standard therapies for this indication. The ordering provider must certify that the usual and customary treatments outlined above would not be successful in managing the member's condition.

SBRT

Literature has increased regarding stereotactic radiosurgery/radiotherapy of other extracranial sites. Numerous studies address SBRT of the lung and liver (for both primary and metastatic lesions), renal cell carcinoma (for both primary and metastatic lesions), pancreas, and adrenal glands. These studies are generally of small sample size but show that the control rate is similar to the control rate for brain metastases (over 90%).

Tchelebi et al. (2016) conducted a systematic review and meta-analysis comparing rates of overall survival and toxicity in SBRT and conventionally fractionated radiation therapy with concurrent chemotherapy. The analysis represented 1147 patients with N0-1 M0 locally advanced pancreatic cancer. The authors compared one- and two-year overall survival and acute and late grade 3/4 toxicity using three different methods of assessment, including rates, random effects estimates

and a sensitivity analysis which excluded three SBRT studies that had utilized unusually high doses of radiation that would not be considered in current practice. Overall, the analysis demonstrated improved overall survival and reduced acute and late grade 3/4 toxicities with SBRT versus chemoradiation utilizing all three methods of analysis. Authors concluded that SBRT may offer modest improvements in overall survival compared with conventional fractionation and concurrent chemotherapy.

SBRT of Pancreatic Adenocarcinoma

Surgical resection is currently the only known treatment with a potential for curing pancreatic adenocarcinoma, with a majority of patients presenting with surgically unresectable disease. The median overall survival for patients with locally advanced disease is only 12 months. The resectability of a pancreatic tumor typically depends on its position within the pancreas, and its location relative to the surrounding blood vessels. The role of radiation therapy in this patient population is evolving. SBRT may allow for a shorter time frame from the start of radiation therapy to the time of resection.

NCCN guidelines (2.2023) for principles of radiation therapy for pancreatic adenocarcinoma state that "If disease progression occurs in patients with locally advanced disease, chemoradiation or SBRT are treatment options if all of the following are true: good performance status is maintained, chemoradiation or SBRT were not previously given, and the primary site is the sole site of progression."

SBRT for Polymetastatic Disease/Oligometastic Disease

Polymetastatic disease typically refers to wide-spread dissemination of metastatic cancer, while oligometastic disease has been described as an intermediate state between limited and systemically metastasized disease and is often synonymous with few (less than five) metastases. Historically, there is not a standard definition in the literature for either, nor is there a clear boundary of where each occurs on the spectrum of disease, which is often not linear and is dependent on an individual's response to therapy. Oligometastatic disease is currently diagnosed via imaging and clinical judgement. An anticipation exists among the literature for the identification of biomarkers that would be able to identify precisely when each oligometastatic stage begins and ends, to guide in treatment planning.

In 2020, The European Society for Radiotherapy and Oncology (ESRO) and the European Organisation for Research and Treatment of Cancer (EORTC) developed a consensus recommendation to characterize and classify oligometastatic disease (Guckenberg, et al., 2020). The document makes several references to initial descriptions of oligometastic disease as defined in 1995 by Hellman and Weischselbaum. Within the consensus recommendation, ESRO/EORTC classify oligometastatic disease as an umbrella term for nine distinct states which are summarized as follows:

I. Oligometastatic Disease- an intermediate state between localized and systemically metastasized disease.
    A. De-novo oligometastatic disease- individual does not have a history of oligometastatic disease
        1. Synchronous oligometastatic disease- there is no history of oligometastatic disease and less than six (6) months have elapsed between the primary cancer diagnosis and oligometastatic disease.
        2. Metachronous oligometastatic disease- individual does not have a history of oligometastatic disease and more than six (6) months have elapsed between the time of primary diagnosis and oligometastatic disease
            a. Metachronous oligorecurrence- the primary cancer was diagnosed and treated, there has been a systemic therapy-free interval of time, and now there is a small number of new oligometastases (occurring greater than six (6) months after the primary diagnosis) detected.
            b. Metachronous oligoprogression- the primary cancer was diagnosed and treated, the individual is currently under treatment with active systemic therapy, and now there is a small number of new oligometastases (occurring greater than six (6) months after the primary diagnosis).
    B. Repeat oligometastatic disease- individual has a previous diagnosis of oligometastatic disease that has not progressed to polymetastatic, after failure of local and/or systemic treatment, and has new oligometastases.
        1. Repeat oligorecurrence- individual has a previous diagnosis of oligometastases, has received local and/or systemic treatment, there has been a systemic therapy-free interval of time, and now there are a few new and growing or regrowing oligometastes.

2. Repeat oligoprogression- individual has a previous diagnosis of oligometastases, the individual is currently under treatment with active systemic therapy, and now there is a small number of new oligometastases.
3. Repeat oligopersistence- individual has a previous diagnosis of oligometastases after receiving local and/or systemic treatment, the individual is currently under treatment with active systemic therapy and is diagnosed with persistent non-progressive oligometastases.

C. Induced oligometastatic disease- individual has a history of polymetastatic disease, systemic therapy has failed to destroy remaining metastases, and has new oligometastases.

1. Induced oligorecurrence- individual has a diagnosis of polymetastatic disease, had systemic and/or local treatment, there has been a systemic therapy-free interval of time, now there are new and growing or regrowing oligometastases.
2. Induced oligoprogression- individual has a diagnosis of polymetastatic disease, has had systemic and/or local treatment, is currently receiving active systemic therapy and is now diagnosed with new and growing or regrowing oligometastases.
3. Induced oligopersistence- individual has a diagnosis of polymetastatic disease, has had systemic and/or local treatment, is currently receiving active systemic therapy and is diagnosed with persistent non-progressive oligometastases.

Lievens et al. (2020) summarized a European Society for Radiotherapy and Oncology (ESTRO)-ASTRO consensus document aimed to define oligometastatic disease from a radiation oncology perspective. The authors acknowledged that several definitions exist in literature for the different states of oligometastatic disease, including the use of the term "induced." The treatment goal for these individuals is improved quality of life or local control, rather than overall survival. Oligoprogression that is identified during active systemic therapy is believed to have worse prognosis compared to disease that is considered de novo. Additionally, the authors address the number of oligometastases that can be safely treated with radiotherapy, when the intent is curative in nature. The most commonly used quantifications in the literature available are up to three (3), or five (5) oligometastatic lesions. Little data includes the treatment of more than five (5) lesions, and therefore, the authors agreed that this should be the upper limit for consideration until further research is available and emphasize the need to consider balancing efficacy with toxicity, which is to be considered dependent on disease location.

ESRO/EORTC (Guckenberger, et al., 2020) address the goals of treatment for individuals with oligometastatic disease. Historically, individuals with induced oligometastatic disease, were not treated radically with curative intent. Recent trials and interest in the oligometastatic state have changed the focus to prolong the time to systemic therapy, enhance sensitivity to the current systemic therapy or potentiate a deeper response. Given the lack of scientific evidence, the value for the use of SBRT in the state of induced oligometastases, is unknown. Additionally to date, there is no data available regarding the frequency or the outcomes of individuals with repeat oligometastatic disease. Future studies are warranted to determine if the use of SBRT improves the net health outcome in these stages of oligometastatic disease.

ESTRO/ASTRO endorse the classification system presented by ESRO/EORTC and are jointly participating in a observational cohort study (NCT03818503) estimated to be completed in 2024 known as OligoCare. The primary outcome measure is the number of patients treated with radiotherapy enrolled in the program. Secondary outcome measures include disease-free survival, local-regional control, distant metastasis free survival, overall survival, and the incidence of adverse events related to treatment. The study has a target follow-up duration of five years.

SBRT to Induce Abscopal Effects

Abscopal effects are reported to be rare immune-response phenomenon in which treatment of one tumor with radiation therapy typically combined with immunotherapy, may cause the regression of other, untreated tumors. Abscopal responses have been documented in case series of patients with melanoma, breast, lung, and liver cancers however, the mechanism of which to induce this reported effect is not clearly understood, nor is the type of patient who is more likely to respond. The evidence is not sufficient to determine that utilizing SBRT to induce an abscopal effect, results in a meaningful improvement in the net health outcome.

SBRT for Prostate Cancer

Literature is active with respect to the use of SBRT for treatment of prostate cancer and the NCCN guidelines v4.2023 consider it an acceptable regimen for patients with very low and low, favorable or unfavorable intermediate, or high and very high risk in the following individuals: those with limited metastatic disease to the vertebra or paravertebral region when ablation is the goal, in patients with oligometastatic progression where progression-free survival is the goal, and in symptomatic patients where the lesion occurs in or immediately adjacent to a previously irradiated field. Studies are small but improvements in quality of life and mild (grade I-II) toxicities have been reported. SBRT using a hypofractionation regimen for treatment of prostate cancer has been suggested as a more cost-effective alternative to IMRT because the treatment time is shorter, it utilizes resources more effectively, and the regimen is more convenient to the patient with less time away from work, and savings in transportation and housing if the treatment center is located away from the patient's home.

Hypofractionation, however, has been shown to increase the risk of acute moderate gastrointestinal (GI) toxicity when compared to conventional fractionation. The ASTRO Guideline on Radiation Therapy for Pancreatic Cancer (2019) states that the radiation oncologist, in collaboration with the qualified medical physicist, will determine the need to utilize devices to stabilize or pull away organs at risk from inadvertently moving into the field of treatment, and includes spacers as an example.

For individuals who have prostate cancer and are undergoing radiation therapy who receive a hydrogel spacer, the evidence includes a pivotal RCT with a 3-year follow up, observational studies, and systematic reviews. Mariados and colleagues (2015) conducted a manufacturer sponsored, prospective, multi-center, single-blind study, evaluating the percent of the rectal volume receiving 70 Gy in dose planning studies of 222 men randomized 2:1 to either a spacer or control group. All men received IMRT (79.2 Gy in 1.8-Gy fractions) to the prostate. Those with spacer use experienced a lower percentage of rectal volume receiving 70 Gy (3.3% versus 11.7%). They evaluated the effectiveness of the SpaceOAR system in reducing adverse gastrointestinal events with IMRT. and demonstrated a significant reduction in mean rectal V70 with the device in place. There were no reports of device-related adverse events, rectal perforations, serious bleeding, or infections, and acute rectal adverse events were similar between the two groups, however there was significantly less pain experience reported by the treatment group. A reduction in late rectal toxicity (three to 15 months after RT) has been observed, and no patients treated with the spacer experienced greater than grade 1 toxicity. The 3-year follow up study (Hamstra et al. 2017) involved 63% of the original participants (94 SpaceOAR subjects and 46 control group) and demonstrated a reduction of Grade ≥ 1 adverse events in the treatment group (2% versus 9%, $p<.03$).

NCCN guidelines v4.2023 for principles of radiation therapy for prostate cancer state that biocompatible and biodegradable perirectal spacer materials may be implanted between the prostate and rectum in patients undergoing external radiotherapy with organ-confined prostate cancer in order to displace the rectum from high radiation dose regions. A randomized phase III trial demonstrated reduced rectal bleeding in patients undergoing the procedure, compared to controls. The guidelines state, "Overall, the panel believes that biocompatible and biodegradable perirectal spacer materials may be implanted between the prostate and rectum in patients undergoing external radiotherapy with organ-confined prostate cancer in order to displace the rectum from high radiation dose regions." Patients with obvious rectal invasion or visible T3 or posterior extension should not undergo perirectal spacer implantation.

Phase 2 trials have investigated the benefits of SBRT in the treatment oligometastatic disease. The STOMP trial (Ost et al., 2018) evaluated the time to start of androgen deprivation therapy (ADT) after metastasis directed therapy (MDT) using SBRT or surgery versus surveillance in 62 patients. Eligibility criteria included oligorecurrent prostate cancer (PCa); biochemical recurrence after primary PCa treatment with curative intent, three or fewer metastases visible on choline PET-CT; serum testosterone levels >50ng/nL; a treated and controlled primary tumor; and WHO performance status 0-1. A total of 31 patients were randomly assigned to each group. The primary outcome was ADT-free survival, defined as time between random assignment and the start of palliative ADT or death (as a result of any cause). Secondary outcomes included quality of life measurement and PSA progression, defined as an increase of ≥25% and ≥ 2 ng/mL if PSA was ≥2 ng/mL from baseline, or a PSA increase of≥25% if PSA was < 2 ng/mL at random assignment. The median follow-up time was three years. SBRT (n=25) was the more common MDT, surgery occurred in six patients. In the MDT group, 11 patients were treated with a repeated course of MDT because of oligometastatic progression. The median ADT-

free survival for the surveillance group was 13 months (80%CI 12-17 months) compared to 21 months for the intervention group. PSA decline occurred in 74% of patients treated with MDT, while 42% had PSA decline in the surveillance group. The median time for PSA progression for the intention to treat analysis was six months for the surveillance group and 4 months for the MDT group. The quality of life measurement between the groups were similar and there were no toxicities of grade 2 to 5 observed. A group of patients received a temporary course of adjuvant ADT at the time of SBRT (n=50%) and the type of ADT provided was left to the discretion of the provider. With no comparator arm, the authors concluded that although ADT-free survival seemed longer with MDT than surveillance alone for oligorecurrent PCa, it should be explored further in phase III trials.

Palma and colleagues (2019) investigated the effect of SBRT on the survival, outcomes, toxicity, and quality of life experienced in patients with a controlled primary tumor and one to five oligometastatic lesions. The SABR-COMET trial was a phase II randomized open-label trial. A total of 99 patients with differing primary tumor histologies were allocated to two treatment arms, palliative standard of care alone (control) or palliative standard of care with SABR. The primary endpoint for the study was overall survival. The median follow-up was 25 months for the control arm and 26 months for the SABR arm. The median overall survival for the control arm was 28 months (95%CI 19-33) versus 41 months for the SABR arm (26-not reached) (HR 0.57, 95% CI 0.30-1.10); stratified log rank p=0.090). Palma published five-year results to the SABR-COMET study in 2020, identifying the most common primary tumor types being breast (n=18), colorectal (n=18), lung (n=18), and prostate (n=16). Median follow up was 51 months. The overall survival rate was 17.7% in the control arm (95% CI, 6% to 34%) versus 42.3% in the SABR arm (95% CI, 28% to 56%; stratified log-rank P= .006). The five-year progression free survival rate was 17.3% in the SABR arm, but not reached in the control group. The death as a result of any-cause rate was 73% for the control arm and 53% in the SABR arm. The Median overall survival was 28 months in the control arm (95% CI, 18-39 months) versus 50 months in the SABR arm (95%CI, 29 to 83 months; stratified log-rank test P=.006; HR, 0.47; 95% CI, 0.27 to 0.81). There were no new adverse events or changes in quality of life noted with the extended follow-up. Although the results of the trial are promising, they cannot be extrapolated onto any particular histology. Further research is warranted.

SBRT for Treatment of Chronic Pain

Due to a lack of clinical trials, there is insufficient evidence to permit conclusions about health outcomes with SBRT for the treatment of chronic pain.

SBRT for Lung Cancer

The NCCN SCLC Panel (2022) recommends SBRT followed by systemic therapy as an option for select patients with clinical stage I to IIA (T1-2 N0) small cell lung cancer who are medically inoperable or decline surgery (category 2A). This decision was based on a study published in 2018 (Shioyama, et al) that retrospectively analyzed 43 patients diagnosed with small-cell lung cancer, treated with SBRT at 11 Japanese institutions. The two-year overall survival was 72.3%, progression-free survival was 44.6%, and distant metastasis free survival rates were 47.2%. Of the patients selected for inclusion, 80% were inoperable. The number of distant metastases was high at 47%, authors noting that only a small number of patients received chemotherapy using standard regimens, but their progression free survival was higher than those treated with SBRT alone (70.0% versus 44.6%). 2-year local control was 80.2% signaling effectiveness in the stage I population.

SBRT for Adrenocortical Carcinoma

The role of radiotherapy in the adjuvant treatment of adrenocortical carcinoma has been controversial. The literature consists of small cohort studies and case series. The evidence is insufficient to determine that treatment with SBRT in this population results in meaningful improvement in the net health outcome. Furthermore, the NCCN guidelines for neuroendocrine and adrenal tumors (v1.2023) do not reference SBRT as a treatment recommendation for this indication.

SBRT for Hepatobiliary Cancers

Surgical resection is the only potentially curative treatment for extrahepatic bile duct (cholangiocarcinoma) and gallbladder cancer. SBRT has not been proven in the peer-reviewed scientific literature to improve the net health outcome in unresectable cases and therefore, it is considered not medically necessary.

## CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

**CPT Codes**

| Code | Description |
|---|---|
| 31626 | Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of fiducial markers, single or multiple |
| 31627 | Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with computer-assisted, image-guided navigation (List separately in addition to code for primary procedure(s)) |
| 32553 | Placement of interstitial device(s) for radiation therapy guidance (e.g., fiducial markers, dosimeter), percutaneous, intra-thoracic, single or multiple |
| 49411 | Placement of interstitial device(s) for radiation therapy guidance (e.g., fiducial markers, dosimeter), percutaneous, intra-abdominal, intra-pelvic (except prostate), and/or retroperitoneum, single or multiple |
| 49412 | Placement of interstitial device(s) for radiation therapy guidance (e.g., fiducial markers, dosimeter), open, intra-abdominal, intrapelvic, and/or retroperitoneum, including image guidance, if performed, single or multiple (List separately in addition to code for primary procedure) |
| 55874 | Transperineal placement of biodegradable material, peri-prostatic, single or multiple injection(s), including image guidance, when performed |
| 61796 | Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); one simple cranial lesion |
| 61797 | Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional cranial lesion, simple (List separately in addition to code for primary procedure) |
| 61798 | Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); one complex cranial lesion |
| 61799 | Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional cranial lesion, complex (List separately in addition to code for primary procedure) |
| 61800 | Application of stereotactic headframe for stereotactic radiosurgery (List separately in addition to code for primary procedure) |
| 63620 | Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); one spinal lesion |
| 63621 | Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional spinal lesion (List separately in addition to code for primary procedure) |

| Code | Description |
|---|---|
| 77371 | Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s), consisting of one session; multi-source Cobalt 60 based |
| 77372 | Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based |
| 77373 | Stereotactic body radiation therapy, treatment delivery, per fraction to one or more lesions, including image guidance, entire course not to exceed five fractions |
| 77432 | Stereotactic radiation treatment management of cranial lesion(s) (complete course of treatment consisting of one session) |
| 77435 | Stereotactic body radiation therapy, treatment management, pretreatment course, to one or more lesions, including image guidance, entire course not to exceed five fractions |



**HCPCS Codes**

| Code | Description |
|---|---|
| G0339 | Image guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session, or first session of fractionated treatment. **Medically appropriate for the diagnosis codes listed below** |
| G0340 | Image guided robotic linear accelerator based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment. **Medically appropriate for the diagnosis codes listed below** |

**ICD10 Codes**

| Code | Description |
|---|---|
| C22.0-C22.9 | Malignant neoplasm of liver and intrahepatic bile ducts (code range) |
| C34.00-C34.92 | Malignant neoplasm of bronchus and lung (code range) |
| C41.0 | Malignant neoplasm of bones of skull and face |
| C41.2 | Malignant neoplasm of vertebral column |
| C61 | Malignant neoplasm of prostate |
| C64.1-C64.9 | Malignant neoplasm of kidney, except renal pelvis (code range) |
| C65.1-C65.9 | Malignant neoplasm of renal pelvis (code range) |
| C70.0-C70.9 | Malignant neoplasm of meninges (code range) |
| C71.0-C71.9 | Malignant neoplasm of brain (code range) |
| C72.0-C72.1 | Malignant neoplasm of spinal cord and cauda equina (code range) |
| C75.1-C75.3 | Malignant neoplasm of other endocrine glands and related structures (code range) |
| C78.7 | Secondary malignant neoplasm of liver and intrahepatic bile duct |
| C79.00-C79.02 | Secondary malignant neoplasm of kidney and renal pelvis (code range) |

| Code | Description |
|---|---|
| C79.31 | Secondary malignant neoplasm of brain |
| D01.5 | Carcinoma in situ of liver, gallbladder and bile ducts |
| D18.02 | Hemangioma of intracranial structures |
| D32.0-D32.9 | Benign neoplasm of meninges (code range) |
| D33.0-D33.4 | Benign neoplasm of brain and other parts of central nervous system (code range) |
| D35.0-D35.4 | Benign neoplasm of other and unspecified endocrine glands (code range) |
| D37.6 | Neoplasm of uncertain behavior of liver, gallbladder and bile ducts |
| D42.0-D42.9 | Neoplasm of uncertain behavior of meninges (code range) |
| D43.0-D43.4 | Neoplasm of uncertain behavior of brain and central nervous system (code range) |
| D44.3-D44.5 | Neoplasm of uncertain behavior of pituitary gland and craniopharyngeal duct and pineal gland (code range) |
| G50.0 | Trigeminal neuralgia |
| Q04.9 | Congenital malformation of brain, unspecified |
| Q06.9 | Congenital malformation of spinal cord, unspecified |
| Q07.9 | Congenital malformation of nervous system, unspecified |
| Q27.9 | Congenital malformation of peripheral vascular system, unspecified |
| Q28.2 | Arteriovenous malformation of cerebral vessels |
| Q28.3 | Other malformations of cerebral vessels |

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*Key Article

## KEY WORDS

CyberKnife, Fractionated stereotactic radiosurgery, Gamma knife, Linac, Linear accelerator, Stereotactic radiotherapy, Space Oar, Perirectal hydrogel spacer, Oligometastases, Oligometastatic, Synchronous disease, Metachronous disease, Oligoprogression, Oligorecurrence, Induced oligometastatic disease.

## CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) (L35076) for Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT). Please refer to the following LCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35076&ver=56&CntrctrSelected=298*1&Cntrctr=298&s=41&DocType=2&bc=AAgAAAQAgAAA& accessed 09/21/23.