Brachytherapy for Oncologic Indications

**Type:**
Medical Necessity and Investigational / Experimental

**Policy Specific Section:**
Radiology (Diagnostic/Therapeutic)

**Original Policy Date:**
January 11, 2008

**Effective Date:**
January 30, 2015

**Definitions of Decision Determinations**

**Medically Necessary:** A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

**Description**
Brachytherapy is a form of internal radiation treatment used to halt the growth of cancer cells and shrink tumors. An implant (e.g., needle, seeds, wire, or a catheter) containing a radioactive source is placed directly into or near the tumor or target tissue. Brachytherapy may be either temporary (radioactive source is withdrawn) or permanent (inactive seeds remain in the body),
and is normally performed in the outpatient setting. However some cases require a short hospital stay. Treatment time may vary, according to the brachytherapy method, type of radioactive material, and cancer site.

**Policy**

**Brain Tumors**

Brain brachytherapy (e.g., intracavitary balloon catheter) is considered *investigational*, alone or as part of a multimodality treatment regimen, for the following indications:

- Primary or recurrent malignant brain tumors
- Metastasis to the brain from primary solid tumors outside the brain

**Breast Cancer**

Breast brachytherapy (e.g., multicatheter interstitial or balloon) may be considered *medically necessary* for any of the following indications:

- As an adjunctive “boost” when combined with whole breast irradiation after prior breast conserving surgery
- As the sole method of breast radiation therapy following breast-conserving surgery when all of the following criteria are met:
  - Age greater than or equal to 50 years
  - Invasive ductal carcinoma or ductal carcinoma in situ (DCIS) or other favorable subtypes (i.e., mucinous, tubular, colloid)
  - Tumor size less than or equal to three centimeters
  - Negative microscopic surgical margins of excision
  - Negative sentinel lymph nodes

**Lung Cancer**

Endobronchial brachytherapy may be considered *medically necessary* for either of the following indications:

- Patients with primary endobronchial tumors who are not otherwise candidates for surgical resection or external beam radiation therapy due to comorbidities or location of the tumor
- Palliative therapy for airway obstruction or severe hemoptysis in patients with primary, metastatic, or recurrent endobronchial tumors

All other applications of endobronchial brachytherapy are considered *investigational* including, but not limited to, the following:

- Use as a radiation “boost” to curative external beam radiation therapy
- Treatment for asymptomatic recurrences of non-small cell lung cancer
- Treatment of hyperplastic granulation tissue
Genitourinary Cancer
Brachytherapy (e.g., interstitial, or intracavitary) may be considered medically necessary for patients with uterine, cervical, vaginal, bladder or endometrial cancers.

Prostate Cancer
Brachytherapy using permanent transperineal implantation of radioactive seeds (e.g., low-dose rate) or temporary seed implantation with high-dose rate brachytherapy may be considered medically necessary as monotherapy or in conjunction with external beam three-dimensional conformal radiation therapy (3D-CRT) for the treatment of localized prostate cancer.

Other Cancer Diagnoses
Brachytherapy is considered not medically necessary for all other cancer diagnoses not discussed in the above indications.

High-Dose Rate Electronic Brachytherapy (See Policy Guidelines for coding)
The use of high-dose rate electronic brachytherapy is considered investigational for all indications, including but not limited to the treatment of breast cancer and endometrial cancer (e.g., Axxent Electronic Brachytherapy system).

Policy Guideline
Palliative treatment is designed to relieve a particular problem without necessarily solving it; for example, palliative therapy is given in order to relieve symptoms and improve quality of life, but does not cure the patient.

The following HCPCS code may be billed for the use of Cesitrex™ (liquid Cesium-131, IsoRay, Inc., Richland, Washington)

- C2644: Brachytherapy source, cesium-131 chloride solution, per millicurie

In December 2013, Cesitrex™ was cleared by the FDA for use with the GliaSite® Radiation Therapy System in treating glioblastomas and metastatic brain cancers.

Effective July 1, 2015, the following CPT codes will replace CPT code 0182T:

- 0394T: High dose rate electronic brachytherapy, skin surface application, per fraction, includes basic dosimetry, when performed
- 0395T: High dose rate electronic brachytherapy, interstitial or intracavitary treatment, per fraction, includes basic dosimetry, when performed

0394T and 0395T are for electronic brachytherapy as opposed to radionuclide brachytherapy which would be reported with the CPT codes for brachytherapy (77750-77799) or superficial radiation treatment which would be reported with 77401.

The following applicators for surface treatment received Food and Drug Administration (FDA) 510(k) clearance:

- Xoft’s Axxent Surface Applicator (San Jose, CA)
- Varian’s Leipzig Applicator (Palo Alto, CA)
- Zeiss’ INTRABEAM flat/surface applicator (Dublin, CA)

**Internal Information**

There is an MD Determination Form for this Medical Policy. It can be found on the following Web page: http://myworkpath.com/healthcareservices/MedicalOperations/PSR_Determination_Pages.htm

<table>
<thead>
<tr>
<th>Documentation Required for Clinical Review</th>
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<tr>
<td>• History and physical</td>
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<tr>
<td>• Oncological radiation consultation notes including: tumor classification, and past medical and/or surgical treatment and response</td>
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<td>• Operative report(s) or procedure report(s)</td>
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<td>• Pathology report(s)</td>
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<td>• Radiation treatment plan including: type of brachytherapy, therapy schedule and number of treatments</td>
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**Post Service**

- Daily radiation treatment records

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.

**APPENDIX to Brachytherapy for Oncologic Indications Policy**

**Prior Authorization Requirements**

This service (or procedure) is considered medically necessary in certain instances and investigational in others (refer to policy for details).
For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

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**Evidence Basis for the Policy**

**Rationale**

Brachytherapy allows the use of higher doses of total radiation to treat smaller areas in shorter amounts of time than is possible with external radiation therapy (RT). Brachytherapy is clinically complex and may involve multiple medical specialists including radiation oncologists, medical physicists, radiation therapists, and dosimetrists. In addition, other specialists may perform related but separate procedures before, during, or after brachytherapy. Brachytherapy applications include intracavitary RT (into the body cavity), interstitial RT (within the body tissues), intravascular RT, or seed implantation.

Brachytherapy may be used alone as the sole treatment or as an adjunctive treatment with external beam radiation therapy (EBRT) or other modalities such as surgery or chemotherapy. Brachytherapy radiation doses may be delivered at a low-dose rate (LDR), high-dose rate (HDR), or a pulsed-dose rate (PDR). Low-dose rate brachytherapy radioactive isotopes may be placed either temporarily or permanently and are manually or remotely loaded into applicators to deliver the prescribed treatment at a continuous rate over several hours or days in a hospital or ambulatory-care setting. High-dose rate brachytherapy radioactive isotopes are temporary and delivered by remote afterloading. Pulsed-dose rate brachytherapy treatment delivery is similar to LDR, but occurs in periodic pulses, usually one per hour rather than continuously.

**Brain Tumors**

Intracavitary balloon catheter brain brachytherapy is localized RT in the brain that requires placement of an inflatable balloon catheter in the surgical cavity, before closing the craniotomy of a resection, to remove or debulk a malignant brain mass. A radiation source is then placed in the balloon to expose surrounding brain tissue to radiation, either continuously or in a series of
brief treatments. After the patient completes therapy, the radiation source is permanently removed and the balloon catheter is surgically explanted.

At present, the GliaSite® radiation therapy system (GliaSite® RTS; Cytyc Corp, Marlborough, MA.) is the only device marketed in the United States (U.S.) for intracavitary balloon catheter brachytherapy in the brain. It includes a catheter tray with a double balloon catheter and accessories used for implantation of an aqueous saline solution of molecularly bound radioactive iodine-125 (Iotrex™) as the radiation source; and, an access tray with items used for afterloading and retrieving the radioactive material. One to three weeks after resection and balloon implantation, the Iotrex™ solution is loaded through a subcutaneous port and left in for three to six days. Prescribed radiation doses are usually 40 to 60 Gray (Gy) measured at 0.5 to 1.0 centimeter (cm) from the balloon surface. This procedure has been performed on an inpatient basis; however, more recently, feasibility of outpatient GliaSite® RTS implantation has been explored (Chino et al., 2008). The GliaSite® RTS received 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA) in 2001, as substantially equivalent to separately marketed ventricular reservoirs and catheters, manual radionuclide applicator systems, and radionuclide sources.

A literature search for studies reporting on intracavitary balloon catheter brain brachytherapy published through February 2010 was conducted. For the treatment of newly diagnosed glioblastoma multiforme (GBM), one prospective (Johannesen et al., 1999) and one retrospective (Welsh et al., 2007) study were identified. Four studies focused on patients treated after surgery for recurrent glioma (Tatter et al., 2003; Chan et al., 2005; Payne et al., 2005; Gabayan et al., 2006). There was one study published on patients treated for newly diagnosed and resected single brain metastasis (Rogers et al., 2006). An additional study on eight patients with glioma or brain metastasis focused on computed tomography (CT) and magnetic resonance imaging (MRI) after balloon placement but did not report patient outcomes (Matheus et al., 2004). The majority of studies concluded comparative evidence and randomized comparative trials were needed. While Johannesen and colleagues (1999) reported hospital stays were shorter and quality of life over the first six months was better than after conventional whole brain RT, they did not report data to support these claims. Welsh and colleagues (2007) concluded additional studies using GliaSite® RTS in conjunction with EBRT following surgery for newly diagnosed GBM would be required to adequately assess safety and efficacy.

Wernicke and colleagues (2010) conducted a single institution, dose escalation study to investigate the safety and feasibility of GliaSite® RTS following surgical resection of localized brain tumors. The balloon was implanted during surgery; then two to three weeks later aqueous solution of iodine-125 was introduced for times ranging from 68 to 120 hours. Median total dose was 52 Gy. Median survival for this cohort was 14 months. There were no reports of Radiation Therapy Oncology Group (RTOG) Grade 3 or 4 toxicities. Similar to the other studies cited, results from this trial suggested the GliaSite® RTS was relatively safe and well-tolerated in patients with localized brain tumors. However, further studies would be required to assess efficacy.

Another study examined the feasibility of outpatient GliaSite® RTS brachytherapy in 37 patients (Chino et al., 2008). Rather than overnight hospitalization, patients were released after the
treatment sessions. Although the study was small and ultimately inconclusive, the outpatient approach did not appear to increase adverse events and seemed to be generally well tolerated.

The National Comprehensive Cancer Network® (NCCN) Clinical Practice Guidelines in Oncology™ for glioblastoma (v.1.2010) stated, “The role of focal radiation techniques in this diffusely infiltrative disease remains undefined.”

To date, no standard medical care is established for primary brain malignancies or brain metastases of solid tumors and, there are no clinical data available to provide convincing evidence that intracavitary balloon brachytherapy extends the duration of survival, time to relapse, quality of life, or progression. Therefore, the use of intracavitary balloon brachytherapy for brain cancer and brain metastases of solid tumors is investigational.

**Breast Cancer**

For the patient with early-stage breast cancer, the gold standard for radiation treatment after breast-conserving surgery (BCS) (lumpectomy, segmentectomy, or quadrantectomy) remains whole breast-radiation therapy (WBRT) (often with a boost) as it reduces recurrences and lengthens survival. Survival after breast-conservation therapy (BCT) is equivalent to survival after mastectomy for patients diagnosed with tumors categorized as stage I or II. Most patients diagnosed with stage I or II breast cancer now are offered a choice of BCT or modified radical mastectomy, but BCT is selected less often than expected. Studies have shown that those living furthest from treatment facilities are least likely to select BCT instead of mastectomy and most likely to forgo RT after BCS (Farrow et al., 1992; Athas et al., 2000).

Recently, partial breast irradiation (PBI) using breast brachytherapy after BCS has been investigated in an attempt to reduce RT treatment time. Accelerated partial breast irradiation (APBI) differs from conventional WBRT in several ways. First, the radiation targets only the segment of the breast surrounding the area where the tumor was removed, rather than the entire breast. This approach was based in part on the finding that recurrences are more likely to occur close to the tumor site rather than elsewhere in the breast. Second, the duration of treatment is four to five days (or one day with intraoperative RT) rather than five to six weeks, because the radiation is delivered in fewer fractions at larger doses per fraction to the tumor bed. Third, the radiation dose is intrinsically less uniform within the target volume when APBI uses brachytherapy (i.e., the implantation of radioactive material directly in the breast tissue). However, APBI may sacrifice some or all of the radiobiological advantages associated with fractionated doses and the slower repair of sublethal radiation damage in tumor versus normal cells.

There are several techniques that deliver breast brachytherapy. Interstitial brachytherapy uses multiple sources (e.g., interstitial catheters) spaced in two or more planes through the breast, with computerized treatment planning to optimize dose homogeneity in the target. The number, spacing, and radiation strength of sources vary with the breast volume to be treated. Balloon brachytherapy uses a single source placed in an inflatable catheter inside the surgical cavity. The cavity is treated plus a surrounding margin of 1 to 2 cm, with radiation dose declining as a function of distance from the source. Differences between interstitial and balloon brachytherapy in geometry and target dose homogeneity are of less concern for boost therapy, since the target
volume is limited to the tumor bed close to the radiation source. External beam radiation separate from the boost adequately treats breast tissue outside the tumor bed.

Brachytherapy devices can be placed during the initial lumpectomy if the decision to use brachytherapy has already been made or at the time of a re-excision if the lumpectomy specimen has positive surgical margins. Intraoperative implantation avoids the need for a separate surgical procedure with anesthesia for brachytherapy. Whether intra- or postoperative, these methods use multiple radioactive sources placed to deliver a prescribed radiation dose to a defined target volume. Both LDR and HDR interstitial techniques have been used, with HDR techniques increasing in popularity.

Brachytherapy devices have been approved through the FDA 510(k) process and are either balloon brachytherapy or hybrid balloon-interstitial brachytherapy devices. The FDA has required a black box warning on each device stating “The safety and effectiveness of the ... [brachytherapy device] as a replacement for whole breast irradiation in the treatment of breast cancer has not been established.” Examples of these devices include SenoRad Multi-Lumen Balloon Source Applicator for Brachytherapy (SenoRx, Irvine, CA) and Savi™ (Cianna, Aliso Viejo, CA). A balloon catheter system (the Mammosite® Radiation Therapy System (Hologic, Marlborough, MA) is also available for brachytherapy. It can be used to deliver local boost or APBI therapy. The Mammosite® delivers 34 Gy doses in 10 fractions over five days.

**Breast Brachytherapy as an Adjunctive Boost**

Breast brachytherapy as an adjunctive “boost” to WBRT is an accepted technique for women who have undergone BCS. External beam radiation treatment may be preceded, or followed by, a supplemental or boost dose administered to the primary tumor site. Perioperatively implanted hollow needles or catheters guide placement of the radioactive material. When used as a boost, radiation is left in place until the dose is delivered. For LDR, the radiation is left for two to three days and for HDR it is a matter of minutes (but may be repeated one or two times a day for one or two days).

The Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessments (1996, 2002) offered the following observations and conclusions regarding brachytherapy as a boost following WBRT:

- While there were no randomized studies comparing brachytherapy to EBRT as a local boost, analysis of seven non-randomized retrospective studies that included 2,022 patients permitted scientific conclusions
- Net health outcomes after brachytherapy for local boost were equivalent to those after EBRT for local boost in women given BCS and WBRT as initial treatment for stage I or stage II breast cancer. Specifically, the rate of local control at five years after treatment was 88% to 98% for those given brachytherapy for local boost compared to 91% to 99% for those given EBRT

The NCCN Guidelines (v.2.2011) for breast cancer recommended WBRT after BCS with or without a radiation boost (by photons, brachytherapy, or electron beam) to the tumor bed to maximize local control, especially in patients age 50 or younger.
Breast Brachytherapy as the Sole Method of Breast Radiation Therapy

The use of APBI with brachytherapy (i.e., multicatheter interstitial or balloon) as the sole method of adjuvant RT for breast cancer after local excision cite is emerging as an alternative to WBRT. Several clinical studies of PBI in conjunction with lumpectomy have demonstrated five-year local recurrence rates that are comparable to WBRT (Vincini et al., 2003; Polgar et al., 2004; Polgar et al., 2007). Additionally, Antonucci et al., (2009) noted the cumulative incidence of ipsilateral breast tumor recurrence rates were comparable to those from WBRT in selected low-risk patients (stages I/II breast cancer including infiltrating ductal carcinomas with diameters < 3.0 cm, negative surgical margins (>= 2 millimeters (mm), age > 40 to 50 years, and negative lymph nodes).

The California Technology Assessment Forum addressed brachytherapy as primary RT following BCS for breast cancer in 2008. The authors concluded the use of breast brachytherapy as primary RT did not meet technology assessment criteria for safety, effectiveness and improvement of health outcomes. Subsequently, a 2010 TEC Assessment regarding accelerated radiotherapy (including APBI using brachytherapy) after BCS for early stage breast cancer was performed. The authors concluded “Overall, the body of evidence on interstitial APBI compared to conventional [whole breast irradiation] WBI is weak, and it is extremely weak (i.e., no comparative studies) for balloon brachytherapy... ”

Phase II studies have suggested local control rates of PBI and WBRT are equivalent. Currently, randomized Phase III trials of APBI with brachytherapy to confirm these results are ongoing (National Cancer Institute Physician Data Query, 2010). One randomized intergroup trial comparing WBRT and APBI is sponsored by the U.S. National Cancer Institute and led by National Surgical Adjuvant Breast and Bowel Project and the Radiation Therapy Oncology Group (NSABP B-39/RTOG-0413). The trial opened in early 2005 and will address the efficacy of new treatment modalities compared with WBI and to each other in addressing local recurrence, disease-free survival, overall survival (OS), quality of life, and cosmesis in several stages of breast cancer. The trial is randomizing 4300 patients to WBRT (total dose = 60 to 66.6 Gy) or APBI (total dose = 34 to 38.5 Gy) after lumpectomy with tumor-free margins verified by histologic examination. Within the APBI group, the participant's physician chose whether to use interstitial brachytherapy, Mammosite® balloon brachytherapy, or EBRT using three-dimensional conformal radiation therapy (3D-CRT). Eligibility includes patients with Stage 0, I, or II breast cancer resected with a lumpectomy. In addition, the tumor must be less than or equal to 3.0 cm, and there must be no more than three positive axillary nodes.

In a review of the APBI trials currently underway, Mannino and Yarnold (2009) raised several concerns regarding variations across the trials. The extent of the initial BCS can vary substantially across studies, as well as the definition of the targeted tumor cavity. A larger margin is usually drawn around the tumor cavity for 3D-CRT, for example, because of the need to allow for variations in set-up and respiration motion. Studies of APBI usually distinguish between “same site relapse,” (i.e., close to the irradiated area and elsewhere relapse), yet it is unclear whether “what constitutes the same site” varies across studies. The percentage of relapses occurring “elsewhere” in the ipsilateral breast in studies of WBRT following BCS range from 18% to 42% (these studies may include some patients at higher risk of recurrence). Proponents of APBI have sometimes asserted that “elsewhere” tumors are rare, that they are...
mostly new primary tumors (rather than a recurrence), or that earlier studies have shown that radiotherapy is not effective on these tumors in any case. Mannino and Yarnold (2009) challenged each of these points in turn, although they also concluded the results of the trials currently underway will provide level 1 evidence for or against APBI.

While there are ongoing randomized phase III studies of APBI with brachytherapy, both the American Society of Breast Surgeons (ASBS) and the American Brachytherapy Society (ABS) have issued position statements APBI, advocating it as an accepted technique for women with small tumors and negative axillary nodes (ASBS, 2008; Arthur, 2008). This position indicates that APBI with breast brachytherapy may be considered medically necessary in certain individuals and reflects general acceptance of these techniques among the medical community.

The ASBS stated several single-institution, non-randomized studies have shown low local recurrence rates that are comparable to standard EBRT. Criteria recommended by the ASBS to select patients for APBI are:

- Age 45 years or older
- Invasive ductal carcinoma or ductal carcinoma in situ (DCIS)
- Total tumor size (invasive and DCIS) less than or equal to 3 cm in size
- Negative microscopic surgical margins of excision
- Sentinel lymph node negative

Additionally, ASBS advised continuous, long term, outcomes-based monitoring of APBI is desirable. The ASBS maintains an ongoing Mammosite® Registry collecting data on more than 1400 patients treated via the balloon catheter technique. They further advised participation in multi-institutional clinical studies, or in single site protocols, or in the context of data-gathering registries, if desirable or available.

The ABS supports protocol enrollment of patients whenever possible and appropriate for the individual patient. However, in situations where this is not possible, conservative guidelines should be applied (Keisch et al., 2007):

- Age >/= 50 years old (age recommendation has been changed to reflect the uncertainty as to the influence of menopausal status and in recognition that most women treated in reported experiences with greater than five-year follow-up were postmenopausal and had a median age of 60 years or older)
- Infiltrating ductal carcinoma only
- Clinical stage T1, and T2; N0
- Tumor size of </= 3 cm in size
- No distant metastasis

The American Society for Radiation Oncology (ASTRO) published a consensus statement on APBI outlining patient selection criteria and best practices for the use of APBI (Smith et al., 2009). The ASTRO Task Force proposed three patient groups:

1) A “suitable” group, for whom APBI outside of a clinical trial is acceptable. Criteria include patients age 60 years and older, a tumor size of 2 cm or less, tumor stage T1, negative margins of
at least 2 mm, pathologically negative nodes, positive estrogen-receptor status, an absence of lymphovascular space invasion, and no multicentricity. Patients with DCIS are excluded.

2) A “cautionary” group, for whom caution and concern should be applied when considering APBI outside of a clinical trial. A patient belongs in the cautionary group if any one of the following are met: age 50 to 59 years, T2 primary disease, pure DCIS or less than 3 cm, close margins (< 2 millimeters), focal lymphvascular space invasion, multifocal or multicentric disease, invasive lobular carcinoma, or estrogen-receptor negativity. “Any of these criteria should invoke caution and concern when considering APBI” (Smith et al., 2009).

3) An “unsuitable” group, for whom APBI outside of a clinical trial is not generally considered warranted. Unsuitable patients are those who meet any of the following: age less than 50 years, use of neoadjuvant chemotherapy, tumor size of more than 3 cm, positive margins, any positive lymph nodes, no axillary surgery, extensive lymphvascular space invasion, multicentricity, DCIS of more than 3 cm, or the presence of a breast cancer susceptibility gene (BRCA) 1 or 2 mutation. “If any of these factors are present, the ASTRO Task Force recommends against the use of APBI outside of a prospective clinical trial” (Smith et al., 2009).

The ASTRO Task Force was unable to determine the optimal technique for APBI delivery as there was insufficient clinical and dosimetric data. Additionally, the authors stated patients who choose treatment with APBI should be informed that WBRT is an established treatment with a much longer track record that has documented long-term effectiveness and safety (Smith et al., 2009).

The NCCN Guideline for breast cancer (v.2.2011) stated:

Preliminary studies of APBI suggest rates of local control in selected patients with early stage breast cancer may be comparable to those treated with standard whole breast RT. Follow up, however is limited and studies are on-going. Patients are encouraged to participate in clinical trials.

Additionally, the NCCN referenced the ASTRO consensus statement regarding “suitable” groups if the patient was not trial eligible.

In summary, in the absence of data from well-designed, randomized clinical trials confirming the effectiveness of APBI as the sole source of radiation for the treatment of early stage breast cancer, the selection criteria included in this medical policy are similar to the selection criteria of the ABS Breast Brachytherapy Task Group (2007) and the ASTRO Task Force (2009) “suitable” and “cautionary” groups when considering APBI outside of a clinical trial.

**Endobronchial Cancer**

Endobronchial brachytherapy is the delivery of RT directly to endobronchial lesions either intraluminally or interstitially using permanently implanted radioactive seeds or a temporary afterloading implant. The technique permits targeted radiation while minimizing exposure to surrounding radiosensitive structures, such as normal lung, heart, and spinal cord. A flexible bronchoscope is passed transnasally; a separate port on the bronchoscope allows passage of the afterloading catheter to the target lesion. Once the catheter is placed, the radioisotope can be administered by the high-dose radiotherapy afterloading machine. Patients with potential airway
compromise due to bleeding may require treatment with a rigid bronchoscope, which requires general anesthesia and frequently an overnight stay. Two to four fractions delivered weekly is a typical schedule. The most serious complications described for endobronchial brachytherapy are massive hemoptysis, formation of tracheoesophageal fistulas, bronchospasm, bronchial stenosis, and radiation bronchitis (Cordona et al, 2008).

Endobronchial brachytherapy is used as both palliative treatment and curative treatment; either alone or in combination with other modalities such as surgery, EBRT, or other endoscopic interventions.

**Palliative Treatment**

Many patients with non-small cell lung cancer (NSCLC) are initially treated with EBRT but ultimately experience local recurrence. Unfortunately, many are not candidates for further EBRT due to the limited tolerance of normal tissue. If symptoms persist following EBRT, endobronchial brachytherapy is well accepted as a short-term palliation for such symptoms as hemoptysis, cough, dyspnea, and resolution of obstructive atelectasis or pneumonitis (Villanueva et al., 1995; Kubaskewska et al., 2008). The median survival of these patients is typically less than nine months.

Several studies have tried to expand the utility of endobronchial brachytherapy to first-line palliative treatment. A Cochrane review concluded EBRT alone is still more effective for palliation of symptoms than endobronchial brachytherapy alone (Cardona et al., 2008). The authors were not able to provide conclusive evidence to recommend endobronchial brachytherapy as an add-on to first-line EBRT, chemotherapy, or Neodymium-Doped Yttrium-Aluminum-Garnet (Nd-YAG) laser palliative treatment. For patients previously treated by EBRT who were still symptomatic, endobronchial brachytherapy may be considered an option. Ung and colleagues (2006), also in agreement with the Cochrane review, conducted a systematic review of endobronchial brachytherapy in the palliative treatment of NSCLC with 29 studies and six randomized trials. The authors concluded EBRT alone is more effective than endobronchial brachytherapy alone for symptom palliation in previously untreated patients. In contrast to the Cochrane review, the Ung review concluded endobronchial brachytherapy with EBRT seems to provide better symptom relief than EBRT alone, yet their final recommendation was to only use endobronchial brachytherapy with symptomatic recurrent endobronchial obstruction following EBRT.

The American College of Radiology (ACR) published ACR Appropriateness Criteria on non-surgical treatment for NSCLC. These criteria were agreed upon by an expert panel. The panel considered endobronchial brachytherapy a palliative treatment, “providing relief for patients with endobronchial lesions causing obstruction or hemoptysis” (Rosenzweig et al., 2009).

Dagnault and colleagues (2010) reported a retrospective review of 81 patients who were treated with brachytherapy in the palliation of symptoms due to endobronchial primary lung tumors or metastases. Between 2002 and 2007, 81 patients who were not candidates for surgery or external radiation because of poor respiratory function, medical comorbidities or previous treatment with thoracic radiation or surgery, were treated at a single institution. Most patients presented with dyspnea, cough, or hemoptysis. After brachytherapy, these three main symptoms were relieved in 85%, 77%, and 100%, respectively. At six weeks' follow-up, 72% of tumors were evaluable.
for bronchoscopic response. A visible bronchoscopic response was evident in 77 patients and for 42 of 81 patients the tumor shrank significantly during treatment. Median survival was 14.7 months and local progression-free survival at 12 months was 77% and at 24 months, 64%. For comparison, the authors stated the survival for most patients with inoperable endobronchial tumors or metastasis was less than six months. The complication rate was low, with all complications resolved.

Guarnaschelli and colleagues (2010) reviewed the treatment outcomes of 52 patients with recurrent endobronchial tumors who underwent palliative HDR endobronchial brachytherapy between 1995 and 2005 at one institution. Objective response was assessed by bronchoscopy and chest CT and subjective clinical response by patient reports. All patients had histologically proven bronchogenic carcinoma, recurrent or persistent symptoms (hemoptysis, cough, dyspnea or postobstructive pneumonia), previous definitive EBRT, and evidence of an endobronchial obstructive component based on bronchoscopy. Complete or partial tumor regression was demonstrated in 44 (85%) of patients and 48 (92%) of patients showed symptomatic improvement (35% with mild improvement and 60% with significant improvement). Median follow-up was 31 months, and median overall actuarial survival for the entire cohort from the time of the first brachytherapy session was seven months (range: 0 to 55 months). Fifty patients (96%) tolerated the treatment without acute, treatment-related complications.

The NCCN Guidelines (v.3.2011) recommend endobronchial brachytherapy for locoregional recurrence of non-small cell carcinoma with endobronchial obstruction or severe hemoptysis (category 2A).

**Primary Treatment**

Candidates for primary treatment have principally included patients with early stage endobronchial tumors who are not candidates for surgical resection or EBRT due to comorbidities or the location of the tumor. Results have predominantly been reported in case series where complete response rates in the range of 50% to 80% have been noted (Rabaen & Mychalczak, 1997; Perol et al., 1997; Hennequin et al., 2007). The indications and outcomes of brachytherapy as primary therapy are comparable to those reported for photodynamic therapy.

Guilcher and colleagues (2010) conducted a retrospective review of records (April 1991 to May 2004) from nine institutions of 226 patients with NSCLC, with no endobronchial spread on CT scans, who underwent HDR brachytherapy because of contraindications to surgery and EBRT. Two-hundred seventeen patients had squamous cell carcinoma. Mean follow-up was 30.4 months (range nine to 116 months). At three months, a complete local response was observed in 213 patients (94%), and 126 out of 137 patients with biopsies (91.3%) had a complete response. The two-year and five-year survival rates were, respectively, 57% and 29% (overall) (median, 28.6 months), 81% and 56% (cancer-specific), and 68% and 50% (local disease-free). Complications led to treatment interruption in 4.5% of patients. The rate of fatal complications was 6%, and consisted mostly of fatal hemoptysis. The authors concluded HDR brachytherapy is an efficient and safe treatment in patients with inoperable endobronchial carcinoma.
Radiation Boost

There have also been early investigations for the use of brachytherapy to deliver a focused radiation boost to patients undergoing curative EBRT. External beam radiation therapy is typically the primary treatment for the majority of patients with NSCLC due to the fact that patients usually present with surgically unresectable disease and that NSCLC is unresponsive to chemotherapy. Huber and colleagues (1997) reported results of a trial that randomized 98 patients with inoperable lung cancer to receive either EBRT or endobronchial brachytherapy. The brachytherapy group experienced a longer period of local control; however there were no significant differences in survival between the two groups.

A 2005 case study by Carvalho and colleagues from Brazil involving four patients with non-resectable primary tracheal tumors used endobronchial brachytherapy in recurrences or as a boost for EBRT and achieved immediate palliation of symptoms and local control for at least six months. Currently, larger studies are needed to further evaluate the use of endobronchial brachytherapy as a curative “boost” therapy with EBRT in tracheal tumors.

Asymptomatic Recurrence of Non-Small Cell Lung Cancer

The NCCN Guidelines (v.3. 2011) specifically addressed the use of brachytherapy for patients who have loco-regional recurrence. Brachytherapy is one of the recommended treatment options for endobronchial obstruction. Other treatment options include laser/stent/other surgery, EBRT, and photodynamic therapy. Because no supportive studies demonstrating impact on outcomes were identified for this application of endobronchial RT, this is considered an investigational application under the policy statement.

Hyperplastic Granulation Tissue

Endobronchial brachytherapy has also been investigated to treat hyperplastic granulation tissue causing recurrent airway stenosis complicating lung transplantation or stent placement. A 2008 case series reported on the use of endobronchial brachytherapy in eight patients following excision of obstructive granulation tissue; six had a good or excellent subjective early response for the first six months (Tendulkar et al., 2008). A case series used endobronchial brachytherapy in five patients with benign granulation tissue following lung transplantation that was refractory to multiple other bronchoscopic interventions. After a median follow-up of 12 months, three of the five patients had marked symptom improvement (Madu et al., 2006). While these cases series offer positive outcomes, larger trials with adequate follow-up are needed to fully evaluate the potential role of endobronchial brachytherapy in the treatment of granulation tissue.

Rahman and colleagues (2010) reported on the long-term follow-up of 115 patients who underwent various flexible bronchoscopic therapeutic modalities for the management of benign tracheal stenosis between 2001 and 2009. High-dose rate endobronchial brachytherapy was used in cases of refractory stent-related granulation tissue formation, defined as a patient requiring three or more interventions within six months due to recurrent granulation tissue formation. A stent was placed in 33 patients for restoration of airway patency, 28 of whom also underwent brachytherapy. All patients presented with signs and symptoms of upper airway obstruction, including shortness of breath, stridor, cough, dyspnea and wheezing. All of the patients who underwent brachytherapy experienced a reduction in therapeutic bronchoscopic procedures after
brachytherapy compared with the pretreatment period, although no further detail of the duration of the response or other patient outcomes were reported for this subset of patients who received brachytherapy. There were no treatment-related complications. While results from this case series are positive, the small numbers of patients and concerns about outcome reporting limit the conclusions that can be reached from this study.

**Prostate Cancer**

Treatment options for clinically localized prostate cancer include surgery, RT (e.g., EBRT, brachytherapy) and watchful waiting. The two forms of brachytherapy performed today for the treatment of prostate cancer are LDR (permanent brachytherapy) in the form of permanent seeds and HDR temporary implants or HDR brachytherapy.

In LDR brachytherapy, permanent seeds contain isotopes (iodine-125 or palladium-103) that slowly emit radiation of relatively low energy. The dose rate of the brachytherapy sources is generally in the range of 40 to 60 Gy per hour. Permanent (LDR) brachytherapy may be used alone as monotherapy or combined with EBRT as a way to boost the dose of RT delivered to the tumor. The brachytherapy boost is typically done two to six weeks after completion of EBRT, although the sequence can vary. Low-dose rate brachytherapy is a well accepted treatment option for clinically localized prostate cancer with excellent long-term treatment outcomes in low-, intermediate-, and high-risk patients (Ragde et al., 1998; Sylvester et al., 2007; Hurwitz, 2008).

In contrast, HDR or temporary brachytherapy involves use of higher energy radioisotopes such as iridium-192. Radiation is delivered at higher dose rates, which may be more effective in destroying rapidly dividing cancer cells. In this technique, needle catheters are placed into the prostate gland using transrectal ultrasound guidance. Once the needles are placed, a dosimetric plan is developed and the radioactive source is inserted into each needle using an afterloading device. The radioactive source is left in the needle for a predetermined time, typically ranging from eight to twelve minutes (called the dwell time). The radiation usually is delivered once or twice daily over a course of several days. The dwell time can be altered at various positions along the needle's length to control dose distribution to the target volume and critical surrounding structures, such as the rectum or urethra. This strategy contrasts with LDR brachytherapy in which dosimetry is calculated prior to needle placement and which cannot be altered after seed implantation. As the case with LDR brachytherapy, HDR brachytherapy may be given alone (monotherapy) or in combination with other therapies. In general, studies in the peer-reviewed literature reported outcomes of biochemical control rates and survival.

The most clinical experience with HDR brachytherapy for prostate cancer involved its combination with EBRT in individuals with poor prognostic factors. The treatment typically consists of 4,000 to 5,000 centigray delivered with EBRT to the prostate and periprostatic tissues, while the HDR brachytherapy is used as the method of dose escalation boost to the prostate gland. The total boost doses are variable. Yamaga et al., (2006) retrospectively reported on 105 patients treated with HDR brachytherapy and EBRT who were followed for a median of 44 months. The five-year PSA relapse-free survival outcomes for low-, intermediate- and high-risk patients were 100%, 98%, and 92%, respectively. Hoskin and colleagues (2007) reported on a European single-center randomized trial of 220 patients conducted between 1997 and 2005 where EBRT was compared to EBRT with HDR brachytherapy. With a median follow-up of 30...
months, the authors noted an improvement in actuarial biochemical relapse-free survival as well as a lower incidence of acute rectal discharge. Phan and colleagues (2007) reported on a case-series of 309 patients treated with EBRT (40 to 45 Gy) and HDR brachytherapy (22 to 24 Gy). At a median follow-up of 59 months, the five-year biochemical control rate was 86% and overall survival was 91%; rates were higher for those with lower-risk disease. More recently, Demanes et al., (2009) prospectively evaluated 411 patients who received HDR brachytherapy and EBRT and were followed for a median of 6.4 years. The overall 10-year biochemical control rate was 81%; stratified by risk group control rates, these results were low-risk 92%, intermediate-risk 87%, and high-risk 63%.

Publications on use of HDR as monotherapy for treatment of prostate cancer are fewer than those that reported its use as combined modality therapy with EBRT. Grills et al., (2004) reported on a series of 149 patients with early-stage prostate cancer who were treated with brachytherapy (65 patients with HDR; 84 patients with LDR) given between 1999 through 2001. Levels of biochemical control were similar in the two groups (LDR 97% and HDR 98%) with median follow-up of 35 months. The authors reported statistically significant decreased rates of dysuria, urinary frequency and/or urgency. In a prospective trial conducted by Yoshioka and colleagues (2006) 111 localized prostate cancer patients (15 low-risk, 28 intermediate-risk, and 68 high-risk) were treated with HDR brachytherapy as monotherapy. The three-year local control, OS, and PSA failure-free rates were 100%, 97%, and 83%, respectively. The corresponding five-year rates were 97%, 92%, and 70%. The authors concluded their study demonstrated acceptable toxicity and promising short-term tumor control, even for locally advanced cases. The largest published series of this modality are results of a phase II study by Corner and colleagues in 2008. This study involved 110 patients treated with three regimens: 34 Gy in four fractions, 36 Gy in four fractions, and 31.5 Gy in three fractions. At six months, two patients had grade 3 bladder toxicity, and one patient had grade 2 gastrointestinal (GI) toxicity. No PSA relapses had been detected, although the median follow-up was just 12 months among the 55 patients that received 31.5 Gy. The authors concluded these early results suggested an excellent biochemical response with no differences seen in acute and late toxicity among the three regimens.

The NCCN Guidelines (v.1.2011) for prostate cancer brachytherapy advised:

Permanent LDR brachytherapy as monotherapy is indicated for patients with low-risk cancers. For intermediate-risk cancers consider combining brachytherapy with EBRT (40 to 50 Gy) +/- four to six months of adjuvant androgen deprivation therapy (ADT). Patients with high-risk cancers may be treated with a combination of EBRT (40 to 50 Gy) and brachytherapy +/- four to six months of neoadjuvant/comcomittant/adjuvant androgen deprivation therapy (ADT).

Data on HDR use in the salvage treatment following failed prior RT remain limited. Other salvage treatment options vary and may include observation; immediate, continuous, or intermittent hormonal therapy; or further local therapy with radio-frequency thermal ablation, high-intensity focused ultrasonography (known as HIFU), salvage cryoablation, or salvage radical prostatectomy. Of these treatments, only salvage radical prostatectomy has been shown to eliminate cancer for ten years or more (Stephenson & Eastham, 2005). Because published data are still limited and clinical trials are ongoing, use of HDR in the treatment of prostate cancer as salvage therapy is considered investigational.
Gynecological Cancer

Brachytherapy is considered the standard of care in patients with gynecologic malignancies, specifically cervical, endometrial, uterine and vaginal carcinoma. Brachytherapy can be used to prevent local cancer recurrences after surgery (adjuvant therapy) or for the treatment of recurrent cancer. Brachytherapy is most commonly performed with either HDR or LDR techniques. Low-dose rate approaches have been predominantly used, notably in cervical and uterine cancers.

In patients undergoing LDR brachytherapy, an applicator is inserted within the cervix/uterus with the patient under general anesthesia. This device is later afterloaded with radiation capsules (e.g., Cesium-137) while the patient is transferred to a lead-shielded hospital room. Patients are placed on strict bedrest for one to three days, with the procedure typically repeated in one to two weeks depending on the dose required and the site treated. Recently, HDR techniques have all but replaced LDR techniques at most tumor sites. In contrast to LDR, HDR is an outpatient procedure avoiding the need for general anesthesia and a prolonged hospital stay at bedrest. High-dose rate brachytherapy uses high activity iridium-192 sources, allowing treatment to be delivered within minutes as opposed to several days. Between treatments, the iridium source is stored in a shielded device and is delivered under computer control.

For cervical and uterine cancer, brachytherapy is typically combined with EBRT or given as a boost to EBRT. However, brachytherapy alone may also be used for selected patients (i.e., vaginal brachytherapy for selected patients with superficial disease). Brachytherapy doses for definitive therapy are based on the clinical situation.

In a Cochrane Review, a systematic meta-analysis of clinical trial data was conducted by Wang et al., (2010) regarding HDR versus LDR intracavity brachytherapy for locally advanced uterine and cervix cancer. The authors reported no significant differences between HDR- and LDR-intracavity brachytherapy when considering OS, relapse-free survival, local control rate, recurrence, metastasis and treatment related complications for women with cervical cancer.

Overall, the peer-reviewed literature, as well as professional societies/organizations, supports the use of brachytherapy for cervical, endometrial, uterine and vaginal cancers (Livi et al., 2003; Bradley et al., 2006; Nout et al., 2009; Viani et al., 2009; ACR, 2010; National Cancer Institute, 2010; Nout et al., 2010; Wang et al., 2010; NCCN, 2011).

Electronic Brachytherapy

Electronic brachytherapy (EBT) has been proposed as an alternative to radioactive brachytherapy for the treatment of certain cancers. Currently, the Axxent® Electronic Brachytherapy System (Xsoft Inc, Fremont, CA) is FDA-cleared for the treatment of early stage breast cancer, endometrial cancer, skin cancer, and for the treatment of other cancers and conditions where RT is indicated. This system received FDA clearance without a human trial (because it was considered similar to a predicate device, Mammosite®). Unlike conventional HDR brachytherapy technologies, the Axxent® system does not require radioactive isotopes, heavy shielding, or major capital equipment. The Axxent® System delivers electronically generated radiation directly to tumor beds by the use of disposable miniaturized x-ray radiation sources. Other proposed advantages of EBT compared to radioactive HDR include the delivery of radiation at a
lower energy, a sharper dose-fall off, and greater protection to surrounding tissue (Dickler, et al., 2008; U.S. FDA, 2008; Xoft, 2009).

A report from the Emerging Technology Committee by ASTRO (Park et al., 2008; Park et al., 2010) advised:

The FDA reviews the safety and effectiveness of the device per a standard that does not assess efficacy, outcomes, or potential clinical applications. Because the devices do not contain a radioactive source, they are not subject to regulation by, or user standard for radioactive devices, as overseen by the U.S. Nuclear Regulatory Commission... Inappropriate use of these devices by a medical practitioner, or non-medical personnel, who is not properly trained in their use or who uses them in inappropriate circumstances may lead to patient harm.

Some early industry-sponsored case reports and case series reported EBT showed acute results similar to HDR brachytherapy for breast cancer (APBI) and endometrial cancer (Dickler et al., 2010; Dooley et al., 2010; Mehta et al., 2010). Additional research is needed to further assess the clinical efficacy and safety of EBT. Additionally, there is insufficient evidence in the peer-reviewed published medical literature comparing outcomes of EBT with standard radioisotope-based brachytherapy.

**Benefit Application**

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

*This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.*

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Radiation Oncology
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### Tables

N/A

### Definitions

**Boost** - An additional dose of radiation to a reduced size radiation field.

**Breast conserving surgery (BCS)** - A treatment alternative to mastectomy for early stage breast cancer that consists of tumor removal (lumpectomy) followed by external radiation to the whole breast.

**External beam radiation therapy (EBRT)** - A beam (or multiple beams) of radiation is directed through the skin to the cancer and the immediate surrounding area in order to destroy the main tumor and any nearby cancer cells. The radiation beam is usually generated by a linear accelerator which is capable of producing high-energy x-rays or electrons for the treatment of cancer. Types of EBRT include: three-dimensional conformal radiation therapy (3D-CRT), intensity modulated radiation therapy (IMRT), proton beam therapy, neutron beam therapy, image guided radiation therapy.

**Interstitial implant** - A procedure in which radioactive material is placed directly into a tumor site.

**Partial breast irradiation** - Radiation focused at the tumor bed of the breast, after prior breast conserving surgery; an alternative to whole breast irradiation; breast brachytherapy is one technique of delivering partial breast irradiation.
Index / Cross Reference of Related BSC Medical Policies

The following Medical Policies share diagnoses and/or are equivalent BSC Medical Policies:

N/A

Key / Related Searchable Words

N/A

References

Medical Policy: Brachytherapy for Oncologic Indications  
Original Policy Date: 1/11/2008  
Effective Date: 1/30/2015  


Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

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<tr>
<th>Effective Date</th>
<th>Action</th>
<th>Reason</th>
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| 1/1/2008       | New Policy Adoption Combined the following BSC policies and addressed medical necessity for additional cancer diagnoses.  
- Brachytherapy for Prostate Cancer  
- Breast Brachytherapy after Breast-Conserving Surgery, as Boost with Whole Breast Irradiation, or Alone as Accelerated Partial Breast Irradiation(APBI)  
- Interstitial or Balloon Breast Brachytherapy | Medical Policy Committee |
<p>| 3/1/2009       | Coding Update Updated Codes for 2009 CPT Updates | Administrative Review |
| 11/4/2009      | Coding Update | Administrative Review |
| 4/1/2011       | Policy revision with position change | Medical Policy Committee |
| 2/22/2013      | Coding Update | Administrative Review |</p>
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<tr>
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<th>Action</th>
<th>Reason</th>
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<tbody>
<tr>
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<td>Coding Update</td>
<td>Administrative Review</td>
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<tr>
<td>1/30/2015</td>
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The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.