



## CONFORMAL AND INTENSITY MODULATED RADIATION THERAPY (IMRT) OF THE BREAST

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### Overview

Randomized, controlled clinical trials have shown that conventional external beam whole breast radiation therapy is effective in treating early stage or locally advanced breast cancer following breast conservation. Conventional external beam radiation therapy typically lasts 5 to 8 weeks and achieves excellent long-term outcomes with a high rate of local control, a low rate of complications, and a high rate of acceptable cosmetic results. (Fisher et al., 1985a; Fisher et al. 1985b; Overgaard et al., 1997; Ragaz et al. 1997; Overgaard et al., 1999; Van de Steene et al., 2000; Fisher et al., 2001; Vinh-Hung et al., 2003; Vinh-Hung et al., 2004; Violet and Harmer, 2004; Ragaz et al., 2005)

Successful treatment with radiation therapy generally requires relatively high doses of radiation administered to the tumor as well as to adjacent regions that potentially contain cancer cells. Incidental irradiation of adjacent normal tissue is inevitable during such treatment. Radiation to normal tissue must be minimized to reduce both acute and long-term side effects. Over the past few decades, new methods have been developed that permit delivery of radiation beams that "conform" to the shape of the tumor, including 3-dimensional conformal radiation therapy (3D-CRT), intensity modulated radiation therapy (IMRT), and most recently, image-guided radiation therapy (IGRT). These and other conformal therapies are designed to allow higher doses of radiation to be delivered to the target tumor while potentially sparing the surrounding normal tissues and decreasing the risk of toxicities.

Multiple studies have generated 3D-CRT and IMRT treatment plans and compared predicted dose distributions within the target and in adjacent tissues at risk. Results of such planning studies show that IMRT improves on 3D-CRT with respect to conformality to, and dose homogeneity within, the target. (Teh et al., 1999; Aref et al., 2000; Kestin et al., 2000, Vincini FA, Sharpe M, Kestin L, et al., 2002; Fogliata et al., 2003; Donovan et al., 2002; Ma et al., 2003; Frazier et al., 2004; Li et al., 2004) Thus, many radiation oncologists hypothesized that IMRT may improve treatment outcomes compared with those of conventional 3D-CRT. However, there is insufficient clinical trial data to determine whether IMRT is superior to conventional 3D-CRT in improving patient outcomes. At the present time, it appears that IMRT will or has replaced 3D-CRT where these are both appropriate treatment options. It is unlikely that there will be any significant number of formal randomized trials to confirm the superiority of IMRT over 3D-CRT. Most major radiation oncology centers have already invested heavily in IMRT technology.



With respect to the use of conformal radiation therapy in the treatment of breast cancer, all of the relevant trials demonstrating the benefit of radiation therapy were conducted using conventional external beam radiation therapy. Preliminary studies have shown that IMRT may reduce acute radiation dermatitis. (Freedman et al., 2006; Strauss et al., 2007; Pignol et al., 2008) However, there is inadequate clinical trial data that demonstrates any consistent improved local control with IMRT. Data for survival over 3 years are scarce. IMRT delivers more total radiation energy to normal tissues than standard or 3D-CRT, but the consequences of this higher dose are unknown. Late toxicity data, especially secondary malignancies, are non-existent. Although IMRT may deliver radiation more precisely to the tumor while limiting radiation exposure to normal tissue at risk, the true benefit of IMRT to the treatment of breast cancer has yet to be proven. IMRT has considerable promise, but also represents considerable challenges.

As the sophistication of the field of radiation oncology has grown, the precise positions of the target and normal tissues becomes of great relevance. Respiratory motion of the breast during radiation treatments is a concern when using IMRT. Both tumor and normal tissues change position over the course of a multi-week treatment plan. Radiation oncologists attempt to compensate for day-to-day variability in patient set-up and for motion of the target and organs at risk by expanding the target volume with uniform margins around the tumor. The need to better understand the uncertainties inherent in the radiation therapy delivery process has led to the development of emerging technologies and clinical processes collectively referred to as image-guided radiation therapy (IGRT). IGRT uses imaging technology such as CT or MRI to locate a tumor target just prior to delivering radiation therapy. IGRT is intended to improve the treatment accuracy thereby eliminating the need for large target margins which have traditionally been used to compensate for errors in localization. As a result, the amount of healthy tissue exposed to radiation can be reduced, minimizing the incidence of side effects. IGRT can be performed by using add-on imaging or with dedicated IGRT devices. A few examples of dedicated devices include: the TomoTherapy Hi·Art® System (TomoTherapy Inc., Madison, WI); the PeacockSystem™ (NOMOS Corp., Sewickley, PA); and Trilogy™ and SmartBeam™ IMRT (Varian Medical Systems, Inc. Palo Alto, CA). Published literature for IGRT is limited to studies where the primary outcome measure relates to feasibility and not to health outcomes. Although the perceived advantages of IGRT over IMRT are considerable, there is no clinical trial data which demonstrates improved patient outcomes. (Gonzalez et al., 2006; Saibishkumar et al., 2008; Moeckly et al., 2008; Langen et al., 2008; McIntosh et al., 2008; Rong et al., 2008; Caudrelier et al., 2009; Goddu et al., 2009; Kainz et al., 2009; O'Donnell et al., 2009)

## Definitions

**Brachytherapy** – A form of radiation therapy in which radioactive seeds or pellets which emit radiation are implanted within the tumor in order to destroy cancer cells.

**Conformal therapy** – the use of careful planning and delivery techniques designed to focus external radiation on a tumor and surrounding tissue which need treatment and



protect areas which do not need treatment; three-dimensional conformal radiation therapy (3D CRT) and intensity modulated radiation therapy (IMRT) are examples of conformal therapy.

**External beam radiation therapy (EBRT)** – two-dimensional external beam radiation treatment that can include conventional photons, or use protons, neutrons, or electrons.

**Image-guided radiation therapy (IGRT)** – IGRT uses imaging technology such as CT or MRI to locate a tumor target just prior to a radiation therapy. The advantage of IGRT is that it allows for adjustments in treatment during the course of treatment.

**Intensity modulated radiation therapy (IMRT)** – an approach to three-dimensional planning and treatment that optimizes the delivery of radiation to irregularly shaped volumes through a process called inverse planning and delivery of radiation that results in modulated fluence (intensity) of photon beams. By varying the fluence across multiple treatment fields, the radiation dose can be modulated to conform to irregular shapes and to design a heterogeneous dose distribution.

**Three-dimensional conformal radiation therapy (3D CRT)** – an external radiation treatment approach that focuses on directing the radiation energy to the tumor target while sparing the surrounding normal tissues.

## Policy

### Commercial plans (defined herein)

FCHP considers conformal radiation therapy, including but not limited to intensity modulated radiation therapy (IMRT) and image-guided radiation therapy (IGRT) for the treatment of breast cancer experimental/investigational.

Note: FCHP covers patient care services related to qualified clinical trials for some commercial plan members. Services that are the subject of a clinical trial are not patient care services. If IMRT is the investigational item, then IMRT planning and delivery and other related services are not covered.

### Fallon Senior Plan™

#### **IMRT for Fallon Senior Plan™ members requires preauthorization by a Fallon Community Health Plan (FCHP) Medical Director.**

FCHP covers IMRT of the breast for Fallon Senior Plan™ members when one of the following criteria/indication is met:

- Where sparing of surrounding normal tissue is essential
- Only IMRT techniques would decrease the probability of grade 2 or grade 3 radiation toxicity as compared to conventional radiation in greater than 15% of irradiated similar cases
- Important dose limiting structures adjacent to, but outside the planned treatment volume are sufficiently close and require IMRT to assure safety and morbidity reduction
- An immediately adjacent volume has been irradiated and abutting portals must be established with high precision



- Gross tumor volume margins are in close proximity to critical structures that must be protected to avoid unacceptable morbidity.

Indications should include some left breast tumors due to risk to immediately adjacent cardiac and pericardial structures, though IMRT would only rarely if ever be medically necessary for tumors of the right breast.

Documentation that supports all of the following must be submitted to FCHP for review:

- A prescription that clearly defines the goals and requirements of the treatment plan, including the specific dose constraints for the target(s) and nearby critical structures.
- A statement by the treating physician documenting the special need for performing IMRT on the patient in question, rather than performing conventional or 3-dimensional treatment planning and delivery.
- Approved IMRT inverse plan that meets prescribed dose constraints for the planning target volume and surrounding normal tissue using either dynamic multi-leaf collimator or segmented multi-leaf collimator) (typical number of steps (segments) per gantry angle required to meet IMRT delivery is 5), or inverse planned IMRT solid compensator to achieve intensity modulated radiation delivery.
- The target verification methodology must include the following:
  - Documentation of the clinical treatment volume (CTV) and the planning target volume (PTV).
  - Documentation of immobilization and patient positioning.
  - Evidence that monitor units obtained from the IMRT treatment plan were checked by an independent method before the patient's first treatment, and that agreement met documented department standards.
  - Documentation that fluence distributions were re-computed in a phantom and that this distribution was shown to be in good agreement with an independent dosimetric measurement.
  - Documentation of measures taken into account for respiratory organ motion if necessary. Voluntary breath holding is not considered appropriate and the solution for movement can best be accomplished with gating technology.

## Exclusions

1. Four-dimensional image-based planning for conformal radiation therapy.

## Codes

Effective March 1, 2010, claims for services related to conformal radiation therapy for commercial plan members for the treatment of primary breast cancer (ICD-9-CM diagnosis codes 174.x and 175.x), including but not limited to planning (CPT code 77301) and delivery (CPT code 77418) will be denied vendor liable.

Treatment delivery (CPT codes 77418 and 0073T) have no professional component.



Codes	Number	Description
CPT	77301	Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications
	77418	Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session
	0073T	Compensator-based beam modulation treatment delivery of inverse planned treatment using 3 or more high resolution (milled or cast) compensator convergent beam modulated fields, per treatment session

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### Products to Which This Policy Applies

#### Commercial plans

- ⊕ FCHP Direct & Select Care
- ⊕ Fallon Preferred Care (PPO)
- ⊕ Major Medical
- ⊕ MassHealth
- ⊕ Companion Care
- ⊕ Commonwealth Care

#### Other

- ⊕ Fallon Senior Plan™

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#### **Committee review dates:**

Technology Assessment Subcommittee: 09/22/09

Technology Assessment Committee: 09/30/09

#### **IMPORTANT NOTE:**

**Not all services are covered for all products or employer groups.** This medical policy expresses FCHP's determination of whether certain services or supplies are medically necessary, experimental or investigational or cosmetic. FCHP has reached these conclusions based upon the regulatory status of the technology and a review of clinical studies published in peer-reviewed medical literature. Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. Members and their providers need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and the plan of benefits, the provisions of the benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this medical policy.