THE AMERICAN SOCIETY OF Breast Surgeons

June 15, 2021

Elizabeth Fowler, J.D., Ph.D.
Director
Center for Medicare & Medicaid Innovation
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Director Fowler:

On behalf of the American Society of Breast Surgeons (ASBrS), I would like to congratulate you on your appointment as director of the Center for Medicare & Medicaid Innovation (CMMI) and offer our organization as a resource for you as you work to move toward models of reimbursement based on the value of services rather than on the volume of services. ASBrS, the primary leadership organization for surgeons who treat patients with breast cancer and benign breast diseases, is committed to continually improving the practice of breast surgery by serving as an advocate for those who seek excellence in the care of breast patients. Founded in 1995, the Society now has more than 3,000 members throughout the United States and in 35 countries around the world.

As you review the portfolio of models coordinated by CMMI, we write to request that as you review the Radiation Oncology (RO) Model originally proposed in 2019 and delayed by Congress in the *Consolidated Appropriations Act, 2021* until January 1, 2022, that you reconsider capturing intraoperative radiation therapy (IORT) as one of the included modalities as originally proposed under the model.

For background, the RO Model was first announced in the *Specialty Care Models To Improve Quality of Care and Reduce Expenditures* proposed rule published in the *Federal Register* on July 18, 2019. As part of this original proposal, CMMI and the Centers for Medicare and Medicaid Services (CMS) stated,

> *We propose to include the following RT modalities in the Model: Various types of external beam RT, including 3- dimensional conformal radiotherapy (3DCRT), intensity-modulated radiotherapy (IMRT), stereotactic radiosurgery (SRS), stereotactic body radiotherapy (SBRT), and proton beam therapy (PBT); intraoperative radiotherapy (IORT); image-guided radiation therapy (IGRT); and brachytherapy. We are proposing to include all of these modalities because they are the most commonly used to treat the 17 included cancer types and including these modalities would allow us to determine whether the RO Model is able to impact RT holistically rather than testing a limited subset of services.*[1]

However, in issuing the final rule in September of last year and addressing changes to the model, CMMI and CMS changed course on IORT and stated,

[1] 84 *Fed. Reg*. 34,502 (July 18, 2019).

. . . A commenter recommended excluding IORT since it is used so rarely. A commenter was concerned that the proposed payment structure will promote the use of short course, less costly forms of treatment such as IORT in cases where traditional external beam radiation would have been preferred.

Response: We thank these commenters for these suggestions. We agree with the commenter that it would be appropriate to exclude IORT from the RO Model because it is not a standard approach to treatment, and we believe that including IORT may incentivize misuse of this treatment . . .[2]

Given the Congressional delay in the program and the need to issue new regulations to accommodate the altered timeline and as you reconsider priorities and models, ***ASBrS respectfully requests that you reconsider the CMMI decision to exclude IORT and place IORT on the list of included modalities of the RO Model as originally proposed*** in order to ensure that the model achieves its initially stated goal of avoiding evaluation of a limited subset of services and rather assesses the radiation therapy course of treatment that best fits the needs of breast cancer patients, affecting outcomes that are of the most importance to patients, including sparing of skin and other non-cancerous tissue, potential for avoidance of post-operative radiation therapy (and the time and activity savings that accrues from that), and reduced financial liabilities.

We are concerned that by excluding IORT from the RO Model, the agency could be inadvertently marginalizing a therapy that has been proven to be cost-effective and a patient-driven choice in treatment for patients living with breast cancer. We do not wish to suggest that IORT does not provide value and benefit in cancer types outside of breast cancer, but breast cancer is the only cancer service line where the IORT is delivered in an outpatient setting and thus affected by exclusion of the therapy under the model. Inpatient claims are already excluded from RO model episode construction and attribution, thus for most cancer types IORT would already be outside of the model parameters. However, this is not the case in breast surgery where IORT is delivered in the outpatient setting. We focused on this as our area of expertise and the need that our members see in ensuring that Federal policies support rather than marginalize this valuable therapy. We believe that even if its inclusion only made sense in the area of breast cancer, it is imperative that the model support the full continuum of care for patients receiving a breast cancer diagnosis.

First, ASBrS believes that for appropriate cases, IORT in the treatment of breast cancer is the standard of care. We believe it is crucially important that no matter CMMI's decision that the Agency remove any question about whether this is the case as it did by suggesting that it was excluded because it is not the standard of care. We have attached the ASBrS *Consensus Guideline on Accelerated Partial Breast Irradiation*[3,4] for your review and to illustrate the industry consensus around the utilization of IORT. This is supported in the randomized TARGIT-A (targeted intraoperative radiotherapy-alone) trial, "a single dose of TARGIT-IORT given at the time of surgery could eliminate the need for whole-breast EBRT in

[2] 85 *Fed. Reg*. 61,174 (September 29, 2020).
[3] https://www.breastsurgeons.org/docs/statements/Consensus-Statement-for-Accelerated-Partial-Breast-Irradiation.pdf
[4] *See also,* Correa, C., et al, *Accelerated Partial Breast Irradiation: Executive summary for the update of an ASTRO Evidence-Based Consensus Statement,* Practical Radiation Oncology (2017) 7, 73-79.

over 80% of suitable patients."[5] And as such, a study from 2018 found that from 2009 and 2014 there was an 20-fold increase in the use of IORT as a percentage of accelerated partial breast irradiation (APBI) treatments.[6]

Second, we believe that the inclusion of IORT as a modality will offer patients a better array of options and provide the opportunity for model participant success under the model. As you well know, key to any alternative payment model (APM) are the quality measures to ensure that the payment mechanisms do not result in the stinting of care and focus on quality outcomes in addition to cost of care. As such, the RO model has planned for the incorporation of patient experience measures based on the *CAHPS® Cancer Care Survey*. While the date of incorporation into the program is yet to be finalized by the Agency given the delays in commencement of the model, we believe its use is critical to evaluating the model and ensuring that the model is patient-focused and not a "cost only" program. However, to evaluate patient experience with the *CAHPS® Cancer Care Survey* for breast cancer patients in the model while excluding consideration of IORT would fundamentally undermine the survey, the model evaluation, and the needs and choices of patients. It is precisely CMS/CMMI's original comment in the proposed rule that the full list of modalities was needed for inclusion in order to holistically evaluate radiation therapy, and we believe it is of the utmost importance that CMS finalize updated regulations that implement its original proposal.

Finally, we agree with the Agency statement in the proposed rule that inclusion of IORT will allow for a holistic evaluation of approaches to radiation therapy. We are extremely concerned that excluding only this modality will serve as an unintended barrier to accessing IORT, relegating it to form of radiation therapy that is treated separately from the full RT continuum of services. We are concerned that patient access to care will be undermined, thus decreasing patient quality of life, outcomes, and potentially increasing their financial liabilities. We are likewise concerned that its exclusion will undermine the goals and integrity of the model which will provide questionable results upon evaluation of the model.

If there is any additional information that we can provide, please do not hesitate to contact us by reaching out to Sharon Grutman, Manager of Advocacy, Communications, & Quality Initiatives at sgrutman@breastsurgeons.org. Again, we congratulate you on your new position and look forward to additional discussions on the RO Model as well as other opportunities to transition care from payment mechanisms based on volume to those that better meet patient needs by focusing on value.

Sincerely,

Julie Margenthaler, MD, FACS
President

Jill R Dietz MD

Jill Dietz, MD, FACS
Past President

CC: Amy Bassano, Deputy Director, CMMI

[5] Alvarado MD, Mohan AJ, Esserman LJ, *Cost-Effectiveness Analysis of Intraoperative Radiation Therapy for Early-Stage Breast Cancer*. Ann Surg Onc. 2013; 20(9):2873-80. DOI 10.1007/s10549-013-2782-9.
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THE AMERICAN SOCIETY OF Breast Surgeons - Official Statement -

Consensus Guideline on Accelerated Partial Breast Irradiation

Purpose

To outline the use of accelerated partial breast irradiation (APBI) for the treatment of breast cancer.

Associated ASBrS Guidelines or Quality Measures

1. Prior consensus statement: Accelerate partial breast irradiation

Methods

This is a comprehensive, but not systematic, review of the modern literature on this subject. The ASBrS Research Committee developed a consensus document, which the ASBrS Board of Directors reviewed and approved.

Summary of Data Reviewed

Background

The surgical and adjuvant radiation treatment of breast cancer has evolved dramatically over the past 50 years. In 1976, the National Surgical Adjuvant Breast and Bowel Project (NSABP) initiated the B-06 trial, which randomized patients with invasive breast cancers to receive modified radical mastectomy, lumpectomy, or lumpectomy plus whole breast irradiation (WBI). After 20 years of follow-up, published data from this study and other randomized trials have established that both mastectomy and breast-conserving surgery (BCS) with WBI are appropriate treatment options for Stage I and II breast cancer, with equivalent survival[1-7]. In 1990, the National Institutes of Health issued a consensus statement that supported the use of BCS and WBI as the preferred management for patients with invasive breast cancer[8]. This report was followed by widespread adoption of BCS with WBI. BCS without WBI is associated with a higher rate of recurrence[1, 9-11].

Despite the potential advantages of BCS, which involves less extensive surgical intervention than mastectomy, many eligible women opt to undergo mastectomy instead of BCS because of the long- and short-term side effects of WBI and the burden of treatment, which involves traveling to a radiation treatment facility for daily treatments for 3-6 weeks[12]. In addition, 20% of women who are treated with BCS never receive radiation as part of their treatment[13]. Multiple factors contribute to the lower-than-expected use of BCS and the associated underutilization of adjuvant radiation, including: specific tumor characteristics, cost, patient social and demographic factors, physician/patient bias, distance from the radiation facility,

and lack of social support[12-15]. Furthermore, WBI has other potential downsides, such as deleterious effects upon adjacent tissues including the heart, lung, contralateral breast, adjacent normal breast, and skin[16-18]. Recent data on the use of WBI administered from 1958 to 2001 have demonstrated that its use is associated with a dose-dependent increase in long-term incidence of ischemic heart disease[19]. Theoretically, a safer and more convenient approach to adjuvant radiation therapy could allow more patients to choose BCS, decrease the number of patients treated with BCS who never received adjuvant radiation, and reduce the complications associated with radiation therapy after BCS.

Accelerated Partial Breast Irradiation

Accelerated partial breast irradiation (APBI) has been studied as an alternative to whole breast radiation to make BCS a realistic and palatable option for more women. Numerous studies have shown that a majority of ipsilateral breast tumor recurrences (IBTR), after treatment with BCS and WBI, occur within the index quadrant[20-22]. The concept that irradiation of the immediate vicinity of the primary tumor is adequate to achieve local control of early-stage breast cancer was used to initiate numerous clinical trials involving APBI to show equivalence and non-inferiority of APBI[23-25]. To address long-term efficacy of APBI, the NSABP B-39/RTOG 0413 trial was initiated. This trial is closed, and long-term results are forthcoming. The use of APBI was included in the most recent National Comprehensive Cancer Center Network (NCCN) guidelines, which encourage patients to participate in APBI clinical trials[26].

APBI is delivered via multi-catheter interstitial brachytherapy, balloon-based applicators, external beam radiotherapy, or intraoperative radiation therapy (IORT). All of the APBI modes involve treating a limited and targeted volume of breast tissue in a much shorter course than traditional whole breast radiation. With more than 10 years of follow-up, multiple series have documented excellent clinical outcomes for patients treated with APBI, thus expanding the patient selection criteria. The American Society for Radiation Oncology (ASTRO), the ASBrS, and the American Brachytherapy Society (ABS) have all published consensus statements regarding “suitable” and “cautionary” and “unsuitable” patients for treatment with APBI[23, 27, 28]. ASTRO and ABS have recently updated their guidelines resulting in more open patient selection criteria[29, 30]. The table below lists ABS, ASTRO, and ASBrS guidelines and updates. From the patient perspective, the tangible benefits of APBI may be found primarily in improved access to radiation treatment, less travel[31], reduced out-of-pocket costs, increased patient satisfaction, decreased radiation therapy exposure to normal tissues, and potentially improved cosmetic outcomes[32-34].

Criterion	ABS Updates	ASTRO update	ASBrS Updates
Age	≥45 years	≥50 years 40-49 years if all other criteria met	≥45 years for all tumor types
Histology	All invasive subtypes and DCIS	All invasive subtypes Pure DCIS	All invasive subtypes DCIS
Tumor Size	≤3cm	≤3cm	≤3cm
T Stage	Tis, T1, T2	Tis, T1, T2	Tis, T1, T2 (≤ 3cm)
Margins	No tumor on ink for invasive, ≥2mm for DCIS	Close margins ok	No tumor on ink for invasive tumors or tumors involved with DCIS ≥2mm for DCIS
Nodal status	Negative	Negative	Negative
Other factors	Unifocal only No LVI ER+ or ER-	Limited LVI ER+ or ER- EIC ≤3 cm	Multifocal ok if total span of tumors is ≤3cm ER+ or ER- Focal LVI No genetic mutations

Recommendations

Recommendations are limited by the data available at the time this document was written. At this time, the long-term results from the NSABP B-39 study are not published.

Patients should be carefully selected for APBI and properly informed of the current benefits and risks when considering APBI, WBI, and no radiation. There are several APBI options that exist. There are risks and benefits to each of these approaches concerning effectiveness, side effect profile, patient access, and patient preference. These relevant techniques include:

1. External beam radiation therapy (EBRT) with 3-D conformal radiation, intensity modulated radiation therapy (IMRT) or protons

2. Brachytherapy with intercavitary or interstitial techniques

3. IORT

The American Society of Breast Surgeons recommends the following selection criteria when considering patients for treatment with APBI:

Age: Minimum of 45 years

1. **Histology**: All invasive subtypes
   Ductal carcinoma in situ (DCIS)

2. **Total tumor size (invasive and DCIS):** less than or equal to 3 cm in size

3. **T Size:** Tis, T1, T2 ($\leq 3\ cm$)

4. **Margins:** No tumor on ink for invasive tumors and invasive tumors with associated DCIS
   ≥ 2mm for DCIS
   Note for patients treated with IORT with unknown margins status: If margins are found to be positive after IORT treatment, patient should be recommended to undergo re-excision. If re-excision margin is acceptable, WBI should be considered and discussed with multidisciplinary tram and the patient. If WBI is administered after IORT, the IORT dose can be substituted for the boost dose.

5. **Nodal Status:** Negative
   Note for patients treated with IORT and subsequently found to have a positive SLN: WBI should be considered. If WBI is administered, the IORT dose can be substituted for the boost dose.

6. **Other Factors:** Multifocal disease is allowed as long as the combined area of tumor is ≤3cm
   Tumor may be estrogen receptor positive or estrogen receptor negative
   Lymphovascular invasion is allowed as long as it is focal
   Patients should not be treated with APBI if they have a BRCA genetic mutation or other genetic mutation that confers an increased risk of breast cancer
   There is no evidence to support use of APBI in male patients
   Patients with a history of ipsilateral breast cancer treated with radiation should only be treated with APBI as part of specific clinical trial
   No contraindication to APBI in patients with history of contralateral breast cancer

7. Patient selection and counseling should be performed in a multidisciplinary fashion with collaboration between the treating surgeon and the treating radiation oncologist

8. It is preferred that all patients treated are part of a clinical trial or registry. All patients should be monitored regularly to identify adverse events as well as local recurrences.

9. The published data for APBI supports the recommendations summarized above. Continuous, long-term, outcomes-based monitoring of APBI is desirable. The American Society of Breast Surgeons maintains an ongoing MammosSite® Registry (registration completed in 2004), collecting data on 1440 patients treated via the MammosSite® balloon catheter technique.

10. These recommendations are intended as a guide to treat patients. Individual treatment decisions could allow treatment outside of the parameters listed above with appropriate discussion with the patient.

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This statement was developed and revised by the Society's Research Committee and on June 5, 2018, was approved by the Board of Directors.