Physician Letterhead

[Date]

[Contact Person]

[Title]

[Insurance Company]

[Address]

[City, State, Zip]

Re: [Patient Identification Number]

[Patient Name]

[Date of Service]

Dear [Contact Person]:

I am writing to appeal the denial for the [prior authorization/claim] of intraoperative radiation therapy (IORT) using an x-ray source for [Patient name].

## Background

The use of IORT in women treated with partial mastectomy has been shown to significantly reduce in-breast cancer recurrence.[[1]](#footnote-1) Conventional radiation therapy following partial mastectomy has classically consisted of external beam whole breast radiation therapy (WBRT), usually taking approximately 6 ½ weeks with treatment 5 days a week.[[2]](#footnote-2) IORT, by contrast, is completed at the time of lumpectomy in the operatory suite. Once the tumor has been removed, the site is prepped, and a dose of radiation is delivered directly to the tumor bed. The dose delivered is equivalent to a full course of external beam radiation therapy or accelerated partial breast irradiation thereby eliminated the need for the patient to return for follow-up radiation therapy is eliminated.

IORT has been used for over 30 years in treating various malignancies.[[3]](#footnote-3),[[4]](#footnote-4),[[5]](#footnote-5) It was initially provided in radiation treatment facilities in specially shielded operating rooms.[[6]](#footnote-6) An alternative treatment protocol would have the patient would be moved from a traditional operative suite, while under anesthesia, to a radiation treatment room, and then back again. Since the late 1990’s, it has been offered to patients in centers equipped with mobile units that can be used in standard operating suites.

The technology being used for my patient is the Intrabeam® IORT device which was cleared for use by the FDA in 1997. It is a portable, lightweight radiation source that produces 50 kV x-rays. The x-rays are created by accelerating electrons and directing them down a needle-like probe that serves as a drift tube. The probe is inserted into the surgical cavity and the radiation is administered through the probe with the intent of killing any residual tumor cells at the surgical margin.

## Clinical Efficacy of IORT

IORT is an important treatment option for women diagnosed with early-stage breast cancer. Clinical documentation supports that IORT has been proven equally effective to standard radiation therapy. The advantages over standard radiation therapy include greatly reduced overall radiation treatment course; the ability to complete surgery and radiation therapy at the same time; side effects that are confined to only one part of the breast, minimized skin side effects; and minimized radiation dose to the lung and heart.

The definitive study demonstrating the safety and efficacy of IORT for the treatment of early-stage breast cancer is the TARGIT-A trial, a large prospective, randomized Phase III trial comparing partial breast IORT to conventional whole breast radiation. The study was initiated in March 2000 and there have been numerous articles detailing the results. The most recent long-term update was published in the British Medical Journal on 8/19/2020.[[7]](#footnote-7) There is no other study of this magnitude demonstrating the long-term safety and efficacy of any Accelerated Partial Breast Irradiation treatment modality compared to traditional beam therapy:

* 2,298 enrolled patients
* 32 centers
* 10 countries
* Long term follow-up: median 8.6 years, maximum 18.9 years, interquartile range 7.0-10.6.

The key findings of the TARGIT-A study include:

* No statistically significant difference was found between immediate TARGIT-IORT and EBRT for the following outcomes:
* Local recurrence-free survival;
* Invasive local recurrence-free survival
* Mastectomy-free survival
* Distant disease-free survival
* Overall survival; and
* Breast cancer mortality
* Mortality from other causes (e.g., cardiovascular) was lower in the TARGIT-IORT arm.
* Single dose TARGIT-IORT during lumpectomy should be accessible to healthcare providers and discussed with patients when surgery for breast cancer is being planned.

In addition, the 2014 publication of the TARGIT-A trial published in *The Lancet* reported significantly reduced grade 3 or 4 skin complications with TARGIT.[[8]](#footnote-8)

IORT also allows patients to return to their normal life far more quickly and, during this unique pandemic period, safely. Many patients with cancer opt out of receiving radiation therapy due to time, distance or difficulty accessing radiation therapy centers. In addition, because of the difficulty many beneficiaries have getting to all their radiation therapy sessions, incomplete courses of radiation therapy occur putting those beneficiaries at increased risk of recurrence. This sub-optimal treatment outcome is obvious; but it can also result in additional costs to the health care system. IORT is uniquely positioned to address these challenges and fits extremely well into a model that is focused on clinically appropriate health care cost savings.

## Accepted as a Standard Approach to Treatment

Since January 2012, Category I CPT codes describing treatment delivery and management of IORT became effective based upon a request submitted by The American Society of Therapeutic Radiation Oncology (ASTRO). Two fundamental criteria that a service or procedure must meet to quality for a Category I CPT code are substantial support of its clinical efficacy in the peer-reviewed literature; and widespread use among providers. In 2017, ASTRO updated their guidelines for accelerated partial breast irradiation (APBI) to support the use of IORT using either electron beam or low-energy x-rays (Intrabeam device, TARGIT) for early-stage breast cancer (Accelerated Partial Breast Irradiation: Executive Summary for the Update of an ASTRO Evidence Based Consensus Statement). In addition, the Consensus Statement for APBI from the American Society of Breast Surgeons (ASBS) and the American Brachytherapy Society (ABS) include IORT as a modality to be considered with patients with early-stage breast cancer.[[9]](#footnote-9),[[10]](#footnote-10),[[11]](#footnote-11) The results of the TARGIT-A trial, established coding, and support from the professional societies have all contributed to a rise in the use of IORT. Between 2009 and 2014 alone, there was a 20-fold increase in the use of IORT.[[12]](#footnote-12)

Clearly, IORT has been demonstrated to be a valid option for treatment of breast cancer and a standard approach to treatment.

[Physician should include some specifics about this particular patient and why IORT is the best/only treatment option for them compared to other treatment modalities as well as how they meet the criteria outlined by ASTRO, ASBS, and ABS – Medical records should be included]

We request an appeal of this [prior authorization/claim] based upon the patient’s medical necessity. If you have any questions or need any additional information about this procedure or request, please contact me.

Sincerely,

Facility Name/address:

Phone:

Fax:

Email:

1. Fisher B, Anderson S, Redmond CK, Wolmark N, Wickerham DL, Cronin WM. Reanalysis and results after 12 years of follow-up in a randomized clinical trial comparing total mastectomy with lumpectomy with or without irradiation in the treatment of breast cancer. N Engl J Med. 1995 Nov 30;333(22):1456-61. [↑](#footnote-ref-1)
2. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology, Invasive Breast Cancer, Principles of Radiation Therapy. Version 2.2013. www.nccn.org [↑](#footnote-ref-2)
3. Calvo FA, Meirino RM, Orecchia R. Intraoperative radiation therapy part 2. Clinical results. Crit Rev Oncol Hematol 2006;59:116-27. [↑](#footnote-ref-3)
4. Vaidya JS, Baum M, Tobias JS, et al *Targ*eted *i*ntraoperative radio*t*herapy (*Targit*): An innovative method of treatment for early breast cancer. Ann Oncol 2001;12:1075-80. [↑](#footnote-ref-4)
5. Reitsamer R, Peintinger F, Kopp M, et al. Local recurrence rates in breast cancer patients treated with intraoperative electron-boost radiotherapy versus postoperative electron-boost irradiation. A sequential interventional study. Strahlenther Onkol 2004;180:38-44. [↑](#footnote-ref-5)
6. Goer DA, Musslewhite CW, Jablous DM. Potential of mobile intraoperative radiotherapy technology. Surg Oncol Clin N Am 2003;12:943-54. [↑](#footnote-ref-6)
7. Vaidya, J, Bulsara M, Maum M, et al, Long term survival and local control outcomes from single dose targeted intraoperative radiotherapy during lumpectomy (TARGIT-IORT) for early breast cancer: TARGIT-A randomized clinical trial. BMJ2020;370:m2836; http://dx.doi.org/10.1136 bmj.m2836 [↑](#footnote-ref-7)
8. [Vaidya, J, Wenz F, Bulsara M et al, Risk-adapted targeted intraoperative radiotherapy versus whole-breast radiotherapy for breast cancer:5-year results for local control and overall survival from the TARGIT-A randomised trial. The Lancet; 2014; 383: 603-](https://www.thelancet.com/action/showPdf?pii=S0140-6736%2813%2961950-9)613 [↑](#footnote-ref-8)
9. [Correa C, Harris E, Leonardi M, 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.](https://www.practicalradonc.org/article/S1879-8500(16)30184-9/fulltext) [↑](#footnote-ref-9)
10. [ASBS Consensus Guideline of Accelerated Partial Breast Irradiation, 2018](https://www.breastsurgeons.org/docs/statements/Consensus-Statement-for-Accelerated-Partial-Breast-Irradiation.pdf). [↑](#footnote-ref-10)
11. [Shah, C, Vicini F, Shaitelman S, The American Brachytherapy Society consensus statement for accelerated partial-breast irradiation. *Brachytherapy*, 2017; . https://doi.org/10.1016/j.brachy.2017.09.004.](https://www.americanbrachytherapy.org/ABS/document-server/?cfp=ABS/assets/file/public/consensus-statements/Guidelines_Accelerated_Partial_Breast_Irradiation.pdf) [↑](#footnote-ref-11)
12. [Morrison C, Gonzalez VJ, Hsu CC, Intraoperative Radiation Therapy (IORT) As Sole Adjuvant RT Modality for Breast Cancer: Patterns of Care in the United States and Utilization after Publication of Guidelines and Randomized Trials. Int J Rad Onc Biol Phys ,](https://www.redjournal.org/article/S0360-3016(18)33110-9/fulltext) [↑](#footnote-ref-12)