Insurance Coverage of INTRABEAM® Procedures

Cracking the Mystery of Cancer-related Reimbursement

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Cracking the Mystery of Cancer-related Reimbursement

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Oncology Analytics Corp.

What We Do...Cancer Care Decision Support Through a Rigorous and Data Based Pre-Approval Process

Why We Do This

Mission:

- Assure each cancer patient receives the highest quality & value cancer care possible

  "The right care at the right cost for the right reasons"

Vision:

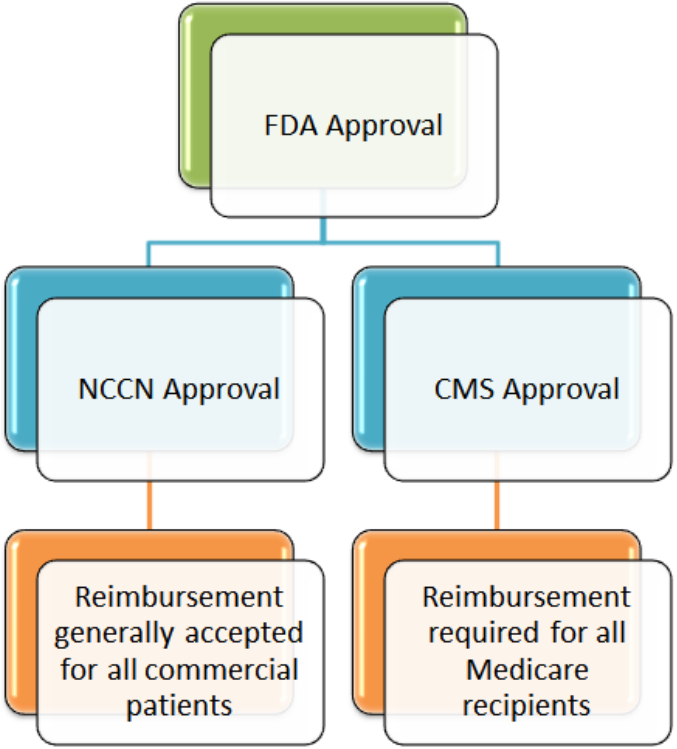
- To be recognized nationally as the source of the most accurate, useful, and reliable source for non-conflicted cancer care management guidance

Who decides which cancer treatments should be reimbursed among the 325 million Americans?

Complex -- NO ONE? Everyone? No *NICE*

- FDA approves based upon efficacy and safety. No value consideration.
- CMS decides which services, products, and devices will be reimbursed for the 50 million Medicare recipients.
- NCCN compendium guidelines, along with individual insurance carriers, largely determine whether reimbursement occurs among the millions of commercial members for cancer care.

Insurance Reimbursement Policy for Cancer Care



Insurance reimbursement policy for cancer care is heavily influenced by:

1. CMS Medicare policy / federal regulations

1. NCCN compendium policy

1. State regulations, guidelines, and local coverage determinations (LCD)

How may these be influenced?

NCCN: Nature and Quality

- NCCN is a self-appointed group of for-profit academic cancer centers, each of which survive economically based upon reimbursement for cancer care.
- NCCN decision-making committee members and chairs are practicing cancer doctors whose salaries depend upon reimbursement.
- NCCN disease-specific chairs and members virtually all participate in commercial clinical trials.
- Most NCCN chairs and committee members speak for and are paid by various and many pharmaceutical companies who sponsor these trials.
- Some NCCN committee members and chairs hold patents for therapies being considered by NCCN for reimbursement recommendations.

OA Guidance

- OA takes no funds from drug or medical device companies.
- No OA employee consults for any pharmaceutical or device firm.
- OA does not accept shared savings in payment for services rendered, freeing decision support from payment for direct savings.
- OA value in savings for choosing highest value therapies exceeds two-fold the cost of OA services.
- OA guidance is updated daily in real-time.
- OA advice is provided to cancer doctors collegially, accompanied by all relevant data.
- All conflicts of interest are avoided.

OA Assistance in Creating High-value Networks

- OA assesses individual cancer doctor/practice value and helps payers build and maintain high-value cancer networks.
- OA provides incentives and assists providers in getting clear, certain and quick pre-approvals for therapies of the highest value.
- When lower value therapies are requested, OA provides complete data, discusses alternatives, and arrives collegially at a mutually acceptable consensus decision.
- All OA medical directors are board-certified in the specialty for which they are interacting with providers.
- All clinical consultations are deep and subtle, and of benefit to the treating physician and patient.

Dirty Little Secrets

- FDA approval studies are frequently flawed or gamed by sponsors
- OA analyzes and points out these games and flaws to payers, providers, CMS and NCCN.
- Many NCCN approvals are given without data, poor quality or incomplete data, or without consideration for superior and/or new data.
- OA makes these data available to providers, payers, NCCN, and CMS.

NCCN Accepts Petitions to Alter Compendium Guidance

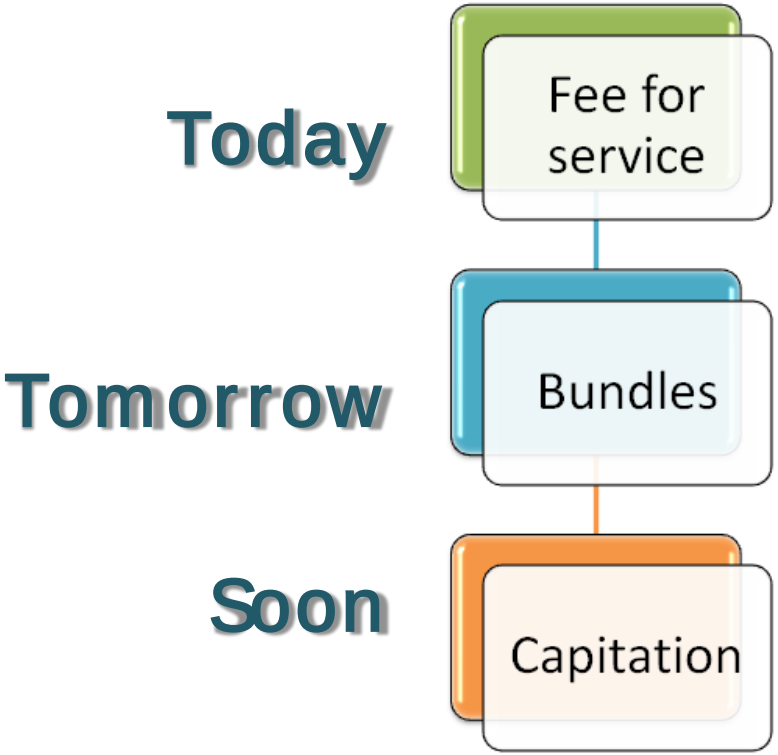
- >200 petitions have been filed
- >193 have originated from drug companies asking for approval of reimbursement for their therapies.
- 1 arose from an academic center
- 6 were submitted by OA; 4 of which successfully altered NCCN recommendations.

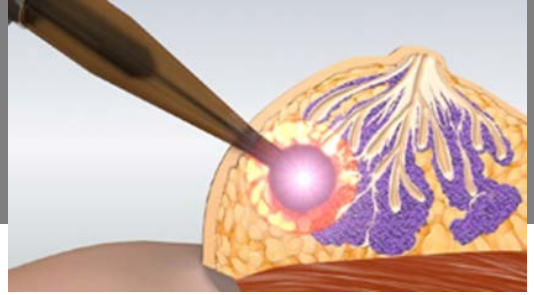
There is hope!

Strategies to enhance the success of reimbursement for high value therapies

- State-based campaigns to demonstrate value to LCD committees.
- Papers which appear in one of the 26 key cancer journals listed by CMS supporting high value cancer therapies.
- NCCN petitions to make high value therapies (recommended).
- Working with OA to recommend high-value therapies as “preferred” choices.

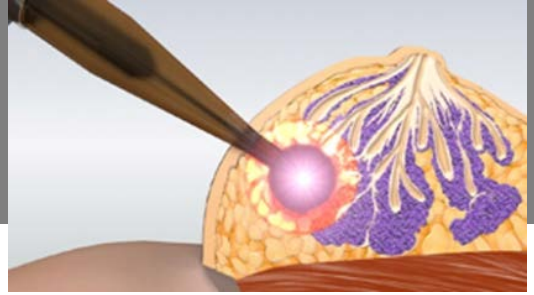
The Future As I See It





IORT in Breast Cancer

- IORT is an OA preferred modality for early stage breast cancer
- Medicare Reimbursement
  - CMS National Policy has approved for IORT for Medicare recipients
    - Multiple states have LCDs for IMRT, SRS, and/or SBRT
    - Without an LCD, less hoops for coverage criteria
    - Although if frequent denials, IORT LCD can be developed
- Commercial Reimbursement
  - Private payers can take different positions on IORT
    - RT type for commercial patients may be dictated by payer
    - OA provides advice on national payer policies



IORT in Breast Cancer

- OA Is recognized as a trusted non-conflicted Source of Data based Cancer Care Guidance.
- OA recognizes the equal efficacy and high VALUE of IORT compared to standard post resection Breast Cancer whole breast XRT.
- The cost of WBXRT is some TEN fold greater for standard therapy than IORT.
- 30 to 35 week day treatments require many weeks and disrupt the lives of women undergoing external WBXRT for months .
- IORT is done concurrent with local resection immediately following that resection adding virtually no additional disruption of these women's lives.

How Oncology Analytics Might Help

- OA prepares white papers summarizing relevant world literature.
- OA publishes these findings in the peer review literature among the 26 CMS approved journals.
- OA supports the approval of high value therapies providing medical directors with convincing evidence.
- OA Radiation Therapy pre-approval process list high value therapeutics including IORT as a preferred choice.
- OA petitions NCCN for appropriate compendium changes.
- OA petitions CMS for appropriate policy changes.
- OA petitions LCD committees for appropriate changes.

Will Medical Directors listen and respond to new clinical evidence?

In general, Medical Directors follow CMS, guidelines, as well as compendia. Medical Directors modulate their decision making according to qualifying medical literature as new evidence becomes available within one of the 26 key CMS approved journals.

This literature must be compiled and presented to them in compelling format demonstrating efficacy, safety and hopefully enhanced value.

How often are LCDs reviewed?

- LCDs for CMS are reviewed at least annually.
- LCDs by state are also periodically reviewed.
- Oncology Analytics reviews relevant data continuously and modulates its recommendations based upon new findings in real time.

How do Medical Directors Generally Handle Appeals?

- They submit the relevant evidence and appeal to an independent expert review board (usually by state) for final adjudication.

- Ultimate results depend upon the completeness and persuasiveness of the submitted documentation.

- Oncology Analytics recommends denial of less than 2% of requested therapies after presenting the requestor with compelling evidence for a better alternative choice.

- OA decisions are upheld in excess of 99% of the time.

LCD Process

1. Comment period (minimum 45 days - public may add comments on the LCD)

2. Comment Review Period, with Development of Responses. (Contractor medical directors review all comments, develop responses, updated LCD)

3. Notice Period (LCD posted to CMS website but not active yet. Providers have 45 days from posting to implement billing changes and educate staff before LCD implementation)

4. Active Period (LCD is in Effect)

Ask Me About...

- OA's new, comprehensive, three-tiered Radiation Oncology Guidance Product
- IORT is a preferred modality for early-stage breast cancer
- Other innovations fostering value, diminishing waste, and eliminating fraud and abuse are key to this product suite.

Contact Info

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