

*Institute for Clinical and Economic Review
Scoping Committee and Evidence Review Group for:*

*Brachytherapy/Proton Beam Therapy for Clinically Localized, Low-Risk
Prostate Cancer*

Conference Call Agenda

*Wednesday, January 30, 2008
3-4 pm EDT*

3:00-3:05	Introductions
3:05-3:10	ICER Background and Appraisal Process
3:10-3:50	Discussion of Key Questions
3:50-4:00	Closure and Next Steps

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Thank you for agreeing to participate on the Scoping Committee for this appraisal. In 2007, the Institute for Clinical & Economic Review (ICER) completed an appraisal of the clinical effectiveness and comparative value of intensity-modulated radiation therapy (IMRT) vs. three-dimensional conformal radiation therapy (3D-CRT) in patients with clinically-localized prostate cancer. We are now evaluating two other important alternative approaches to radiation therapy for prostate cancer: brachytherapy and proton beam therapy. Each of these approaches will be evaluated fully and comparisons of harms, benefits, and cost-effectiveness will be made with 3D-CRT.

The role of the Scoping Committee is to provide guidance to ICER staff on the key questions and issues that we must address in our examination of the comparative clinical effectiveness and value of these therapies, such as: comparator(s) of interest; key patient outcomes and the measures used to capture them; critical measures of cost and system impact; considerations regarding the quality and sources of available evidence; and key patient subpopulations of interest. Today's call is intended to initiate the discussion of these issues; our approach to this assessment will be refined and finalized through subsequent discussion and interaction in the coming months.

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Key Questions for Scoping Committee:

1. What are the most important questions about the clinical effectiveness of brachytherapy and proton beam therapy whose answers drive or will drive the use of these interventions?
2. We plan to focus on early-stage, localized, low-risk disease for our assessment, given the large and increasing prevalence of this population in the era of widespread PSA screening. As such, we expect our assessment to be limited to the following:
 - a. permanent, low-dose-rate brachytherapy only, with general anesthesia and intra-operative planning, and use of either radioactive iodine or palladium
 - b. proton beam therapy alone to doses of 75-80 Gy, in daily fractions of 1.8-1.9 Gy each, using a standard passive beam and rotating gantry

Are there other variants of these approaches you would recommend that we consider?

3. To provide a common reference point, we are planning to compare brachytherapy and proton beam specifically to outcomes among low-risk of 3D-CRT delivered at 75-79 Gy. Is this a reasonable comparator?
4. Are there particular patient sub-groups we should evaluate separately in the assessment (e.g., stratification by age)?
5. Patient input during our IMRT appraisal led us to focus on cancer-free survival and overall mortality as the primary clinical outcomes, along with consideration of “long-term” side effects of moderate to high severity (urinary, sexual, and bowel). For brachytherapy and proton beam are there additional outcomes of high importance to our review and modeling?
6. What are the most important issues about the existing published data that our appraisal should take into consideration? Are there additional sources of data that should be included in our review?
7. Should the economic model assume that patients who are not cured by initial therapy receive the same type of salvage therapy, regardless of initial treatment type?
8. Should we include in our review consideration of hypothesized rates of secondary malignancy associated with initial treatments?

9. Are there any key considerations to the costs that should or should not be included for these interventions? For example, current Medicare reimbursement rates for proton therapy range from \$50,000-\$60,000 per course, depending on complexity and number of treatments. Does this accurately reflect the price being paid by insurers for PBT?
10. What, if any, are the key costs from a societal perspective that we should consider including in our modeling? For example, should we try to consider patient time in treatment, effects on productivity, or impact on care givers?

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Scoping Meeting Participants:

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Bill Corwin, MD, Harvard Pilgrim Health Care

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Wendy Everett, ScD, New England Healthcare Institute

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