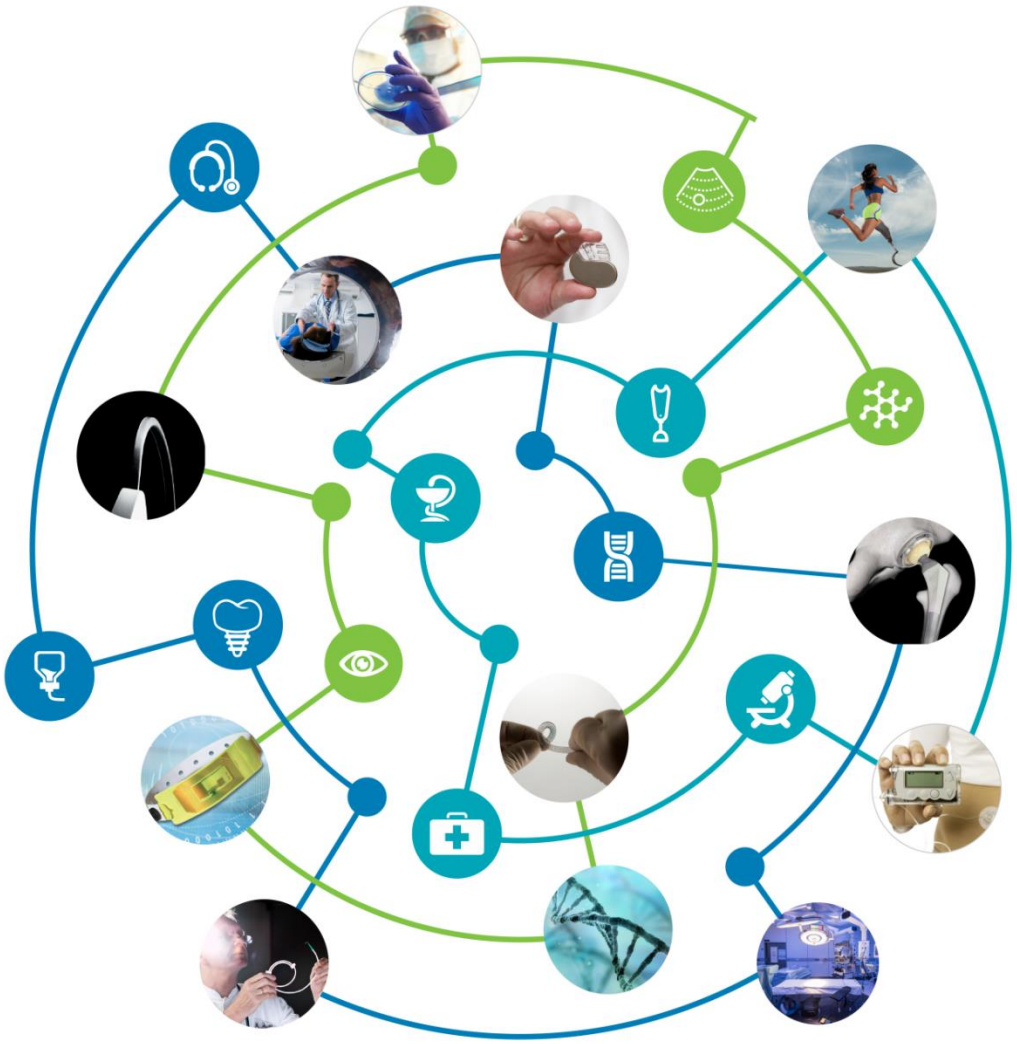
AdvaMed Medtech Value Assessment Framework *in Practice*



Application of the Medtech Value Assessment Framework to Stereotactic Body Radiation Therapy for Non-Small Cell Lung Cancer

AdvaMed
Advanced Medical Technology Association

Value Framework Overview

In response to the growing need to demonstrate how medical technologies fit into the emerging value-based paradigm for providers, payers, and patients, AdvaMed launched a Strategic Value Initiative to develop an approach to value assessment for medical technologies that can be used by Medical technology companies as well as by health systems, payers, and other stakeholders.[1]

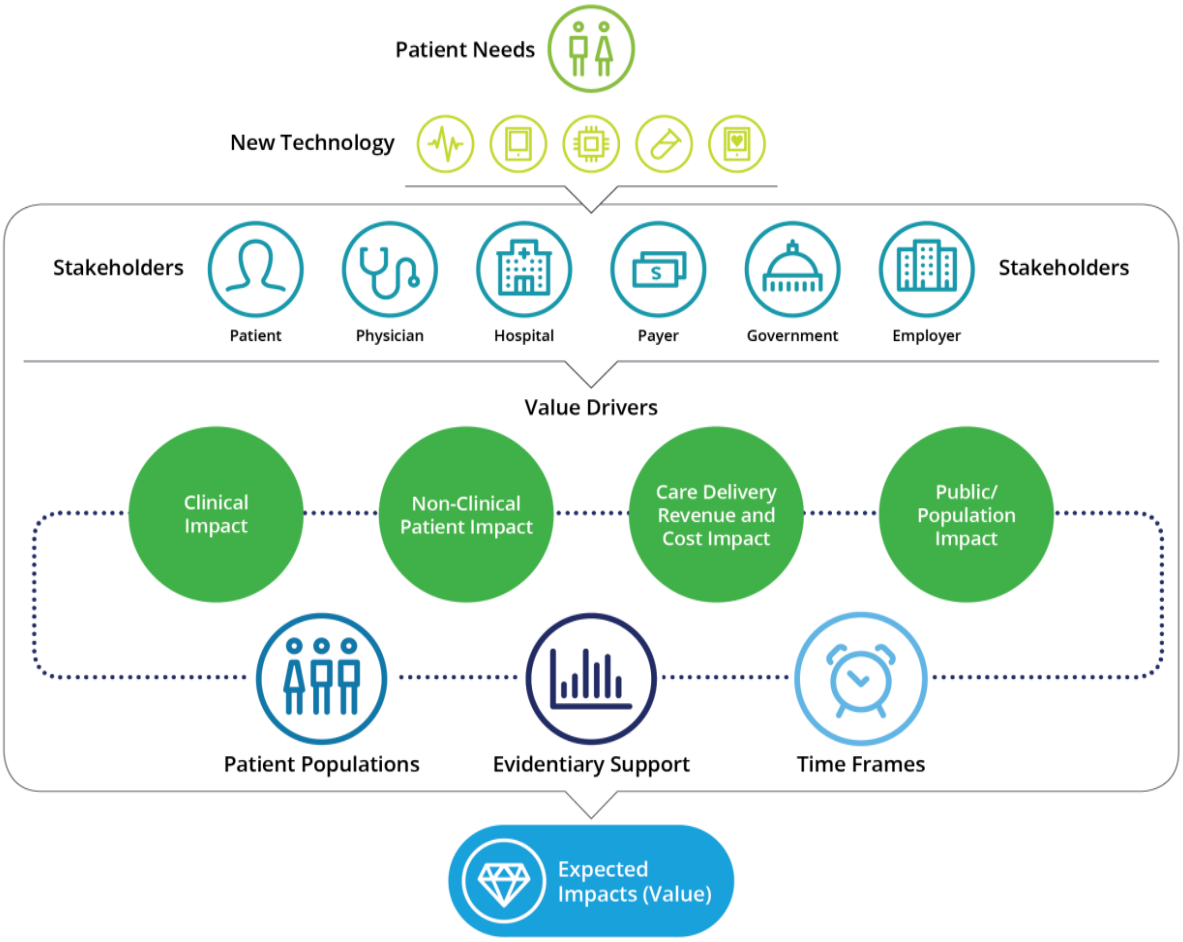
AdvaMed's Value Assessment approach goes beyond traditional HEOR and clinical efficacy metrics to assess the value that medical technologies may contribute to improving patient care and experience, economic outcomes, and the overall health of populations. This approach uses four broad categories, or "value drivers," to describe the value of medical technologies: clinical impact, non-clinical patient impact, care delivery revenue and cost impact, and public/population impact relevant to an array of stakeholders who may evaluate and measure value differently.

The AdvaMed Value Assessment approach can be used to guide the development of a value proposition that successfully communicates the full breadth of expected impacts offered by medical technologies while taking into account the demands of the changing health care ecosystem. The collection of information associated with the value drivers reflects quantitative and qualitative metrics of value, gives appropriate weight to patient experience and societal impacts, and also accounts for the consideration of evidence collected through a variety of methods. An illustration higlighting the value drivers and components of AdvaMed's apporach is on the following page.

In order to demonstrate the application of this framework across different types of technologies, AdvaMed has partnered with member companies to develop use cases. These use cases address the clinical need for the technology, alternative and existing technologies on the market, the expected impacts of the technology, and the evidence to support such a value assessment.

Radiation Therapy

This use case demonstrates the value of Stereotactic Radiation Body Therapy (SBRT) technologies developed by members of AdvaMed's Radiation Therapy Sector across all of the identified value drivers and for a range of stakeholders. This use case examines SBRT as a viable alternative for the treatment of patients with non-small cell lung cancer.



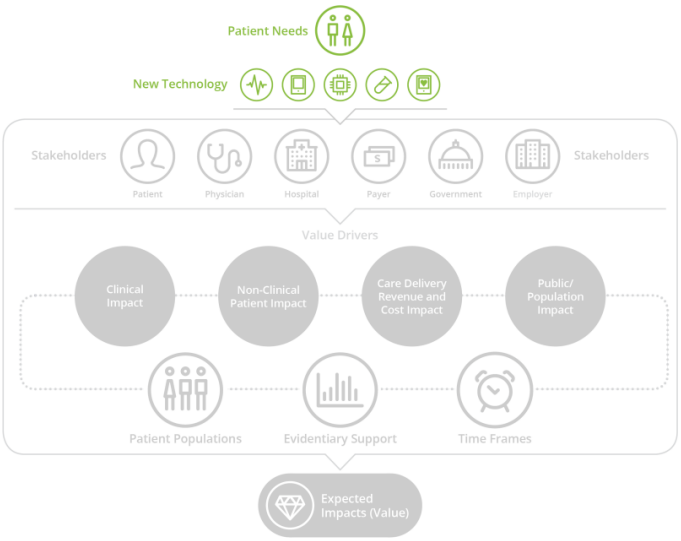
Source: "A Framework for Comprehensive Assessment of Medical Technologies: Defining Value in the New Health Care Ecosystem", co-developed with Deloitte Consulting LLP

SBRT

Medical technology developers with a new product concept in development should start early, not only to address the FDA requirements, but also the value proposition that the technology conveys to patients, providers, and the health care system.

Stereotactic Body Radiation Therapy (SBRT) used in treating Non-Small Cell Lung Cancer demonstrates value across all of the drivers. It also serves as an example of the appropriate application of the AdvaMed value assessment approach in establishing value for a range of stakeholders.

SBRT is an FDA-cleared treatment that is approved for use in patients with marginally and non-operable non-small cell lung cancer. Use of this treatment modality in this patient population improves outcomes and reduces unnecessary treatment and costs.



Unmet Need

AdvaMed's assessment process begins with understanding and addressing the unmet need and value imparted through the new technology.

Unmet patient need can be framed in terms of clinical efficacy, safety, patient preferences, costs, quality of care, ease of use, etc.

Lung cancer is the second most common cancer and the leading cause of cancer death in both men and women. The American Cancer Society expects there to be approximately 222,500 new cases and 155,870 deaths from lung cancer in 2017.[2]

Lung cancer is divided into two main categories – non-small cell lung cancer (NSCLC) and small cell lung cancer (SCLC). NSCLC accounts for approximately 85% of lung cancers and has significantly different treatment regimens and prognoses than SCLC.[3] NSCLC is divided into five stages with SBRT typically being used in the treatment of cancer in stages I or II.

About 40% of individuals with early stage NSCLC (stage I or II) have a form that is not easily operable or is in-operable. For these patients SBRT presents an alternative to more toxic and costly conventional radiotherapy and drug based treatments.

Patient Populations

Assessments should consider the extent to which the populations where the technology is most effective aligns with the population focus for the stakeholder evaluating the technology.

This section demonstrates the value of the technology to patients through addressing the need for the technology in the context of the affected patient sub-population and the available alternatives to treat their condition.

SBRT, when used in the treatment of Stage I and II NSCLC patients, allows the delivery of measured doses of radiation to targeted areas of the lung where the tumor is located. This targeted method of treatment reduces toxicity and damage to surrounding tissue and structures. Treatment using SBRT also improves survival rates.[4]

Timeframes

The assessment should identify patient populations and time frames that are important in understanding the value of the technology.

NSCLC can be divided into several stages that describe how far the cancer has spread. Five year survival rates are generally better for those in the earlier stages of lung cancer: [5] [6]

- **Stage 0:** In this stage, the cancer is limited to the top layers of cells lining the air passages.
- **Stage I:** In this stage, the tumor is no larger than 5cm in diameter, and has not spread to lymph nodes or distant sites. The five year survival rate for those diagnosed in Stage I is 45-49%.
- **Stage II:** The cancer has spread to the lymph nodes within the lung and/or the hilar lymph nodes but has not spread to distant sites. In this stage, the five year survival rate is 30%.
- **Stage III:** In stage III, the cancer can be described as locally advanced. Cancer has spread to the lymph nodes in the middle of the chest and may spread to the lymph nodes on the opposite side of the chest from the tumor. For those diagnosed in Stage III, the five year survival rate is 5-14%.
- **Stage IV:** At this point, the cancer is advanced and has spread to both lungs and possibly to other parts of the body. At this stage, NSCLC is very hard to treat. When metastatic, the five year survival rate for Stage IV NSCLC is 1%.

Once the cancer is identified, it is critical to identify and begin the most appropriate treatment for the individual as soon as possible to prevent the cancer from progressing to later stage disease.

Stakeholders

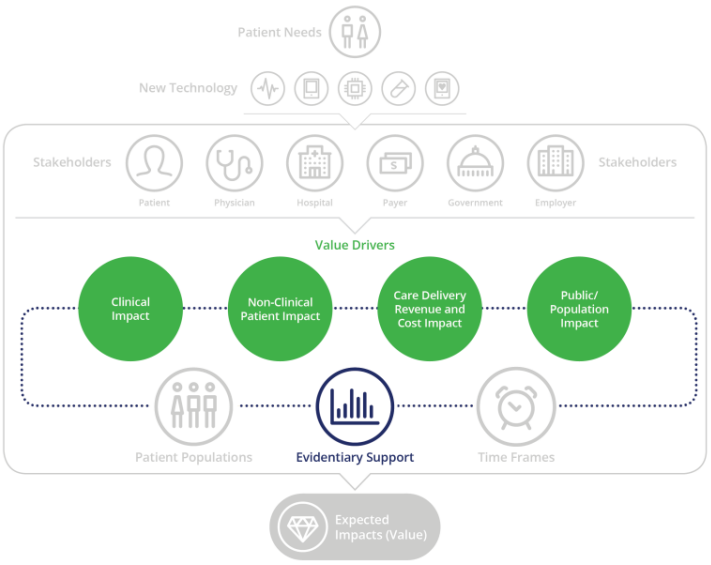
The intended audience for a value assessment affects the framing of the assessment and the drivers and metrics that could be highlighted.

Both the intended audience/stakeholders and the purpose of the assessment should dictate which types of value are considered and emphasized via the assessment process, as well as the types and quality of evidence needed to support that this early assessment can help determine evidence development needs and point to the appropriate strategies for collecting annual performance information.

The chart on the following page highlights potential value for various stakeholders based on use of SBRT in treating marginally and non-operable NSCLC:

SBRT for NSCLC Value Drivers Impact by Stakeholder

	Clinical Impact	Non-Clinical Impact	Care Delivery Revenue and Cost Impact	Public/Population Impact
Patient	• Reduced toxicity • Improved survival • Shorter rehabilitation and recovery times • Inoperable patients can be treated • Treatment option for elderly patients age 80 and older	• Ability to resume activities of daily living quicker • Less fatigue • Reduced toxicity • Easier recovery • Less anxiety provoking • Fewer side effects	• Lower cost • Shorter treatment duration than other treatment options	• Superior patient experience than lung surgery patients • More convenient, less time away from work • Less strain on caregiver • Higher quality of life compared to conventional RT
Physician	• More targeted delivery of radiation • Improved outcomes • Spend less time immobilizing patient • Shorter treatment duration than other treatment options • Minimizes exposure to healthy tissues	• Better patient outcomes • Viable treatment for inoperable patients	• Reduced post-procedure physician visits.	• Improved overall survival rates
Hospital	• Manage most at-risk patients effectively, reducing adverse outcomes	• Fewer toxicity related treatments • Shorter treatment times, faster turnaround of patients	• Lowers treatment costs • Fewer sessions • Reduced treatment cost for toxicity related issues • Reduction in unnecessary admissions • More efficient resource/staff time use	• Improved survival rates • Lowers overall treatment costs • Increases overall survival rates
Payer	• Manage most at-risk patients effectively, reducing adverse outcomes	• Payer can offer a highly effective treatment to patients	• Lowers treatment costs • Reduced treatments due to side effects and toxicity • Fewer sessions	• Lowers overall healthcare costs • Increases overall survival rates • Higher quality of life compared to traditional RT



Evidence Across the Value Drivers

Medical technology innovators must determine the best way to show value with evidence.

It is critical to identify and evaluate the quantity and quality of available types of evidence for the technology early in product development to determine how each can be used across the relevant drivers to offer robust evidentiary support.

The evidence on the use of SBRT in the treatment of NSCLC patients focuses on the treatment's ability to target and administer an exact dose of radiation therapy negating some of the negative side effects associated with other treatments. Manufacturers and users of these technologies have conducted multiple clinical studies to support the use of this treatment in patients with marginally and non-operable Stage I and II NSCLC tumors.

The chart on the following page highlights evidence that applies to patients identified for SBRT in the treatment of their NSCLC:

SBRT for NSCLC Value Drivers by Evidence Source

Evidence	Type of Evidence	Clinical Impact	Non-Clinical Patient Impact	Care Delivery Revenue and Cost Impact	Public/ Population Impact
The patient's perspective on stereotactic body radiation therapy (SBRT) vs. surgery for treatment of early stage non-small cell lung cancer (NSCLC). (Published)[7]	Patient satisfaction	• Patients reported fewer side effects and treatment anxiety than surgery	• Higher patient satisfaction • More convenient than other treatment options		• Patients return to work sooner • Less strain on caregivers
Long-term outcomes of stereotactic body radiation therapy (SBRT) with fiducial tracking for inoperable stage I non-small cell lung cancer (NSCLC) (Published)[8]	Retrospective Study	• Minimal toxicity to healthy tissue	• Less burdensome for patient	• Less staff time immobilizing patient • Quicker patient turnaround	• Patient returns to workforce sooner
Prospective Trial of Stereotactic Body Radiation Therapy for Both Operable and Inoperable T1NOMO Non-Small Cell Lung Cancer (Published)[9]	Prospective trial	• Low incidences of severe toxicity	• Demonstrates SBRT is a viable alternative to surgery for patients with operable lung cancer	• Recommended alternative for inoperable patients	
Stereotactic ablative radiotherapy vs. lobectomy for operable stage I non-small-cell lung cancer (Published)[10]	Randomized Trial	• Higher survival rate compared to surgery • Higher recurrence-free survival than other treatment options • Lung preservation • Less risk of complications		• Higher survival rate compared to surgery • Less likely to be treated for recurrence • Less risk of complications	• Less strain on caregivers • SABR could be an option for treating operable stage 1 NSCLC

Evidence	Type of Evidence	Clinical Impact	Non-Clinical Patient Impact	Care Delivery Revenue and Cost Impact	Public/ Population Impact
Cost-Effectiveness Analysis of Stereotactic Body Radiotherapy and Radiofrequency Ablation for Medically Inoperable, Early-Stage Non-Small Cell Lung Cancer (Published)[11]	Cost Effectiveness Analysis	• Shorter treatment time than other radiotherapy options	• Lower cost than other radiotherapy options	• Lower cost than other radiotherapy options	• SBRT is more cost-effective than 3D-CRT and RFA in treating medically inoperable NSCLC over a range of treatment and disease assumptions
Cost-effectiveness of stereotactic body radiation therapy versus surgical resection (Published)[12]	Cost Effectiveness Analysis	• Improved local control and survival • Low treatment-related toxicity • Utility in marginally operable NSCLC	• In marginally operable patients, SBRT is nearly always the most cost-effective treatment strategy	• More cost effective than wedge resection for marginally operable NSCLC	• Expands treatment access to a new pool of patients

Expected Impacts (Value)

The value assessment should clearly demonstrate the impact of the technology across select value drivers including clinical impact, non-clinical patient impact, care delivery revenue and cost impact, and societal impact.

Clinical Impact Value – SBRT provides substantial clinical impact to the patient. Importantly, the treatment provides a viable option for Stage I and II NSCLC patients with marginally and non-operable tumors. When using this treatment, patients saw improved overall survival and reduced toxicity and side effects.

Non-Clinical Impact Value – SBRT also provides non-clinical benefits to patients and other stakeholders. Using SBRT leads to shorter treatment times and easier recovery. The patient experience is enhanced because they have an increased chance of survival compared to other treatments. This may lead to a quicker return to work and daily activities and a lessened burden on caregivers.

Care Delivery Revenue and Cost Impact Value – SBRT also delivers economic impacts. More targeted treatment of NSCLC tumors can lead to reduced costs to treat toxicity and other side effects, can reduce the costs associated with additional types of treatment, and can lower overall cost compared to other radiotherapy treatments. This ultimately leads to decreased downstream utilization of physician and hospital services and cost savings.

Societal Impact Value – SBRT creates beneficial societal impacts by potentially increasing survival rates for NSCLC patients. Increased survival rates can result in fewer absences from work for both patients and their caregivers, increased productivity, and a reduced strain on health care resources.

[1] "A Framework for Comprehensive Assessment of Medical Technologies: Defining Value in the New Health Care Ecosystem", available at www.advamed.org and co-developed with Deloitte Consulting LLP
[2] "Key Statistics for Lung Cancer." American Cancer Society.
[3] "Targeted Therapy Drugs for Non-Small Cell Lung Cancer." American Cancer Society.
[4] Toxicity Data For Hypofractionated Radiosurgery Using the Linear Quadratic Model to Constrain Normal Organ Tolerance Doses. Choe, J. et al. International Journal of Radiation Oncology • Biology • Physics , Volume 78 , Issue 3 , S140 (2010).
[5] Ibid.
[6] "Non-Small Cell Lung Cancer Survival Rates, by Stage." American Cancer Society.
[7] Shaverdian N, Wang PC, Steinberg M, Lee P. The patient's perspective on stereotactic body radiation therapy (SBRT) vs. surgery for treatment of early stage non-small cell lung cancer (NSCLC) Lung Cancer. 2015;90(2):230–233. doi: 10.1016/j.lungcan.2015.07.009
[8] Lischalk Jonathan W., et al. Long-term outcomes of stereotactic body radiation therapy (SBRT) with fiducial tracking for inoperable stage I non-small cell lung cancer (NSCLC). J Radiat Oncol. 2016; 5(4): 379–387. Published online 2016 Aug 20. doi: 10.1007/s13566-016-0273-4.
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[10] Chang, Joe Y et al. Stereotactic ablative radiotherapy vs. lobectomy for operable stage I non-small-cell lung cancer: a pooled analysis of two randomized trials. The Lancet Oncology , Volume 16 , Issue 6 , 630 – 637.
[11] Sher DJ, Wee JO, Punglia RS. Cost-Effectiveness Analysis of Stereotactic Body Radiotherapy and Radiofrequency Ablation for Medically Inoperable, Early-Stage Non-Small Cell Lung Cancer. Int J Radiat Oncol Biol Phys. 2011 Dec 1;81(5):e767-74. doi: 10.1016/j.ijrobp.2010.10.074. Epub 2011 Feb 6.
[12] Shah A., et al. Cost-effectiveness of stereotactic body radiation therapy versus surgical resection for stage I non-small cell lung cancer. Cancer. 2013 Sep 1;119(17):3123-32. doi: 10.1002/cncr.28131. Epub 2013 May 29.

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SBRT for NSCLC

Lung cancer is divided into two main categories – non-small cell lung cancer (NSCLC) and small cell lung cancer (SCLC). About 40% of individuals with early stage NSCLC (Stage I or II) have a form that is marginally operable or inoperable. Stereotactic Body Radiation Therapy (SBRT) can be used in this patient population to deliver more precise, less toxic, and less costly treatment than some other alternatives.

Patient Needs

New Technology

Stakeholders

Patient | Physician | Hospital | Payer | Government | Employer

Stakeholders

Value Drivers

Clinical Impact

- Reduced toxicity
- More targeted delivery
- Improved outcomes

Non-Clinical Patient Impact

- Easier recovery
- Less fatigue
- Fewer side effects

Care Delivery Revenue and Cost Impact

- Lower costs
- Shorter treatment duration
- Fewer sessions

Public/ Population Impact

- Faster return to work
- Improved overall survival
- Less caregiver strain

Patient Populations

- Patients with not easily operable or inoperable early stage (I or II) NSCLC

Evidentiary Support

- Numerous published studies:
  - Patient satisfaction
  - Retrospective studies
  - Prospective trials
  - Randomized trials
  - Cost-effectiveness analysis

Time Frames

- Treatment period
- Recovery time

Expected Impacts (Value)

- Improved overall survival
- Reduced toxicity
- Fewer side effects

- Shorter treatment times
- Easier recovery
- Faster return to work

- Reduced caregiver burden
- Reduced costs (immediate and downstream)
- Reduced utilization

- Increased productivity
- Reduced strain on health care resources

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