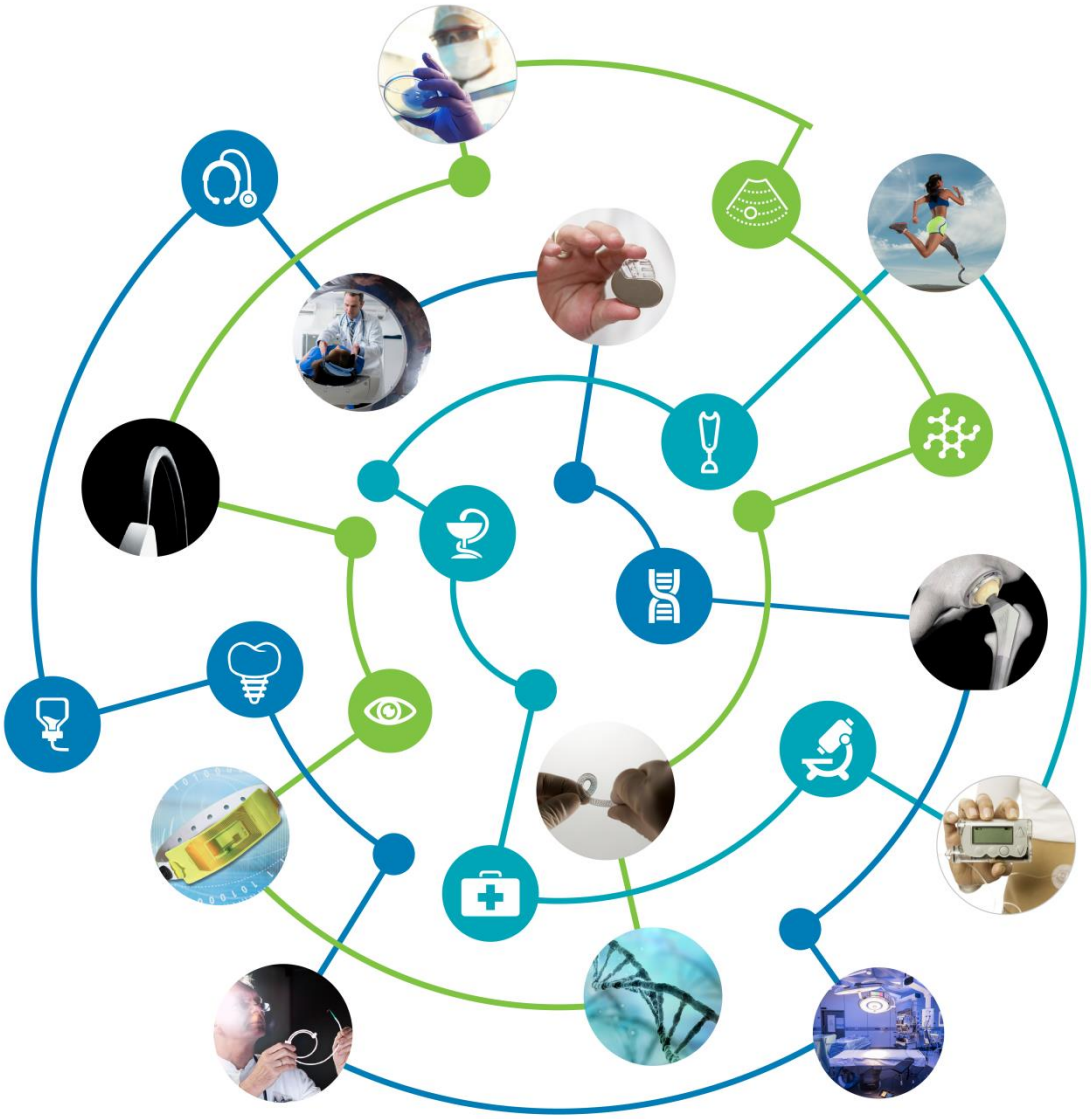
AdvaMed Medtech Value Assessment Framework *in Practice*



Application of the Medtech Value Assessment Framework to Cymedica's e-vive™ System

CyMedica™ ORTHOPEDICS

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 Health Economic Outcomes Research (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.

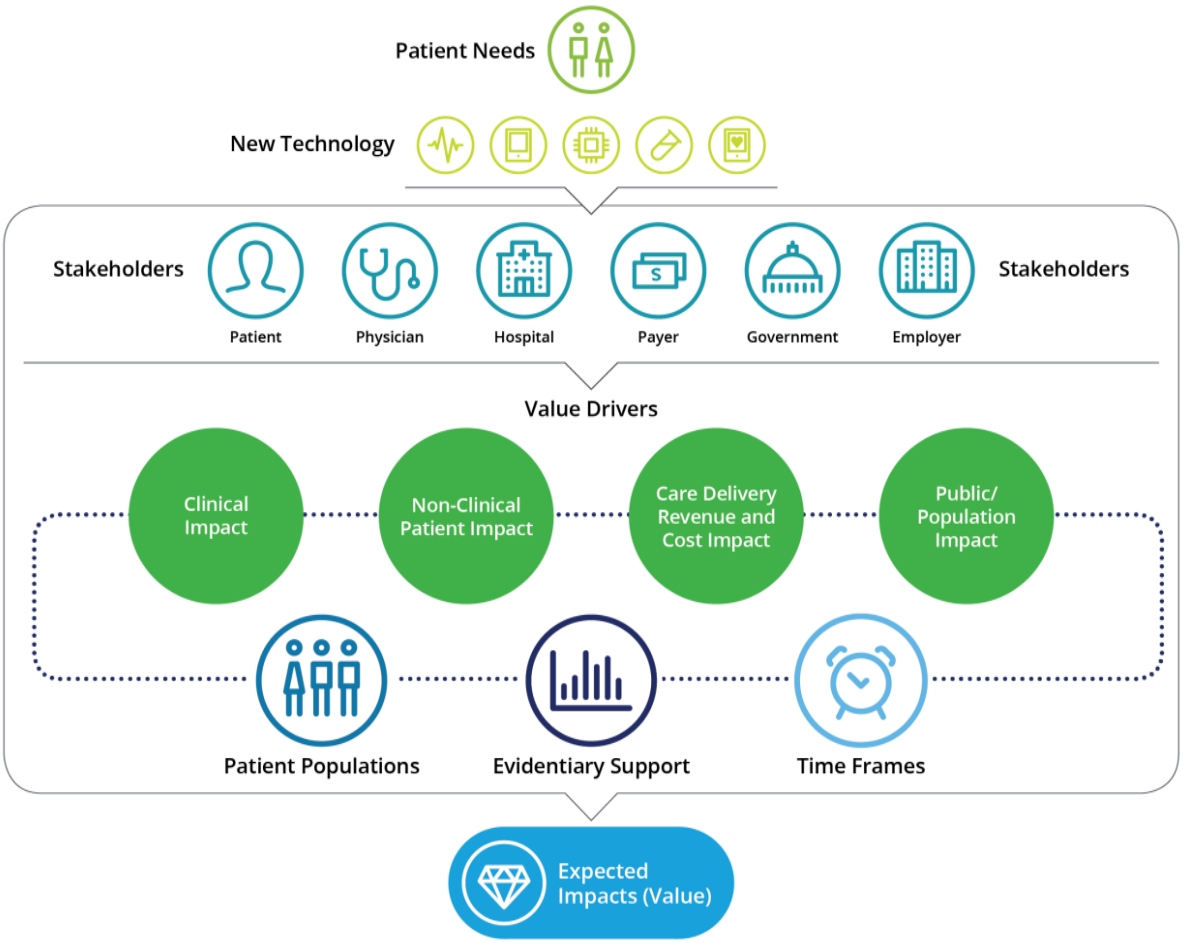
The AdvaMed Value Assessment approach can be used to guide the development of a value proposition that successfully communicates the full breadth of expected impacts offered by medical technologies while taking into account the demands of the changing health care ecosystem. The collection of information 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 highlighting 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. The use cases have been developed as a way to directly demonstrate the application of the AdvaMed Value Framework to the featured technology and should not be construed as an endorsement or promotion thereof.

CyMedica Orthopedics

This use case demonstrates the value of the CyMedica e-vive™ system technology across all of the identified value drivers and for a range of stakeholders.

Illustration of AdvaMed's Value Assessment Approach



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

CyMedica e-vive™ system

Medtech companies 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.

The CyMedica e-vive system demonstrates value across all of the drivers and serves as an example of the appropriate application of the AdvaMed value assessment approach in establishing value for a range of stakeholders.

CyMedica's e-vive system is a knee rehabilitation device that combines an app-controlled therapy for muscle atrophy with a cloud-based data collection and patient monitoring platform. E-vive uses neuromuscular electrical stimulation (NMES) therapy, which has been clinically proven to activate muscles and enhance strength and motor control. It combines this muscle activation therapy with a patient centric app, equipped with tele-rehabilitation communication features. The muscle activation NMES technology is delivered to the patient through a compressive conductive garment with embedded motion sensors for pre- and post-surgical rehabilitation. An optional, fully integrated post-operative rigid brace is available for more support in knee cruciate reconstruction surgeries. Clinically, the e-vive system improves knee and joint functional outcomes, reduces pain, and reduces falls, and preventable outcomes. The system also has a wide-range of other impacts as well, such as shorter rehabilitation times, faster return to daily activities, and less out of pocket therapy costs.

> The e-vive system impacts cost and care delivery by reducing readmissions due to falls and manipulation under anesthesia, decreasing lengths of stay in hospitals and rehabilitation centers due to improved functional outcomes and remote patient monitoring, and significantly reducing overall episode costs.

Finally, the CyMedica technology can benefit society by potentially reducing medication use and associated narcotic addiction treatment costs by creating a coordinated care system among the various stakeholders.

Unmet Need

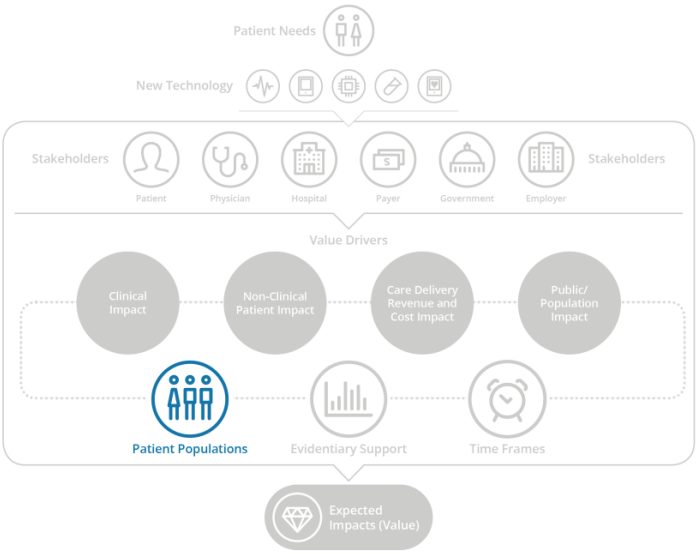
AdvaMed's assessment process begins with understanding and addressing the unmet need and value imparted through the new technology.

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

The main objectives of knee replacement surgeries are to restore knee function to pre-injury levels and promote long-term joint health. During recovery some patients suffer from muscle atrophy or waste (MAW), or the immediate and dramatic loss of quadricep strength that occurs as the result of knee surgery. MAW is one of the main clinical challenges post-surgery. Studies have shown that patients may lose over 60% of quadriceps strength, in the affected leg, following knee surgery. Traditional clinical physical therapy programs alone may not be sufficient to restore critical muscle activation and strength. The direct clinical impact of MAW is impaired balance, reduced walking speed, diminished sit-to-stand ability, increased fall risk, pain, and dependent living. The direct financial impact of MAW is approximately $2700-$9400 per patient.[2 3 4 5]

In addition, approximately 6-7% of patients who undergo knee revision surgeries experience stiffness and a decreased range of motion post-surgery. A technique known as Manipulation under Anesthesia (MUA) – a non-surgical procedure performed in the hospital with the patient under general or spinal anesthesia – is used to break up fibrous adhesions around the joint and surrounding tissue.[6]

Value can be shown for the treatment of disuse atrophy in Total Knee Arthroplasty (TKA), Anterior Cruciate Ligament (ACL), and Osteoarthritis (OA) patients, but it is most significant for the TKA and OA patient population due to the higher cost of care associated with TKA surgery and management of OA symptoms and the number of TKA surgeries and OA diagnosis.



Patient Populations

Assessments should consider the extent to which a technology may be more or less effective for various patient populations and align with the population focus of the stakeholder evaluating the technology.

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

The patient populations who undergo knee surgery are significant. Every year there are approximately 650,000 TKA surgeries on patients 45-80 years of age in the US; 100,000 ACL reconstruction surgeries on patients 16-60 years of age; and 12.4 million OA procedures on patients 25-80 years of age. [7 8 9] Rehabilitation options – including outpatient physical therapy, skilled nursing services, inpatient rehabilitation services, and home health agencies – are costly and often lack care coordination. Treatment options also do not typically include a

pre-rehabilitation protocol, which has been shown to improve the post-surgical clinical outcomes and reduce post-care (PAC) utilization and costs.

Additional emphasis on the value of orthopedic interventions has led to the development of payment models that look at factors beyond clinical outcomes. For instance, the Comprehensive Care for Joint Replacement (CJR) payment bundle model places emphasis on patient outcomes and efficiency during a 90-day episode of care. Another growing area of focus is on the period post-surgery when the majority of care costs are incurred and improving patient engagement and rehabilitation outcomes in an effort to reduce episode costs.

Time Frames

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

The orthopedic rehabilitation period is critical to patient success and the overall cost containment of the episode. For the Centers of Medicare & Medicaid Services (CMS) CJR bundles, 60% of the cost of the entire episode is incurred post-hospitalization. The e-vive™ product addresses a hospital's need to track patient progress during this post-discharge period by providing access to a cloud-based portal that contains critical, real-time patient data including rehabilitation progress and the level of patient engagement in their recovery. The e-vive™ portal allows hospitals to track patients during the 90-day post-operative period to ensure patients are receiving consistent, high quality rehabilitation to ensure better and more cost effective outcomes.

To date, there have been over 6,000 patients treated by CyMedica using the proprietary Neuro-Muscular Electrical Stimulation (NMES) therapy. There is a strong body of published clinical evidence related to the effectiveness of NMES therapy for the treatment of quadriceps atrophy. In this scientific literature, NMES has been shown to treat quadriceps muscle atrophy due to surgery and to significantly reduce rehabilitation times. Surgeon and patient testimonials show that patients are experiencing faster quadriceps activation, recovery, and independence, as well as less pain with the therapy.

The specific studies for the newest e-vive™ product with NMES technology and patient engagement system are ongoing. Publication of a post-market study, conducted by two leading orthopedics institutes, validating outcome improvements associated with use of the e-vive™ system are pending. In addition, two retrospective studies using CyMedica's NMES will be published in the near future. The findings from these studies will be useful in further identifying impacts of the CyMedica NMES technology over varying timeframes.

Stakeholders

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

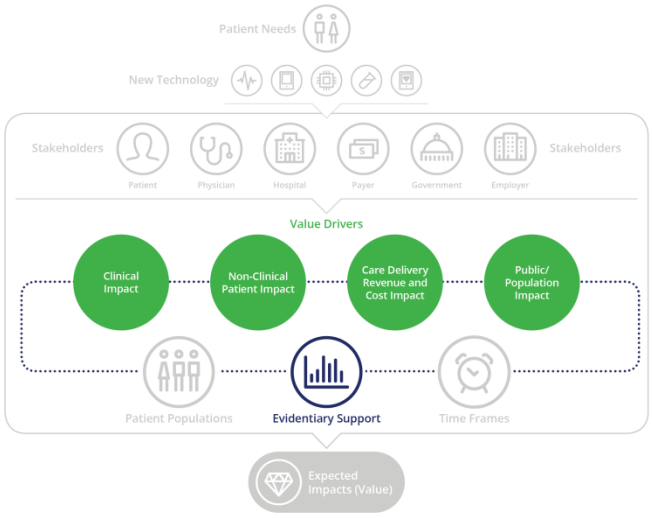
Both the intended audience/stakeholders and the purpose of the assessment should dictate which types of value are considered and emphasized via the assessment process, as well as the types and quality of evidence needed to support evidence development needs and appropriate strategies for collecting annual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

It is important for stakeholders to consider the full range of value drivers and impacts.

The chart on the following page highlights potential value for various stakeholders based on the use of the CyMedica e-vive ™ system technology in post-surgery knee rehabilitation.

CyMedica e-vive™ Value Drivers Impact by Stakeholder

	Clinical Impact	Non-Clinical Impact	Care Delivery Revenue and Cost Impact	Public/Population Impact
Patient	• Improved knee (joint) functional outcomes • Increased patient independence and reduction in the use of assistive devices • Shorter rehabilitation and recovery times	• Quicker return to work • Ability to resume activities of daily living quicker • Increased compliance through app connectivity with patients and providers • Convenient, at-home therapy which improves patient compliance and engagement	• Lower rehabilitation costs • Fewer fall-related and manipulation under anesthesia readmissions • Lower out-of-pocket Physical Therapy expenses	• Reduced need for narcotics • Reduced caregiver burden with faster recovery • Reduced Physical Therapy visits • Quicker return to work • Homecare with providers' visibility, where providers are able to review the patient's progress in real-time • Coordinated care among the stakeholders
Surgeon	• Ability to produce and report Patient Reported Outcomes for quality metrics • Manage most at-risk patients effectively, eliminating unexpected outcomes • May delay TKA in OA patients	• Convenient, at-home therapy which improves patient compliance and engagement	• Reduced Physician Part B visits • Impact in Merit-based Incentive Payment (MIPS) for OA management • Significant reduction in bundled payment models (CJR and BPCI) episode costs	• Homecare with providers' visibility, where providers are able to review the patient's progress in real-time • Coordinated care among the stakeholders
Hospital	• Ability to produce and report Patient Reported Outcomes for quality metrics • Manage most at-risk patients effectively, eliminating unexpected outcomes		• Fewer fall-related and manipulation under anesthesia readmissions • Impact in MIPS for OA management • Significant reduction in bundled payment models (CJR and BPCI) episode costs • Improved care coordination • Reduced Physician Part B visits	
Payer	• Manage most at-risk patients effectively, eliminating unexpected outcomes	• Lower out-of-pocket Physical Therapy expenses • Convenient, at-home therapy which improves patient compliance and engagement	• Lower rehabilitation costs • Reduced readmissions due to fewer falls and manipulations under anesthesia • Reduced Physician Part B visits • Impact in MIPS for OA management • Significant reduction in bundled payment models (CJR and BPCI) episode costs	• Lowers overall healthcare costs • Lower rehabilitation costs crucial • Quicker return to work • Coordinated care among the stakeholders



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 and on an ongoing basis to determine how each can be used across the relevant drivers to offer robust evidentiary support.

CyMedica has been engaged in the development of evidence to support the effectiveness of its technology and to demonstrate the value that it brings to the health care system. Specifically, CyMedica has published an NMES therapy effectiveness study and health economics evidence based on the current clinical publications. To date, the CyMedica NMES technology has been used in nearly 6,000 commercial cases as well. The technology is also being evaluated in a post-market study by two leading orthopedic institutes.

The chart on the following page applies to TKA, OA, and ACL patient populations:

CyMedica e-vive™ Value Drivers by Evidence Source

	Type of Evidence	Clinical Impact	Non-Clinical Patient Impact	Care Delivery Revenue and Cost Impact	Public/Population Impact
6,000 Commercial Cases	Retrospective Study	• Patients experience faster quadricep activation, recovery, and independence, and less pain			• Patients would recommend the therapy to others
NMES Therapy Effectiveness Study (Published)	Clinical Trial	• NMES shown and proven to treat quadricep muscle atrophy due to surgery and to improve the knee functional outcomes • NMES shown and proven to treat quadriceps muscle atrophy in OA patients and slowed OA progression • Patient rehabilitation significantly shorter than standard PT			
Health Economics Evidence (Published)	Health Economics Outcomes/ Analysis			• Significantly lower healthcare spending for patients who do not develop TKA-related quadriceps atrophy • Significant healthcare spending reduction when pre-rehabilitation was provided to TKA patients	
e-vive Post-Market Study at Two Leading Orthopedics Institutes (In Progress)	Post-Market Surveillance	• Fewer discharges to Skilled Nursing Facilities (SNF) or Home Health Agencies (HHA) • Fewer patient falls • Reduced admission rate • Improved hospital score, HCAHPS (Quality Measures) • Shorter length of stay for TKA patients at hospital, SNF, HHA • Fewer outpatient Physical Therapy visits	• Increased patient satisfaction		

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.

These impacts would be offset by the cost of acquiring the technology to derive the total expected value impacts.

Clinical Impact Value – CyMedica's e-vive™ system provides significant clinical benefit compared to patients without the e-vive™ treatment. The e-vive™ system improves a patient's knee and joint function, which reduces the number of falls, the need for costly manipulations under anesthesia, and pain. E-vive™ patients have more independence and fewer adverse outcomes than other patients. The device is also beneficial to clinicians, hospitals, and insurers because it reduces admission rates and allows for collection of Patient Reported Outcomes data.

Non-Clinical Impact Value – The e-vive™ system also produces beneficial non-clinical impacts for many stakeholders. For patients, the e-vive™ system is a convenient at-home therapy that is easy to use. Patients also experience shorter rehabilitation times and can resume daily activities sooner. The device also improves patient compliance and engagement and connects patients with providers to better optimize treatment.

Care Delivery Revenue and Cost Impact Value – CyMedica's e-vive™ system technology reduces PT visits, lowers rehabilitation costs, and significantly reduces the cost of the episode of care. Additionally, it impacts Merit-based Incentive Payment System (MIPS)-related OA management through pain management and increased physical function, as demonstrated through the results of a soon to be published CyMedica study. After accounting for the average spending per episode and the cost of the device, the e-vive™ system has a potential savings of $906.[10]

Public/Population Impact Value – The e-vive™ system creates beneficial societal impacts through reducing recovery times and caregiver burdens. There is also a potential for reducing the need for opiates due to the treatment alleviating long-standing pain.[11] Finally, there is a quicker return to work and productivity.

[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] Stevens-Lapsley et al. "Early Neuromuscular Electrical Stimulation to Improve Quadriceps Muscle Strength After Total Knee Arthroplasty: A Randomized Controlled Trial." *Physical Therapy* 92.2 (2012): 210–226. PMC. Web. 7 Apr. 2017.

[3] Risberg et al. "Prospective Study of Changes in Impairments and Disabilities After Anterior Cruciate Ligament Reconstruction." *Journal of Orthopedic & Sports Physical Therapy* 29.7 (1999): 400-412.

[4] Chen et al. "Association between Muscle Atrophy/weakness and Health Care Costs and Utilization among Patients Receiving Total Knee Replacement Surgery: A Retrospective Cohort Study." *Journal of Pain Research* 6 (2013): 595–603.

[5] Kittelson et al. "Neuromuscular electrical stimulation after total joint arthroplasty: a critical review of recent controlled studies." *European Journal of Physical and Rehabilitation Medicine* 46.6 (2013): 909-920.

[6] "MUA (Manipulation Under Anesthesia) After Total Knee Replacement." BoneSmart.

[7] Kittelson et al. "Neuromuscular electrical stimulation after total joint arthroplasty: a critical review of recent controlled studies." *European Journal of Physical and Rehabilitation Medicine* 46.6 (2013): 909-920.

[8] Wilk et al. "Recent Advances in the Rehabilitation of Anterior Cruciate Ligament Injuries." *Journal of Orthopedic & Sports Physical Therapy* 42.3 (2012):153-171.

[9] Williams et al. "Hospitalization for Total Knee Replacement Among Inpatients Aged 45 and Over: United States, 2000-2010." *Centers for Disease Control and Prevention*.

[10] Based on health economics modeling, there is a range for TKA savings per episode which varies across hospitals.

[11] CyMedica retrospective study showed a reduction of 48% in NSAID use post-CyMedica NMES therapy intervention in OA patients.

Medtech Value Assessment Framework *in Practice*

CyMedica Orthopedics: e-vive™ System

The main objectives of knee replacement surgeries are to restore knee function to pre-injury levels and promote long-term joint health. Studies have shown that during recovery, some patients suffer from muscle atrophy or waste (MAW) and may lose over 60% of quadriceps strength in the affected leg. Traditional clinical physical therapy programs alone may not be sufficient to restore critical muscle activation and strength.

Patient Needs

New Technology

Stakeholders

Patient | Physician | Hospital | Payer | Government | Employer

Stakeholders

Value Drivers

Clinical Impact
- Improved knee functional outcomes
- May delay TKA in OA patients

Non-Clinical Patient Impact
- Improved patient compliance
- Faster return to work and activities

Care Delivery Revenue and Cost Impact
- Reduced rehab costs
- Reduced bundled model episode costs

Public/ Population Impact
- Faster return to work
- Decreased opioid use

Patient Populations

- Patients needing the following knee procedures:
  - OA
  - TKA
  - ACL

Evidentiary Support

- 6000 Commercial cases
- Published NMES Therapy Effectiveness Study
- Health Economics Evidence
- e-vive™ Post-market Study at Two Leading Orthopedics Institutes

Time Frames

- Recovery Time
- Rehab Time

Expected Impacts (Value)

- Improved knee and joint function
- Improved hospital score and quality measures
- Faster quadriceps activation
- Reduced rehab time v. PT
- Faster return to work and activities
- Reduced falls
- Significantly lower healthcare spending ~$906/episode savings
- MIPS impact related to pain management and increased physical function
- Reduced caregiver burden
- Alleviates long-standing pain and opioid use
- Slowed OA progression

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