Reimbursement and Emerging Medical Technologies: Considerations for Investors and Lenders

Overview

As the Affordable Care Act ("ACA") continues to be implemented, the healthcare industry is facing a significant period of change defined by increased scrutiny regarding the containment of health care costs. To address this growing need, players in the healthcare industry should focus their efforts on preventive care and adoption of value-based metrics for improved patient outcomes. Within the ACA there is, in fact, a provision that includes the formation of an independent non-profit governing board called the Patient-Centered Outcomes Research Institute (“PCORI”), which is tasked with defining the requirements of comparative clinical effectiveness research for technologies and treatments. Despite increased scrutiny, an interesting post-ACA development is the increasing rate of growth for investments in emerging medical technologies for specific niche healthcare industries.

It is important to note that, given the number of variables impacting a return on investment, investing in emerging medical technologies is complex and uncertain. When analyzing an investment’s growth rate, reimbursement and insurance coverage challenges may be significant, and are sometimes overlooked. While there are many who support change that includes the need for more transparent policies for obtaining insurance coverage acceptance, significant headwinds remain.

Insurance reimbursement is one of the most essential components for the profitability and viability of any healthcare investment. Without realistic reimbursement assumptions driving financial models and business plans, the results can be disastrous for private equity firms and lenders investing in this space. The environment for emerging medical technology reimbursement remains difficult; investors need to explore strategies that mitigate challenges, as well as address why being in-network with an insurance provider does not necessarily equate to a patient being covered for an emerging medical technology. These issues are critical when reviewing long-term business plans, liquidity forecasts and setting financial covenants for companies. Since these investments may be capital intensive, an unsustainable leverage and interest coverage situation can arise.
Financial flexibility is critical as the medical community – not only physicians and patients, but also insurance companies – learns to adapt to new technologies. This can take years, or sometimes decades, to develop with clinical trials. Companies may not have the structure and resources to sustain such prolonged business stress. Only with proper and thorough due diligence can investors and lenders avoid potential negative scenarios.

**Medical Necessity**

Determinations of medical necessity for any procedure are vital for calculating potential reimbursement. In the case of emerging medical technologies, the evidence required to support medical necessity may not yet exist. Most procedures require a pre-authorization for services rendered, and there is a probability of denial based on medical necessity. There is no standard definition of medical necessity and these variations lead to confusion and frustration among providers, physicians and patients. Medicare defines medical necessity as “health care services or supplies needed to prevent, diagnose or treat an illness, injury, condition, disease or its symptoms and that meet accepted standards of medicine”.

Disparities among commercial health plans include:

- Variations in the development and distribution of guidelines and the impact on decision making
- Variations on the logic and process of authorization
- Variations in the quality and quantity of communication among health plans, medical groups, physicians and consumers

The adoption of emerging medical technologies by health plans as a medical necessity is less controversial when there is a well-defined clinical need and minimal alternatives. However, if the emerging technology is a derivative of a standard procedure or treatment, coverage determinations may be a greater challenge. It can be even more difficult when an emerging technology has a significantly higher capital and operating cost structure with similar, or yet unproven, patient outcomes than its alternatives. To overcome this hurdle, it is crucial that there be a foundational commitment to monitoring patient outcomes and sharing results that comprises both immediate and long-term outcomes, coupled with the success rates of specific conditions being treated and long-term health benefits compared to alternatives.

**Investigational / Experimental**

Emerging technologies can also be deemed “investigational” by health plans despite being approved by the U.S. Food and Drug Administration (“FDA”). Unfortunately, there is limited coordination among the FDA, CMS and commercial health plans regarding the coverage of new technologies. Similar to medical necessity, the definition of investigational is not uniform, with governmental entities and commercial health plans having different criteria when assessing new technology.
**Payor Contracting (In-Network vs. Out-of-Network Strategy)**

With any emerging medical technology, a thorough understanding of how health plans make medical coverage determinations is paramount. To have an effective payor contracting strategy, it is essential to develop a cost-benefit analysis that determines whether to remain out-of-network with each health plan. This is particularly important when comparing out-patient service providers to full service hospitals. Full service hospitals may have a greater ability to trade rates elsewhere for coverage while out-patient service providers may not have the trade-off opportunity.

The decision to become an in-network provider with a particular health plan must be heavily scrutinized due to the implications of potential reimbursement, and it is important to remember that becoming an in-network provider does not necessarily change medical necessity and investigational determinations for services. Just because a provider is in-network, it does not mean the services rendered will become medically necessary. The implications on reimbursement are substantial as payments out-of-network can be significantly higher than contracted in-network rates once a service has been approved.

The need for evidence-based outcomes to obtain general service approval is, however, dependent on volume. While the primary service may not be included in a medical coverage policy, it is likely that many normal ancillary services could be covered. When creating a cost-benefit analysis, the ability to drive volume through contracting could help obtain the results necessary for general acceptance through improved patient outcomes, so long as capacity constraints have been carefully considered. The patient volume required to support improved patient outcomes will be more difficult to achieve in an out-of-network environment. A committed and reliable network of physicians that understand the impact of reimbursement challenges and can support the patients through a potential appeals process is necessary. Additionally, out-of-network providers must make an investment in tracking the claims process closely through iron-clad procedures to reduce the time from billing to cash collections.

**Conclusion**

The complexity associated with investments in emerging medical technology requires thorough due diligence of potential reimbursement rates, health plan coverage, physician acceptance and potential volume. Stress testing business plans with detailed scenario analyses will help investors and lenders understand the associated opportunities and challenges of an emerging technology’s financial viability. Consulting with subject matter experts in the field can facilitate navigating these challenges with physicians, patients and insurance providers in order to avoid potential costly pitfalls. With its full suite of advisory, consulting and corporate finance services, LM+Co is uniquely positioned to advise investors and lenders on how best to mitigate potential risks in today’s medical technology market.

**Authors + Contacts**

Tom Wang
Managing Director
twang@lmcopartners.com
Profile

Andrew Knizley
Healthcare Industry Expert
aknizley@lmcopartners.com
Profile