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## Pharma Industry, The Next Challenge— Improving Clinical and Economic Value

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**A new economic framework for end-to-end management for pharmaceutical companies—one that starts in the R&D phase and delivers value to payors, patients and shareholders in today's health care system.**



### Executive Takeaways

The traditional model for pharmaceutical commercialization—compound discovery, clinical trials, regulatory approval, promotional campaigns—worked for a long time but is under increasing pressure from stronger cost-containment measures and declining research productivity.

To remain competitive and financially successful, pharmaceutical companies should become more proactive in addressing both the economic and clinical value of products across the product life cycle.

Companies should be able to demonstrate their value economically to patients and payors and to create more innovation around delivering economic value.

To achieve these objectives, pharma companies and health care systems are investing in new approaches like Comparative Clinical and Economic Value (CCEV™). These approaches can help distinguish the specific characteristics of a drug, medical device or intervention and then for each distinctive feature more closely measure its economic value (including reduced physician time, decreased bed days, smaller diagnostic costs and lower requirements for additional drugs).

CCEV™ enables companies to focus their efforts on creating value for patients and payors and enables companies to apply economic value-based thinking across the entire development, commercialization and health care delivery process.

### The Challenge

As the pharmaceutical industry matures and enters a stage of slower growth, companies should fundamentally reconsider their approach to drug commercialization. Faced with economic pressures, fewer new therapeutic categories to exploit and aggressive generic competitors, drug manufacturers will need to become more proactive in addressing both the economic and clinical value of each product across its lifecycle. Companies require a different strategy to evaluate and maximize the economic value of their assets, a strategy that encompasses a clear understanding of what various constituents (payors, providers, patients) value most and an ability to communicate the benefits of their offerings in the terms that resonate with each decision-maker.

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## Until recently, pharmaceutical companies focused less on meeting the needs of the economic buyer, instead relying on the skills of field sales teams to secure use of the product.

A new approach to understanding and delivering economic value, which we call Comparative Clinical and Economic Value (CCEV™), is a response to several structural problems in the existing commercialization model. Historically, pharmaceutical companies have tended to assign a lower priority to understanding the economic value of the products they develop. Pricing models are typically driven by benchmarks around payors' willingness to pay. Until recently, pharmaceutical companies focused less on meeting the needs of the economic buyer, instead relying on the skills of field sales teams to secure use of the product. Companies routinely have spent approximately 15 percent of their gross sales in rebates to payors, driven by promotions designed to achieve sales targets. Increasingly, regulators are limiting the use of certain promotional tactics. The strong move toward evidence-based medicine has also lessened the impact that promotional teams can have.

As health care financing tightens, payors (regional authorities, insurers, and employers) are likely/anticipated to continue to increase their influence on price setting and access to markets—adding new gate-keepers on top of traditional government drug approvers like the European Medicines Agency and the U.S. Food and Drug Administration. Some payors are even performing their own comparative effectiveness studies to determine the value of medications instead of relying on reports from government agencies or prices set by drug makers. These changes help to explain why the effectiveness of traditional selling approaches (such as physician detailing and direct-to-consumer promotions) is in decline. But while there is a clear recognition of these systemic changes by pharmaceutical executives, in many cases the responses appear to focus primarily on shorter term alternatives.

Adopting an approach like CCEV™ provides pharmaceutical companies an opportunity to address payors' focus on economic value and comparative effectiveness and offers an innovative way to embed economic value consideration throughout the development, commercialization and health care delivery process.

### A Framework for End-to-End 'Value Management'

With the increasing strength and sophistication of payors (the economic buyer), pharmaceutical manufacturers should consider adapting their own role and approach to collaboration with health care systems. The main challenge: determine how to commercialize a product with both the economic and clinical buyers in mind and increase returns, both for drugs on the market and those under development.

For products already launched, the challenge will be to protect use and avoid value erosion. With products in development, a proportion will need to be reprioritized, others discarded.

Addressing this challenge requires a systemic change from win-lose price negotiation to an approach based on collaboration with the health care system, a focus on specific areas of differentiation and measurements of economic value (resources saved or used more productively).

A clear, quantified, value-based commercialization strategy represents a major shift in the way pharmaceutical companies will need to bring their products

to market—by defining where the product fits in the disease pathway, how it changes patient outcomes and the impact on economic value. Development and commercialization decisions from early stage through end of life cycle should be informed by a quantified understanding of economic and clinical value.

### Applying Clinical and Economic Value (CCEV™)

Comparative Clinical and Economic Value (CCEV™) is an approach that allows companies to measure the economic and clinical impact of a drug across the commercialization process. The approach can be applied to main therapeutic areas, for example diseases such as hepatitis, which migrate from chronic to acute episodes, and cancers, where the shift is increasingly from acute events to chronic management. It can also be applied across interventions (including drugs, medical devices and supporting procedures) and at each stage of a drug's lifecycle, from simulating and modeling the impact prior to Phase 3 trials to assessing the health economic impact over multiple years using actual health care data.

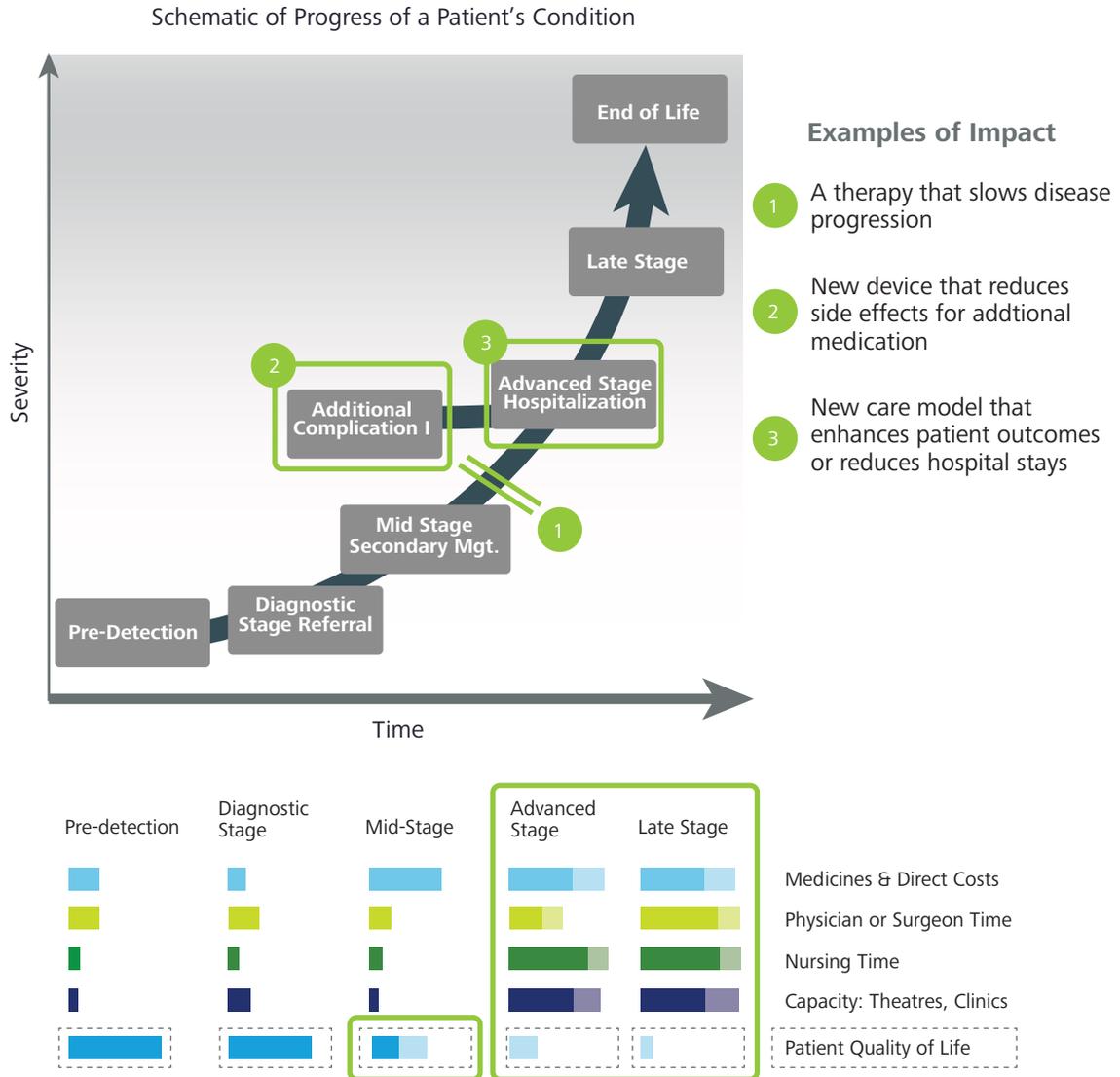
## New Questions from New Economic Buyers

Payors are less interested in one-off price-setting or annual renegotiations about the pricing of particular drugs; they are focused on the ongoing management of their spending plans. In Europe, the pressure on health care budgets has led to a progressive devolution of decision making. Regional and local payors now effectively control funding decisions for hospital products and access to these markets. This move has significantly increased the number of economic stakeholders and the complexity of managing them. These new economic buyers have questions for the drug manufacturers, such as:

- What outcomes will actually be achieved for my patient population? What outcomes have already been achieved?
- What is your clinical rationale for the price point of the product?
- Which of your product's attributes drive price?

Absent the answers they are seeking, regional authorities have shown they are willing to make controversial decisions about access to a drug.

Figure 1: Illustration of Disease Progression and Impact on Health Care System Resources



**CCEV™ Approach**

There are four parts to the CCEV™ approach. First, the approach maps the medical events and treatment activities (see Figure 1) for a disease over time and calculates the resulting accumulation of costs.

Second, the approach allows the identification of the specific points where the use of the pharmaceutical drug has impact and evaluates how it affects the patient and their treatment, for example on slowing disease progression, reducing the need for additional medication and enhancing patient outcomes.

**The Impact of CCEV™**

Once the clinical and economic benefits have been identified, they can be analyzed within the context of the standard of care, alternative therapies, and current and future competitors. For pharmaceutical companies, CCEV™ enables them to address three critical issues:

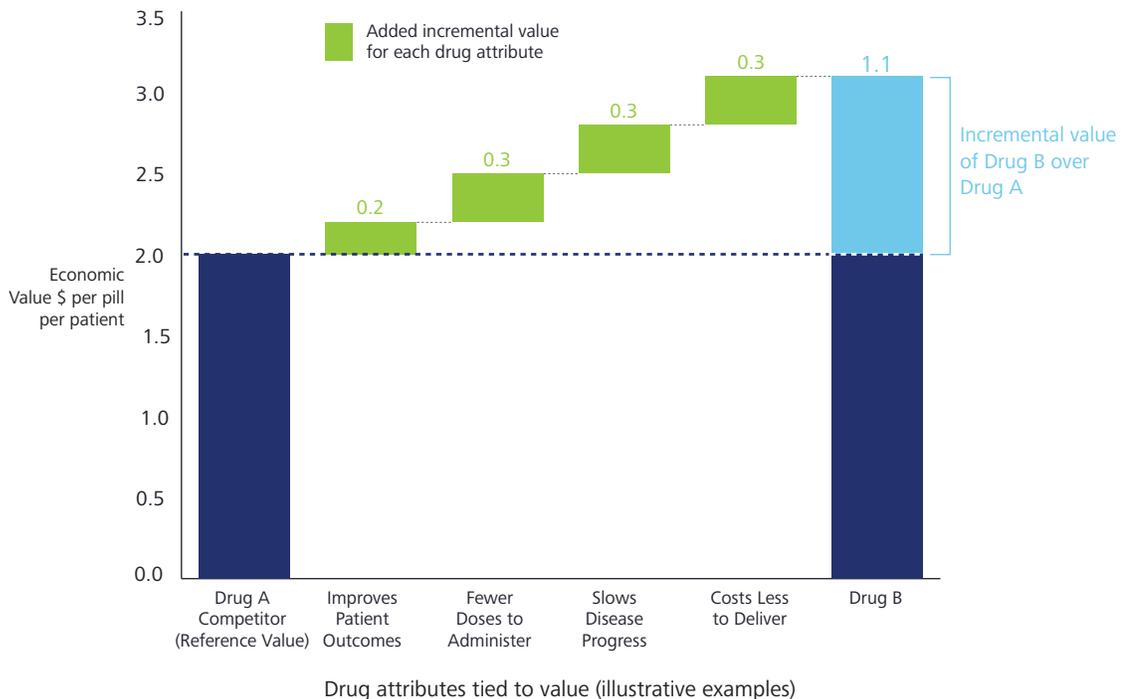
**Calculating a drug’s clinical and economic value to a health care system to determine desired/ effective positioning.** For pharmaceutical companies, CCEV™ is used to inform choices about where and how to go to market with a particular drug. It helps to provide the input to decisions such as where in the

disease pathway the drug creates significant benefit, with which patient groups and under what conditions of use. The understanding of economic value provides a counterbalance to the current framework for selecting where to position the drug, which is typically based on addressing a substantial unmet medical need.

**CCEV™ enables pharmaceutical companies to communicate with payors in a way that reinforces the economic value of their products.**

**Identifying which of the drug’s main points of differentiation create value to justify price and usage in a health care system.** CCEV™ provides information to demonstrate how a new product offers an effective combination of clinical and economic value compared to the next alternative. This can be built up using a pragmatic analysis of “best available” data, including simulation techniques, and leveraging real-world sources to build upon existing medical and scientific literature and specialists’ opinion. (See Figure 2 for an illustrative example.)

**Figure 2: Comparative Economic Value for Two Therapeutic Alternatives (illustrative example)**



**Supporting commercial portfolio management and clinical trial design.** Building clinical and economic value questions into the drug development process helps pharmaceutical companies narrow their efforts to only those projects which make sense for the health care system. It also provides an effective platform for assessing economic benefits during drug clinical trials. Given the rapidly changing external environment, questions about the economic value—or defensible price—of a drug should begin in the lab, not later in the development cycle. Pricing will need to become increasingly based on “defensible value” that highlights why the health care system should invest in the new product.

### **Building an Economic Framework for Managing a Pharmaceutical Company**

An economic value-based approach to commercialization opens the opportunity to develop more rational conversations between payors and providers about how pharmaceutical products should be used and the benefits they offer in treating patients. The approach has delivered benefits to patients by improving access to effective drugs, increasing productivity in health care systems and improving the performance of drugs companies (by improving sales and increasing margins by taking steps so that drug prices more closely reflect real value). CCEV™ enables pharmaceutical companies to communicate with payors in a way that reinforces the economic value of their products. It focuses on value: a product’s specific attributes and how it creates different outcomes compared to alternatives; and how use of this product can create value for the health care system. Economic value-based commercialization appeals to both clinical and economic buyers because it defines value in terms that are meaningful to the health care system: patient outcomes.

## ENDNOTES

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