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HEOR VALUE DEMONSTRATION AND EVIDENCE GENERATION CHALLENGES

MEETING NEEDS OF DIVERSE HEOR CONSUMERS AMIDST THE EVOLVING REIMBURSEMENT LANDSCAPE

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An Axtria Point of View

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MEETING NEEDS OF DIVERSE HEOR CONSUMERS AMIDST THE EVOLVING REIMBURSEMENT LANDSCAPE

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VALUE-BASED HEALTHCARE

Growing healthcare expenditures, new and expensive product launches, and competitive pressures are forcing a 'volume-to-value' shift globally. Now more than ever, manufacturers are under pressure to demonstrate their products' value. It is no longer enough to demonstrate the efficacy of drugs but also improved clinical and financial outcomes that justify the higher price against established therapies – preferably with real-world evidence (RWE).

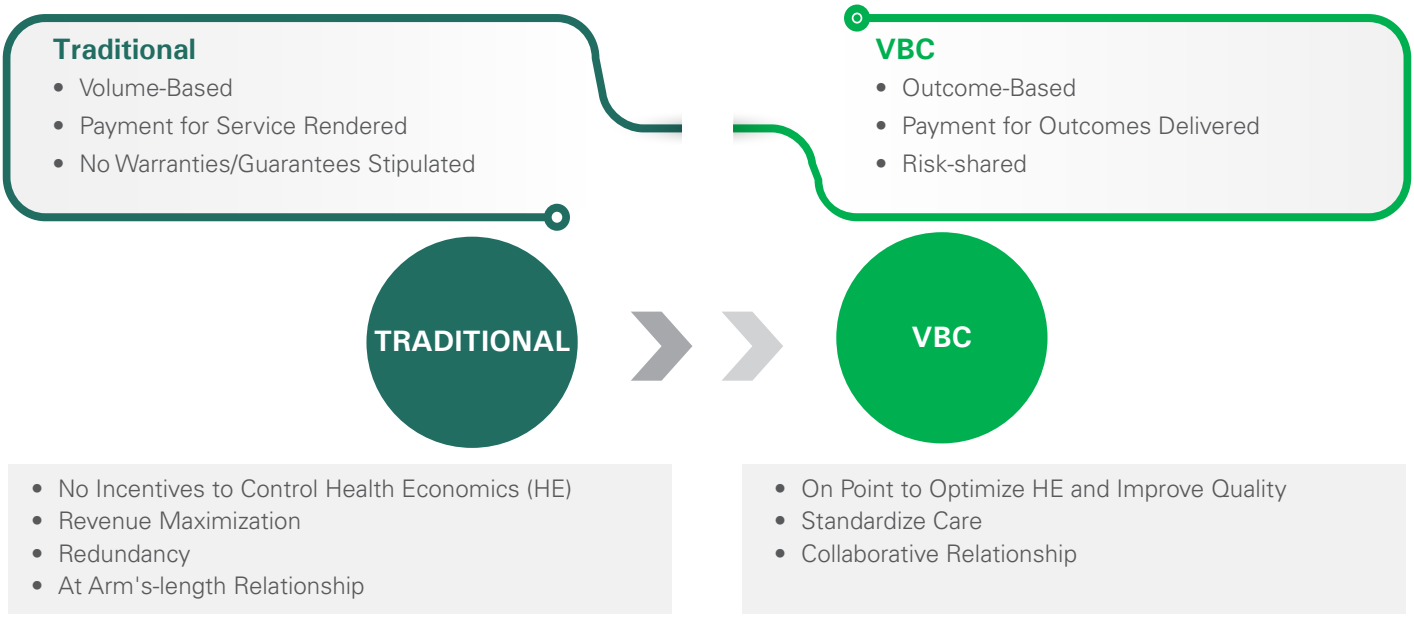
This shift to a value-based approach has raised questions on what is 'VALUE'. Since there is no universally accepted definition of value-based healthcare or what value means in the health context, the term 'value-based' is often misused and hence causes translation issues between stakeholders within the healthcare ecosystem.

While a systematic review of value definitions in context to socialized vs. privatized healthcare, various disease states, and at arm's length relationships is beyond the scope of this article; we will attempt to clarify a few most commonly used terms:

Value-based pricing (VBP):

- One of the approaches to move to value-based care
- Defined as the price of a drug based on its measured benefits,

FIGURE 1: SHIFT FROM TRADITIONAL/FEE-FOR-SERVICE TO VALUE-BASED CONTRACTING (VBC) MODELS



Source: Axtria, Inc.

as evaluated through a health technology assessment (HTA).

Value-based contracts (VBCs):

- Another approach to shifting to value-based care
- Link coverage, reimbursement, or payment for a product to a prespecified clinical or financial outcome or set of outcomes.
- Comprise contractual arrangements among manufacturers, payers, and providers to achieve contracted clinical and/or finanacial goals.
- Also refer to value-based care in which treatment decisions are driven by overall value assessments that include not just treatment cost but patient outcomes, social impact, and healthcare budget impact

Value-based frameworks (VBF):

- Are used to outline outcomes, value dimensions, and measurements within a time horizon aligned with stakeholders' interests for a specific disease area

THE VALUE-BASED SHIFT IS FAVORING HEALTH TECHNOLOGY ASSESSMENT (HTA) AS A TOOL TO DECIDE ACCESS AND REIMBURSEMENT OF NEW DRUGS

Global attempts to rein in healthcare expenditures and decelerate adoption of new and expensive drugs while favoring existing cost-effective treatments have led to replacing price and concession based negotiations with a more systematic cost-effectiveness review of drug coverage. It has become a common practice for healthcare systems to use HTA, and many markets across the world are moving to HTA based reimbursement decision making.

HTA is an evidence-based process that seeks to examine the medical, economic, social, and ethical implications of the use of medical technology, including pharmaceuticals, in healthcare and uses the evidence to inform decision-making. For example, in reviewing a drug, HTA may include investigating the efficacy (how the drug works in a clinical trial), safety, real-world effectiveness, and the likely social, legal, ethical, and political impact of using the drug.

The goal of conducting HTA is to inform the development of safe and cost-effective health policies and standards of care that are patient-focused while attempting to achieve the best value defined by decision-makers. HTA supports decisions such as:

- Should treatment 'A' be reimbursed in a national healthcare system?
- For which patients should this treatment be provided?
- What are alternative treatments that should be used before this treatment?
- When should this treatment be provided to the patient?
- For how long should patients receive this treatment?

HTA examines the impact of a technology on an individual patient, a group of similar patients, the entire healthcare system, or all of these. HTA may comprise assessing evidence from various sources such as systematic reviews of clinical trials, economic evaluations, evidence from users of the technology, and assessments of implications for healthcare services.

Many of the markets globally have a well-defined and established HTA process - United Kingdom, France, Germany, and Canada. Many emerging markets are adopting HTA based reimbursement – China, Korea, Cambodia, Saudi Arabia, and South Africa).

Limitations in getting to the 'right' value-based pricing remains the key barrier to shift away from a list price approach that rationalizes access and reimbursement of drugs to the most beneficial patient segments. High ingredient cost remains the most prohibitive driver of approving radical treatments that alter patients' lives while saving systems long range health expenditures.

HTAs are limited in application or pushed back for mainly:

- Lack of systemic sophistication of markets – getting the value equation (i.e. value-based framework) right requires a keen understanding of therapy costs, impact on the total cost of care, patient journey, and patient and social outcomes.
- Limited availability of Health Economics and Outcomes Research (HEOR), epidemiology, and reimbursement experts – making

rational reimbursement decisions require a keen understanding of a society's healthcare system, values, healthcare transactional model, vested interests within the healthcare value chain, and disease state.

- Limited availability of data to support HTA – evidence generation and value demonstration require long-range contiguous datasets across clinical and financial dimensions. Only a few markets globally have the maturity and established infrastructure to capture uninterrupted patient-level clinical encounters and financial transactions that can support value assessments.

EMERGING LANDSCAPE IN VALUE-BASED REIMBURSEMENT

Payers have pushed back on clinical trial generated evidence as manufacturers' design bias for a very long time. Real-world data (RWD) represents a powerful tool to garner payer confidence in manufacturers' generated evidence. RWE is healthcare information derived from multiple sources outside of typical clinical research settings, including electronic medical records (EMRs), claims and billing data, product and disease registries, and data gathered by personal devices and health applications.

Additionally, RWD enables manufacturers' to generate incremental clinical outcomes evidence required by payers beyond limited clinical trial generated evidence available at launch. It has become common practice to formulate a strategy to demonstrate long-term, real-world effectiveness post-launch. This generally includes observational studies and pragmatic clinical trials to provide comparative effectiveness evidence (improved patient outcomes and reduced costs) against current care standards over a longer duration and are more representative of the patient population than phase III clinical trials.[2]

Another important consumer of evidence generated is medical affairs. This is an essential commercial function for disseminating messaging to the scientific community, providing value demonstration for pricing and access functions, and brand value for product lifecycle management (PLCM) groups.

Many pharmaceutical companies have developed centralized RWD and Evidence capabilities. Quite commonly, these teams are a part of the global medical affairs functions. Such teams consist of people with in-depth knowledge of real-world data and analytics and business leaders who support and communicate a wider vision for the real-world evidence function within the organization and externally.

VALUE-BASED CONTRACTING ACTIVITY IN THE US

While interest in value-based contracting is high among both payers and pharmaceutical companies globally, value-based contracting activity is limited in the US.

73 VBCs
were executed and publicly announced in the US during 2009-2019.[1]

Underlying barriers to adoption include:

- Data collection, analysis, and privacy issues (ensuring value-based data sharing complies with HIPAA)
- Lack of universal value framework with the integration of patient-reported outcomes, incorporation of ways for patients to share in any savings associated with the agreement, and identification of target patient population characteristics
- Regulatory barriers such as price reporting requirements, Medicaid rebate requirements, the federal Anti-Kickback Statute, and Best Price requirements
- Implementation challenges such as cost, capacity, internal support, patient adherence, churn, and aligning with existing agreements
- Contractual challenges such as incentive mechanism (tying payment to the outcome), financial terms, time horizon, formulary status, and population management

THE CHANGING HEALTHCARE ENVIRONMENT REQUIRES PHARMACEUTICAL COMPANIES TO EVOLVE

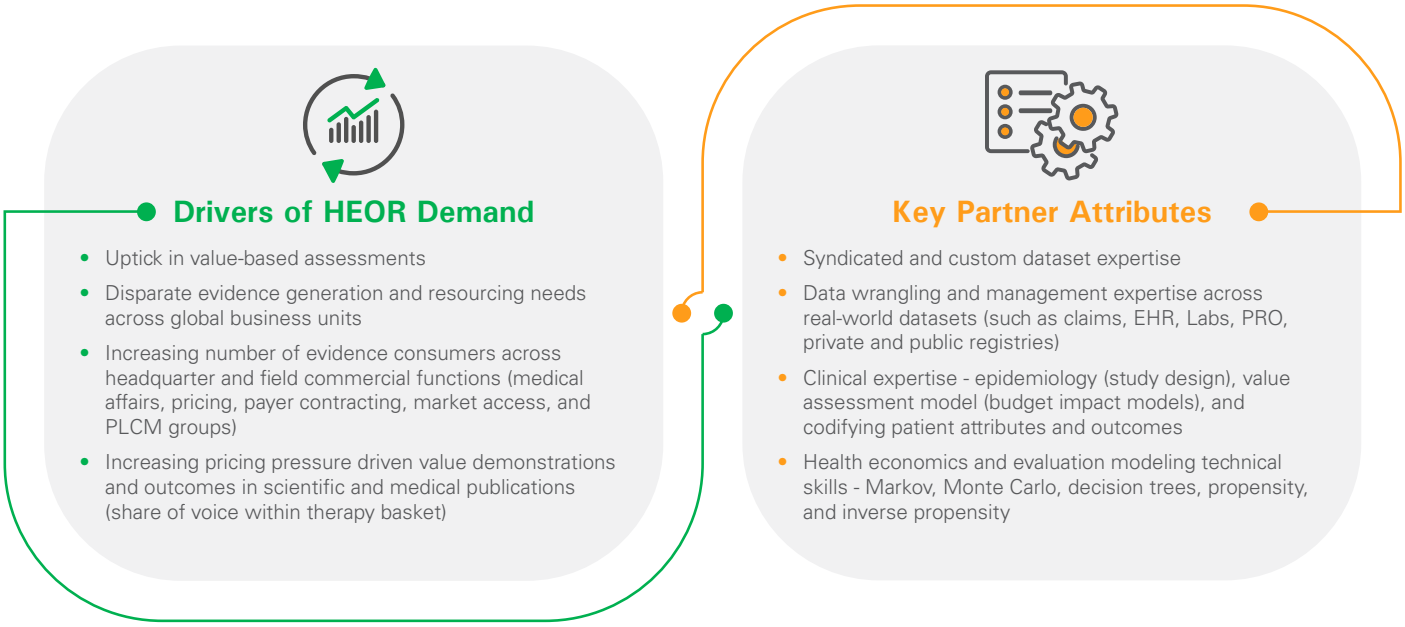
Pharmaceutical companies need to be agile to succeed in this evolving healthcare landscape, building their critical organizational capabilities to support market access and pricing throughout their products' lifecycle. These capabilities include:[3]

- Initial launch planning centered on discussions with payers to understand their disease and cost burden and partnering with patients to identify real-life experiences and need gaps
- Designing innovative contracts that meet the needs of the healthcare system, payers, and patients
- Utilizing RWE to understand the challenges faced by the healthcare system, physician and patient experiences, and the benefits of products and services
- Providing patients and providers with educational materials and tools to understand and adhere to treatments and assurance on data use and privacy
- Developing transparent and collaborative relationships with payers
- Revisiting their internal HEOR function design
- Adopting new methods of working and deploying multidisciplinary teams that possess a good understanding of healthcare systems and the clinical trial process, have great technical skills (such as data analytics, problem-solving, and health economic modeling), along with advocacy and engagement expertise

Pharmaceutical companies often need answers to the following questions regarding the design of their HEOR function:

- What is the best organizational design (centralized or decentralized) that can support (with business efficiency and agility) global HEOR demand pipelines?
- What is the right size of each type of role needed to meet current and emerging HEOR demands? Are there industry-level data points that manufacturers can use as benchmarks?
- How to overcome HEOR talent shortages in the market today?

MEETING GLOBAL DEMANDS FOR EVIDENCE GENERATION AND VALUE DEMONSTRATION



Source: Axtria, Inc.

Resolving demand spikes and global HEOR resourcing requirements need the help of a partner that can scale health economics and evaluation capabilities, skills, and resources on a global level and keep pace with the specialized needs of HEOR line managers.

But it is not a simple matter of workload balancing and/or best shore sourcing. Partners also need to understand the disparate and broad range of HEOR's internal customers and their objectives and the application of evidence and value to those objectives. Hence, an ideal partner will need to demonstrate delivery excellence and robust capabilities for:

- Value and evidence applications across PLCM
- Global reimbursement landscape: HTA and non-HTA reimbursement and market access strategies
- Patient longitudinal datasets: syndicated and non-syndicated
- Real-world datasets, private and public registries, and advanced analytics
- Global program management

Therefore, a pharmaceutical company needs to find the right partner who can deliver business efficiency and operational improvements while providing clinical and health evaluation support to make every HEOR project successful.

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