THE RADICAL IMPLICATIONS OF INDICATION-SPECIFIC PRICING

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This paper discusses one of the potentially more impactful new dynamics in the pricing of pharmaceuticals—the advent of indication-specific pricing. Our goal is to provide context to this important change, highlight some of the implications about which biopharma companies should be aware, and leave you with a framework for raising and addressing pertinent questions across the biopharma value chain.

A major change is under way that has the potential to impact the entire process of developing, pricing, and selling pharmaceuticals. Express Scripts, a leading pharmacy benefit manager (PBM) and pioneer in drug cost management, has introduced an indication-specific pricing model, whereby drugs are reimbursed differently based on their effectiveness in treating a particular indication rather than at the same rate across all indications. Express Scripts is piloting the model in oncology, and, if it proves effective, the company next plans to expand indication-specific pricing to immunology. Given that most of the highest-selling products are currently approved for multiple indications, the impact could be profound. If broadly adopted, this new pricing model has the potential to radically change the approaches by which biopharma companies price their products, moving the industry closer to performance-based pricing.

Historical Challenges to Value-Based Contracts

The indication-specific pricing model builds on the value-based and pay-for-performance pricing models (in which payment is linked to outcomes) that long have been discussed but largely failed to take off. Express Scripts' indication-specific pricing model (see "What is ESI doing?" in sidebar) builds on some of the themes of other attempts at value-based contracting.

Many of these models have had challenges in implementation; for example, as early as 2009, there was much fanfare around an outcomes-based contract for the osteoporosis drug Actonel, in which the manufacturers agreed to be held at financial risk for poor outcomes.[1] Despite the best of intentions, operational challenges limited the impact of these programs—the environment and technology were not yet right for success.

WHAT IS ESI DOING?

Express Scripts (ESI) is piloting indication-specific pricing with a select group of oral and self-injectable cancer drugs on its National Preferred Formulary for plan year 2016[2] through its Oncology Care Value (OCV) program.

Key inputs for deciding on "value" include Drug Abacus[3], a tool developed by Peter Bach, director of the Center for Health Policy and Outcomes at Memorial Sloan Kettering Cancer Center (MSKCC), as well as a new drug value framework[4] from the American Society of Clinical Oncology (ASCO).

Under its OCV program, ESI receives a blended discount across all claims for a given drug based on relative efficacy in the following cancers:

- Renal cell carcinoma
- Non-small cell lung cancer
- Prostate cancer

The manufacturers who participate receive preferential handling for their products. ESI has suggested that truly innovative or clinically superior drugs will not be affected, though prices can continue to evolve as new clinical data emerge.[5]

On the environmental front, the rising cost of healthcare continues to raise the stakes for finding a workable form of value-based pricing. Even oncology, typically a lightly managed class, is changing; one seismic shift occurred in 2012, when MSKCC took a stand against a perceived mismatch in efficacy and price by excluding the colorectal cancer drug Zaltrap from the institution's formulary because they concluded that the product showed no advantage over less-expensive Avastin.[6] In a similar vein, in 2015, ASCO released a conceptual framework for assessing the value of new cancer drugs based on treatment benefits, toxicities, and costs.[7] Such events are showing a clear trend toward the application of value considerations for oncology.

On the technological front, the success of indication-specific pricing depends on sophisticated electronic medical records and the ability to track diagnoses, both of which have significantly advanced in recent years. In its pilot, Express Scripts will require exclusive dispensing of all oncology medications through its wholly owned specialty pharmacy Accredo, enabling the company to track utilization at the indication level rather than the drug level—a requirement for indication-specific pricing to work.[5]

EXPRESS SCRIPTS AS A CATALYST FOR CHANGE

Express Scripts has already demonstrated that its decisions can have a major impact. Pressure in the market for the treatment of hepatitis C built over the course of 2014, as Gilead's Sovaldi achieved unprecedented commercial success. Toward the end of 2014, once AbbVie's Viekira Pak[8] was available as a viable competitor to Sovaldi, ESI moved swiftly to partner with AbbVie, trading price concessions for preferential handing. This led to significant savings for their customers—up to $1 billion in 2015 alone—and started a broad movement among other PBMs and health plans to aggressively follow suit.[9] In the same way that conditions were favorable for rapid change in the hepatitis C space, the time may be right for ESI to trigger change elsewhere with indication-specific pricing today.

What Are the Implications for Biopharma?

At this point, it is not yet clear that indication-specific pricing will be widely adopted. That said, because the implications are so far reaching, biopharma companies must consider how it would impact their operations. If broadly implemented, indication-specific pricing will require change from research and clinical development to pricing and market access and commercial functions. In this section, we will examine the implications and key questions manufacturers will need to address to prepare for the changes this new model could bring.

RESEARCH AND CLINICAL: FIND AND DEMONSTRATE VALUE

Traditional indication strategy—whereby developers determine the disease states to pursue for a given asset—involves such factors as probability of clinical success, unmet medical need, competitive intensity, and pricing flexibility. An important factor in determining launch sequence is that once a product has launched at a specific price point, the price is the same even when new indications are approved, unless new formulations or strengths are developed. Thus, in deciding launch sequence between two indications with similar unmet need, a manufacturer must balance the potential size and pricing potential of different indications, and may choose to first pursue an indication with a higher potential price point and later move to an indication with the lower potential price point. Should indication-specific pricing become common, such a launch sequence strategy will no longer be appropriate. It is even possible that manufacturers may bring products to market more quickly, with less need to optimize around the price of the first indication.

In the future, it will be critical that trials be designed not just to get approval but to demonstrate and prove the clinical value of the product across the full range of indications. It is as yet unclear how Express Scripts will make its indication-specific pricing decisions and what the metrics will be; therefore, manufacturers will need to watch for future guidance around these issues to ensure they are designing trials correctly to adequately establish a product's value. Key stakeholders to watch include leaders like Express Scripts, groups like The Institute for Clinical and Economic Review (ICER), ASCO and its ASCO Value Framework[4], and leading oncology centers like MSKCC, with its published and widely cited Drug Abacus.[3]

RESEARCH AND CLINICAL | KEY CONSIDERATIONS

TRIAL DESIGN AND CLINICAL STRATEGY

How can you design trials that show impact on the endpoints that demonstrate value, beyond what is required for regulatory approval?

How should you incorporate endpoints focused on survival, toxicity, and quality of life (or other patient-reported outcomes)?

How can you monitor key stakeholders, like ESI, MSKCC, ASCO, and others, to ensure that you are designing trials that deliver critical information and demonstrate value?

How should you build your clinical strategy to provide early signals of performance on these "value" metrics?

How can you continue to make efficient clinical investments and decisions within this new context?

CLINICAL INVESTMENT

What is the impact on the priority of your clinical investments? Which indications should be accelerated?

Is there new potential for label-expansion strategies—to indications that are substantially higher or lower in value?

PRICING AND MARKET ACCESS: INCREASE ANALYTICS—AND FLEXIBILITY

Indication-based pricing will be a game changer in the way that companies think about pricing and market access. Under the new model, early incorporation of market access considerations will be critical in the product planning and development process to ensure that companies are prepared to demonstrate value for their drugs and that they focus efforts on drugs and indications that offer the greatest potential clinical impact. It is unlikely that all health plans and PBMs (collectively referred to as payers for the purposes of this article) will share the same value frameworks, so biopharma companies will need to explore new ways to segment and prioritize payers. Indeed, some payers will be more (or less) aggressive in moving to a value-based approach. More broadly, pharmaceutical companies will have to rethink how they develop and communicate their product value proposition to providers and payers.

Pricing will become a more complex interplay between biopharma companies and payers, and as payers and biopharma companies move toward indication-specific contracts, the dynamics become more complex. Price, rebate, access, and handling may vary by indication, necessitating new approaches to pricing and contracting.

PRICING AND MARKET ACCESS | KEY CONSIDERATIONS

DECIDING IF AND WITH WHOM

How should you decide whether to participate in an indication-specific pricing arrangement for any given asset? With which payers?

MARKET DYNAMICS

Is there an opportunity to lead the market toward indication-specific pricing? What would be the potential costs and benefits of doing so?

How should you manage an access environment in which some payers have adopted indication-specific pricing, while others have not? Or in an environment in which multiple value rubrics exist?

What are the potential implications for ASP and government best price?

PAYERS

How can you appropriately partner with payers to manage the administrative burden of these indication-specific deals?

Are risk-sharing models more feasible?

How can you convey the value proposition for your product to payers?

What are the implications for portfolio contracting strategy?

How will non-approved use be reimbursed—a particularly important question in oncology?

How will this change your payer segmentation and prioritization for contracting?

PROVIDERS AND PATIENTS

How can you estimate, plan for, and mitigate patient cost exposure?

How can you mobilize patients, advocates, and clinicians to influence the conversation and support coverage?

To what extent and how will such an approach affect prescribing and utilization of your product?

POST-LAUNCH

What is the best strategy for changing price after launch? Should price changes be the same across different indications? What if a new competitor emerges that changes the perceived value of a product?

COMMERCIAL: ALIGN WITH RESULTS, TAILOR MESSAGES

When it comes to commercializing products, manufacturers need to develop and communicate messages that tell the value story and highlight their product's greatest advantages and benefits. Under indication-specific pricing, a challenge will be developing a coherent story around a product when different value is associated with different indications. This is particularly difficult if one physician is treating patients across a number of a drug's indications. Sales teams will have to absorb new value messages as new indications are launched. Furthermore, as leaders like Express Scripts generate new value metrics that gain momentum, biopharma companies may be challenged to overcome negative perceptions of their products' value in particular indications. Fortunately, truly innovative or clinically superior drugs should be affected less, as Express Scripts has commented that they would be left alone (at least until something similar is launched).[10]

COMMERCIAL | KEY CONSIDERATIONS

MESSAGING

How will you develop and communicate messages that highlight a product's biggest benefits and tell a coherent value story to providers and patients, even when the product has different "assigned" values in different indications?

On which indications should you focus promotional investments and messaging? What elements will be consistent to all indications? What elements will be customized to specific indications?

SALES FORCE

How will you prepare your sales force to be effective in a more complex market environment?

How can you train them and arm them with new messages and materials?

How will you address provider confusion regarding varying reimbursement levels and patient cost exposure?

Conclusion: It's Always Better to Be Ready

It is rare that a disruption comes along that changes almost everyone's job within an industry, but this could be such an event. As the healthcare marketplace becomes increasingly focused on price and value, and as the technology improves to make utilization and outcomes tracking more achievable, there are reasons to believe that indication-specific pricing models will come into their own. It is too soon to tell whether this will have a net positive or negative effect on the industry, but it is certain to make life different, to create winners and losers. For research and clinical, it could turn traditional indication sequencing strategy upside down. For pricing and market access, it may require a revolution in pricing and contracting. And for commercial, it will mean finding a new way to tell a coherent value story. It is as yet unclear how the models will work, on which key value metrics they will rely, which types of products and indications will be most appropriate, and how broad the adoption will be among health plans and PBMs. Companies that proactively plan for this new reality, and do so immediately, will be well-positioned to take advantage of the changes that come.

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