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Strategies to avoid innovation/market access trade-off

By Ramon Mohanlal — 2016-11-29

In an expert view piece, Ramon Mohanlal, chief medical officer at BeyondSpring, a USA-based clinical stage biopharma company, tackles the issue which threatens to undermine the entire drugmaking cycle.

The pricing of pharmaceutical products needs to take into account the interest of patients, physicians, pharma co-economic evaluations, managed care organizations, pharmacy benefit managers and national governments – all the while ensuring adequate returns for the pharmaceutical company involved.

As is the case with all industry sectors, both price and volume are important considerations to maximize revenues and profits for pharma companies. The current trend with pharmaceutical pricing is to focus on obtaining the highest possible price as opposed to the highest possible volume with, in some cases, price increases being introduced for products that have been on the market for extended periods, such as the recent EpiPen example.

Generally, a high degree of product innovation and product differentiation are strong justifications for a high price point, particularly in areas of high unmet medical needs.

Pharmaceutical companies often argue that high price points for innovative drugs are essential to recoup the cost of research and development (R&D), which results from a perceived innovation/market access trade-off. Such a trade-off, however, only occurs if higher innovation would be linked to higher prices.

Avoidance of innovation/market access trade-off could also be achieved through a volume-driven strategy, rather than a price-driven strategy.

Under certain circumstances, it is difficult to implement a higher volume strategy – for example, in the case of orphan indications where the prevalence of patients is very low, and the only way to recoup the cost of R&D would be to issue a high price point.

However, with high-prevalence disease conditions/indications, this argument would not hold, as market access, penetration and share will typically not be exhausted in these cases.

The right product at the right price

One example where the innovation/market access trade-off could be avoided is the indication of chemotherapy-induced neutropenia, one that represents a large patient population but is severely underserved.

Currently, granulocyte-colony stimulating factor (G-CSF) and its analogues are approved for the chemotherapy-induced neutropenia indication; however, G-CSFs are only indicated and prescribed in patients with a high risk (greater than 20% risk) for febrile neutropenia (FN) with myelo-suppressive chemotherapy. This represents 20% or less of the neutropenia market.

In the patient segment with an intermediate risk for FN (with still 10% to 20% risk for FN), which represents the largest market segment of 50% or more oncology patients, G-CSFs are currently not indicated, primarily due to price-sensitivity of this market segment.

The cost of prescribing G-CSFs would not justify the potential cost-savings by the prevention of FN, and hence patent admissions and hospitalizations, in the intermediate risk segment.

An innovative therapeutic option with a product profile that would be at least comparable for efficacy, safety, patient convenience and management to G-CSFs and their biosimilars – but offered at a competitive price point versus G-CSF analogues and relative to the G-CSF biosimilars – would likely be embraced in the intermediate FN risk segment since between 10% and 20% still represents significant risk to the patient.

Design trials to please payers

Another important factor to avoid innovation/market access trade-off is the inclusion of clinical, economic and patient outcomes and quality-of-life measures in clinical trials, which enable adequate market access and reimbursement.

Payers are increasingly moving to market access based on real-world outcomes, and the global trend toward the need for real-world data is changing. Whereas this concept was generally well-accepted and an important determinant for pricing decisions in the European Union, this is now increasingly becoming important in the USA.

Key factors to enabling market access include demonstrating positive outcomes in clinical trials, such as clinical outcomes (biological measures of morbidity and mortality); economic outcomes (the estimated measure of medical and non-medical resources that are used or saved) and patient reported outcomes (any measure of a report that's coming directly from the patient).

Obtaining reimbursement is increasingly difficult due to intensified payer scrutiny amid budgetary constraints and concerns and increased evidence needs.

Furthermore, key elements of payer evidence requirements include evaluation of comparators, target and specific patient populations and certain endpoints, such as quality of life, patient reported outcomes and resource utilization.

To address these challenges and insights that are related to market access and reimbursement, it is important to incorporate these measures for clinical outcome, economic outcome, quality of life assessments and patient reported outcomes in clinical trial design to maximize the returns from monetary and resource investments in these trials.

All in all, through implementing a unique model for avoiding innovation/market access trade-off, we can achieve a win-win-win-win situation for all parties involved: patients, payers, physicians and pharmaceutical company stakeholders.

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