

Real-World Comparative Effectiveness Data for COPD Treatments

Leveraging FDAMA Section 114 promotional opportunities

Situation

Section 114 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) was designed to allow pharmaceutical manufacturers to share health economic information with payers and other decision makers. FDAMA 114 provides pharmaceutical companies an opportunity to differentiate products on economic outcomes not typically included in clinical trials. When used properly, health economic data can offer payers critical information when selecting products for coverage.

When considering treatment for chronic obstructive pulmonary disorder (COPD), cost is a significant issue. For the approximately 30 million Americans suffering from COPD, treatments are typically limited to inhaled bronchodilators and inhaled combination bronchodilators plus inhaled corticosteroids. The Centers for Disease Control and Prevention reports that the total medical costs attributable to COPD are estimated at \$32.1 billion per year and are expected to increase to \$49 billion by 2020. Effective control of COPD symptoms is critical to managing costs.

Challenges

- The COPD treatment classes are crowded, with the substantial competition making preferred placement on commercial formularies critical to gaining and maintaining market share
- Given the high cost of COPD to payers, how can manufacturers differentiate their products from a cost standpoint to support preferred formulary status?



JME
Journal of Medical Economics

The study was published in the *Journal of Medical Economics*, reporting fewer patients treated with the client's COPD medication required rescue medications¹

Solution

Working in partnership with a pharmaceutical manufacturer, Precisions' scientists conducted a comparative analysis of economic outcomes using a retrospective cohort study that assessed COPD-related outcomes based on administrative claims data among combination therapy-naïve patients.

- Patients taking the comparison treatments were matched using a propensity score matching technique
- Cost and effectiveness were measured as total healthcare expenditures, exacerbation events (hospitalizations, emergency department visits, or outpatient visits associated with oral corticosteroid or antibiotic prescription fills), and treatment medication adherence
- Differences in COPD symptom control were assessed via proxy measure through claims for rescue medications and outpatient encounters

Results

The study, published in the *Journal of Medical Economics*, found fewer patients treated with the client's COPD medication required rescue medications, with no substantial differences in other clinical and economic outcomes.

- In accordance with FDAMA 114, the published results were incorporated into a field tool that could be used proactively with payer decision makers to generate discussion on the value of COPD treatments
- Results enabled the manufacturer to engage payers on the potential benefits of its treatment while emphasizing little clinical or economic downside to preferential tiering of the product

1. Roberts M, Mapel D, Petersen H, Blanchette C, Ramachandran S. Comparative effectiveness of budesonide/formoterol and fluticasone/salmeterol for COPD management. *J Med Econ*. 2011;14(6):769-776.

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