A Bayesian decision framework can be used to choose among multiple likelihood (predictive) priors to optimize the posterior economic risk trade-off for payers and manufacturers. METHODS: A Bayesian decision-analytic, hypothetical data-based, cost-effectiveness model was developed. Prior probabilities and QALYs were assigned for 6-, 1-, and 1-month survival, and treatment costs. A plausible prior likelihood (predictive) structure represented the (ROC) relationship between the sensitivity and specificity of CR/PR in predicting survival. Expected (posterior) probabilities of survival, conditional on CR/PR, were generated. At a threshold of $30,000/QALY, the cost-effectiveness of the intervention, conditional on achieving CR/PR, and an optimal sensitivity-specificity trade-off was derived. RESULTS: At a hypothetical treatment cost of $5,000/month for a 4-month cycle, a minimal EP of 13% (maximum specificity of 87%) and a minimal FP of 33% (maximum sensitivity of 67%) emerged as necessary conditions for payers and manufacturers respectively to ensure viable risk-sharing. At higher sensitivity, payer risk did not meet the reimbursement threshold, while at higher specificity, manufacturers would assume excessive financial risk. Other illustrations will be discussed. CONCLUSIONS: Manufacturers should propose evidence-based payment arrangements that utilize clinical trial data to develop economic implications of being at various points on the ROC curve in order to optimize the trade-offs between payer and manufacturer incentives.

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HEALTH CARE UTILIZATION AND COST OF COPD IN A MEDICARE POPULATION: THE ROLE OF CO-MORBID CONDITIONS

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OBJECTIVES: Comorbidities in patients with chronic obstructive pulmonary disease (COPD) are associated with higher mortality, hospitalization, and poor quality of life. The objectives of this study were to characterize a comprehensive comorbidity profile among COPD patients, and to explore the impact of comorbidities on medical utilization and cost in a low-income Medicare population. METHODS: This retrospective cohort study analyzed medical claims from the Maryland Medicare database. We employed a 1:2 case-control design to select 1388 COPD patients aged 40 to 64 years with at least 24 months of continuous enrollment and 2776 demographically-matched controls without COPD. Logistic regressions were performed to calculate odds ratios that compared differences in the prevalence of comorbidities, including 17 conditions defined by the Charlson Comorbidity Index (CCI) and 6 additional conditions known to coexist with COPD. Generalized linear models were performed to estimate the average medical utilization and cost by specific comorbidity. RESULTS: Medications COPD patients had more comorbidities compared with non-COPD controls (CCI w2 = 1.36 vs. 1.37; p = 0.004), and were more likely to have myocardial infarction, congestive heart failure, cerebrovascular disease, peptic ulcer, mild liver disease, hyper-tension, sleep apnea, tobacco use, and edema. COPD patients on average had 16 more medical claims (81.4 vs. 65.4, p < 0.001) and incurred $1871 higher medical cost per year than non-COPD controls ($7673 vs. $1732, p < 0.001). Ten out of the 17 conditions defined by the CCI as well as hypertension, tobacco use, and edema were associated with the excess medical utilization and cost in COPD patients. Depression was associated with excess medical utilization but not cost. CONCLUSIONS: Medications COPD patients have higher prevalence of comorbidities, which translate into higher medical utilization and cost. Effective disease management and treatment protocols are needed to reduce co-morbidity burden.

USE OF HEALTH CARE SERVICES IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) TREATED WITH BUDENOIDE/FORMETOROL VIA DRY POWDER INHALER (BUD/FM DPI) VERSUS TIOTROPION DPI

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OBJECTIVES: To assess real-world effectiveness of BUD/FM DPI versus tiotropion DPI in COPD patients. METHODS: Data from the Quebec health care databases were used to construct a matched cohort of COPD patients aged 440 years newly treated with BUD/FM DPI or tiotropion DPI from 2003-2007. Patients were matched on age, sex, COPD exacerbations (short-course prescription of oral corticosteroids [OCS]; emergency room visit or hospitalization [ED] visits or hospitalizations for COPD; ED events occurring within 15 days counted as 1 exacerbation), and use of short-acting inhaled β2-agonists (SABAs) and ipratropium in the year before therapy began. The number of exacerbations, ED visits, and hospitalizations for COPD; claims for OCS, and the average weekly doses (dose = 2 inhalations) of SABAs and ipratropium were compared for BUD/FM DPI versus tiotropion DPI users for a 1-year post-therapy period. Poisson and linear regression models were used to produce adjusted rate ratios (RR) and mean differences (MD). RESULTS: Of 981 BUD/FM DPI and 981 tiotropion DPI users in the cohort, 78% were aged ≥65 years and 53% were men. No significant differences were seen for COPD exacerbations (RR = 0.94; 95% CI, 0.77–1.15), ED visits for COPD (RR = 0.80; 95% CI, 0.54–1.20), and claims for OCS prescriptions (RR = 0.93; 95% CI, 0.72–1.21) between BUD/FM DPI and tiotropion DPI users in the year after the start of therapy. However, BUD/FM DPI users had significantly fewer hospitalizations for COPD (RR = 0.65; 95% CI, 0.44–0.97), used less SABAs (MD = 0.48; 95% CI, 0.67 to 0.28), and used more ipratropium (MD = 0.35; 95% CI, 0.21–0.50). CONCLUSIONS: These findings showed that patients using BUD/FM DPI were significantly less likely to have COPD exacerbations leading to a hospitalization, but not to be hospitalized, or require emergency care or OCS therapy in the year after initiation of therapy.

OUTCOMES ASSOCIATED WITH TIOTROPION USE IN COPD PATIENTS

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OBJECTIVES: To date, there is mixed evidence on the safety and effectiveness of tiotropium. Our objective was to evaluate the comparative effectiveness of regimens containing tiotropium versus other medication regimens for chronic obstructive pul-

monary disease (COPD) in real-world clinical settings. METHODS: We conducted a cohort study on two separate cohorts with a diagnosis of COPD in the VA health care system. Patients with a COPD diagnosis prescribed tiotropium and patients in a historic cohort prior to the introduction of tiotropium were selected for comparison using propensity scores, with the base case including scores from 0.1 to 0.4. Outcomes identified during follow-up were all-cause mortality, COPD exacerbations, and COPD hospitalizations. Exposure to COPD medication regimens was defined in a time-varying manner and Cox proportional hazards regression were employed to evaluate substantial burden of comorbidities, the regimen of tiotropium plus inhaled corticosteroids plus long-acting beta-agonists was associated with 40% reduced risk of death (HR = 0.60 [95% CI 0.64, 0.79]) compared to inhaled corticosteroids plus long-acting beta-agonists. This combination was also associated with reduced risk of hospitalization (HR = 0.84 [0.73, 0.97]) and COPD hos-
pitalizations (HR = 0.78 [0.62, 0.98]). Tiotropium in combination with other medica-
tion regimens was associated with increased risk of events compared to inhaled corticosteroids plus long-acting beta-agonists. CONCLUSIONS: When used with inhaled corticosteroids and long-acting beta-agonists, tiotropium use was associated with a decreased risk of mortality compared to treatment with inhaled corticosteroids and long-acting beta-agonists. However, this result was not consistent in other medica-
tion regimens that included tiotropium.