**EFFECT OF PATIENTS’ OUT-OF-POCKET COST ON ADHERENCE AND PERSISTENCE WITH OMALIZUMAB (XOLAIR) THERAPY FOR ALLERGIC ASTHMA**

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**OBJECTIVE:** Assess the effect of patients’ out-of-pocket expenditures (OOPE) on adherence and persistence with omalizumab treatment for allergic asthma.

**METHODS:** An incidence cohort of asthma patients age \(\geq 12\) with \(\geq 1\) claim for omalizumab during 2003–2006 and 6 months of prior insurance eligibility was selected from a managed care claims database. Persistence was determined using a survival analysis of the elapsed time between first omalizumab claim and omalizumab discontinuation date (30 days after last omalizumab claim). Discontinuation was defined when \(>90\) days elapsed between omalizumab claims. Adherence was assessed in patients with \(\geq 1\) year of insurance eligibility following first omalizumab claim. Adherence was defined as the total “days supply” of omalizumab during the one-year follow-up period. Proportional hazards models of persistence and general linear regression models (log-linked gamma distribution) of adherence estimated the impact of OOPE.

**RESULTS:** In the persistence cohort (N = 677), OOPE per omalizumab claim was skewed to the right: average \$105 (\(\pm \$175\)), 33rd percentile \$25, median \$40, 66th percentile \$100. The hazard ratio (HR) for discontinuing was 1.29 (95% CI: 1.05–1.59) comparing patients with OOPE \(\geq\$100\) vs \(<\$100\). Using the bottom tertile as a reference, the HR for the top tertile was 1.31 (95% CI: 1.03–1.68) and the middle tertile was 1.03 (95% CI: 0.81–1.31). In the adherence cohort (N = 413), average OOPE was \$110 (\(\pm \$19\)), median \$125 and average therapy days per year was 216 (\(\pm 119\)). Adherence decreased with increasing OOPE. Overall, the coefficient on \$1\) of OOPE was \(-0.0004\) (95% CI: \(-0.0007\) to \(-0.0001\)), implying that an increase of \$25 per claim would cause 1% therapy days lost for each patient.

**CONCLUSION:** Increasing patients’ OOPE may decrease adherence and persistence with omalizumab. The effect on persistence was significant at higher levels of OOPE but not at lower levels. The effect on adherence was small at the OOPE levels in this insured population.

**CEILING EFFECTS AND DISCRIMINATION OF TREATMENT BENEFIT FOR PATIENTS WITH LOWER SYMPTOM SEVERITY: MEASUREMENT OF HEALTH UTILITIES IN ALLERGIC RHINITIS**

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**OBJECTIVES:** Uncertainty exists about the most meaningful measure of health utilities for treatment comparisons, especially for conditions with lower severity. This study explores these issues for patients with allergic rhinitis (AR), which is a bothersome and costly condition, but is not highly morbid. Inclusion criteria for trials may select only patients with mild or moderate symptom severity; furthermore, these patients often have access to symptomatic medications. Consequently, discrimination of treatment benefit may be difficult.

**METHODS:** The study reviews and compares the measurement properties of the EQ-5D and SF-6D, with particular focus on their ability to discriminate at lower levels of severity, a circumstance of AR. Data from several studies of patients with AR demonstrate that a subset of patients have severity of symptoms that can be meaningfully captured with the EQ-5D (i.e., they are not at the ceiling), while a large subset of patients have lower severity and may be better assessed by the SF-6D.

**RESULTS:** Several published studies of patients with AR and data from this research team indicate that the EQ-5D values are often at or near the ceiling (mean values \(\approx 0.94\)), reflecting low symptom severity. Consequently, the ability to discriminate and make meaningful resource allocations may be compromised. Data from our naturalistic study found that half of the patients with AR reported low symptom severity (mean score of 1.3 on a scale from 0 to 3), suggesting that EQ-5D values would be close to 1.0. **CONCLUSIONS:** For conditions with lower overall severity and morbidity, such as AR, using more than one utility measure may be informative. The EQ-5D would provide more international comparability, since it is the more generally accepted utility measure. However, inclusion of another utility measure that can capture the lower end of symptom severity may be a useful strategy for patients with AR.