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USE OF TNF-INHIBITORS IN THE UNITED STATES: UTILIZATION PATTERNS AND DOSE-ESCALATION FROM A REPRESENTATIVE UNITED STATES RA POPULATION

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OBJECTIVES: TNF-inhibitors were the first biological therapies approved for RA treatment and five are approved by the US FDA: etanercept (ETN), adalimumab (ADA), infliximab (IFX), certolizumab pegol (CZP) and golimumab (GOL). The study objective was to understand “real-life” dosing patterns, including dose-escalation, which may impact costs/outcomes of TNF-inhibitor therapy. METHODS: We used a longitudinal claims database (i3 Pharma Informatics) to assess RA patients receiving ETN, ADA, or IFX. Due to product launch date, CZP and GOL were excluded. Patients having a TNF-inhibitor claim, RA diagnosis (ICD-9: 710.4), at least 6 months pre-biologic eligibility and 24-months enrollment post-claim from January 2007–March 2009 were included. Dose-escalation was defined as an increase in bi-weekly dosing from 40 to 80mg for ADA, an increase in weekly dosing from 25 to 50/100mg or 50 to 100mg for ETN, and the addition of 1 vial to the subsequent 8-week maintenance treatment dose, or a reduction in weeks between IFX treatments.

RESULTS: A total of 59,928 patients filled a TNF-inhibitor prescription and 3484 were eligible for inclusion in this analysis. Dose-escalation rates were 13% for ADA, 3% for ETN, and 39% for IFX. Additionally, 6% of patients initiated on 25mg ETN experienced dose-escalation versus baseline. Switching to another biologic occurred in 14% (ETN), 16% (ADA) and 17% (IFX).

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ESTIMATING THE ECONOMIC BENEFITS OF POSITIVE SHIFTS IN FIBROMYALGIA SEVERITY

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OBJECTIVES: Fibromyalgia (FMS) is a chronic condition characterized by widespread pain and can impose substantial economic burden. This study estimates the annualized differences in healthcare costs associated with improvement in FMS severity among pregabalin-treated patients. METHODS: Data from 3 similarly designed, 3-month placebo-controlled, clinical trials of pregabalin in FMS patients were modeled. Efficacy results were based on a 1-year open-label study. Mean annual costs (direct and indirect) were assigned based on FMS severity levels (mild: $10,219; moderate: $26,217; severe: $42,456) and were derived from the US FMS Burden of Illness Study. FMS severity levels were defined using established validated FMS impact questionnaire. Mean annualized costs at endpoint were estimated for all patients within each cohort and the mean differences in costs were compared between cohorts using a regression model. RESULTS: Relative to placebo, the proportion of mild subjects at endpoint was significantly lower with pregabalin 450mg and significantly lower for severe sub-

jects. Mean total costs were lower with pregabalin (300mg, $25,721; 450mg, $24,103) than placebo ($26,162). Relative to placebo, the difference in mean annual costs was $2059 lower for pregabalin 450mg (P = 0.003) and $441 lower for pregabalin 300mg (P = 0.079). Costs were higher with pregabalin (300mg, $47,774; 450mg, $4820) than placebo ($43,364). Relative to placebo, the difference in mean annual direct costs for pregabalin 450mg was significantly lower by $429 (P = 0.001), and for pregabalin 300mg was lower by $951 (P = 0.12). CONCLUSIONS: Improvements in FMS severity are associated with overall reductions in costs that may offset the costs of treatment with pregabalin.

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BURDEN OF RHEUMATOID ARTHRITIS DISEASE FLARES

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OBJECTIVES: To assess the association of disease flares with clinical outcomes, health status, and work productivity loss among patients with RA. METHODS: Data were collected from individuals aged ≥18 and reporting an RA diagnosis through a cross-sectional, self-administered, Internet-based questionnaire. Frequency of disease flares were categorized as: no flares (reference group), <1 per month, 1 per month, 2-3 per month, 1 per week, 2-3 per week, 4-6 per week, and daily. Clinical outcomes included the Health Assessment Questionnaire (HAQ) and severity of morning stiffness, fatigue, and pain, measured as 1-none experienced to 10=se-

vere. Health status was assessed using the SF-36, and work productivity loss (em-

ployed individuals only) and activity impairment were assessed using the Work Productivity and Activity Impairment questionnaire. Logistic regression analyses and comorbidities were adjusted using linear regression and negative binomial regres-

sion as appropriate. RESULTS: Of 2,135 patients, 47.4% (n=1,011) experienced a disease flare in the past six months and 52.7% (n=1,124) experienced no flares. Greater frequency of flares was significantly associated with greater functional disability, severity of morning stiffness, fatigue, and pain; poorer physical and mental health status; greater lost work productivity and activity impairment. Specifically, daily flares were associated with greater functional disability (HAQ regression coefficient b = 0.56, P < 0.001), greater severity of morning stiffness (b = 2.27, P = 0.001), fatigue (b = 2.20, P = 0.001), and pain (b = 2.27, P = 0.001); poorer health status (SF-36 physical component summary: b = -8.76, P < 0.001 and mental component summary: b = -7.48, P = 0.005); and greater work impairment (activity ratio = 2.20, P < 0.001) and activity impairment (activity ratio = 1.68, P < 0.001).

CONCLUSIONS: Disease flares associated with worse clinical outcomes, poorer health status, and greater lost work productivity. However, due to the cross-sectional nature of the study, the direction of these associations cannot be deter-

mined. Treatments that minimize disease flares may provide additional benefit in clinical outcomes, health status, and work productivity.