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RHEUMATOID ARTHRITIS PATIENT EXPERIENCE WITH SELF-INJECTION WITH SUBCUTANEOUS BIOLOGICS

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OBJECTIVES: To report patient experience with self-injection and describe injection site reactions and reasons for treatment compliance/discontinuation. **METHODS:** In first quarter 2010, RA patients completed a cross-sectional, self-administered, Internet-based questionnaire. In the survey, SC was defined as "medication administered via needle just under the skin". Data were weighted to reflect general population proportions for age, gender, race, education, household income and region. **RESULTS:** Of 58 SC biologic patients, 67% experienced pain during or after receiving injections. On a scale from 1-10 describing severity of pain (1 = "not at all painful" and 10 = "extremely painful"), 9% during injection and 22% after injection rated severity of pain as ≥8. Stinging, bruising, pain, redness, burning and swelling were the most common injection site reactions experienced by biologic users. Of these patients, 21% experienced at least one or more of these symptoms 'most or all the time'. Among the 58 SC biologic patients, 41% were 'somewhat willing', 12% were 'very willing" and 8% were 'extremely willing' to switch treatments as a result of injection site reactions. Among SC patients who self-reported that they did not take biologics as prescribed, 22% described injection fear and another 22% described general fear of needles as "very influential" in not complying with their treatment. 19% of patients who discontinued SC biologics (n=55) cited 'felt uncomfortable about needles" as 'very influential' and 'extremely influential' reasons for discontinuation. **CONCLUSIONS:** In this analysis, many patients experience injection related pain associated with SC biologics and this may be impacting therapy compliance and continuation. Therefore, it may be important to evaluate different injection options within SC biologics when making treatment selection and patient access decisions. Given the small sample size (n=58), further research is needed to quantify impact of injection experience on self-reported vs. observed compliance and treatment continuation.

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EARLY AND SUSTAINED REMISSION ASSOCIATED WITH NORMALIZED PHYSICAL FUNCTION AND HEALTH-RELATED QUALITY OF LIFE AND SIGNIFICANTLY IMPROVED PRODUCTIVITY IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS TREATED WITH GOLIMUMAB: TWO YEAR DATA FROM THE PHASE III GO-REVEAL CLINICAL TRIAL

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OBJECTIVES: Evaluate golimumab's(GLM) impact on disease remission, physical function, work productivity and healthcare utilization in patients with psoriatic arthritis (PsA) over 2 yrs. **METHODS:** In GO-REVEAL, 405 adults with active PsA were randomized to GLM(50 or 100 mg) q4wks or placebo. At wk16, patients with inadequate response entered early escape. All placebo-treated patients received GLM50mg from wk24. Clinical responses parameters included 20% improvement in American College of Rheumatology (ACR20) criteria, 75% improvement in Psoriasis Area and Severity Index(PASI75); a disease activity score (DAS28) <2.6 defined remission. Patient-reported outcomes included health assessment questionnaire (HAQ), self-reported productivity and medical visits. Comparisons between GLM and placebo before wk24 employed ANOVA on van der Waerden normal scores (continuous outcomes) or Chi-square test (categorical). **RESULTS:** Baseline HAQ and PASI scores were 1.02 and 7.8. A greater proportion of GLM- than placebo-treated patients achieved DAS28 remission by wk4(16.3% vs. 3.6%, $p<0.001$) and wk14 (30.6% vs. 1.9%, $p<0.001$). Remission rates increased over time, exceeding 50% for GLM-treated patients at wk104. Greater proportions of GLM-treated patients achieved ACR20 and PASI75 responses, normalized HAQ (≤0.5) or health-related quality-of-life (HRQoL), or significantly improved work productivity versus placebo at wk14 (all $p<0.01$). These improvements were sustained through wks52 and 104. A greater proportion of patients achieving versus not achieving DAS28 remission also achieved normalized physical function or had significantly improved work productivity from baseline at wks52 and 104. Improvements in employability, time lost from work by patients and caregivers and healthcare utilization were observed at wks52 and 104, especially among patients achieving DAS28 remission. The overall GLM safety profile through wk104 was similar to other anti-TNFα agents indicated for PsA. **CONCLUSIONS:** GLM treatment induced early and sustained remission (DAS28<2.6), resulting in long-term improvements in physical function, QoL, and work productivity and reduced healthcare utilization, in PsA patients.

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FREQUENCY OF SELECT ANTI-TNF ADMINISTRATION OR RE-FILL IN PATIENTS WITH RHEUMATOID ARTHRITIS

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OBJECTIVES: Limited information exists on real-world patient adherence to the FDA recommended prescribing schedules for adalimumab (ADA) (40 mg bi-weekly), etanercept (ETA) (50 mg/week), and infliximab (IFX) (every 8 or 4 weeks following induction) in the treatment of patients with rheumatoid arthritis (RA). This study evaluates the days between infusions for IFX and refills for ADA and ETA. **METHODS:** Data between 01/2004-12/2007 were extracted from a retrospective multi-source claims database. Inclusion criteria were aged ≥18, ≥2 diagnoses of RA (ICD-9 code 714.xx), ≥1 claim for biologic therapy, absence of any biologic claim for 12 months prior to index date, and absence of any biologic claim other than the index biologic for ≥730 days post-index date. Patients with diagnoses of other selected inflammatory disorders were excluded. IFX patients were required to have ≥4 doses. Days between infusions or re-fills for the first 12 infusions of IFX and fills of ADA and ETA are reported. Time to re-fill was calculated as the difference between fill dates minus days supply. **RESULTS:** Intervals between IFX infusions during the maintenance period ranged from a mean of 52.3 to 55.0 days over the first 12 infusions. Refills for ADA ranged from a mean of 7.3 to 11.4 days beyond recommended refill schedule over the first 12 prescription fills. Refills for ETA ranged from a mean of 6.7 to 14.2 days beyond the recommended refill schedule. **CONCLUSIONS:** Data from real-world community practice indicate that patients treated with IFX are infused at intervals consistent with prescribing information and patients undergoing treatment with ADA and ETA are refilling prescriptions one to two weeks later than the recommended refill schedule. Further studies are warranted to understand the clinical implications of gaps in therapy with the more frequently dosed subcutaneous agents vs. the less frequently dosed infused medications such as IFX.

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ANALYSIS OF INFLIXIMAB DOSE CHANGES OVER TIME IN MEDICARE BENEFICIARIES WITH RHEUMATOID ARTHRITIS

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OBJECTIVES: To describe patient level infliximab (IFX) dosing changes over time during maintenance treatment in Medicare Beneficiaries with rheumatoid arthritis (RAMB). **METHODS:** This retrospective claims analysis used the 2001-2008 Centers for Medicare and Medicaid Services (CMS) Medicare Beneficiary 5% Standard Analytical Files. This database includes Medicare beneficiaries that are eligible due to age (≥65 years) or other criteria such as disability or end-stage renal disease. Inclusion criteria included RAMBs receiving >8 and <12 consecutive quarters of IFX treatment, a diagnosis of RA, and no IFX treatment during the preceding quarter. IFX dosing was analyzed at the patient level to determine the dosing change from quarter to quarter, not including the first quarter of IFX treatment. IFX dosing was determined from the Medicare billing units submitted for payment. Mean quarterly per patient IFX dose was determined by dividing the total infliximab unit amount by the number of administrations per quarter. **RESULTS:** A total of 395 RAMBs receiving IFX were identified. Mean age was 67.5 years, and 75% were female. Mean IFX dose was 380 mg and mean treatment duration was 9.7 quarters. The mean IFX dose increase was 11.7 mg per quarter. IFX dosing changes over time: 41% had no change or an IFX dose decrease, 35% had a dose increase of <20 mg per quarter, 19% had a dose increase of >20 and <40 mg per quarter, and 5% had a dose increase of >40 mg per quarter. **CONCLUSIONS:** This patient level analysis of maintenance IFX dosing in RAMBs observed minimal dose escalation, with only 5% of RAMBS requiring more than 40 mg IFX dose increase per quarter over 2-3 years of IFX treatment. Nearly half of RAMBs had no dose increase, or a decrease in IFX dose during maintenance treatment.

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THE USE OF MIXED TREATMENT COMPARISONS IN NICE TECHNOLOGY APPRAISALS

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BACKGROUND: Comparative effectiveness research is seen as a powerful tool to assist payers in determining the most effective treatment option when multiple possibilities exist. Whilst head-to-head trials of relevant comparator treatments are uncommon, indirect comparisons, such as Mixed Treatment Comparisons (MTCs), offer the potential to help assess the comparative efficacy of therapies, which can inform payers about their comparative effectiveness. **OBJECTIVES:** To review the use of MTCs in published technology appraisals from the National Institute for Health and Clinical Excellence (NICE) in the UK. **METHODS:** All NICE technology appraisals from January 2006 to December 2010 were searched for 'mixed treatment comparison'. **RESULTS:** Overall, 17 appraisals containing MTCs were identified. Of these, 24% were for rheumatoid arthritis, 24% for cardiovascular conditions, 18% for cancer and the remainder were for other conditions. In 2010, NICE published 26 appraisals, of which 8 (30.8%) utilised MTCs; in 2009, 26% of appraisals (5/19) incorporated MTCs; in 2008 this figure was 17.4% (4/23) and in 2007 and 2006 no appraisals, out of 19 and 14 published appraisals respectively, contained MTCs. The justification in most cases for the use of the MTCs was to provide an indication of comparative effectiveness for the intervention compared with major competitors and often the findings were incorporated into the manufacturer's economic model. However, in the majority of appraisals, the Evidence Review Group criticised the design of the MTCs, and in at least 5 cases this led to the Committee either disregarding the results of the MTC or interpreting them with caution. **CONCLUSIONS:** The value of MTCs for determining comparative effectiveness in Health Technology Assessments cannot be disputed, and they are increasingly becoming a more common feature in the NICE appraisal process. However, manufacturers should ensure that their MTCs are robustly designed otherwise the success of their submission may be jeopardised.