OBJECTIVES: To report patient experience with self-injection and describe injection 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, household income, and education. RESULTS: Of 58 SC biologic patients, 67% experienced fear 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, 2% described 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 cohort, 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 was needed to quantify impact of injection experience on self-reported vs. observed compliance and treatment continuation.

PMS65 RHEUMATOID ARTHRITIS PATIENT EXPERIENCE WITH SELF-INJECTION WITH SUBCUTANEOUS BIOLOGICS Tandon N1, Ellis L1, Bolge S1, Iqbal R2, Buck L2
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OBJECTIVES: To evaluate golimumab’s (GLM) impact on disease remission, physical function, and healthcare utilization in patients with psoriatic arthritis (PsA) over 2 yrs. METHODS: In GO-REVEAL, 405 adults with active PsA were randomized to GLM50 mg 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 were performed using ANOVA on log 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 ACR28 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 remissions, 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 wk52 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 wk52 and 104. Improvements in employability, time lost from work by patients and caregivers and healthcare utilization were observed at wk52 and 104, especially among patients achieving DAS28 remission. The overall GLM safety profile through wk104 was similar to other anti-TNFa 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.

PMS66 FREQUENCY OF SELECT ANTI-TNF ADMINISTRATION OR RE-FILL IN PATIENTS WITH RHEUMATOID ARTHRITIS Schmeichel-Mueller C1, Bartsch A1, Silver J2, Bolge S1, Ingham M3
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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 claims within 3 months prior to the index date, and absence of any biologic claims within 90 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 in days between fills. 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. 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 to therapy with the more frequently dosed subcutaneous agents vs. the less frequently dosed infused medications such as IFX.

PMS68 ANALYSIS OF INFliximAB DOSE CHANGES OVER TIME DURING MEDICARE BENEFICIARIES TREATED WITH RUHEMATOID ARTHRITIS Cugel M1, Baker RA2, McKenzie RF3, Ingham M3, Feldman B1
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OBJECTIVES: To describe patient level infliximab (IFX) dosing changes over time during Medicare beneficiairies treated with infliximab (IFX) for rheumatoid arthritis (RAMB). METHODS: This retrospective claims analysis used the 2001-2008 Centers for Medicare and Medicaid Services (CMS) Medicare Beneficiary 5% Summary 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 Eligible Expended Amount (CEEA) in the UK Master file. All 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 ± 7.5 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 receiving 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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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 between 2001-2009 and evaluate the use of 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 18% for cancer and the remainder were for other conditions. In 2010, 26% of appraisals (5/19) incorporated MTCs; in 2008 this figure was 17.4% (4/23) and in 2007 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 18% for cancer and the remainder were for other conditions.

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.