PSY56 IMPACT OF EARLY VERSUS LATE SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) DIAGNOSIS ON CLINICAL AND ECONOMIC OUTCOMES
Oglesby AK1, Dennis G2, Kores C3, Laliberté F4, Suthoff ED5, Wei R2, Duh MS6
1Oakland Scientific Affairs, LLC, Horsham, PA, USA, 2Centocor Ortho Biotech Services, LLC, Horsham, PA, USA, 3IMS Health Consulting Group, Watertown, MA, USA
OBJECTIVES: SLE is an autoimmune disease with a broad list of differential manifestations, further complicating its diagnosis. The objective of this study was to compare clinical outcomes, resource utilization and costs between patients with earlier and later diagnosis of SLE.
METHODS: This was a retrospective cohort analysis of patients with SLE from 8 large US administrative claims databases from 2000-2010. For each database, we identified a cohort of patients with SLE diagnosis coded in the database (E06-09). The follow-up period was 2 years. Treatment data were collected from 2 years prior to SLE diagnosis. Costs associated with SLE care were estimated using publishedPrevail® and Remission® costs. Statistical comparisons were performed with a t-test.
RESULTS: The study included 3,398 patients with early SLE diagnosis (mean age 40.6 years, 98.7% female) and 7,191 patients with late SLE diagnosis (mean age 31.9 years, 94.1% female). The early diagnosis group had more female patients (p=0.001) and was more likely to receive prednisone (p=0.023) compared to the late diagnosis group. The mean total cost during the follow-up period was $11,794 for the early diagnosis group and $15,652 for the late diagnosis group (p=0.001). The mean cost per patient per year was $4,798 for the early diagnosis group and $6,030 for the late diagnosis group (p=0.001). The cost of medications for SLE was significantly lower in the early diagnosis group compared to the late diagnosis group ($1,205 vs. $1,704, p=0.001). The cost of hospitalization was significantly lower in the early diagnosis group compared to the late diagnosis group ($4,415 vs. $5,671, p=0.001).
CONCLUSIONS: Early diagnosis of SLE is associated with lower healthcare costs compared to late diagnosis. More research is needed to understand the reasons for these differences and to explore strategies to promote early diagnosis.

PSY57 VARIATION IN HEALTH-RELATED QUALITY OF LIFE ASSOCIATED WITH CHANGES IN TRANSMUTATION STATUS OF PATIENTS WITH MYELODYSPLASTIC SYNDROMES ACROSS SIX MONTHS OF TREATMENT WITH AZATIDINEIN
Pashos CL1, Grinblatt DL2, Sekeres MA3, Komoroki RS4, Narang M, Swem AS5, Street TK6, Sullivan KA7, Harding G8, Khan ZM9
1United BioSource Corporation, Bethesda, MD, USA, 2Northwestern University Health Science Institute, Evanston, IL, USA, 3Cleveland Clinic, Cleveland, OH, USA, 4Moffitt Cancer Center, Tampa, FL, USA, 5Maryland Hematology Oncology, Westminster, MD, USA, 6Celgene Corporation, Summit, NJ, USA
OBJECTIVES: To assess how health-related quality of life (HRQoL) of patients with myelodysplastic syndromes (MDS) who were red blood cell transfusion dependent (RBC TD) at baseline and remained so across six months of treatment with Azati-ridine (AZA) compared with HRQoL of MDS patients who were RBC TD at baseline but became RBC transfusion independent (TI) across six months of AZA treatment.
METHODS: Data were collected in AVIDA®, a prospective registry of patients treated with AZA. MDS patients who were RBC TD at baseline and who received 56 days or more of AZA were analyzed. RBC TD was verified centrally. Clinicians provided information on clinical characteristics, including transfusion status. Patients completed the EORTC-QLC-C30 at baseline and quarterly thereafter. Summary statistics on global health status, functional scales, and symptom/scales were analyzed. Statistical significance was determined by ANOVA (SA 9.1).
RESULTS: At baseline, the AZA patients and RBC TI patients had similar characteristics. Six months after AZA treatment, AZA patients who remained RBC TD had statistically significant and clinically meaningful differences in change between baseline and 6 months as compared to AZA patients who were RBC TI (p=0.014). Statistically significant and clinically meaningful differences in change between baseline and 6 months were seen in physical and role function (p=0.005 and p=0.015), but not in emotional, cognitive or social function.
CONCLUSIONS: This study supports the use of AZA for MDS patients who are RBC TD at baseline and have unmet need for RBC TD treatment. AVIDA is ongoing, and there is a need for additional studies to confirm these findings.

PSY58 PAIN MANAGEMENT: OBSERVATION AND SIDE EFFECTS
Tai CH1, Crea PS2, Bouillon, France
OBJECTIVE: Pain treatment is a real challenge for Public Health and a requirement for the quality and evolution of a health system. It responds primarily to a human and social objective, intrinsic to the dignity of the humankind. The physical pain and moral suffering experienced during all ages of life makes those already weakened by the disease even more vulnerable. Treatment compliance is essential to the efficacy of the treatment offered. Side effects or undesirable effects may be caused by non-compliance when they appear in the first 24 or 48 hours after treatment.
METHODS: The objective is to describe the side effects perceived during the first 48 hours and spontaneously cited by the subjects treated with an analgesic. Methods: Prospective, longitudinal, multicenter observational study, conducted in France using data collected by the general practitioners who agreed to participate.
RESULTS: Patients were treated either with a paracetamol-codeine combination (n=742) or with a paracetamol-tramadol combination (n=107). Nausea/vomiting, dizziness, drowsiness and constipation were the 4 most commonly cited side effects. In the first 24 hours prevalence after 2005 was 44.4% and 108% respectively, versus 13.89%, 7.41, 2.78% and 2.78% in the second group. On the 2nd day, prevalence in the first group was 3.9%, 2.01, 3.4% and 2.8% respectively, versus 11.1, 3.7, 1.8% and 2.78% in the second group. Prevalence of at least one side effect perceived during the 7 days of treatment was 28.74% in the first group versus 40.74% in the second treatment group.
CONCLUSIONS: A study was published in 2005 (Patients and chronic-exercer magazine January 2005-Le Goaziou et call) indicated 37% constipation, 24% nausea and vomiting and 22.4% dizziness. For a group of patients undergoing treatment. It appeared that the patients treated with one of these treatment had fewer complaints of the same side effects.
OBJECTIVES: The Nplate® NEXUS (NEXUS) Program included a registry of patients in the United States to monitor the long-term safety and assure safe use of Nplate®. Adverse events of special interest include changes in bone marrow reticulin formation and collagen fibrosis, worsened thrombocytopenia after cessation of Nplate®, thrombotic/thromboembolic complications, new hematologic malignancies and progression of malignancy in patients with pre-existing hematologic malignancy and aplastic syndromes (MAS) and medication errors associated with serious outcomes. METHODS: Data were collected through structured questionnaires completed by healthcare professionals registered for the NEXUS Program at baseline and every 6 months thereafter. RESULTS: Between August 22, 2008 and January 31, 2011, 5,235 patients (51% female; mean age 62 years; median baseline platelet count 200x10^9/L) had enrolled in the NEXUS Program and received Nplate®. The reported diagnoses were ITP (88.3%), other (8.9%), thrombocytopenia from hematologic or lymphatic malignancies (1.1%), MDS (1.0%), and thrombo- cytopenia of unknown etiology (0.6%). Before entry, 81.6% of patients had received other therapies, most commonly corticosteroids (61.8%), IVIG (55.4%), and rituximab (42.5%). At baseline, 62.9% of patients were receiving concurrent ITP therapy, including corticosteroids (43.8%), IVIG (17.7%), and rituximab (11.4%). Prior to enrollment, 24.7% of patients had a splenectomy. As of December 2011, the FDA and Amgen concluded that the restricted elements of the REMS could be eliminated. CONCLUSIONS: The majority of patients in the NEXUS Program receiving Nplate® were reported to have an ITP diagnosis with a history of previous ITP therapies and were receiving concurrent ITP medications. Further information regarding the data from the NEXUS Program and the evolution of the REMS program will be discussed.

PSYS2 PREDICTORS OF PAIN MEDICATION SELECTION AMONG PATIENTS DIAGNOSED WITH CHRONIC LOWER BACK PAIN Wu N1, Chen SY2, Andrews JP3, Roulanger L1, Peng X3
1Tibb Lilly and Company, Inc., Indianapolis, IN, USA; 2Tibb Lilly and Company, Inc., Indianapolis, IN, USA
OBJECTIVES: Little is known about the characteristics of duloxetine patients initiating therapy for chronic lower back pain (CLBP). This study identified demographic characteristics associated with the initiation of duloxetine and other pain medications among CLBP patients. METHODS: Adult CLBP patients who initiated medication therapy (duloxetine, anticonvulsants, antidepressants, muscle relaxants, non-steroidal anti-inflammatory drugs [NSAIDs], opioids, or benzodiazepines) between November 1, 2010-March 31, 2011, were selected from medical and pharmacy claims from Medco Health Solutions. Treatment initiation was defined as no pill coverage of the medication over the previous 90 days. The dispense date of the first initiated medication was set as the index date. Comorbidities and prior medication use was assessed during the 6 months before the index date. Multiple logistic regression models were performed to identify predictors of initiating duloxetine versus other pain medication. Separate models were estimated with Charlson comorbidity index (CCI) + use of selected medications, and individual comorbidities + number of unique medications, respectively. RESULTS: We identified 38,943 CLBP patients (mean age 58 years; 62.8% female) who initiated opioids (36.0%), NSAIDs (21.1%), muscle relaxants (13.6%), benzodiazepines (8.9%), antidepressants (8.7%), anticonvulsants (7.5%), or duloxetine (4.1%). Patients who initiated duloxetine had significantly higher CCI and more inpatient stays than patients who initiated other pain medication, except for antidepressants. The regression results showed older patients were less likely to initiate duloxetine than anticonvulsants or opioids. Patients with higher CCI were more likely to initiate on duloxetine except for anticonvulsants and opioids. Prior use of pregabalin, gabapentin, antidepressants, and benzodiazepines were associated with a higher likelihood of initiating duloxetine. Patients who had more unique medications, peripheral vascular disease, or depression were more likely to initiate duloxetine. CONCLUSIONS: Presence of selected demographic characteristics, comorbidities and prior use of medications were significant predictors of duloxetine initiation among CLBP patients.

PSYS3 FACTORS PREDICTING THE INITIATING DOSE OF DULOXETINE AMONG PATIENTS WITH CHRONIC LOWER BACK PAIN: A RETROSPECTIVE COMMERCIAL CLAIMS ANALYSIS Andrews JS1, Wu N2, Peng X3, Chen SY2, Roulanger L1
1Tibb Lilly and Company, Inc., Indianapolis, IN, USA; 2Tibb Lilly and Company, Inc., Indianapolis, MA, USA
OBJECTIVES: The purpose of this study was to identify the demographic and clinical characteristics associated with the initiating dose of duloxetine among patients with chronic lower back pain (CLBP). METHODS: Medical and pharmacy claims of CLBP patients who initiated duloxetine were analyzed. Initiation was defined as no duloxetine coverage in the 90 days preceding the first duloxetine claims of CLBP patients who initiated duloxetine were analyzed. Initiation was classified as on PPL (vs. OD) regimen. Each algorithm was assessed against actual data with physician notes using sensitivity, specificity, positive and negative predictive values (PPV & NPV). RESULTS: 445 patients were identified with 65% on PPL regimens. Patients receiving OD regimens were significantly older than those receiving PPL regimens (Mean [years] OD: 24.4 ± 17.1, PPL: 19.6 ± 13.0; p = 0.02). The best-performing algorithm was based on TUFVIII thresholds of 45.920 (age group 2-14), 104.0±15.1 (15-19); 139.200 (20-27), and 178.700 (28-). RESULTS: 445 patients were identified with 65% on PPL regimens. Patients receiving OD regimens were significantly older than those receiving PPL regimens (Mean [years] OD: 24.4 ± 17.1, PPL: 19.6 ± 13.0; p = 0.02). The best-performing algorithm was based on TUFVIII thresholds of 45.920 (age group 2-14), 104.0±15.1 (15-19); 139.200 (20-27), and 178.700 (28-). CONCLUSIONS: The best-performing algorithm showed promising performance validity with PPV=0.89 for ascertainment of PPL TUFVIII regimens in PA patients. Further refinement of the classification algorithm on larger populations is needed.

PSYS6 USE OF MEDICAID ANALYTIC EXTRACT FOR EVALUATION OF DRUG USE AND HEALTH SERVICES UTILIZATION AMONG PATIENTS WITH HEMOPHILIA A Bykof K1, Bohn RL2, Ewenstein BM3, Avorn J4, Seeger JD5
1Brigham and Women’s Hospital, Boston, MA, USA; 2Rhonda L. Bohn, LLC, Walnut, MA, USA; 3Baxter Healthcare Corporation, Westlake Village, CA, USA; 4Brigham and Women’s Hospital, Harvard Medical School, Boston, MA, USA
OBJECTIVES: To evaluate the Medicaid Analytic Extract (MAX) database for use in pharmacoeconomic research using hemophilia as a case test. METHODS: This research was conducted using MAX data (years 2000-2004) for 49 states (excluding AZ and DC). We identified patients who received recombinant factor VIII (rFVIII), factor VIII inhibitor bypass activity (FIBRA), factor VIII or factor IX or had a diagnosis code for coagulation defects (ICD-9 286.xx). Use of antihemophilic drugs was iden-