optimize spending on MS treatments and for clinical experts looking for improved understanding of the therapeutic benefits of natalizumab.

PND4
A MIXED TREATMENT COMPARISON (MTC) TO COMPARE THE EFFICACY OF BOTULINUM TOXINS TYPE A TREATMENTS FOR CERVICAL DYSTONIA
Han Y1, Stevens A1, Dashpouge K2, Hauser R2, Mari Z3
1WG Consulting, New York, NY, USA, 2Loma Linda University School of Medicine, Loma Linda, CA, USA; 3National Parkinson Foundation Center of Excellence, Tempe, AZ, USA, 4Johns Hopkins University, School of Medicine, Baltimore, MD, USA
OBJECTIVES: This research was conducted to provide a systematic pairwise comparison of all available botulinum toxin type A treatments for cervical dystonia (CD) as there is a lack of direct head to head clinical trial data evidence. Three botulinum toxin type A products have been approved by the FDA for managing CD: AbobotulinumtoxinA, OnabotulinumtoxinA and IncobotulinumtoxinA. A pair-wise efficacy comparison was performed for all three toxins based on literature-reported clinical outcomes. METHODS: Multi-arm randomized controlled trials (RCTs) for inclusion were identified using a systematic literature review. RCTs were assessed for comparability based on patient population and comparable efficacy outcome measures. Total scale change from baseline for all treatments were: Placebo (mean -4.487, SE 1.447, SE 1.402), AbobotulinumtoxinA (mean -11.08, SE 1.41), OnabotulinumtoxinA (mean -11.77, SE 1.79); where a negative number indicates symptom improvement. CONCLUSIONS: This research suggests that all botulinum toxin type A treatments were effective compared to placebo in cervical dystonia. However, based on this MTC analysis, there is no significant efficacy difference between AbobotulinumtoxinA, OnabotulinumtoxinA and IncobotulinumtoxinA.

PND5
OUTCOMES IN SCHIZOPHRENIA: WHAT DOES "CLINICALLY MEANINGFUL" MEAN TO PATIENTS?
Kilburg A1, Gallani Berardo S2, Souto D2, Llorca PM3
1Wellesley AG, Basel, Switzerland, 2Pharmacia – La Roche Ltd., Basel, Switzerland, 3Centre Hospitalier Universitaire de Clermont-Ferrand, Clermont-Ferrand, France
OBJECTIVES: The understanding of the clinical meaningfulness of outcomes in schizophrenia is important to determine the value of new treatments for patients, caregivers, practitioners and payers. The aim of this research was to provide an overview of general concepts and methodologies applied to determine meaningfulness of endpoints, to describe how outcomes are measured in schizophrenia and how treatment clinical meaningfulness is defined in schizophrenia from a Health Technology Assessment (HTA) perspective. METHODS: We conducted a targeted literature search focusing on antipsychotic treatment and clinical meaningfulness of outcomes. Data was extracted and summarized. RESULTS: In schizophrenia, a survey on individual country requirements in sixteen countries and an analogue analysis to identify payer definitions of clinical meaningfulness were conducted. CONCLUSIONS: No consistent approach exists from payers, or in the research literature, to determine clinical meaningfulness of schizophrenia outcomes. While theoretically, payers have based their value assessments of antipsychotics on available clinical evidence using systematic literature reviews and meta-analyses. Most widely used efficacy endpoints in antipsychotic trials are changes in PANSS scores, BPRS and CGI (CGI-I and/or CGI-S). Payers noted considerable variation in the definition of clinical meaningfulness to determine treatment response (20%-60% change in PANSS or BPRS score from baseline). Payers recommend validity should be demonstrated for clinical relevance of change on these endpoints using anchors such as patient-reported, functional and global outcomes. Overall, payers suggest establishing a minimal clinically important difference (MCID) based on robust scientific criteria. Beyond the traditional clinical measures, payers would like to see complementary evidence of quality of life, patient satisfaction, family burden, resource utilization and hospitalization. CONCLUSIONS: Approaches to determine clinical meaningfulness in schizophrenia outcomes vary widely. Further research is needed to validate the meaningfulness of changes in commonly used clinical endpoints and generate additional payer relevant evidence on patient and caregiver burden.

PND6
ASSOCIATION BETWEEN ANTIDEPRESSANTS AND C – REACTIVE PROTEIN AMONG ADULTS WITH INFLAMMATORY CONDITIONS – A POPULATION-BASED STUDY
Garza R1, Pan Y1, Sambamourthi U2
1West Virginia University, Morgantown, WV, USA, 2West Virginia University School of Pharmacy, Morgantown, WV, USA
OBJECTIVES: To examine the association between antidepressant drug use and C – Reactive Protein (CRP) among adults with inflammatory medical conditions after controlling for gender, race, age, income, Non-steroidal anti-inflammatory drug use, smoking status, alcohol use and physical activity. METHODS: Retrospective cross-sectional study with linked data from laboratory, prescription medication, medical conditions and demographic files of the National Health and Nutrition Examination Survey (NHANES). The study sample (N = 3,401) consisted of adults (≥20 years) with any inflammatory condition (arthritis, gout, chronic obstructive pulmonary diseases, asthma, coronary artery disease, diabetes, obesity, liver, or heart disease), cancer or HIV. Ordinary least square regression (OLS) and multinomial logistic regressions on log (≤ 1.0 mg%), average (1-3 mg%) and high (>3 mg%) were used to analyze the association between antidepressant use and CRP. RESULTS: Antidepressant use was reported by 13% of the adults and the overall mean CRP value for the adults was 1.85 mg% (SE 0.415). When CRP ≥ 3 mg%, 33% had average CRP and 45% had high CRP values. Average CRP values were not statistically different between antidepressant users and non-users. Other factors that were significantly associated with CRP were perceived health status, smoking and income. For example, adults with excellent perceived health status had significantly lower CRP values (p < 0.004) as compared to those with poor health status. CONCLUSIONS: In this population-based study, no statistically significant associations were found between antidepressant use and clinical outcomes. Future research may need to focus on specific inflammatory conditions including depression.

PND7
PHARMACEUTICAL UTILIZATION AND EXPENDITURES FOR PERIPHERAL NEUROPATHIC PAIN, UNITED STATES, 2005-2011
Van der Goes D1, Watanabe J.H.2, Zhang J.3
1University of Washington, Seattle, WA, USA, 2University of New Mexico, Albuquerque, NM, USA, 3Western University of Health Sciences, Pomona, CA, USA
OBJECTIVES: To estimate the annual aggregate expenditures of prescription pharmaceuticals in the treatment of peripheral neuropathic pain in the United States over a seven year period. METHODS: We utilized annually compiled data for the years 2005-2011 of the Medical Expenditure Panel Survey (MEPS), a publically available, national, random sample, retrospective survey of medical expenses and utilization for the civilian, non-institutionalized US population. We identified cases using International Classification of Disease-Ninth Revision, Clinical Modification codes (ICD-9-CM) which denoted conditions of peripheral neuropathy (diabetes mellitus and herpes zoster), or indicated peripheral neuropathy directly. These were associated with pharmacy records using Cerner Multum™ classification. In any given year, CRPs commonly used for treating neuropathic pain. Prescriptions counts and costs were aggregated by year. Survey weighting, clustering and stratification variables were used to give unbiased national estimates of prescription utilization and expenditures. All costs were inflated to 2011 dollars using the Consumer Fixed. RESULTS: A total of 2782 survey respondents had at least one prescribed medicine associated with treatment of a neuropathic pain diagnosis, representing 2.9 million persons in 2005 and increasing to 3.9 million in 2011 (annual increase of 3.1%, p < 0.05). Both total prescriptions and total expenditures peaked in 2008 ($1.1 billion) and 20.3 million (m) prescriptions, respectively, then declined through 2011. Narco tic analgesics and gabapentinoids were the drug classes with the largest mean annual expenditures ($850m and $211m), followed by antidepressants and sedative-hypnotics. CF prevalence was stratified by race (1.3%) and gender (1.0%). Both the number of neuropathic pain treatment experienced large swings in usage and expenditures from 2005 to 2011, peaking in 2008 despite steady increases in the number of neuropathic pain medication users.

PND8
PREVALENCE AND TRENDS IN CYSTIC FIBROSIS AMONG THE UNITED STATES MEDICAID POPULATION IN 2008 AND 2009
Xia L1, Disinger AH2, Wang L1, Zhang J1, Shreeta S1, Wang Y1, Karibuyo MF3, Baser O2, SSATInMED Research, Ann Arbor, MI, USA, 2SSATInMED Research & The University of Michigan, Ann Arbor, MI, USA, 3SSATInMED Research and The University of Michigan, Ann Arbor, MI, USA
OBJECTIVES: This study examined patient age and gender as well as geographic variations in the prevalence of cystic fibrosis (CF), a chronic lung disease common in children and young adults, in the U.S. Medicaid population. METHODS: A retrospective study was performed among the U.S. Medicaid fee-for-service (FFS) population from 2008 through 2009. CF patients were identified using International Classification of Disease, 9th Revision, Clinical Modification (ICD-9-CM) diagnosis code 277.0x. Both total prevalence and individual prevalence rates for CF among the Medicaid FFS population in 2008 and 2009 were included for analysis. Any managed care enrollment during the period was not permitted. CF prevalence was stratified by region, state, age, gender and race, for all patients and measured by number and percentage, in each category. RESULTS: A total of 2,550 patients were diagnosed with CF among the Medicaid FFS population in 2008 and 2009. Prevalence was the highest in CF prevalence by race was also examined, with the following results: White (0.06%), Hispanic (0.04%), Black (0.03%), Native American (0.02%) and Asian (0.02%). Male patients had a relatively higher prevalence compared to female patients (0.06% vs. 0.05%). Geographic variation was also analyzed, and the highest CF prevalence was observed in Minnesota (0.16%), followed by Ohio, Maryland, North Dakota (all at 0.1%) and West Virginia (0.09%). Patients residing in the Midwest had the highest prevalence rate (0.07%), compared to the Northeast (0.05%), South (0.04%) and West (0.03%). CONCLUSIONS: Statistical evidence shows that younger patients had a higher probability of being diagnosed with CF, with patients under age 40 years more likely to be diagnosed with CF compared to those of other races. Male patients who resided in the Midwest U.S. region were also found to be at higher risk for a CF diagnosis.

PND9
TRIFURAL USE FOR MIGRAINE HEADACHE AMONG ADULTS WITH CARDIOVASCULAR RISK
Ahluwalia M1, Sambamourthi U2
1West Virginia University School of Pharmacy, Morgantown, WV, USA, 2West Virginia University School of Medicine, Morgantown, WV, USA

OBJECTIVES: Triptan medication use is contraindicated in adults with migraine who have a history of cardiovascular or cerebrovascular risk factors (i.e., hypertension, diabetes, hyperlipidemia, and obesity). The objective of this study is to compare Triptan use among Migraineurs with and without cardiovascular disease (CVD) or cerebrovascular disease (CVD or CVR) risk factors such as those with diabetes, hypertension, hyperlipidemia, and obesity.

PND10 BUDGET IMPACT OF ADDING DELAYED-RELEASE DIMETHYL FUMARATE TO THE FORMULARY FOR THE TREATMENT OF RELAPSING FORMS OF MULTIPLE SCLEROSIS

Matsuiop S1, Fay M2, Iyer R2, Livingston T2

RTI Health Solutions, Research Triangle Park, NC, USA; 2Bigen Idec, Weston, MA, USA; 3Bigen Idec, Cambridge, MA, USA

OBJECTIVES: To estimate the budget impact of adding delayed-release dimethyl fumarate, a new oral drug indicated for the treatment of relapsing forms of multiple sclerosis for a managed care formulary in the US. The budget impact model was developed to compare the drug-related costs of the current mix of treatments with the costs of an estimated treatment mix including delayed-release dimethyl fumarate for a managed care organization (MCO) with 1,000,000 members. The number of people with relapsing forms of MS was estimated using published prevalence data. Market share of delayed-release dimethyl fumarate was assumed to increase from 10% in 2013 to 25% in 2017 taken proportionately by market share of DMTs. Drug costs were reviewed and adjusted by patient payments and dispensing fees as well as administration, monitoring and adverse event costs. Annual relapse treatment costs were estimated using the relative risk reduction of a relapse for each DMT derived using a mixed-treatment comparison analysis. A one-way sensitivity analysis was performed.

RESULTS: The estimated budget impact of adding delayed-release dimethyl fumarate to the formulary was negative for the first 3 years: in 2014, with a market share of 13%, the estimated budget decrease was 0.29% of the total annual costs for DMT-related and relapse treatment costs and a decrease of $0.011 per member per month (PMPM); in 2017, with a market share of 25%, the estimated budget decrease was 0.50% of the total annual costs and a decrease of $0.018 PMPM. Sensitivity analyses showed that the model was most sensitive to the acquisition costs of delayed-release dimethyl fumarate. CONCLUSIONS: Under model assumptions for market shares, adding delayed-release dimethyl fumarate to the MCO formulary would result in a small decrease in MCO costs for patients with relapsing forms of MS.

PND12 A BUDGET IMPACT ANALYSIS OF THE COCHRANE COLLABORATION REVIEW OF TRIPLE LINE TREATMENTS FOR RELAPSING-REMITTING MULTIPLE SCLEROSIS MELEZICHE DMA1, Park S2, Rutkowsk T2, Chowdhury CA2, Beckerman R2

1EMD Serono, Inc., Rockland, MA, USA; 2CBPartners, New York City, NY, USA

OBJECTIVES: To quantify the number and costs of relapses avoided over 2 years in the first-line treatment of RRMS based on the findings of the Cochrane report. METHODS: An Excel-based financial model estimated the relapses and costs incurred by a hypothetical cohort of 1000 RRMS patients treated with first-line disease modifying drugs (DMDs). The modelled cohort evaluated the consequences of treatment with subcutaneous (SC) interferon beta-1a versus intramuscular (IM) interferon beta-1a, as this was the only comparison whose data quality was assessed as “strong” by the methodology review group (MRG). Risk of relapse was based on the 2-year data from the Cochrane Review network meta-analysis. The analysis was performed from a US payer perspective. The cost of a relapse was sourced from Farnich et al., 2005, and adjusted to 2012 US dollars. Net annual cost of relapse was based on wholesale acquisition cost. Given the model’s short time horizon, disability-related costs were not included as these tend to be an important economic driver only over the long-term progression of the disease. In order to test how variably the model’s inputs might impact the analysis’ results, two-way sensitivity analyses were performed based on the reported 95% risk of relapse credible intervals for SC interferon beta-1a and IM interferon beta-1a. RESULTS: In a hypothetical cohort of 1000 RRMS patients, treatment with SC interferon beta-1a in extended use resulted in a 5% higher PMPM compared to IM interferon beta-1a versus IM interferon beta-1a. 14% of subcutaneous interferon beta-1a is likely to result in fewer relapses and lower direct costs of relapse versus IM interferon beta-1a over a 2-year period treatment.

PND13 POTENTIAL BUDGET IMPACT OF INTEGRATING TALIGLUCerase ALFA THERAPY FOR GAUCHER DISEASE IN THE UNITED STATES

Li X1, Feijo L.F. 1, Guo S2, Sandor S3

1RTI Health Solutions, Research Triangle Park, NC, USA; 2Bigen Idec, Weston, MA, USA; 3Bigen Idec, Cambridge, MA, USA

OBJECTIVES: Gaucher disease (GD) is a lysosomal storage disorder caused by mutations in the gene encoding the enzyme glucocerebrosidase, requiring lifelong treatment with enzyme replacement therapy (ERT). Current available ERTs include imiglucerase, vilaglucerase alfa, and taliglucerase alfa. Taliglucerase alfa is the first plant cell-expressed beta-glucocerebrosidase ERT approved for adults with type 1 GD in the US. This study estimates the potential budget impact of taliglucerase alfa therapy for GD in the US. METHODS: A hypothetical budget impact model analysis was performed, based on total estimated number of GD patients treated, treatment costs, and estimated treatment distribution of each ERT. CONCLUSIONS: Cost in USD ($) per 200-unit vial were based on wholesale acquisition costs on RediPrice and Medi-Span databases. Annual costs were calculated using number of vials needed. Actual cost savings may vary with factors beyond drug acquisition costs such as pharmacy redistribution and pharmacy retail activity and may not reflect actual costs paid. The estimated number of GD patients treated with ERT in the United States was 3,000. Drug costs for 200 units of ERT were: taliglucerase alfa-$595, vilaglucerase alfa-$675, and imiglucerase alfa-$765. The estimated annual budget impact was $13,640, $137,600, and $457,736 for taliglucerase alfa, vilaglucerase alfa, and imiglucerase, respectively. Switching 50 patients to taliglucerase alfa, assuming same market share as national average, could save up to $4 per member per month (PMPM). The ERT system could save $101,000/patient annually if patients were switched to taliglucerase alfa. A 20% increase in the number of patients receiving taliglucerase alfa could translate to an overall savings of $46 million annually. CONCLUSIONS: Taliglucerase alfa may have the potential to provide a cost-saving alternative to other ERTs. This study was sponsored by Pfizer. Editorial support was provided by Peloton Advantage, LLC with funding from Pfizer.

PND14 SOUVENAID® FOR THE DIETARY MANAGEMENT OF MILD ALZHEIMER’S DISEASE: 5-YEAR BUDGET IMPACT ANALYSIS (BIA) FROM THE BRASILIAN PUBLIC PAYERS PERSPECTIVE (PPP)

Borges L1, Feijo LF1, Clark OA2, Souza TT2, Sturion C2, Gumbs F1, Wallace M3

1Evainças, Campinas, Brazil; 2Donone Specialized Nutrition, São Paulo, Brazil; 3Nutência, Amsterdam, The Netherlands

OBJECTIVES: Souvenaid® is a medical food - an enriched nutritional formula - that contains specific nutrients reported to be deficient in patients with Alzheimer’s Disease (AD) and that are important in cognitive function, synaptic formation and function. Clinical studies demonstrate that dietary management with Souvenaid® for 12 to 24 weeks results in a significant improvement in memory in patients with early AD. This study aims to estimate the budget impact of Souvenaid® for the dietary management of AD using a static budget impact model. Average cost of AD was derived from a 7-state Markov model developed to estimate the effect of Souvenaid® for mild AD versus no dietary management (NMD) of mild AD and combined with demographic data in each age stratum. Only direct costs, obtained from a public hospital in Brazil, were considered. The estimated annual budget impact of adding Souvenaid® for 5 years in the Brazilian public payer perspective was -$874,332, representing a savings of $437,086, $607,973, $1,211,946, $1,816,919, and $2,421,893, respectively, for years 1-5. Compared to NMD, the inclusion of Souvenaid® in the protocol of mild Alzheimer’s Disease: 5-year budget impact analysis (BIA) from the Brazilian public payer perspective (PPP).