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 TOXIN TYPE A TREATMENTS FOR CERVICAL DYSTONIA

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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-armed 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. The Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) total score was selected as the efficacy outcome measurement for assessment. A mixed treatment comparison (MTC) was conducted using a Bayesian hierarchical model allowing indirect comparison of the efficacies of the interventions. **RESULTS:** The network of six RCTs with fourteen arms formed a linear series of "steps" which facilitated the comparison of all botulinum toxin type A treatments of interest. Due to the limitation of available clinical data, this study only investigated the main effect of toxin treatments without explicitly considering potential confounding factors such as gender and formulation differences. There was reasonable agreement between the number of unconstrained data points, residual deviance and pair-wise results, suggesting a coherent network. The results for TWSTRS total scale change from baseline for all treatments were: Placebo (mean -4.487, SE 1.402), AbobotulinumtoxinA (mean -11.08, SE 1.41), OnabotulinumtoxinA (mean -11.77, SE 1.44) and IncobotulinumtoxinA (mean -12.38, 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 PAYERS?

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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 success and clinical meaningfulness are 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 schizophrenia outcomes, a review of HTA submission guidelines, HTA reports in schizophrenia, a survey on individual country requirements in sixteen countries and an analogue analysis to identify payer definitions of clinical meaningful differences. **RESULTS:** No consistent approach exists from payers, or in the literature, to determine clinical meaningfulness in schizophrenia outcomes. Historically, 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 on 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

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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, perceived health 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 Nutritional examination Survey (NHANES). The study sample (N = 3,492) consisted of adults (≥20 years) with any inflammatory condition (arthritis, gout, chronic obstructive pulmonary diseases, asthma, coronary artery disease, diabetes, obesity, liver, or thyroid condition, cancer and stroke). Ordinary least square regression (OLS) and multinomial logistic regressions on low (< 1.0 mg/l), average (1-3 mg/l) and high (>3 mg/l) were used to analyze the association between antidepressant use and CRP. **RESULTS:** Antidepressant use was reported by 13% of the adults and the average CRP value for the sample was 4.85 mg/l (SE = 0.0113). 22% had low CRP, 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 association between antidepressant use and inflammatory bio-markers were found in individuals with an inflammatory condition. 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

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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 dataset to construct cross-sectional, representative estimates of medical expenses and utilization for the civilian, non-institutionalized US population. We identified cases using International Classification of Disease-Ninth Revision, Clinical Modification (ICD-9-CM) codes which denoted conditions prone to peripheral neuropathy (diabetes mellitus and herpes zoster), or indicated peripheral neuropathy directly. These were associated with pharmacy records using Cerner Multum™ classifications for classes of medication 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 medical Consumer Price Index. **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(b) and 20.3 million (m) prescriptions, respectively), then declined through 2011. Narcotic analgesics and gabapentinoids were the drug classes with the largest mean annual expenditures ($305m and $211m) , followed by serotonin-noradrenalin reuptake inhibitors ($141m). Non-gabapentinoid anticonvulsants, tricyclic antidepressants, and topical analgesics had substantial declines in usage and expenditures from 2005 to 2011. Non-narcotic analgesics utilization and expenses, including NSAIDs and tramadol, remained largely stable during the study period. **CONCLUSIONS:** Prescription medications for peripheral neuropathic pain treatment experienced large swings in usage and expenditures from 2005-2011, 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

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OBJECTIVES: This study examined patient age and gender as well as racial and 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. Patients with continuous Medicaid FFS enrollment in both 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 (0.15%) for patients under age 40 years, followed by patients age 40 to 59 (0.03%), and 60+ (0.01%). 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 0.11%) 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 have a higher probability of being diagnosed with CF, with white patients 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

TRIPTAN USE FOR MIGRAINE HEADACHE AMONG ADULTS WITH CARDIOVASCULAR RISK

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OBJECTIVES: Triptan medication use is contraindicated in adults with migriane who have cardiovascular disease or cardiovascular (CV) 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 CVD risk factors such as those with diabetes, hypertension, hyperlipidemia, and obesity. **METHODS:** This is a retrospective cross-sectional study using data from 2009 and 2011 Medical Expenditure Panel Survey (MEPS). The study sample consisted of adults with migraine aged 22-64 years and alive during the calendar years (N = 1,142). Chi-square tests were used to compare rates of Triptan use among adults with and without CVD/CVD risk factors. Multiple logistic regressions were used to compare the likelihood of Triptan use among Migraineurs with and without CVD/CVD risk factors. All analyses accounted for the complex survey design of the MEPS. **RESULTS:** Among adult Migraineurs, 26.3% with CVD/CVD risk and 34.3% without CVD reported Triptan medication use. After controlling for gender, age, race/ethnicity, marital status, education, employment, income level, insurance and medication coverage, perceived physical and mental health, current smoking and exercise, adults with CVD/CVD risk were less likely to use Triptans compared to adults without CVD/CVD risk. (Adjusted Odds Ratio: 0.59, 95% Confidence Interval [0.43-0.82]). **CONCLUSIONS:** Although adults with CVD/CVD risk were less likely to report Triptan use compared to adults without CVD/CVD risk, nearly 26% of Migraineurs with CVD/CVD risk reported Triptan use. The study findings suggest that Triptan medication use among adults with CVD/CVD risk is not consistent with recommended clinical guidelines.

NEUROLOGICAL DISORDERS – Cost Studies

PND10

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

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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 (MS) to a managed care formulary in the US. **METHODS:** An Excel 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 covered lives. 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 shares from all other DMTs. Drug costs included acquisition costs 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 5 years: in 2014, with a market share of 13.0%, 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 25.0%, 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.

PND11

BUDGET IMPACT ANALYSIS OF USING AMYLOID POSITRON EMISSION TOMOGRAPHY (PET) IN THE DIAGNOSIS OF ALZHEIMER'S DISEASE (AD) IN THE UNITED STATES

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OBJECTIVES: In 2013, the Amyloid Imaging Taskforce (AIT) proposed that individuals with unexplained mild-cognitive impairment, possible AD, and early-onset dementia are potentially appropriate for amyloid PET in the diagnosis of AD and other forms of dementia. This analysis quantified the budgetary impact of using amyloid PET according to the AIT's criteria from the US payer perspective. **METHODS:** An Excel-based model was developed for this analysis. The model projects the number of patients eligible for amyloid PET over a 3-year time horizon and calculates the incremental cost of using amyloid PET by considering direct medical resource uses for diagnostic work-up, dementia medications, and dementia care for patients staying in communities or institutions. Amyloid PET's cost could be potentially offset by reducing diagnostic work-up time and resources use, unnecessary dementia treatments and delaying disease progression and time to institutional care. The model was mainly populated with data from claims data analysis (Truven MarketScan® 2007–2012) and a survey of 75 dementia practitioners in the US, supplemented with data from literature, public databases, and assumptions. All costs were estimated in 2013 dollars. **RESULTS:** Assuming an uptake of 5% incrementally each year, using amyloid PET increased the total cost by about $560,000 to $1,140,000 per 1 million covered lives over 3 years (or $0.016 to $0.032 per member per month) when amyloid PET's cost was set between $2,500 and $6,000 per scan. Amyloid PET's cost was partially offset by reductions in diagnostic work-up time and resources use and costs of institutional care due to more timely and accurate diagnosis and treatment. These results were most sensitive to variations in the cost of amyloid PET and time horizon. **CONCLUSIONS:** Using amyloid PET in the diagnosis of AD according to the AIT's criteria could result in better clinical outcomes with little impact on the annual budget.

PND12

A BUDGET IMPACT ANALYSIS OF THE COCHRANE COLLABORATION REVIEW OF FIRST-LINE TREATMENTS FOR RELAPSING-REMITTIMG MULTIPLE SCLEROSIS

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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 'high' by the Cochrane Review (Filippini et al., 2013). 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 Panitch et al., 2005, and adjusted to 2012 US dollars. Net annual cost of therapy 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 variability in 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 is expected to result in the avoidance of 173 (sensitivity analysis range: -20 to 399) relapses versus IM interferon beta-1a over 2 years. Assuming a direct cost of relapse of $5141, this represents a savings of $890,212 (sensitivity analysis range: -$102,138 to $2,052,934) versus IM interferon beta-1a. **CONCLUSIONS:** 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

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OBJECTIVES: Gaucher disease (GD), a lysosomal storage disorder caused by mutations in the gene encoding the enzyme glucocerebrosidase, requires life-long treatment with enzyme replacement therapy (ERT). Currently available ERTs include imiglucerase, velaglucerase alfa, and taliglucerase alfa. Taliglucerase alfa is the first plant cell-expressed beta-glucocerebrosidase ERT approved for adults with type 1 GD. The purpose of this analysis was to model the potential budget impact of taliglucerase alfa therapy for GD in the United States. **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. Costs in USD ($) per 200-unit vial were based on wholesale acquisition costs on ReadyPrice and Medi-Span databases. Annual costs were calculated using number of vials required. Actual cost savings may vary with factors beyond drug acquisition costs (eg, rebate programs) and may not reflect actual costs paid. **RESULTS:** 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, velaglucerase alfa–$675, and imiglucerase–$793. Annual costs/patient were estimated at $328,440, $372,600, and $437,736 for taliglucerase alfa, velaglucerase alfa, and imiglucerase, respectively. Switching 50 patients to taliglucerase alfa, assuming same market share as national average, could save up to $4 million annually. The US health care system could save ~$100,000/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 has 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 BRAZILIAN PUBLIC PAYER PERSPECTIVE (SUS)

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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, synapse 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 mild AD according to SUS perspective. **METHODS:** An age related incidence of AD approach was used. Population size, according to different age categories, was derived from Brazilian statistics (IBGE) and combined to estimate the number of patients per age stratum. 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 (NDM) 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 difference between Souvenaid® group and NDM was the 5-year budget impact estimated for SUS. **RESULTS:** Considering a market penetration of 10%, 13%, 15%, 17% and 20% each year, the estimated number of patients under Souvenaid® treatment is 11.002, 15.733, 19.969, 24.894 and 32.216, respectively, for years 1-5. Compared to NDM, the inclusion of Souvenaid® in the protocol of mild