Stimulation (SCS) provides pain relief and improves patients' health. We assessed in a naturalistic context the cost-utility of SCS in FBSS patients unresponsive to conventional medical management (CMM). **METHODS:** We conducted an observational, multicenter, longitudinal prospective study in which a sample of patients assigned to receive SCS in addition to CMM was observed for 24 months after the intervention. We collected before and after undergoing SCS the following data: direct and indirect costs, adopting the National Health Service (NHS) and the societal perspectives, pain status, using the Numerical Rating Scale (NRS, scoring from 0 (no pain) to 10 (maximum pain)), and HRQoL, using the SF-36 and EQ-5D. Costs and benefits pre-SCS versus post-SCS were compared to estimate the incremental cost-effectiveness and the cost-utility ratios. The following results focus on the cost/QALY ratio. **RESULTS:** Eighty patients (40% male, mean age 58 years) were recruited. Significant improvements in pain intensity and HRQoL were reached after 6 months from SCS and maintained or further improved until the end of the observational period. In particular, after 24 months from SCS the mean NRS significantly decreased ($p<0.01$) from 7.6 to 5.1, and the mean EQ-5D-utility significantly ($p<0.01$) increased from 0.07 to 0.40. The ICUR was equal to 27,519€/QALY, according to the NHS perspective. The cost-utility acceptability curve shows that if decision makers' willingness-to-pay per QALY was 45,000€, then SCS implantation would be cost effective in 97% and 99% of cases, according to the societal and NHS perspectives, respectively. **CONCLUSIONS:** In a 2-year observational period, SCS+CMM treatment of FBSS patients increases medical direct costs but allows to improve significantly patients' clinical health and HRQoL, resulting in a cost/QALY ratio largely lower than the commonly accepted willingness-to-pay threshold.

PSY47

RAPID ECONOMIC EVALUATION REVIEW FOR RARE DISEASES TREATMENTS – THE CASE OF PEGVISOMANT FOR ACROMEGALY

Koury CDN[1], Silva MT[2]

[1]*FIPE -Fundação de Ensino e Pesquisas Econômicas, Brasília, Brazil,* [2]*Brazilian Ministry of Health, Brasília, DF, Brazil*

OBJECTIVES: Under the standard methods of health technology assessment (HTA) incorporating economic evaluation, orphan drugs do not usually prove to be cost-effective. Adding their high cost, it meant that funding and patient access may be limited in the Brazilian Public Health System (SUS). Acromegaly is one example, with annual incidence of 3-4 cases/million and prevalence of 40-90 cases/million. There is a new drug, pegvisomant, which presents a relative efficacy at a high cost. With the objective to identify the best pharmacoeconomics evidence for pegvisomant in acromegaly and to review the knowledgment transfer to support a rapid economic review of rare diseases under the perspective of SUS. **METHODS:** In the case of the rare disease acromegaly a search was conducted on February 10th, 2013 using \'cost\'/exp OR cost AND effectiveness AND (\'pegvisomant\'/exp OR pegvisomant) AND (\'acromegaly\'/exp OR acromegaly) in Medline (PubMed), EMBASE, Virtual Health Library (BVS), Center for Reviews and Dissemination (CRD), The Cochrane Library. **RESULTS:** Only the study *"Clinical effectiveness and cost-effectiveness of pegvisomant for the treatment of acromegaly: a systematic review and economic evaluation"* was identified and selected. The study was conducted in the UK, where health costs are different from the Brazilian structure RESULTS: The study´s evidence indicates that pegvisomant is not cost-effective to treat pacients with resistant agromegaly. In Brazil the cost of each dose in the public health system is about 25% more expensive than the UK, and so is the cost of labor. **CONCLUSIONS:** The need of economic assessment transferability as a tool to support the management of political decisions, especially to high cost technologies and rare diseases, are not set as priority in the research fostering agenda of the SUS

PSY48

COST-UTILITY OF VELAGLUCERASE ALPHA FOR THE TREATMENT OF TYPE I GAUCHER DISEASE IN SPAIN

Giraldo P[1], De La Serna J[2], Espinós B[3]

[1]*Miguel Servet University Hospital, Zaragoza, Spain,* [2]*Hospital Universitario 12 de Octubre, Madrid, Spain,* [3]*IMS Health, Barcelona, Spain*

OBJECTIVES: Type I Gaucher disease (GD) is an autosomal recessive disorder caused by a deficiency in β-glucocerebrosidase enzyme, causing hepatosplenomegaly, anaemia, trombocitopenia, bone injuries and other complications. Intravenous enzyme replacement therapy (ERT) is the current standard of care, which has demonstrated in several studies its efficacy in the prevention and amelioration of progressive and systemic manifestations. Velaglucerase alpha is a glycoprotein with the same amino acid sequence as the human enzyme β-glucocerebrosidase. The aim of this study is to assess the cost-effectiveness of velaglucerase alpha versus imiglucerase for the treatment of type 1 GD from the perspective of the Spanish National Healthcare System (NHS). **METHODS:** A cost-utility analysis was performed using a semi-Markov model that embedded one decision tree for the initial treatment during two years and a Markov health state structure after the response to the second year receiving ERT, from the NHS perspective. The Markov framework was structured around six health states: asymptomatic, mild, moderate, severe, splenectomy and death and used annual cycles with a time horizon of 39 years. Model structure was validated by a panel of GD experts. Efficacy data were obtained from the HGT-GCB-039 study. Resources consumption was based on expert opinion. Outcomes were quality-adjusted life years (QALY) and costs (€ in 2011). Threshold sensitivity analysis was conducted to determine cost-neutrality between strategies. **RESULTS:** Both strategies provided a mean gained of 25.55 QALYs. The average cost per patient for velaglucerase alpha was €7,265,332 compared to €7,327,966 for imiglucerase. The difference in costs was mainly due to the difference in administration costs. The threshold sensitivity analysis showed that velaglucerase alpha will reach cost-neutrality even with a higher unit price. **CONCLUSIONS:** Velaglucerase alpha is a cost-saving option for the treatment of type 1 GD in the Spanish setting, providing annual savings compared with imiglucerase. (This study was supported by Shire Pharmaceuticals Iberica)

PSY49

CLINICAL AND ECONOMIC ASSESMENT OF THE EFFECTIVENESS OF ENTECAVIR IN COMPARISON WITH PEGYLATED INTERFERON, LAMIVUDINE, TELBIVUDINE, TENOFOVIR IN TREATMENT OF CHRONIC VIRAL HEPATITIS IN RUSSIAN FEDERATION

Luneva A[1], Holownia M[2], Krasnova L[1], Vorobyev PA[1], Znoyko O[3]

[1]*Russian Society for Pharmacoeconomics and Outcomes Research, Moscow, Russia,* [2]*Russian Society for Pharmacoeconomis and Outcomes Research, Moscow, Russia,* [3]*Moscow State University of Medicine and Dentistry named after A.I. Evdokimov, Moscow, Russia*

OBJECTIVES: The purpose of this study was to conduct an economic analysis of clinical effectiveness of antiviral drugs in monotherapy (entecavir, lamivudine, telbivudine, tenofovir, peginterferon alfa-2a) compared with no specific treatment for patients with chronic hepatitis B in Russia. **METHODS:** Clinical-economic study was carried out with the Markov model.The duration of one cycle-1 year,the duration of antiviral treatment-5 years.As a measure of utility QALY were used. Due to the absence of Russian studies, a multinational study from 2008 was used. **RESULTS:** Total cost of one year of treatment of chronic hepatitis B were: lamivudine-35732.97 rubles, for entecavir-96104.00 rubles for tenofovir-103279.55,for telbivudine-116933.75 for peginterferon-alfa-2a-502238.40 rubles. The lowest cost-utility ratio (CUR) was for lamivudine-91159.54 rubles/QALY. The highest CUR is for pegylated interferon alfa-2a and then tenofovir/entecavir-183263.00 rubles/QALY and 176936.58 rubles/QALY, respectively. More cost-effective treatment is to start with the third-line drugs-entecavir/tenofovir. The study showed that the use of entecavir,lamivudine,tenofovir is clinically and economically more effective than using no specific antiviral therapy.The CURs for these tactics is lower than that for the natural course of the disease.More effective from a clinical and economic point of view, for the treatment of chronic hepatitis B is to use as single one of these:entecavir/tenofovir/lamivudine. **CONCLUSIONS:** The quality of life of patients with chronic hepatitis B without the specific treatment will be lower than that with the antiviral drugs,since without the treatment increases the rate of formation of severe fibrosis in the liver, there is a quicker outcome to cirrhosis and other complications.Lowest CUR is for lamivudine due to the low cost of it,but the high rate of resistance to lamivudine and the need to add additional third-generation drug may increase the cost.The highest CUR is with administering pegylated interferon-alfa-2a and then applying tenofovir/entecavir. It seems economically feasible to begin therapy immediately with the administration of the third generation drug - entecavir or tenofovir.

PSY50

WORK PRODUCTIVITY AFTER LAP-BAND AP® SYSTEM IMPLANTATION IN OBESE PATIENTS - ONE YEAR RESULTS OF THE HELPING EVALUATE REDUCTION IN OBESITY (HERO) STUDY

Lusco V[1], Voellinger D[2], Leeder P[3], Di Micco R[4], Jin J[5], Burk CT[6], Finkelstein E[7]

[1]*Louisville Surgical Bariatric Associates, Louiville, KY, USA,* [2]*Southeast Bariatrics, Charlotte, NC, USA,* [3]*Royal Derby Hospital, Derby, UK,* [4]*Università di Napoli Federico II, Naples, Italy,* [5]*Allergan Inc, Bridgewater, NJ, USA,* [6]*Health Outcomes Consultant, Laguna Beach, CA, USA,* [7]*Duke-NUS Graduate Medical School, Singapore, Singapore*

OBJECTIVES: Few studies have reported the impact of laparoscopic adjustable gastric banding (LAGB) on work productivity in obese patients. The objective of this HERO study analysis is to examine the effect of weight loss (WL) on work productivity (absenteeism, presenteeism, and productivity loss) and non-work activity impairment 1 year (yr) after laparoscopic placement of LAP-BAND AP® System. **METHODS:** HERO is a 5-yr registry of 1,106 obese patients from 29 centers in the United States (US), Canada, Europe, and Australia who underwent LAGB. Our descriptive analysis included about 70% of subjects who provided complete baseline (BL) and 1 yr health related quality of life data based on Work Productivity and Activity Impairment questionnaire, a well validated instrument generating scores in absenteeism, presenteeism, work productivity loss and non-work activity impairment. **RESULTS:** The mean age was 43.1 yrs and females constituted 79.3%. At BL, 59% worked full time and 10% worked part time. Mean (SD) baseline weight was 126.2 (24.14) kg. At 1 year, the average %WL was 16.9% (SD, 9.02). Baseline presenteeism was 4.5%, absenteeism 33.4%, work productivity 3.8%, and non-work activity impairment was 51.2%. At 1 year, there was reduction in presenteeism to 2.8% ($p<0.05$), in absenteeism to 20% ($p<0.05$), in work productivity to 2.3% ($p<0.05$), and non-work activity impairment to 28% ($p<0.05$). There was a decreasing trend in presenteeism (23.4%, 20.4%, 18.2%, 14.1%, $p=0.01$) and less non-work activity impairment (32.9%, 29.7%, 22.7%, 17.5%, $p<0.001$) as %WL increased from 0-10%, to >10-20%, to >20-30%, and to >30%. This decrease was not observed with absenteeism (1.9%, 3.8%, 2.5%, 1.7%, $p=0.28$) nor productivity loss (2.1%, 2.2%, 2.7%, 1.8%, $p=0.74$) as %WL increased. **CONCLUSIONS:** LAGB was associated with significant WL and improvement in work productivity and reduction in non-work activity impairment by 1 yr. Further analysis will examine the sustainability of WL effect on impact on work productivity.

PSY51

COST TO SOCIETY DUE TO UNDEREMPLOYMENT IN PERSONS WITH HEMOPHILIA A AND B – HEMOPHILIA UTILIZATION GROUP STUDY V (HUGS V)

Niu X[1], Poon JL[1], Riske B[2], Baker J[3], Ullman M[4], Gwadry-Sridhar F[5], Lou M[6], Nichol MB[1]
[1]University of Southern California, Los Angeles, CA, USA, [2]University of Colorado Denver, Aurora, CO, USA, [3]UCLA Division of Hematology/Oncology, Los Angeles, CA, USA, [4]University of Texas Health Science Center at Houston, Houston, TX, USA, [5]University of Western Ontario, London, ON, Canada, [6]USC School of Pharmacy, Los Angeles, CA, USA

OBJECTIVES: To examine cost to society due to underemployment among adults or parents of children (aged<18 years) with hemophilia A or B. **METHODS:** Data were obtained from HUGS Va and Vb, two multi-center cohort studies of persons with hemophilia A and B, respectively, who received comprehensive care at Hemophilia Treatment Centers in the United States. Underemployment, based on participants' self-report, is defined as being employed part-time or unemployed due to hemophilia. Cost to society includes annualized aggregate earnings and non-wage benefits lost due to underemployment. The average hourly compensation rate was assumed to be US$30.80 based on the employer costs for employees' compensation from the Bureau of Labor Statistics (2012). Part-time work was assumed to be 20 hours/week. Sensitivity analysis was conducted to determine the variation of cost by varying part-time work hours from 10 to 30 hours/week. **RESULTS:** Of 474 patients (329 hemophilia A), 275 (58%) had severe hemophilia, of which 211 (64%) and 64 (44%) had hemophilia A and B, respectively. The number of adults or parents of children working full-time, part-time or unemployed was 214 (45%), 96 (20%) and 163 (34%), respectively. Among the latter two groups, 24 (25%) part-time participants and 49 (30%) unemployed participants attributed their employment status to hemophilia. Adults or parents of children with severe disease were more likely to be underemployed than those with mild/moderate disease (p=0.0002). The proportion of underemployed parents of children (12%) was comparable to that of underemployed adult patients (19%). Among the HUGS population, the estimated annual cost of underemployment to society due to hemophilia was US$3.91 million (range: $3.52-$4.29 million when varying part-time hours worked). **CONCLUSIONS:** Hemophilia involves costly life-long therapy, affecting the employability of patients and/or their families and imposing significant financial burden on society. Looking at new ways to support patients and families is essential in hemophilia care.

SYSTEMIC DISORDERS/CONDITIONS – Patient-Reported Outcomes & Patient Preference Studies

PSY52
FACTORS PREDICTING MEDICATION PERSISTENCE AMONG PATIENTS INITIATING BUPRENORPHINE TRANSDERMAL SYSTEM

Pergolizzi J[1], Hess G[2], Chang CL[2], Shah D[3], Pierz K[3], BenJoseph R[3]
[1]Johns Hopkins University, Naples, FL, USA, [2]IMS Health Incorporated, Plymouth Meeting, PA, USA, [3]Purdue Pharma L.P., Stamford, CT, USA

OBJECTIVES: Buprenorphine transdermal system therapy (BTDS) is indicated for the management of moderate to severe chronic pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. This study assessed factors associated with medication persistence among patients initiating BTDS. **METHODS:** Patients aged >18 years initiating BTDS during January 1, 2011 - November 30, 2011 were identified in the IMS Private Practitioner Medical Claims database and IMS Pharmacy Claims database. The index date was defined as the first prescription of BTDS. Demographics, Charlson Comorbidity Index (CCI) and prior medication use were assessed in the pre-index 6-month period. Persistence was measured as the duration of BTDS prior to the first 28-day refill gap in the post-index 6-month period. Cox proportional hazards models were run to assess predictors of BTDS persistence controlling for demographics, CCI, and prior and 30-day concomitant drug use. **RESULTS:** The study included 10,457 patients newly treated with BTDS. Patients' mean age was 55 years (±15); 30% were male and the mean CCI was 1 (±1.4). Prior to the index BTDS prescription 92%, 35% and 59% of the patients used opioids, NSAIDs and neuropathic pain agents, respectively. Multivariate regression analyses showed that patients with prior opioid and neuropathic pain agent use were 20% and 5% less likely to discontinue BTDS (p<0.05), respectively as compared to patients not using these agents. Patients with concomitant use of neuropathic pain agents were 15% less likely to discontinue therapy (p<0.01) as compared to patients without concomitant use of neuropathic pain agents. Sensitivity analyses with 30-day prior opioid use and including patients with ≥2 claims of BTDS confirmed these findings. **CONCLUSIONS:** Prior and concomitant use of neuropathic pain agents and prior use of opioids were associated with significantly longer persistence among patients initiating BTDS. These data help to characterize the patient population treated with BTDS.

PSY53
IMPACT OF DOSAGE STRENGTH ON MEDICATION PERSISTENCE AMONG PATIENTS TREATED WITH BUPRENORPHINE TRANSDERMAL SYSTEM

Pergolizzi J[1], BenJoseph R[2], Chang CL[3], Pierz K[2], Shah D[2], Hess G[3]
[1]Johns Hopkins University, Naples, FL, USA, [2]Purdue Pharma L.P., Stamford, CT, USA, [3]IMS Health Incorporated, Plymouth Meeting, PA, USA

OBJECTIVES: Buprenorphine transdermal system (BTDS) is indicated for the management of moderate to severe chronic pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. The purpose of this study was to assess medication persistence in patients on BTDS across varying dose strengths and in patients who had a dose change. **METHODS:** Patients aged >18 years initiating BTDS during 1/1/2011-11/30/2011 were identified in the IMS Private Practitioner Medical Claims database and IMS Pharmacy Claims database. The index date was defined as the first prescription of BTDS. Medication persistence, dose change and final dose strength were assessed in the post-index 6-month period. Persistence was defined as the duration of BTDS therapy prior to the 1st28-day refill gap. Descriptive statistics, t-tests and ANOVA were used to compare differences in persistence across patient cohorts. **RESULTS:** The study included 10,457 patients newly treated with BTDS. Medication persistence was significantly higher across patients receiving higher final doses (49.1 days (n=3,769), 69.2 days (n=4,463) and 97 days (n=2,225) for 5mcg/hr, 10 mcg/hr and 20 mcg/hr doses, respectively, p<0.0001). Additionally, persistence for patients who had a dose change (n=3,297) was 111.4 days, compared to 47.8 days for those who did not (p<0.0001). Sensitivity analyses on patients with ≥2 BTDS claims (n=5,444) showed that patients on final dose strength 10 mcg/hr and 20 mcg/hr had 8.9 days and 19.2 days longer persistence when compared to patients on 5 mcg/hr (p<0.0001). Also, among patients with ≥2 BTDS claims, persistence was, on average, 17.1 days longer for patients who had a dose change compared to patients who did not (p<0.0001). **CONCLUSIONS:** BTDS persistence was longer among patients with higher final dose strengths and who had a dose change. Management of BTDS dosage over time and appropriate dose titration may impact persistence on BTDS therapy.

PSY54
IDENTIFYING POTENTIALLY NON-ADHERENT RHEUMATOLOGY PATIENTS: APPLICATION OF THE COMPLIANCE-QUESTIONNAIRE-RHEUMATOLOGY

Ingham M[1], Bolge S[1], Kopenhafer L[2]
[1]Janssen Scientific Affairs, LLC, Horsham, PA, USA, [2]Kantar Health, New York, NY, USA

OBJECTIVES: The 19 item Compliance-Questionnaire-Rheumatology (CQR) is an open access questionnaire that was developed by Rheumatologists in the Netherlands, to predict the potential for non-adherence specifically in rheumatology patients. It was validated against gold standard compliance measures. The questionnaire item bank came from home and focus group patient interviews. Responses are provided on a 4 point Likert scale delineated by strength of agreement. **METHODS:** Patients self-reporting a diagnosis of rheumatoid arthritis (RA) and residing in the United States completed a self-administered, internet-based questionnaire in the Fall of 2011, which included the CQR. CQR data were analysed using an automated analytical tool provided by the developers. Based on the validation paper, individual raw CQR questions are weighted to produce adjusted total summary scores for each patient, which can then be compared to validated cutoff values for specified levels of desired compliance ranging from 50-95%, to establish whether the patient is or is not likely to be non-compliant. Different weights exist depending on whether the user is interested in the potential for "dosing" compliance (the percentage of days the correct number of doses were taken) or dose "taking" compliance (the percentage of prescribed doses taken). **RESULTS:** Survey respondents were 76.2% female, 86.2% Caucasian, with mean age 56.4 years. At the 90%, 80%, and 50% minimum thresholds for "dosing" compliance, 99.2%, 83.8% and 66.1% of patients were identified as potentially non-compliant respectively. **CONCLUSIONS:** Depending on desired compliance thresholds, at least 60% of self-reported RA patients demonstrate attributes identifying them as potentially non-compliant with treatment. This instrument may be useful in streaming patients into adherence programs, identifying appropriate patients for specific treatments or improving patient/physician discourse during shared decision making discussions. Future work should look at validating against other common adherence measures and fine tuning patient attributes most likely to lead to non-compliance.

PSY55
HOW COMPLIANCE IS MEASURED IN TRANSPLANT PATIENTS TAKING IMMUNOSUPPRESSIVE AGENTS: A SYSTEMATIC LITERATURE REVIEW

Baker TM[1], Kiss N[2], Fortier KJ[2], Sidhu M[2]
[1]Oxford Outcomes, Bethesda, MD, USA, [2]Oxford Outcomes, Morristown, NJ, USA

OBJECTIVES: Non-adherence to medication is one of the biggest issues in health care today, where roughly half of all prescriptions for drugs to be taken on an ongoing basis are either not completed or are never even filled. Non-adherence can lead to increased rates of AEs and increased cost of care; thus, adherence to medication may impact the effectiveness of a product in the real-world. This is especially relevant for transplant patients, where the consequences of non-adherence can increase the risk of acute rejections. Despite this concern, information on transplant patient medication adherence is still uncommon, and a standard measure of adherence is not available. Our objective was to examine the existing literature to assess what adherence measures are implemented and whether they are implemented routinely. **METHODS:** A systematic review of peer-reviewed literature was conducted to identify RCTs and observational studies that measured compliance in transplant patients taking immunosuppressive agents. We searched Embase and Medline for studies from 2008-present in which adherence, compliance, or persistence appeared in the title, abstract, or as an index term. **RESULTS:** The search identified 46 studies, of which 11 measured adherence. Methods of measuring compliance varied among the included studies, some of which used multiple measurements: Basel Assessment of Adherence Scale to Immunosuppressives, 2; Medication Event Monitoring System, 2; blood test, 3; self-report, 2; VAS, 1; Likert scale, 1; pill counts, 1; questionnaire, 1; continuous measures of medication adherence, 1; measure not specified in remaining studies. In most studies, the patient, not physicians, assessed their own compliance. **CONCLUSIONS:** Adherence to medication in transplant patients is neither measured regularly nor in a consistent manner. All studies of transplant patients should assess medication adherence, and further studies must be conducted to discern a single reliable and economical measurement of compliance in transplant patients.