

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

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**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 knowledge 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 10<sup>th</sup>, 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 patients with resistant acromegaly. 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

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**OBJECTIVES:** Type I Gaucher disease (GD) is an autosomal recessive disorder caused by a deficiency in  $\beta$ -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. Velaglycerase alpha is a glycoprotein with the same amino acid sequence as the human enzyme  $\beta$ -glucocerebrosidase. The aim of this study is to assess the cost-effectiveness of velaglycerase alpha versus imiglucerase for the treatment of type I 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 velaglycerase 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 velaglycerase alpha will reach cost-neutrality even with a higher unit price. **CONCLUSIONS:** Velaglycerase alpha is a cost-saving option for the treatment of type I GD in the Spanish setting, providing annual savings compared with imiglucerase. (This study was supported by Shire Pharmaceuticals Iberica)

#### PSY49

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

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**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

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**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)