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 a prospective, multicenter, longitudinal, observational 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 data on costs, 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 calculated 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 increased (p < 0.01) from 0.7 to 0.8. The ICUR was equal to 27,519,946/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 achieving significant 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 advantage for acromegaly as compared to the standard of care. We conducted an observational, multicenter, longitudinal prospective study in 80 patients with acromegaly undergoing SCS the following data: direct and indirect costs, adopting the unit price.

RESULTS: Fifty-two of these patients were male, mean age 57 years. Cost/QALY ratio (LDT=27.5mio. QALY) was found to be cost-effective (p=0.01) compared to the standard of care, which has demonstrated in several studies its efficacy in improving HRQoL and mortality 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-GBB-039 study. Resources consumption was based on expert opinion, clinical records and clinical guidelines. Threshold sensitivity analysis was conducted to determine cost-neutrality between strategies. RESULTS: Both strategies provided a mean gained of 25.5 QALYs. The mean cost per patient was 762,352€ compared to 7,327,966€ for pegvisomant. The difference in costs was mainly due to the difference in administration costs. The threshold sensitivity analysis showed that pegvisomant alpha will reach cost-neutrality even with a higher unit price.

CONCLUSIONS: Pegvisomant 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 ASSESSMENT OF THE EFFECTIVENESS OF ENTECAVIR IN COMPARISON WITH PEGINTERFERON ALFA-2B, LAMIVUDINE, TELBIVUDINE, TENOFIVIR 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) combined 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=1year, the duration of antiviral treatment=5years. 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=35,732.97 rubles, for entecavir=9,610.04 rubles for telbivudine-103278.21 rubles for tenofovir=2131,96 rubles. Tenofovir is with administering pegylated interferon alfa-2a and then tenofovir/entecavir/3236.00 rubles/QALY and 17693.58 rubles/QALY, respectively. More cost-effective therapy was tenofovir with telbivudine in combination with third-line drugs-entecavir/tenofovir. The study showed that the use of entecavir, lamivudine, tenofovir is clinically and economically more effective than using two of the drug treatment. 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. LOWER 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 CURS for the treatment administration of tenofovir/entecavir/tenofovir. 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 OBESSE 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. Therefore, the purpose 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 yrs and females constituted 79.3%. At BL, 59% worked full time and 10% worked part time. Mean (SD) baseline weight was 126.2 (24.1) kg. At 1 year, the average %WL was 16.9% (SD, 9.0). Baseline presenteeism was 4.5%, absenteeism 33.4%, work productivity 18.4% and non-work activity impairment was 51.2%. At 1 year, there was a 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%, 16.1%, 14.1%, p<0.01) and less non-work activity impairment (32.9%, 29.7%, 27.2%, 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%, 5.1%, 7.1%, p=0.28) or productivity loss (2.1%, 2.2%, 2.7%, 1.8%, p=0.74) and remained unchanged.

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)

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