OBJECTIVES: To estimate health care costs of alternative therapeutic strategies: no treatment versus peginterferon and ribavirin (PR) versus protease inhibitor (PI) boceprevir added to PR for Russian treatment experienced chronic HCV patients, who had failure previous treatment, in short- and long-term time horizon. **METHODS:** An Excel-based model was developed to evaluate costs and outcomes of chronic HCV treated with dual therapy with PR and triple therapy with boceprevir in combination with PR. Costs for two time periods were analysed: antiviral therapy costs (0-48 weeks) and disease-progression related costs (from 48 weeks to 25 years), depending on the chosen therapy. Antiviral drug costs were calculated on the base of registered prices from the list of vital and essential drugs. Incidence of compensated and decompensated cirrhosis, hepatocellular carcinoma, liver transplant and post-liver transplant in the outcome of chronic HCV in long-term period was derived from available published data. Treatment costs of liver disease progression events were estimated according to the tariffs of the Russian health care system in 2014. **RESULTS:** Boceprevir +PR compared to no treatment strategy and PR therapy was associated with more avoided liver-disease progression events at lesser costs, resulting in boceprevir+PR as the dominant treatment option in patients with chronic HCV genotype 1 non-responders to previous treatment in Russia. Additional costs per avoided event of liver-disease progression for boceprevir plus PR and dual PR therapy were € 12,654.26 and € 45,082.82 respectively. **CONCLUSIONS:** Antiviral therapy with boceprevir plus PR in comparison with only PR therapy and no treatment strategy is cost effective due to reduced frequency of disease progression events and associated costs.

PGI20

LUBIPROSTONE IN CHRONIC IDIOPATHIC CONSTIPATION: A COST-EFFECTIVENESS ANALYSIS

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OBJECTIVES: The clinical efficacy of lubiprostone in chronic idiopathic constipation has been demonstrated in three randomised clinical trials (RCTs). This analysis assesses the cost effectiveness of lubiprostone compared to prucalopride (the current standard of care), placebo and immediate referral to secondary care from the perspective of the UK National Health Service (NHS). **METHODS:** A state-transition model was constructed to represent the treatment pathway for chronic idiopathic constipation from an NHS perspective with a 1-year time horizon. The model considered treatment continuation rules, at Week 2 for lubiprostone and Week 4 for prucalopride. Clinical data were taken from RCTs and an indirect comparison with prucalopride. Long-term duration of treatment was estimated by fitting curves to open-label study data. Costs included drug costs, medical resource use, and the cost of the pathway including primary and secondary care, obtained from published sources. Quality of life was modelled according to whether constipation was resolved or unresolved, with values taken from a large published study (n=1,200). **RESULTS:** Compared to placebo, lubiprostone delayed referral to secondary care and improved quality of life, but resulted in increased costs due to treatment, the incremental cost-effectiveness ratio was £2,924. Lubiprostone and prucalopride were found to have similar efficacy, with lubiprostone generating an additional 0.0014 QALYs in the base case. The cost per day for lubiprostone is lower than for prucalopride; leading to lower total costs (£1,596 v £1,655), and meaning lubiprostone dominated prucalopride (lower cost and higher QALYs). Probabilistic sensitivity analysis showed lubiprostone to have an 84% chance of being the most cost-effective treatment at a threshold of £20,000 per QALY. **CONCLUSIONS:** Treatment with lubiprostone provides substantial value to both patients and the NHS, being highly cost effective compared to placebo and dominant compared to the current standard of care.

PGI21

COST-EFFECTIVENESS OF LINACLOTIDE: A VALUABLE OPTION IN THE TREATMENT OF IRRITABLE BOWEL SYNDROME

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OBJECTIVES: Constipation-predominant irritable bowel syndrome (IBS-C) affects more than 2% of the population carrying a heavy burden in developed countries and leading to significant losses in patients' quality of life. Treatment goals are to provide relief of abdominal pain, restore the bowel transit and alleviate associated symptoms. Linaclotide has been shown to significantly improve abdominal and bowel symptoms in two phase III trials being the only EMA approved therapy indicated for the treatment of IBS-C. Therefore, this study aimed to perform a cost-effectiveness analysis comparing linaclotide with no active treatment for the treatment of IBS-C from the Portuguese societal perspective. **METHODS:** A Markov model was developed to simulate the natural course and treatment of the disease. Patient-level satisfaction data from linaclotide's randomised clinical trials was used to define 4 health states: 'Not Satisfied', 'Moderately Satisfied', 'Satisfied' and 'Dead'. These data were linked to utility scores based on patients' responses to the EuroQol-5D questionnaire. Transitions between health states were assumed to occur every 4 weeks, with probabilities derived from observed efficacy data up to 20-weeks. Extrapolation beyond this period was based on last observation carried forward data. Effectiveness was measured in quality-adjusted life years (QALY). Only direct costs were incorporated. Resource utilization was estimated from a literature review. Unit costs came from official Portuguese databases and pricing lists. Time horizon was fixed at 10 years. Probabilistic sensitivity analysis was conducted with Monte Carlo simulations. **RESULTS:** A mean gain of 0.22 QALY (95%CI: [0.1; 0.35]) was estimated for each patient treated with linaclotide versus no treatment. Additionally, linaclotide utilization led to an overall average cost reduction of 402€ (95%CI: [-1,735; 536]) thus representing a dominant option. **CONCLUSIONS:** When compared with no active treatment, linaclotide is a cost-saving and more effective therapeutic option for the treatment of IBS-C from the Portuguese societal perspective.

PGI22

COST-EFFECTIVENESS ANALYSIS OF A PERSONALIZED THERAPY FOR GENOTYPE 1, NAIVE, CHRONIC HEPATITIS C PATIENTS IN ITALY

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OBJECTIVES: Rapid Virologic Response (RVR) is currently used as the best predictor of Sustained Virologic Response (SVR) with dual therapy (DT) in genotype-1 chronic hepatitis C (G1-CHC), to optimize the adoption of the triple therapy (TT) with direct-acting antivirals (boceprevir: BOC and telaprevir: TVR). Bio-mathematical modelling of viral dynamics during DT has potentially higher accuracy than RVR in the identification of SVR patients. The objective of this study was to analyse the cost-effectiveness profile of a personalized anti-HCV therapy in F0-F2 G1-CHC based on a bio-mathematical model (model-guided strategy: MG) rather than on the RVR (guideline-guided strategy: GG). **METHODS:** A deterministic bio-mathematical model of the infected cell dynamics was validated in a cohort of 135 G1-CHC patients treated with DT at the University Hospital in Pisa, Italy. A lifetime health economic (HE) model was then developed to compare MG and GG strategies in the perspective of the Italian National Health Service. The model was alimented with observed data in the validation cohort, clinical variables and economic data available in the literature. A 3.5% discount rate was applied to outcomes and costs. One-way and probabilistic sensitivity analyses were run. **RESULTS:** The outcomes with MG- and GG-strategy were 19.1-19.4 and 18.9-19.3 quality-adjusted-life-years (QALY). Total per-patient lifetime costs were €25,200-€26,000 with MG-strategy and €28,800-€29,900 with GG-strategy. When comparing MG-with GG-strategy the former resulted more effective and less costly, being defined as dominant. **CONCLUSIONS:** The adoption of a SVR predictive criterion based on a bio-mathematical model, has the potential to improve the cost-effectiveness of a personalized anti-HCV therapy, allowing a more accurate identification of patients who can be effectively treated with DT and reserving high-cost BOC- and TVR-based TT for those who really need it.

PGI23

SOFOSBUVIR FOR THE TREATMENT OF CHRONIC HEPATITIS C: A COMPREHENSIVE COST-EFFECTIVENESS ANALYSIS ACROSS HCV GENOTYPES, PRETREATMENT CONDITIONS AND HIV CO-INFECTION

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OBJECTIVES: Pegylated interferon-α plus ribavirin (PR) has been the standard of care for Chronic Hepatitis C (CHC). Therapy adding boceprevir (BOC) or telaprevir (TVR) to PR in HCV genotype-1 patients has failed to achieve generalized market acceptance, in part due to the approval of newer more efficacious and safer options like sofosbuvir (SOF), a new pan-genotypic RNA-polymerase inhibitor. Objective: To assess the cost-effectiveness of sofosbuvir based therapy for CHC across HCV genotypes, pretreatment conditions and HIV co-infection in Portugal. **METHODS:** Costs and effectiveness were estimated based on discrete-time Markov-type model for CHC evolution accounting for different subpopulations in terms of HCV genotype, fibrosis progression, HIV co-infection status and previous treatment experience. The model incorporates 13 health states: 5 Metavir score, 2 SVR (with and without cirrhosis) and 3 advanced liver disease states (decompensated cirrhosis, hepatocellular carcinoma, liver transplant). Results are expressed in incremental costs per life year (LY) and quality-adjusted life year (QALY). **RESULTS:** Overall sofosbuvir-containing regimens are expected to result in an increment of 3.49 LY (3.05 QALY) after weighting for the different subpopulations assuming Portuguese epidemiology. The corresponding weighted incremental cost-effectiveness ratios (ICER) was 14,649€/LY (16,720€/QALY). In the comparison against the BOC and TVR containing regimens (genotype-1), ICER of 10,675€/LY (12,238€/QALY) and 14,618€/LY (16,495€/QALY) were obtained, respectively. For HIV co-infected and PegIFN eligible/tolerant patients, estimated ICER varied between 6,463€/LY (6,902€/QALY) and 21,281€/LY (28,245€/QALY), for G1 and G2, respectively, when comparing against treatment with PR. Additionally, in HCV/HIV coinfected patients ineligible/intolerant to PegIFN, the comparison against lack-of-therapy resulted in ICER of 15,656€/LY (17,756€/QALY) and 12,915€/LY (19,077€/QALY), for HCV G1 and G3, respectively. **CONCLUSIONS:** Sofosbuvir-containing regimens for the treatment of adult CHC patients, irrespective of HIV co-infection status, are expected to result in significant health gains at an incremental cost within the range of European Health Authorities acceptability.

PGI24

COST-EFFECTIVENESS ANALYSIS OF ANTIVIRAL PHARMACOTHERAPIES FOR TREATMENT OF CHRONIC HEPATITIS C VIRUS INFECTION IN RUSSIA

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OBJECTIVES: To evaluate the clinical and economic expediency of adding simeprevir (SMV) to pegylated-interferon and ribavirin (PR) versus PR only, or triple therapies with PR plus boceprevir (BOC) or telaprevir (TVR) for treatment of genotype 1 chronic hepatitis C (CHC) virus infection in patients who have failed previous therapy with interferon and ribavirin in Russia. **METHODS:** A Markov model developed earlier was adapted to the Russian settings. The analysis consists of 2 time periods: 1st the antiviral therapy (AVT) phase and 24 week follow-up (0-72 weeks) and 2nd the disease progression of CHC (72 weeks - lifetime). Incidences of disease progression health-states (decompensated cirrhosis, hepatocellular carcinoma, liver transplant, post-liver transplant and death, associated with high health care costs, high mortality rates) based on available published data. Costs and outcomes (life years, LY) were analyzed for treatment experienced CHC patients from Russian health care system perspective. The incremental cost-effectiveness ratio (ICER) per

LY was calculated. Sensitivity analyses were performed. **RESULTS:** Model results for treatment-experienced patients show that SMV is the dominant treatment compared to TVR+PR and BOC+PR therapies as more total LYs are saved and less costs accrued. ICER of SMV+PR vs PR was € 22,967 per LY. Results were robust in sensitivity analyses. **CONCLUSIONS:** SMV + PR is cost-effective compared to dual PR-therapy and appears the dominant strategy compared to other PI (telaprevir, boceprevir) for CHC treatment-experienced patients in Russia.

PGI25

COST-EFFECTIVENESS ANALYSIS OF TRIPLE THERAPY WITH PEGINTERFERON, RIBAVIRIN, AND BOCEPREVIR FOR THE TREATMENT OF CHRONIC HEPATITIS C VIRUS GENOTYPE 1 WITH SEVERE FIBROSIS UNDER "REAL-LIFE" CONDITIONS

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OBJECTIVES: Studies based on the data of clinical trials have proved that the triple therapy for hepatitis C is cost effective. This study we assessed the cost-effectiveness of triple therapy in treatment of Chronic Hepatitis C with Severe Fibrosis under "real-life" conditions. **METHODS:** The analysis was conducted from the data included in the prospective, multicentre, Spanish registry that includes patients with HCV-genotype-1 infection, who had severe fibrosis and were treated with triple therapy (peginterferon alfa-2a or 2b, ribavirin, and boceprevir). The cost effectiveness analysis of antiviral treatment includes the costs of antiviral treatment, of concomitant treatments and costs in relation to health care resources (in relation to clinical practice and the adverse events). **RESULTS:** 170 patients were included. 68.2% male, mean age of 53 (29-76) years. 80% had received prior treatment. 36.5% of patients reported at least one SAEs. The overall percentage of patients with SVRw12 was 46.5%. The cost of triple therapy represented a total of 4,916,652.84€, the pharmacological cost (triple therapy+concomitant treatment) involved a total cost of 5,161,168.98€. The consumption of health resources generated an additional cost of 240,000 €, which is about 1,500€/patient. The total cost per patient cured was 70,262€. This cost varies greatly based on different baseline characteristics of the patients, with significant differences in patients with albumin <3.5, 120,597€; prior null response 120,727€ and platelets <90,000,104,464€. **CONCLUSIONS:** The current scenario of the hepatitis C treatment is changing. Triple therapy is more costly for patients with severe fibrosis and predictors of poor response. However, keeping in mind that the timeframe for the release of IFN-free regimens remains uncertain and considered that the actual access to the new DAA in the real world setting could be delayed, boceprevir could remain as an option for patients with intact liver function and a high unmet medical need, regardless of the degree of liver fibrosis, in locations where a delay in the access to the newer therapies is foreseen and hepatic transplant would not be readily available.

PGI26

THE COST EFFECTIVENESS ANALYSIS OF THE ORAL ANTI-VIRAL TREATMENTS ALTERNATIVES FOR THE CHRONIC HEPATITIS B IN TURKEY

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OBJECTIVES: The aim of this study is to compare the cost effectiveness of oral antiviral treatment strategies in CHB for Turkey using lamuvidine, telbuvidine, entecavir, and tenofovir as medications. **METHODS:** The analysis was conducted using Markov model. Inadequate response or resistance after receiving 12 months of the treatment with entecavir and telbivudine were compared to the results found from switching from entecavir to tenofovir or from switching from telbuvidine to tenofovir. In additional, inadequate response or resistance after receiving 6 months of the treatment for lamivudine was compared to the results found from switching from lamivudine to tenofovir. The model duration was constructed to evaluate a treatment strategy duration of 40 years. Years of Potential Life Lost (YPLL) was used as the health outcome. An incremental cost-effectiveness ratio (ICER) analysis of the results was conducted. **RESULTS:** In a life time period, the lowest YPLL and the cost of treatment were calculated for the NS. Tenofovir treatment with 0.54 years and 37,213.75 TL. Depending on the results, the lowest YPLL and the cost of treatment were served by NS. Tenofovir treatment with 2.06 years and 276,468.45 TL. The highest YPLL and the cost of treatment were calculated for the NS. The ICER analysis found that all treatment strategies were dominated by NS. Tenofovir and S. Entecavir. Only these two treatment strategies were found to be cost-effective. **CONCLUSIONS:** The cost of providing 40 years of treatment for patients with CHB, if reimbursement agencies includes Tenofovir and Entecavir as part of the first line treatment strategy for CHB, it can be expected that this approach would result in a positive contribution to the health budget in Turkey.

PGI27

COST-EFFECTIVENESS OF EVEROLIMUS PLUS REDUCED TACROLIMUS IN DE NOVO LIVER-RECIPIENTS IN THE ITALIAN SETTING

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OBJECTIVES: Prolonged exposure to CNI-based immunosuppressant therapy (IS) in liver transplant (LTx) recipients is associated with long-term complications. In the global registration trial H2304, patients receiving everolimus + reduced tacrolimus (EVR + reduced TAC) demonstrated non-inferior efficacy and superior renal function at Month 12 that was sustained at 36 months compared to tacrolimus alone (TAC). A peer-reviewed Markov model has been adapted to the Italian setting to explore the cost-effectiveness of EVR + reduced TAC compared to TAC, in *de novo* liver-recipients. **METHODS:** The model estimates long-term outcomes associated with IS following LTx along two independent pathways: 1. liver-related (acute rejection, hepatocellular carcinoma, hepatitis C [HCV] recurrence, graft loss); 2. kidney-related (chronic kidney disease, dialysis, renal transplantation) and death. All patients, stratified by liver diagnosis, entered the model at time of LTx and followed both pathways, allowing for multiple combinations of liver and kidney health states. The lifetime model used an annual cycle length except for the 1st year post LTx (quarterly). Efficacy and safety of IS strategies were assessed through the risk of acute rejection, change in renal function, HCV fibrosis progression and frequency of adverse events. Utilities and costs were assigned to each renal and liver state. Subgroup and sensitivity analyses were performed. **RESULTS:** With a mean life expectancy of 18 years, the model predicts patients treated with EVR + reduced TAC gain on average 1.84 years of life and 1.55 QALYs vs. TAC. The risk of acute rejection was reduced by 20%. The incremental cost of EVR + TAC was €38,884 per life year gained and €46,103 per QALY gained vs. TAC. **CONCLUSIONS:** This model shows a strategy of EVR + reduced TAC post-LTx improves survival and quality of life. Higher treatment costs are offset by slower progression of renal deterioration predicted in the first 10 years and fewer lifetime liver complications.

PGI28

COST-UTILITY ANALYSIS OF SCREENING STRATEGIES FOR NONALCOHOLIC STEATOHEPATITIS

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OBJECTIVES: Nonalcoholic fatty liver disease (NAFLD) is the most common liver condition in Western countries. To date, no studies have examined the cost-effectiveness of screening for nonalcoholic steatohepatitis (NASH), its advanced form. **METHODS:** We performed a cost-utility analysis of annual non-invasive screening strategies using a third-party payer perspective in a general population and compared it to screening in a high-risk obese or diabetic population. Screening algorithms involved well-studied non-invasive techniques including NAFLD fibrosis score, ultrasound transient elastography (TE), and ultrasound acoustic radiation force impulse (ARFI) imaging for detecting advanced fibrosis (≥ F3); and plasma cytokeratin-18 for NASH detection. Liver biopsy and magnetic resonance elastography (MRE) were compared as confirmation methods. Model uncertainties were tested using sensitivity analyses. Canadian dollar costs were adjusted for inflation and discounted at 5%. Incremental cost-effectiveness ratio (ICER) of $C50,000 per quality-adjusted life year (QALY) or less was considered cost-effective. **RESULTS:** Compared with no screening, screening with NAFLD fibrosis score/TE/CK-18 algorithm with MRE as confirmation for advanced fibrosis had an ICER of $C26,143 per QALY gained. Screening in high-risk obese or diabetic populations was more cost-effective, with an ICER of $C9,051 and $C7,991 per QALY gained respectively. Screening algorithms with liver biopsy confirmation were not found to be cost-effective. Sensitivity analyses revealed that the screening starting age, the annual transition probability from simple steatosis to NASH, and the cost of a TE exam had the most impact on the results. **CONCLUSIONS:** Our model suggests that annual NASH screening in high-risk obese or diabetic populations can be cost-effective.

PGI29

THE COST-EFFECTIVENESS OF SOFOSBUVIR AND RIBAVIRIN TREATMENT IN HCV-INFECTED PATIENTS LISTED FOR LIVER TRANSPLANTATION

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OBJECTIVES: Sofosbuvir in combination with ribavirin (SOF/RBV) is a novel treatment able to suppress HCV viremia when applied to HCV patients listed for transplant, preventing HCV recurrence. Aim of this study was to assess the cost-effectiveness of this regimen in HCV patients listed for transplant for cirrhosis (HCV-cirrhosis) or for hepatocellular carcinoma (HCV-HCC). **METHODS:** a semi-Markov model was developed. The model simulates the progression of HCV-cirrhosis or HCV-HCC patients from the time of listing until death considering the risk of HCV recurrence post-transplant. The model compared 2 different strategies: 1) SOF/RBV up to a maximum of 24 weeks or until OLT if performed before the 24th week, 2) No antiviral treatment. The model estimated the costs related to the treatment with SOF/RBV, the costs associated to each health state, the life-years (LYSs), the quality-adjusted life-years (QALYs), and the incremental cost-effectiveness ratio (ICER) expressed as € per QALY gained. The analysis was performed from the Italian National Health System perspective with a lifetime time horizon and one-month Markov cycles. Future costs and clinical benefits, expressed as QALYs, were discounted at 3% per year. **RESULTS:** in the base-case analysis the ICER for 24 weeks of SOF/RBVR was €30,518 per QALY gained in HCV-cirrhosis patients and €41,610 in HCV-HCC patients. The reliability of our results was confirmed by the one way sensitivity-analysis and by the cost-effectiveness acceptability curve. Further, SOF/RBV cost-effectiveness was clearly sensitive to the duration of treatment; assuming 12 weeks SOF/RBV treatment duration, the ICER decreased to €19,317 in HCV-Cirrhosis and €29,540 in HCV-HCC. **CONCLUSIONS:** our study shows that treating patients with HCV-cirrhosis or HCV-HCC listed for transplant with SOF/RBV is cost-effective and may become the new standard of care for these patients. However a well-defined prospective study is needed to confirm the value of the parameters assumed in the model and the results.