OBJECTIVES: Establish the potential resource and cost savings from using ePTFE covered stent-grafts configured for TIPS (SG) compared to bare metal stents (BMS). Most centres have adopted SGs to treat portal hypertension because of their reduced re-intervention rates, elimination of regular monitoring of patency and improved survival. However there is no published economic analysis identifying the related cost consequences. Understanding the improved efficiencies is essential in the current financial environment. **METHODS:** A Markov economic model was developed to measure the incremental costs of the initial procedure and re-interventions with SG compared to BMS. Re-intervention procedures included angioplasty (67%), introducing a balloon expandable stent (22%) or a second stent (10%). The adverse events were hepatic encephalopathy and clinical relapse. Clinical data came mainly from a published RCT (Bureau 2007), whilst health care costs were from UK national databases. **RESULTS:** Compared to BMS, using SG in TIPS resulted in a cost saving of over £1,150 per patient over 2 years. Modelling 100 patients, compared to BMS, the SG cohort had 25 fewer re-interventions including angioplasties, saving 41 hours staff time in theatre and 16 inpatient days; with fewer cases of encephalopathy (16), recurrent ascites (8), variceal bleeds (5) and a markedly reduced mortality (13). **CONCLUSIONS:** The model showed that ePTFE covered stent-grafts configured for TIPS reduced mortality and re-interventions, saved theatre time and bed-days, and reduced overall costs despite the higher initial device cost.

PGI25

AN ECONOMIC EVALUATION OF THE TRIPLE HCV TREATMENT REGIMEN FOR G1 NAÏVE PATIENTS IN THE GREEK HEALTH CARE SYSTEM

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OBJECTIVES: In 2011 EMA approved Boceprevir and Telaprevir with PegIFN and Ribavirin for the treatment of Genotype 1 Chronic Hepatitis C patients. In 2013 the Greek and other European HCV Guidelines recommend treatment allocation in G1 naïve patients according to the IL28B genotype or the RVR profile. Local studies indicate that the IL28B-CC and the RVR (+) rates are approximately 30%. The objective of this study was to implement this guidance and examine whether triple therapy with PegIFNa-2a+RBV and the two protease inhibitors, Boceprevir or Telaprevir, constitutes a cost-saving option for the treatment of naïve G1 patients in the Greek health care setting. **METHODS:** For the needs of this analysis, a cost-consequence model was utilized, to compare the costs incurred when: i) patients with IL28B CC aplotype (30%) were treated with SoC (PegIFN alfa-2a + RBV) and patients with IL28B non-CC aplotypes (70%) were treated with triple therapy and ii) all patients are treated with triple therapy. The economic inputs are based on official and publically available sources while the clinical inputs are taken from published clinical trial results. The number of patients treated per year was provided by local bibliography. **RESULTS:** The total cost to treat 509 naïve patients with triple therapy was €13,8 million compared to €10.9 million to treat based on IL28B allocation, maintaining the same SVR rate of 70% for either of the treatment strategies. **CONCLUSIONS:** This personalized approach based on a baseline predictor of response such as the IL28B profile was proven to be a cost-saving resource allocation choice compared to the option of treating all treatment naive patients with triple therapy, providing SVR rates of 70% and a constrain of cost for the Greek health care system of €2,9 million/year (aprox.25%).

PGI26

COST-EFFECTIVENESS OF EARLY VERSUS DELAYED HEPATITIS C VIRUS (HCV) TREATMENT WITH TELAPREVIR/PEGYLATED INTERFERON ALPHA/RIBAVIRIN TRIPLE THERAPY IN ADULTS AGED 40+ IN FRANCE

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OBJECTIVES: To assess the cost-effectiveness of treating HCV infection (genotype 1) with telaprevir/pegylated interferon alpha/ribavirin (TPR) at METAVIR fibrosis stage F2 ("early") versus delaying treatment until progression to F3 ("delayed") from the French health care perspective. **METHODS:** A Markov model tracked the HCV+ French population aged 40+ over a lifetime horizon to compare outcomes of early versus delayed treatment. Model health states are defined by fibrosis stage (F0-F4) and complications of advanced HCV including decompensated cirrhosis, hepatocellular carcinoma, liver transplant, and death. During each 1-year cycle, individuals may remain in the current health state, respond to treatment or progress, at probabilities determined by disease status, age at infection, current age, gender, and treatment received. Transition probabilities, treatment efficacy, health-state utilities, resource utilization and costs were derived from published literature and standard French sources. Costs and outcomes were discounted at 4.0% for 30 years and 2% thereafter. Cost-effectiveness was assessed as incremental cost per life year gained (LYG) and QALY gained. **RESULTS:** An estimated 203,644 French residents aged 40+ years are diagnosed with HCV in 2013. Treating with TPR at F2 versus F3 is projected to result in 135,240 versus 113,728 individuals treated, at an incremental lifetime cost of €654.65M from the French health care perspective. Early treatment avoided 2,205 HCV-related deaths and saved 11,384 life-years, and 17,599 QALYs, at a cost of €57,506/LYG and €37,197/QALY gained. Results are most sensitive to efficacy parameters, time horizon, and discount rates and least sensitive to diagnosis and treatment parameters. **CONCLUSIONS:** Treating HCV-infected individuals at F2 is expected to results in better clinical outcomes but at higher cost compared to delaying treatment until the individual progresses to F3. Earlier treatment with TPR should be considered as an efficient choice by the French health care system based on its estimated incremental cost-effectiveness ratio of €37,197/QALY gained.

PGI27

COST-EFFECTIVENESS OF LINACLOTIDE COMPARED TO ANTIDEPRESSANTS IN THE TREATMENT OF IRRITABLE BOWEL SYNDROME WITH CONSTIPATION IN SCOTLAND

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OBJECTIVES: Presently, linaclotide is the only EMA approved therapy indicated for the treatment of irritable bowel syndrome with constipation (IBS-C). This study sought to determine the cost-effectiveness of linaclotide compared to antidepressants for the treatment of adults with moderate to severe IBS-C who have previously received antispasmodics and/or laxatives from the perspective of the Scottish National Health System (NHS). **METHODS:** A Markov model was created to estimate costs and QALYs over a 5-year time horizon from the perspective of NHS Scotland. Health states were based on treatment satisfaction (satisfied, moderately satisfied, not satisfied) and death. Transitions between states were based on satisfaction data from the linaclotide pivotal studies (MCP-103-302 and LIN-MD-31) and Scottish general all-cause mortality statistics. Treatment costs were calculated from the British National Formulary. NHS resource use and disease-related costs for each health state were estimated from Scottish clinician interviews in combination with NHS Reference costs. Quality of life was based on EQ-5D data collected from the pivotal studies. Costs and QALYs were discounted at 3.5% per annum. Uncertainty was explored through extensive deterministic and probabilistic sensitivity analyses. **RESULTS:** Over a 5-year time horizon, the additional costs and QALYs with linaclotide were £659 and 0.089, resulting in an incremental cost-effectiveness ratio of £7,370 per QALY versus antidepressants. Results were most sensitive to health state transitions probabilities, NHS resource use assumptions and health state utilities. Threshold analyses showed that the effectiveness of linaclotide would have to be at least 11% lower than the base case to exceed a willingness-to-pay threshold (WTP) of £20,000 per QALY. Based on the probabilistic sensitivity analysis, the likelihood that linaclotide was cost-effective at a WTP of £20,000 per QALY was 74%. **CONCLUSIONS:** Linaclotide is a cost-effective treatment for adults with moderate to severe IBS-C who have previously received antispasmodics and/or laxatives.

PGI28

COST-EFFECTIVENESS OF HEPATITIS C VIRUS (HCV) TREATMENT WITH TELAPREVIR/PEGYLATED INTERFERON ALPHA/RIBAVIRIN TRIPLE THERAPY VERSUS WAITING FOR NEW REGIMENS IN FRANCE

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OBJECTIVES: To assess the cost-effectiveness of treating chronic HCV infection (genotype 1) with currently available telaprevir+pegylated interferon alpha/ribavirin (TPR) compared to waiting for new regimens with improved efficacy (hypothetical treatment assumed) currently in development from the French health care perspective. **METHODS:** A Markov model tracked the adult naïve HCV+ French population over a lifetime horizon. Model health-states are defined by METAVIR fibrosis stage (F0-F4) and complications of advanced HCV (decompensated cirrhosis, hepatocellular carcinoma, liver transplant, and death). During each 1-year cycle, individuals may remain in the current health-state, respond to treatment or progress, at probabilities determined by disease status, age at infection, current age, gender, and treatment received. Individuals were eligible for treatment in F2-F4. Transition probabilities, treatment efficacy, health-state utilities, resource utilization and costs were derived from published literature and standard French sources. The efficacy of a new hypothetical treatment regimen was based on currently published results; cost for the new treatment was assumed at €50,000 for a full treatment (excluding PR backbone). **RESULTS:** A treatment lag of 1, 2, and 3 years resulted in 142,777 individuals, 140,417 individuals, and 137,930 individuals being treated by the new regimen, respectively, versus 145,010 with immediate TPR treatment. The new treatment option resulted in additional life years saved (range 11,230-27,536), QALYs gained (range 12,528-29,359), and prevented more HCV-related deaths (range 3,839-5,756). Total costs incurred were higher for the new regimen versus TPR, from the health care perspective. ICERs were €58,294.49/QALY, €73,295.59/QALY, and €107,403.02/QALY gained for a 1, 2, and 3 year treatment lag, respectively. **CONCLUSIONS:** These findings suggest waiting for new regimens currently in development should not be the most efficient choice to be considered by French Health care system. Waiting for new treatments should yield better clinical outcomes, but with higher costs and ICERS that may be challenging for the payer.

PGI29

CROHN'S DISEASE: AN ECONOMIC ASSESSMENT OF BIOLOGICAL DRUGS IN ITALY

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OBJECTIVES: This study had a dual objective: verify the improvements in quality of life (QoL) due to biological drugs administration and evaluate their cost-effeffectiveness versus the standard steroid-based therapy in Crohn's Disease (CD). High-cost biological drugs' efficacy is well-established, but they still lack of cost-effectiveness studies. **METHODS:** A survey was prepared with clinicians and pharmacoeconomists and administered in 9 centers in Italy. The questionnaire was set up to detect QoL through a Visual Analogue Scale and EQ-5D and to assess patients' profile (age, gender, job) and clinical features (time-to-first diagnosis, current and at-diagnosis Montreal classification, current and at-diagnosis treatments, past surgical procedures, hospitalizations). Collected data were then used in a statistical regression model and an economic assessment complete of probabilistic sensitivity analysis was performed comparing costs and utilities of the considered treatments. **RESULTS:** A total of 348 questionnaires were collected, giving back a

population with a mean age of 42, 52% male, 58% actively working, 52% undergone surgical interventions, and 66% being already administered previous therapies. The mean number of outpatients visits was 4.15/year, with 0.23 hospitalizations/year. At diagnosis, the 55% of patients were treated with steroids, while only the 3% with biological drugs. At the time of survey administration, the 9% of patients were treated with steroids, and the 50% with biological drugs. The statistical model showed a significant QoL improvement due to biological drugs therapy of about 6%. The economic assessment showed biological drugs to be cost-effective only in more severe settings of patients (€ 26.000 – 38.000 /QALY), but not in mild and moderate CD (€ 58.000 to 328.000 /QALY). **CONCLUSIONS:** The results of the analysis, based on simulation models and real practice data, are consistent with evidences from other countries and thus biological drugs can be considered a good health care investment in severe cases of CD.

PGI31

IS THE USE OF ESOMEPRAZOLE IN GASTROESOPHAGEAL REFLUX DISEASE A COST-EFFECTIVE OPTION IN POLAND?

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OBJECTIVES: To compare the cost-effectiveness of therapy of different forms of GERD with esomeprazole and other proton pump inhibitors (PPIs) in Poland. **METHODS:** Results of clinical trials with esomeprazole in comparison with equivalent doses of other PPIs in the treatment of erosive esophagitis (EE - 6 RCTs), non-erosive reflux disease (NERD – 1 RCT) and GERD maintenance therapy (2 RCTs) were systematically reviewed. Meta-analysis was conducted as appropriate, relative risk values were calculated. Cost data derived from Polish Ministry of Health and pharmacies in Wroclaw. Cost effectiveness ratios and incremental cost effectiveness ratios were assessed for 100 patients. **RESULTS:** In the treatment of EE esomeprazole was significantly more effective than other PPIs. For 4 weeks therapy ICER values (esomeprazole 40 mg vs. omeprazole 20 mg and pantoprazole 40 mg) were 614 PLN and 906.33 PLN respectively if original and generic esomeprazole products were taken into account and 118.22 PLN and 162.67 for generics. For 8 weeks therapy ICER values (esomeprazole 40 mg vs. omeprazole 20 mg, lansoprazole 30 mg and pantoprazole 40 mg) were: 430.45 PLN, 329.47 PLN and 325.33 PLN (for generics and original esomeprazole) and 1869.58 PLN, 2677.89 PLN and 1812.67, respectively for generics. Differences in effectiveness of NERD therapy with esomeprazole and other PPIs were not statistically significant. The replacement of pantoprazole 20 mg with more effective esomeprazole 20 mg in the 6-month maintenance therapy was associated with a marginal cost of 3078.01 PLN (only generics included) and 4590.91 PLN (for original esomeprazole and generics) respectively. **CONCLUSIONS:** 1) For 4 and 8 weeks therapy of EE esomeprazole has to be recognized as a cost-effective option. 2) In the NERD treatment the choice of PPI should be based on the price of medicament. 3) The use of esomeprazole in GERD maintenance therapy is associated with a very high ICER.

PGI32

COMPARATIVE ECONOMIC ANALYSIS OF RETREATMENT STRATEGIES FOR HCV GENOTYPE 1 PATIENTS IN RUSSIA

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OBJECTIVES: To assess the cost-effectiveness of retreatment with pegylated interferon and ribavirin in combination with boceprevir of HCV genotype 1 patients, who failed to respond to previous treatment, in comparison with absence of retreatment and retreatment with pegylated interferon and ribavirin. **METHODS:** We performed cost-effectiveness analysis. Based on the published data we modeled the number of long-term unfavorable outcomes of HCV (liver cirrhosis, hepatocellular carcinoma and death) in the hypothetic cohort of HCV genotype 1 patients following one of three retreatment strategies: "no treatment" (NT), "peginterferon+ribavirin" (PR) and "peginterferon + ribavirin + boceprevir" (PRB). We have evaluated direct medical costs for a short-term (only cost of HCV retreament) and for a long-term (costs of medical care for adverse outcomes) periods for all strategies. Costs were estimated on the basis of average price for the drugs and reimbursement rates for medical services in the compulsory medical insurance system. Incremental cost-effectiveness ratio (ICER) for PR and PRB strategies vs NT were calculated as additional cost per unfavorable outcome avoided. **RESULTS:** It is expected that in hypothetic cohort of 10000 HCV genotype 1 patients 58,1% would fail to respond to the treatment. The estimated costs of retreatment for this group were EURO 69,07 mln in case of PR strategy and EURO 235,58 mln for PRB. The cumulative number of unfavorable outcomes of HCV during 25-year period would be 5075 cases for NT strategy, 4262 for PR and 2012 for PRB. The long-term costs of NT strategy were EURO 205,35 mln, EURO 168,37 mln in case of PR strategy and EURO 81,4 mln for PRB. ICER for PR strategy was EURO 44532 and for PRB - EURO 36379 per unfavorable outcome avoided. **CONCLUSIONS:** The use of PRB strategy is efficient as it allows reducing the number of unfavorable outcomes of HCV at a lesser cost.

PGI33

COST-UTILITY ANALYSIS OF LINACLOTIDE IN THE TREATMENT OF IRRITABLE BOWEL SYNDROME WITH CONSTIPATION IN BELGIUM

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OBJECTIVES: Linaclotide is the first drug that received EMA approval in the management of irritable bowel syndrome in its constipation form (IBS-C). We aimed at estimating the cost-utility of linaclotide, compared to standard of care (SoC) in Belgium. **METHODS:** The analysis was conducted using data from a 6-month randomized trial of linaclotide 290µg once daily (N=401) versus placebo (N=403), which provided monthly EQ-5D measures, treatment duration, adverse events (diarrhoea) and responder status (abdominal pain/discomfort improvement ≥ 30% from baseline). Belgian EQ-5D tariffs were used to estimate utilities and trapezoidal rule to estimate QALYs. A Delphi panel including 6 general practitioners and 5 gastroenterologists provided the resource use for IBS-C patients in different treatment phases: controlled with 2nd line or new drug else non-responders. Patient-level costs were applied using first-order Monte-Carlo simulation (gamma distribution function; per treatment arm and responder status; health care payer perspective). A stopping rule was implemented at 4 weeks for linaclotide non-responders. A non-parametric bootstrap with 1000 replications was performed. The 2012 Belgian GDP per capita (€34,000) was used as willingness-to-pay threshold. **RESULTS:** The responder rate at 4 weeks was 54.6% with linaclotide vs. 35.5% with SoC. There was on average 0.0129 QALYs gained per linaclotide patient vs SoC at 6 months (0.385 vs. 0.372), with an incremental cost of €95 (€1,376 vs. €1,280). The incremental cost-effectiveness ratio of was €7,364/QALY. The diarrhoea costs were higher with linaclotide (+€19.4) while savings were observed in clinical management (-€132.2) compared to SoC. Using a willingness-to-pay threshold of €34,000/QALY, 66% of the simulations were cost-effective. **CONCLUSIONS:** Due to improvements in abdominal pain/discomfort complaints in patients receiving linaclotide, savings were generated in the clinical management of IBS-C compared to SoC. Using the GDP per capita as willingness-to-pay threshold, linaclotide seems a cost-effective alternative to today SoC of IBS-C in Belgium.

PGI34

COST-EFFECTIVENESS OF CAPSULE ENDOSCOPY (PILLCAM®) IN THE DIAGNOSIS OF SMALL BOWEL CROHN'S DISEASE

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OBJECTIVES: Capsule endoscopy (CE) is a minimally invasive endoscopic technology that uses a disposable capsule containing a small camera to monitor and diagnose disorders of the gastrointestinal tract such as Crohn's disease and obscure gastrointestinal bleeding. This study examines cost-effectiveness of CE (PillCam®, Given Imaging) for the diagnosis of small bowel Crohn's disease in Australia. **METHODS:** A modelled cost-utility analysis of CE vs. no CE followed by empiric treatment is performed. The population under consideration consists of patients with a clinical suspicion of Crohn's disease despite non-confirmatory results with prior endoscopic/radiologic tests. Due to a lack of alternative diagnostic options, many of these patients currently receive empiric treatment, whereby a diagnosis is achieved based on long-term response to therapy for Crohn's disease. CE increases the proportion of patients who receive a confirmed diagnosis for Crohn's disease or for other bowel conditions (represented by irritable bowel syndrome in the model), thereby allowing more patients to promptly receive a correct treatment and thus improving the down-stream treatment effectiveness. The administration of correct and effective treatment, as aided by CE, thus produces additional QALYs and potential cost savings, which are captured by the current model. The model has a 12-month time horizon and takes the perspective of Australian health care system. **RESULTS:** CE is estimated to produce 0.057 additional QALYs over the 12-month period. The additional cost of CE is in part offset by cost savings arising from the improved treatment selection. The incremental cost-effectiveness ratio (ICER) is estimated to be $23,672 per additional QALY. **CONCLUSIONS:** The current model suggests CE is highly cost-effective. Importantly, the target patient population currently experience a unique and special unmet clinical need because the currently funded endoscopic/radiologic technologies are unable to provide a confirmed diagnosis. The evidence for cost-effectiveness clearly supports that CE represents good value for money.

PGI35

THE COST-UTILITY OF FIDAXOMICIN AS COMPARED TO CURRENT STANDARD TREATMENT IN THE MANAGEMENT OF CLOSTRIDIUM DIFFICILE INFECTIONS IN BELGIUM

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OBJECTIVES: Clostridium difficile infection (CDI) is one of the most common hospital acquired infections in industrialised countries. CDI is responsible for severe morbidity, partly driven by the high proportion of patients experiencing a recurrence after an initial successful response to treatment. In Belgium, CDI incidence and mortality has more than doubled between 1998 and 2007. The aim of this study was to assess the cost-utility of fidaxomicin as compared to current standard treatment for managing CDI in Belgium. **METHODS:** A Markov model with a 1-year time horizon and 10-day cycles was developed to compare fidaxomicin, metronidazole and vancomycin in patients with all CDI and two subpopulations (severe CDI and first recurrence of CDI). Clinical data from two pooled published phase-3 trials (fidaxomicin vs. vancomycin) were used along a mixed treatment comparison of fidaxomicin vs. metronidazole. Treatment paths and data input were approved during an advisory board. Costs of first episode and recurrent CDI hospitalizations were taken from the IMS Hospital Disease Database. Cost per quality-adjusted life-year (QALY) gained was calculated from the health care payer perspective. **RESULTS:** The model showed cost savings and QALY gained versus vancomycin and metronidazole. Fidaxomicin versus an average of these comparators delivered benefits for all CDI patients (-1,100€; 0.008 QALY), for severe CDI (-1,300€; 0.009 QALY) and for first recurrence CDI (-1,500€; 0.009 QALY). One-way sensitivity analyses revealed that time horizon and the odds ratio of recurrence with fidaxomicin had most affect on the results. Applying a cost-effectiveness threshold of €30,000 per QALY gained, probabilistic sensitivity analysis showed acceptable cost-effectiveness in 80% of all CDI cases. **CONCLUSIONS:** Based on the available clinical data the model showed that fidaxomicin dominates vancomycin and metronidazole generating additional QALYs with cost-savings not only in patients with all CDI, but also in subpopulations with severe CDI or a first recurrence.