Clinical efficacy and adverse event costs were not taken into consideration. The model also assumed reimbursement of infliximab-biosimilars in 2015 with low market-penetration and conventional treatment almost steady throughout the three-year time horizon. Input data for estimated volumes were validated separately by two opinion leaders in gastroenterology (from a tertiary public and a private hospital), with vedolizumab experience through early-access programs. Any assumptions that showed discrepancies to expert opinion were converted to the average value of the two inputs. Values are in €2015. **RESULTS:** The increase in total costs from the introduction of vedolizumab and biosimilars to the Greek healthcare system, would be €255,926, €673,491 and €814,924 for the three respective years post-entry (cumulative €1,744,341). Average incremental per patient cost for the first year was found to be €249 when vedolizumab and biosimilars received 21% and 11% of total UC biologic volumes respectively. Yearly total pharmaceutical UC expenditure ranged from €2,735,702 to €3,016,905 in the absence of vedolizumab and €2,991,628 to €3,831,829 when vedolizumab was available with estimated expenditure on biosimilar therapies not exceeding €853,470 over three years. **CONCLUSIONS:** Irrespective of the limitations due to lack of country-specific data, vedolizumab introduction is not expected to exert significant pressure on third party pharmaceutical UC expenditure.

PGI5

## VEDOLIZUMAB IN CROHN'S DISEASE; A BUDGET IMPACT MODEL FOR A NOVEL DRUG IN A RECESSION ENVIRONMENT

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**OBJECTIVES:** Crohn's disease (CD) exerts significant burden to IBD-patients and payers. The aim of this study was to estimate the budget impact of vedolizumab in moderate/severe CD, from the perspective of the Greek healthcare setting. **METHODS:** A Microsoft Excel-based budget impact model was adapted for a hypothetical cohort of IBD patients with moderate/severe CD within the total Greek population. The budget impact was calculated and presented as incremental drug-acquisition and administration costs, using input values obtained from National official databases, before and up to three years after the introduction of vedolizumab versus standard of care. Clinical efficacy and adverse event costs were not taken into consideration. The model also assumed reimbursement of infliximab-biosimilars in 2015 with low market-penetration and conventional treatment almost steady throughout the three-year time horizon. Input data for estimated volumes of vedolizumab and biosimilars were validated separately by two opinion leaders in gastroenterology from a tertiary public and a private hospital, with vedolizumab experience through early-access programs. Any assumptions that showed discrepancies to expert opinion were converted to the average value of the two inputs. Values are in €2015. **RESULTS:** The increase in total costs from the introduction of vedolizumab and infliximab-biosimilars to the Greek healthcare system, would be €195,600, €519,429 and €788,147 for the three respective years post-entry (cumulative €1,503,176). Average incremental per patient cost for the first year was found to be €164 when vedolizumab and biosimilars received 10.9% and 3.3% of total CD biologic volumes respectively. Yearly total pharmaceutical CD expenditure ranged from €5,024,036 to €5,653,930 in the absence of vedolizumab and €5,219,636 to €6,442,077 when vedolizumab was available with estimated expenditure on biosimilar therapies not exceeding €745,000 over three years. **CONCLUSIONS:** Irrespective of the limitations due to lack of country-specific data, vedolizumab introduction is not expected to exert significant pressure on third party pharmaceutical CD expenditure.

PGI6

## INTRODUCTION OF NEW COMBINATION THERAPY FOR TREATMENT OF EXPERIENCED HCV GT1 PATIENTS: BUDGET IMPACT ANALYSIS, THE CROATIAN PERSPECTIVE

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**OBJECTIVES:** The new combination therapy of paritaprevir, ombitasvir, dasabuvir, with/without ribavirin is highly tolerable, all-oral, interferon-free regimen for treatment of chronic hepatitis C virus (HCV) infection. The objective of present study was to evaluate the financial impact on the Croatian Health Insurance Fund (CHIF) budget following the introduction of the therapy for experienced HCV genotype 1 (GT1) patients. **METHODS:** The size of the eligible population for the new pharmaceutical combination was estimated by local demographics information, literature, and experts' opinion. Only direct costs of pharmaceuticals were taken into account. Budget impact calculations were based on health-economic outcomes of the new therapy in comparison to alternative interventions (standard dual-therapy and triple therapies that include boceprevir, telaprevir and simeprevir) for different patient subpopulations. Patient subpopulations were differentiated by response to previous treatment (relapse, partial response and null response), presence of cirrhosis and HCV GT1 subtype. Sensitivity analysis was performed in the form of alternative scenarios. Final parameters were estimated by Monte Carlo simulations. **RESULTS:** The new combination therapy showed better efficiency, shorter duration and better tolerance in comparison to alternative interventions. For certain patient subpopulations, the new therapy is cheaper per achieved SVR in comparison to other therapies. The estimated number of patients eligible for the new combination therapy is 90-100 per year and the expected annual value of increased expenditures for CIHF budget is in between approximately 200,000 – 900,000 €. **CONCLUSIONS:** Although the impact on CHIF budget is significant, due to high efficiency and high tolerability, the new combination therapy for some patient subpopulations is cost-effective, that being the reason for its consideration as an alternative to standard therapies. Further, this economic evaluation could be the starting point for negotiations between pharmaceutical industry and insurance companies, as well as an introduction of specific contracts and some new technical solutions in those negotiations.

PGI7

## OPTIMAL TREATMENT OF CHRON'S DISEASE WITH BIOLOGICALS IN A WESTERN BALKAN COUNTRY: ESTIMATES OF COST/UTILITY BY MARKOV MODEL AND BUDGET IMPACT ANALYSIS

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**OBJECTIVES:** The aim of this study was to estimate cost/utility of infliximab for treatment of Chron's disease in Serbia and to calculate impact on national health budget if it is used according to evidence-based guidance for treatment of inflammatory bowel diseases. **METHODS:** Cost/utility of biological therapy of Chron's disease (infliximab in the first line, adalimumab for the patients unresponsive to infliximab) vs. azathioprine was estimated by Markov model written in Excel 2007. The model has 9 health states, with 30 two-month cycles. The model was populated from the perspective of Serbian society, taking into account both direct and indirect costs expressed in Serbian dinars (1 Euro = 120 RSD). Both costs and quality-adjusted life years (QALYs) were discounted at uniform rate of 3%. The model outputs were generated by Monte Carlo microsimulation, and further used for budget impact analysis. Conclusions of the model were challenged by probabilistic sensitivity analysis. **RESULTS:** Biological therapy was cost effective in comparison with standard therapy, with ICER value of 2,091,348.98 ± 1,156,213.78 RSD per QALY gained (99% CI), and Neto monetary benefit of 90,183.84 ± 135,055.30 RSD (99% CI). About 62% of virtual patients generated by the model simulation were below the willingness of pay of 3 GDP per capita per QALY gained. Price of infliximab was the most influential variable on Neto monetary benefit in the sensitivity analysis. If infliximab and adalimumab are 100% reimbursed by Serbian health insurance fund for 3,927 patients with Chron's disease in Serbia who need biological therapy, additional annual burden on health budget in Serbia would be 180,248,853.03 ± 333,531,117.81 RSD (99% CI), or about 0.29% of total drug budget. **CONCLUSIONS:** Biological therapy of Chron's disease in Serbia is cost/effective option, which would impose moderate burden on national health budget after full implementation according to recommendations of evidence-based international guidelines for treatment of inflammatory bowel diseases.

PGI8

## IS NICE TOO OPTIMISTIC ABOUT SAVINGS FROM FAECAL CALPROTECTIN TESTING?

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**OBJECTIVES:** Calprotectin is a calcium binding protein released by neutrophils associated with inflammation. A recent systematic review has confirmed the value of testing faecal calprotectin to help distinguish between organic (inflammatory bowel disease - IBD) and non-organic gastrointestinal disease (irritable bowel syndrome - IBS). National Institute of Clinical Excellence (NICE), UK guidelines were thus written to guide general practitioners (GPs) in excluding IBD and to achieve savings by reducing the number of referrals to secondary care. We aimed to determine the 12 month clinical outcomes of patients undergoing FC testing in primary and secondary care settings. **METHODS:** 495 FC test results between July 2012 to October 2013 were reviewed. Paediatric patients (<16 years old) were excluded. Patients not referred to secondary care/tertiary care had their GPs contacted for further details. Long term clinical data was available in 275 patients; 208 normal, 41 intermediate and 26 raised FC results. **RESULTS:** 40% of patients with a normal FC result were still referred to secondary gastroenterology care, with only 26% managed in primary care. 12 months post FC testing revealed 9% of normal FC results remained in secondary care, compared to 34% for intermediate and 73% for raised results. A new diagnosis of IBD was made in 1% of patients with normal FC results, 19% of intermediate and 38% of raised FC results. Conversely a new diagnosis of IBS (non-organic) was made in 40% of normal FC, 27% of intermediate and 7.7% of raised results. **CONCLUSIONS:** Despite a normal FC, this study suggests that 40% are still being referred to secondary care for investigation. This suggests that the cost saving intended by NICE may have been overestimated. The proportion of normal FC results which are managed in primary care could be improved with better GP education and more stringent pathways.

PGI9

## COST ANALYSIS OF PROTON PUMP INHIBITORS IN THE TREATMENT OF GASTROESOPHAGEAL REFLUX DISEASE IN UKRAINE

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**OBJECTIVES:** The objective of this study is to determine the direct costs of the use of PPI for the treatment of erosive form (EF) and non-erosive form (NEF) of GERD in patients of working age in Ukraine. **METHODS:** Cost analysis for PPIs was conducted for a minimum course of treatment of GERD in one patient: NEF – 4 weeks, EF – 8 weeks. Daily doses of preparations were used in calculations: omeprazole, rabeprazole - 20 mg; pantoprazole, esomeprazole - 40 mg; lansoprazole – 30 mg, (as recommended by the Ukrainian unified clinical protocol "Gastroesophageal Reflux Disease", 2013). When calculating the direct costs, the cost of PPIs was only taken into account. Prices of drugs were taken from the Morion information system "Drugs" (November 2014). The rate of hryvnia to dollar (USD) as of 28.11.14 was 14.96:1. To determine the range of costs for the use of PPIs, their trade names with the minimum and maximum costs of treatment of the disease in one patient were determined. **RESULTS:** Ilaprazole achieved a better overall efficacy, because it is less impacted by CYP2C19 genotype subgroups. Compared with omeprazole, ilaprazole achieved an incremental cost effectiveness ratio of ¥132,056 per QALY gained which is less than the 3 times of China average GDP per capital (2014). A subgroup analysis suggests Ilaprazole is most cost-effective in the CYP2C19 subpopulation of