PGI13

ECONOMIC BURDEN AND TREATMENT PATTERNS OF ADULT PATIENTS WITH CHRONIC CONSTIPATION IDENTIFIED THROUGH RETROSPECTIVE DATABASE RESEARCH

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OBJECTIVES: To collect real-world data on the economic burden and treatment patterns associated with chronic constipation in Swedish patients through retrospective database research. **METHODS:** A regional Swedish database was used that combines diagnostic and health care data with prescription drug use and mortality data from national registers. The drug register comprises all dispensations made at pharmacies, defined as dispatches. According to Swedish legislation, a dispatch can last for up to 90 days, which is common for chronic diseases. Adults with chronic constipation (≥2 primary constipation diagnoses, or one primary constipation diagnosis and two associated laxative dispatches, over 12 months) were selected during 2005-2008. Patients with irritable bowel syndrome (IBS) or opioid-induced constipation were excluded. Data were retrieved on: health care contacts and drug use for 12 months from the first constipation diagnosis; patient demographics; and comorbidities. **RESULTS:** Of the initial selection, 2119 patients were excluded owing to opioid use (32%) and 435 owing to IBS (7%). The final population comprised 4043 patients (60% women) with a mean age of 67 years (range: 18-106 years). A history of arrhythmia or diabetes mellitus was common (≥10%), with prevalence increasing with age. During follow-up, patients had, on average, 2.3 constipation-related health care contacts and 15.2 additional health care contacts, at average annual costs of €1642 (standard deviation [SD]: €14 618) and €5944 (SD: €18 209), respectively. Most patients (54%) used ≥1 type of laxative during follow-up and 17% used ≥3 types. On average, patients had four laxative dispatches and 43 non-laxative dispatches, at average annual costs of €61 (SD: €74) and €624 (SD: €1137), respectively. **CONCLUSIONS:** Patients with chronic constipation were mainly elderly with high disease burden, as demonstrated through frequent health care contacts (17.5/year) and extensive drug use (47 dispatches/year). Constipation-related care accounted for 22% of total resource utilization, while laxatives made up 10% of total drug costs.

PGI14

CHARACTERISTICS OF DIVERTICULITIS-RELATED EMERGENCY DEPARTMENT VISITS IN THE UNITED STATES

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OBJECTIVES: Diverticulitis (DV) exerts a significant burden on health care systems and payers. Although DV is often first diagnosed as an emergent condition in emergency department (ED) settings, few details on characteristics of DV-related encounters in ED settings exist. This study characterizes DV-related ED visits in the US in 2007. **METHODS:** Data were from the 2007 Healthcare Cost and Utilization Project (HCUP) Nationwide Emergency Department Sample (NEDS), a nationally representative sample of ED visits in the US. For each visit in the NEDS, clinical and resource use information is recorded, including patient demographics, diagnoses and procedures performed, payer information, and total charges. Patients with a primary DV diagnosis (ICD-9-CM 562.11 or 562.13) were identified. Patient-, stay-, and facility-specific characteristics were documented for each DV-related ED visit, and compared to all ED visits in the US during the same period. Sampling weights in the NEDS allow for generation of nationally representative estimates. **RESULTS:** Of 122.3 million ED visits in the US in 2007, 284,853 involved a primary DV diagnosis. Among these visits, mean patient age was 58.3 years, ~20 years older than non–DV-related patients (37.8 years; $P<0.0001$); 55.4% were for female patients. DV-related visits most often occurred in the southern US (38.1%), private health insurance was the most frequent payer for these visits (45.6%), and >50% were admitted to an inpatient facility from the ED (56.7%). The mean charge per DV-related ED visit (2011 US dollars) was $3,211, nearly double than for non-DV-related visits ($1,677; $P<0.0001$). Total charges across all DV-related ED visits were ~$1 billion. **CONCLUSIONS:** DV requires careful clinical management, across a variety of health care settings. This study presents novel information on DV-related ED visits in the US. Adding to the body of knowledge regarding DV-related care may help providers and decision makers optimize allocation of resources to treat all DV patients.

PGI15

COST-EFFECTIVENESS ANALYSIS OF LACTEST, A NEW DIAGNOSTIC DRUG TEST FOR HYPOLACTASIA IN SPAIN

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OBJECTIVES: To compare the cost and effectiveness of LacTest® versus other diagnostic procedures available to identify lactose intolerance using the perspective of Spanish National Health System. **METHODS:** A cost-effectiveness analysis was carried out using a decision tree comparing LacTest® with the hydrogen breath test, the capillary blood glucose test and the intestinal biopsy. Data on the effectiveness of each diagnostic procedure, expressed as the sensitivity of each test or the proportion of true positives identified by the test for all patients, were taken from the clinical results of the EUDRA study. The use of health care resources associated with the tests and their costs were obtained from literature review. Costs considered included diagnostic tests, laboratory tests, physician visits and time of health care personnel. The time horizon of the analysis was one year. All costs are expressed in Euro 2012. Results were expressed as the effectiveness and costs of LacTest® compared with those of the other diagnostic procedures. **RESULTS:** The proportion of diagnosed patients, as measured by sensitivity, was higher for LacTest® with 0.991 than for the other diagnostic procedures with values of 0.953 for the intestinal biopsy, 0.785 for the hydrogen breath test and 0.748 for the capillary blood glucose test, respectively. Direct health care costs per patient were €187 with LacTest®, €143 with the hydrogen breath test, €140 with the capillary blood glucose test and € 458 for the intestinal biopsy. **CONCLUSIONS:** The results indicate that LacTest® is demonstrating a higher sensitivity in the diagnosis of new cases of hypolactasia compared with the other tests in this study. LacTest® showed to be the dominant option compared with the intestinal biopsy. When compared with the hydrogen breath test and the capillary blood glucose test, LacTest® showed to be more effective at an incremental cost of €44 and €40, respectively.

PGI16

COST EFFECTIVENESS OF BOCEPREVIR PLUS PEGINTERFERON ALPHA AND RIBAVIRIN VERSUS TELAPREVIR PLUS PEGINTERFERON ALFA AND RIBAVIRIN IN THE TREATMENT OF CHRONIC HEPATITIS C (CHC) IN PREVIOUSLY UNTREATED GENOTYPE I PATIENTS

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OBJECTIVES: In previously untreated adults with hepatitis C virus (HCV) genotype 1 infection the combination of boceprevir (B) or telaprevir (T) plus peginterferon alpha/ribavirin (PR) have shown to produce a higher rate of sustained virologic response (SVR) than peginterferon alfa/ribavirin (PR). The aim of this study is to assess the cost effectiveness of these two antiviral regimens. **METHODS:** We developed a Markov model to describe the clinical history of CHC genotype 1 patients in which one cohort (1) receives PR for 4 weeks followed by BPR for 24 weeks and those patients with a detectable HCV RNA level between weeks 8 and 24 receive PR for an additional 20 weeks; cohort 2 patients receive TPR for 12 weeks followed by PR for 12 weeks and those patients with a detectable HCV RNA level between weeks 4 and 12 receives PR for an additional 24 weeks. All patients are followed for their expected lifetime. The reference patient is 30-year-old with CHC without cirrhosis. The SVRs to BPR and TPR cohorts came from SPRINT 2 and ADVANCE studies. Quality of life for each health state was based on literature. Costs for each health state were based on three Delphi panels, one with hepatologists, one with intensivists and another with oncologists. Costs in 2011 Brazilian Reais and benefits were discounted at 3%. **RESULTS:** BPR increases life expectancy by 0.78 years and quality adjusted life years (QALY) by 1.20 years compared to TPR. BPR is cheaper than TPR (-25,924 Brazilian Reais). **CONCLUSIONS:** In Brazil, for the treatment of previously untreated adults with HCV genotype 1 boceprevir plus peginterferon alpha/ribavirin is dominant compared with telaprevir plus peginterferon alpha/ribavirin.

PGI17

COST-EFFECTIVENESS OF TELAPREVIR WITH PEGINTERFERON AND RIBAVIRIN FOR TREATMENT-NAIVE PATIENTS CHRONICALLY INFECTED WITH HCV OF GENOTYPE 1 IN JAPAN

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OBJECTIVES: Telaprevir introduced recently as a new protease inhibitor for chronic HCV infection showed promising results used in conjunction with peginterferon and ribavirin (triple therapy: TT). We assess the cost-effectiveness of TT compared to peginterferon-ribavirin dual therapy in the treatment of previously untreated Japanese patients with genotype1 chronic hepatitis. **METHODS:** We created a Markov decision model of HCV natural history and progression toward advanced liver disease to evaluate the cost-effectiveness of alternative treatment strategies, in a previously untreated Japanese cohort consisted of patients aged 50 years with genotype 1 chronic hepatitis for a time horizon of lifetime. We compared 3 strategies; no treatment, standard 48 weeks of dual therapy with further 24 weeks of extended treatment for late viral responders (DT+; total 72 weeks) and 24 weeks of TT. The data sources of natural history model were mainly derived from Japanese epidemiological studies. Due to lack of the evidence of the direct comparative effectiveness between TT and DT+ in Japanese HCV patients, the results of a randomized control trial compared TT with standard dual therapy was combined with those of an observational study which compared effectiveness between standard dual therapy and those with extended treatment. **RESULTS:** Our model estimated TT and DT+ strategies could yield 0.67 and 0.48 of the sustained viral response, respectively. In the base case analysis, TT was most effective in comparison with those treated by DT+ and no treatment strategies and could increase by 0.92 and 2.83 the quality-adjusted life years and reduce the lifetime cost by 1.3 and 0.7 million yen, respectively. This dominance of TT over DT+ was robust to sensitivity analysis. **CONCLUSIONS:** TT would be more effective and cost-saving strategy compared with DT+ for untreated patients chronically infected with HCV of genotype 1 in Japan.

PGI18

COST-EFFECTIVENESS OF BOCEPREVIR IN COMBINATION WITH PEGYLATED INTERFERON ALFA AND RIBAVIRIN FOR THE TREATMENT OF GENOTYPE 1 CHRONIC HEPATITIS C: SUBMISSION TO THE NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE (NICE)

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OBJECTIVES: Despite available treatment options, chronic infection of individuals with the hepatitis C virus (HCV), together with associated chronic liver diseases, remains a significant public health burden in England and Wales. Fewer than half of patients with genotype 1 chronic hepatitis C (CHC) achieve sustained virologic response (SVR) following the current standard treatment with peginterferon alfa and ribavirin. The aim of this analysis was to evaluate the cost-effectiveness of boceprevir, a protease inhibitor, in combination with peginterferon alfa and ribavirin, compared to peginterferon alfa and ribavirin alone, among treatment naïve and previously treated patients with genotype 1 CHC in England and Wales. **METHODS:** Specific treatment strategies for boceprevir have been outlined in the UK licence for different patient groups. A Markov model was developed to evaluate these treatment strategies for boceprevir triple-therapy compared to peginterferon alfa and ribavirin alone, and to estimate the expected costs and health-related quality of life benefits associated with them. The incremental cost-effectiveness of including boceprevir in a new triple-therapy standard of care was assessed from the perspective of the National Health Service and Personal Social Services over the lifetime of the patient cohort. Clinical data inputs for each treatment strategy were estimated based on subgroup analyses of the phase III trials for boceprevir. **RESULTS:** The incremental cost-effectiveness ratio (ICER) for treatment-naïve patients was £11,601 when boceprevir triple-therapy was compared to current standard treatment with peginterferon alfa and ribavirin. For treatment-experienced patients, the ICER with boceprevir triple-therapy was £2,909. These results were robust to sensitivity analyses and below a threshold of £20,000. **CONCLUSIONS:** The inclusion of boceprevir as part of a new triple-therapy standard of care for patients with genotype 1 CHC is clinically efficacious and cost-effective, irrespective of whether patients have been previously treated. The use of boceprevir in this setting is recommended by NICE.

PGI19

COSTS AND EFFECTS OF DUAL THERAPY WITH PEGYLATED INTERFERON AND RIBAVIRIN IN PATIENTS WITH CHRONIC HEPATITIS C IN GERMANY

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OBJECTIVES: Dual therapy with ribavirin and peg-interferon over a duration of up to 72 weeks (W) has been the former standard of care in patients with chronic Hepatitis C (HCV) genotype 1 and is still used in some patients. The aim of this analysis is to evaluate the direct HCV-related costs and effects of dual therapy in therapy-naïve and pretreated patients in Germany. **METHODS:** In this retrospective chart review study, dual therapy in patients with chronic HCV genotype 1 in 2008/2009 was evaluated in Germany. Data from patients treated with a combination of ribavirin and peg-interferon were retrospectively documented during the treatment period and thereafter (on average 61 W of post-treatment follow-up). A total of 208 therapy-naïve and 182 pretreated patients from 31 study sites were included in the analysis. **RESULTS:** Mean time since first diagnosis of HCV was 6.0 years and 10.4 years in therapy-naïve and pretreated patients, respectively. 33.0% of pretreated patients were prior non responders, 37.9% were relapsers. The average treatment duration during study was 42 W (SD 22W) both in therapy-naïve and pretreated patients. Sustained virological response (SVR) was demonstrated in 58.1% of therapy naïve and 36.6% of pretreated patients with HCV-RNA measurements available (167 and 142 patients with measurement, respectively). Mean per patient costs related to HCV during therapy from the statutory health insurance perspective were 14,554€ (SD 9,139€) for therapy-naïve and 14,590€ (SD 10,443€) for pretreated patients. Main cost-driver of treatment was medication cost, accounting for 87% of total costs, followed by sick leaves and diagnostics. Hospitalizations and physician visits played a less important role in terms of costs. **CONCLUSIONS:** Especially in pretreated patients, HCV dual therapy is costly due to the low treatment success rate. This emphasizes the need for treatments with improved efficacy, minimizing costly non-response resulting in potential cost savings.

PGI20

COST-EFFECTIVENESS OF ADALIMUMAB FOR TREATMENT OF CROHN'S DISEASE IN GERMANY

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OBJECTIVES: To assess cost-effectiveness of adalimumab versus standard care (SC) for treating patients with severely active Crohn's disease (CD) in Germany from a societal perspective. Additionally, cost-per-remitter for adalimumab was estimated and compared with infliximab 5mg/kg maintenance therapy. **METHODS:** To compare adalimumab to SC, a 4-disease-state clinical model (ie, remission, moderate, severe, very severe) based on the Crohn's Disease Activity Index (CDAI) was constructed tracking patients over their lifetimes. The model estimated direct costs, indirect costs, and quality-adjusted life-years (QALYs) from the German societal perspective. Efficacy inputs for adalimumab were based on actual observations from CHARM (Crohn's Trial of the Fully Human Antibody Adalimumab for Remission Maintenance). Using data from CLASSIC I (Clinical Assessment of Adalimumab Safety and Efficacy Studied as Induction Therapy in Crohn's Disease), a regression model was used to predict efficacy of SC. Direct/indirect costs and utility inputs were derived from public sources and literature. To compare adalimumab to infliximab, cost-per-remitter was estimated by dividing costs by the percentage of patients in remission on a yearly basis. Remission rates of adalimumab and infliximab upon baseline matching adjustment for patients with moderate-to-severe CD came from CHARM and ACCENT I (A Crohn's Disease Clinical Trial Evaluating Infliximab in a New Long-Term Treatment Regimen), respectively. **RESULTS:** The incremental costs per QALY gained for adalimumab versus SC were €37,270 (2012 Euro) over a lifetime horizon in the base case. One-way sensitivity analyses varying key parameters produced incremental costs per QALY gained ranging from €23,011–€51,528 when compared with SC. An average of 47.2% adalimumab-treated and 37.1% infliximab-treated patients were in remission yearly. The corresponding cost-per-remitter was €54,823 for adalimumab and €88,506 for infliximab. **CONCLUSIONS:** Adalimumab appears to be cost-effective compared with SC for treating patients with severely active CD. The cost-per-remitter for maintenance therapy was less for adalimumab than for infliximab.

PGI21

COST EFFECTIVENESS OF THE COMBINATION OF BOCEPREVIR PLUS PEGINTERFERON ALPHA AND RIBAVIRIN VERSUS TELAPREVIR PLUS PEGINTERFERON ALFA AND RIBAVIRIN IN THE RETREATMENT OF PATIENTS WITH CHRONIC HEPATITIS C VIRUS GENOTYPE I INFECTION

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OBJECTIVES: In patients with chronic infection with hepatitis C virus (HCV) genotype 1 who did not achieve a sustained response to the standard therapy with peginterferon/ribavirin (PR) the combination of boceprevir (B) or telaprevir (T) plus peginterferon alpha/ribavirin have shown to produce a higher rate of sustained virologic response (SVR) than the retreatment with PR. The aim of this study is to assess the cost effectiveness of these two (BPR and TPR) antiviral regimens. **METHODS:** We developed a Markov model to describe the clinical history of previously treated HCV genotype 1 patients who did not achieve SVR in which one cohort (1) receives PR for 4 weeks followed by BPR for 32 weeks and, those patients with a detectable HCV RNA level at week 8 receive PR for an additional 12 weeks; cohort 2 patients receive 12 weeks TPR followed by 36 weeks PR. All patients are followed for their expected lifetime. The reference patient is 30-year-old with CHC without cirrhosis. The SVRs to BPR and TPR cohorts came from RESPOND 2 and REALIZE studies. Quality of life for each health state was based on literature. Costs for each health state were based on three Delphi panels, one with hepatologists, one with intensivists and another with oncologists. Costs in 2011 Brazilian Reais and benefits were discounted at 3%. **RESULTS:** The combination BPR increases life expectancy by 0.60 years and quality adjusted life years (QALY) by 0.89 years compared to TPR. BPR is cheaper than TPR (-23,428 Brazilian Reais). **CONCLUSIONS:** In Brazil, for the treatment of previously treated patients with HCV genotype 1 infection boceprevir plus peginterferon alpha/ribavirin is dominant compared with telaprevir plus peginterferon alpha/ribavirin.

PGI22

COST-EFFECTIVENESS ANALYSIS OF DEXLANSOPRAZOLE FOR THE TREATMENT OF EROSIVE ESOPHAGITIS COMPARED TO CONVENTIONAL PROTON PUMP INHIBITORS

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OBJECTIVES: The study compares the cost-effectiveness (CE) of dexlansoprazole with other proton pump inhibitors (PPI) currently included in the Mexico National Formulary (Positive List) for treatment of erosive esophagitis (EE). **METHODS:** A decision tree with the 8-week temporal horizon was designed for patients over 18 with EE confirmed by endoscopy. The perspective taken is that of second-level public health institutions. Treatment alternatives modelled are dexlansoprazole 60 mg/day, esomeprazole 40 mg/day; omeprazole 20 mg/day, pantoprazole 40mg/day, rabeprazole 20 mg/day. Possible outcomes considered were healing or not healing, the latter possibly leading to surgery. Costs included in the model were treatment regimens, consult, endoscopy, surgery (when necessary), and hospitalization days (when necessary) and were taken from official or published sources. Effectiveness was measured in terms of percentage of patients with healed oesophagus. A weighted average of effectiveness was calculated for use in the model. One-way sensitivity analyses of cost and effectiveness variables and a Monte Carlo (MC) simulation of a 1000 cohorts were also conducted to test the robustness of the results. **RESULTS:** Compared to all PPIs modelled/tested, dexlansoprazole was highly dominant, being more effective (0.9270) and less costly (USD$ 1.27 per day), even when compared to omeprazole's USD$ 0.015 per DDD. It was therefore not considered necessary to calculate the Incremental Cost-Effectiveness Ratio (ICER) since these would be negative. The sensitivity analyses and Monte Carlosimulations found omeprazole to be the second-best alternative, and actually dominant in 16.7% of the MC simulations. **CONCLUSIONS:** Dexlansoprazole was found to be dominant compared to all PPIs evaluated for EE, being both more effective and less costly for public institutions in Mexico.

PGI23

COST-EFFECTIVENESS OF EPISODIC OR MAINTENANCE INFLIXIMAB VERSUS STANDARD TREATMENT IN AN INCIDENCE COHORT OF CROHN'S DISEASE PATIENTS WITH 10-YEARS FOLLOW-UP