GASTROINTESTINAL DISORDERS - Patient-Reported Outcomes & Patient Preference Studies

PG127 PREDICTORS OF HEALTH-RELATED UTILITY WEIGHTS IN A CONSECUTIVE COHORT OF REAL-WORLD CROHN’S DISEASE PATIENTS IN ISRAEL

Greenberg D, Vardi H, Schwartz D, Friger M, Saron D, Sliomov-Nevo V, Odes S. Ben-Gurion University of the Negev, Beer-Sheva, Israel, 2Yad Mordechai Medical Center, Beer-Sheva, Israel

OBJECTIVES: The approval of direct-acting antivirals for Interferon-free treatment revolutionized the therapy of chronic Hepatitis C infection. As of August 2014, two treatment regimens for genotype 1 infection received approval in the European Union: Sofosbuvir and Ribavirin for 24 weeks and Sofosbuvir and Simeprevir for 12 weeks. We aim to analyze the cost-effectiveness of both regimens in Germany.

METHODS: We set up a Markov model with a lifetime horizon to simulate immediate treatment success and long-term disease progression for treat- ment-naive and treatment-experienced patients. The model analyzes both short-term and long-term costs and benefits from the perspective of the German Statutory Health Insurance. We apply the efficiency frontier method, which was suggested by German Institute for Quality and Reimbursement of Health Care for cost-effectiveness analysis in Germany.

RESULTS: The efficiency frontier is defined by dual therapy and first generation direct-acting antiviral Boceprevir, yielding a maximum of $1,447 69 per additional percentage point of sustained virologic response gained. Even without rebates, Sofosbuvir/Simeprevir was more effective and less expensive than Sofosbuvir/Ribavirin.

CONCLUSIONS: In addition to higher sustained virologic response rates, new direct-acting antivirals save long-term costs by preventing complications such as liver cirrhosis, hepatocellular carcinoma and ultimately liver transplants, thereby offsetting part of higher drug costs. Our findings are in line with the guidance published by German Society for Gastroenterology, Digestive and Metabolic Diseases, which recommends Sofosbuvir/Simeprevir for interferon ineligible or intolerant patients.

PG125 LONG-TERM COST PER SUSTAINED VIROLOGIC RESPONSE IN PATIENTS WITH GENOTYPE 1 CHRONIC HEPATITIS C VIRUS TREATED WITH VIEKIRA PAK +/- RIBAVIRIN AND STANDARD OF CARE IN THE US

ViroPhak N1, Johnson S1, Joshu A1, Marx S1, Sanchez Y1, Wang A2

1Medicus Economics, LLC, Milton, MA, USA, 2Payer Liver Institute, Los Angeles, IL, USA

OBJECTIVES: This study reports the long-term cost per sustained virologic response (SVR) of Viekira Pak (SOF+SMV) compared to self-reimbursement and interferon-free treatment of GT1 chronic hepatitis C virus (HCV) infection. METHODS: A Markov cost-effectiveness model was used to estimate the long-term cost of HCV. The analysis modeled independent cohorts of GT1 HCV patients over a lifetime horizon with annual cycles from a US payer perspective. Liver disease progression was assessed based on previous natural history model. Direct medical costs (in 2014 prices and discounted at 3% per year) were obtained from the published literature. Efficacy and safety data were obtained from published clinical trials. SVR rates were stratified by patient treatment history, cirrhosis status, and sub-genotype, where available. Long-term cost per SVR for a patient segment was calculated by dividing total cost of HCV over patient’s lifetime by the mean SVR rate in that patient segment.

RESULTS: The long-term cost per SVR with Viekira Pak ranged from $88,305 to $94,433 in GT1 non-cirrhotic patients (12-week regimen), $125,748 per patient segment.

CONCLUSIONS: The results of this study demonstrated that Viekira Pak is more effective and less expensive than Sofosbuvir/Ribavirin.

PG28 PSYCHOMETRIC VALIDATION OF THE DYSPHAGIA SYMPTOM QUESTIONNAIRE IN ESOINOPHILIC ESOPHAGITIS PATIENTS TREATED WITH ORAL BUDENOSIDE SUSPENSION

Huang Y1, Evans C5, Philips E5, Hill M3

1Clinical Outcomes Solutions, Tucson, AZ, USA, 2Endpoint Outcomes, Boston, MA, USA, 3Meritage Pharma Inc, San Diego, CA, USA

OBJECTIVES: Eosinophilic Esophagitis (EE) is an inflammatory disorder that can have an impact on quality of life in individuals. The psychometric properties of the Dyphagia Symptom Questionnaire (DSQ) were assessed in a Phase 2, random-ized, double-blind, placebo controlled study of oral budesonide suspension with an open-label extension program.

METHODS: The evaluation focused on three items of the DSQ. Psychometric data were analyzed against the FDA guidance and included item level analysis as well as score validation including floor/ceiling item discrimination, construct validity and known group's method. The test-retest reliability, responsiveness, and calculation of minimally important differences (MID).

RESULTS: Patients were 69% male, 62% age ≥18, 95% white. Test-retest reliability was 0.94 (calculated on worst and best possible scores for all items (range 6.5-8.6%). There was strong item discrimination with 98.1% of patients indicating dyphagia in the quartile of DSQ scores. Physician's global ratings of severity and EE symptom scores were consistent with monotonically increasing DSQ scores. Anchor-based MIDs were 6.5 “a little better” and 13.5 “better” respectively.

CONCLUSIONS: The DSQ is a reliable and valid measure able to clinically discriminate patients along the continuum of dysphagia severity.

PG29 SELF-REPORTED HEALTH STATUS OF PATIENTS WITH CHRONIC HEPATITIS B IN CHINA

Chen Q1, Zhang M1, Zhang S1, Shang M1, Han T1, Guo Y1, Wang X2, Liu J1, Bo Q1, Wang X3, Jia F1

1Sau Suee Hack School of Public Health, National University of Singapore, Singapore, Singapore, 2The Sixth People’s Hospital of Shenyang, Shenyang, China, 3Hepatology Hospital of Jilin Province, Jilin, China, 4Yuan Nan Provincial People’s Hospital, Zhengzhou, China, 5Tianjiang 3rd Central Hospital, Tianjing, China, 6The 3rd People’s Hospital of Tianyuan, Tianyuan, China, 7Bristol-Myers Squibb, Shanghai, China, 8GCP Clinica Plus Co., Ltd, Beijing, China

OBJECTIVES: To study the variations in self-reported health status of mainland Chinese patients with chronic hepatitis B (CHB) prior to initiating nucleotide analogues (NAs) treatment. This study is the first part of the EVOLVE study, an ongoing observational clinical study of NUs for treating CHB patients with or without compensated cirrhosis in China. All patients underwent a back ground assessment for liver function and clinical characteristics, such as demographics, life styles, health status (using the EQ-5D-3L questionnaire), and socio-economic status was obtained from medical records or personal interviews. Variations in self-reported health problems and global health were analyzed with logistic and linear regression analysis, respectively. The significance of the variance was determined by the selection method.

RESULTS: Two thousand nine hundred and fifty-eight of the 3,344 NUC naive CHB patients enrolled from 63 hospitals across China (mean age 36 years; male: 73.1%; HBeAg positive: 61.1%; compensated cirrhosis: 20.4%) were included in this analysis. Among those, less than 2% reported problems in mobility.