review and calculated placebo-adjusted risk ratios for achieving good pain relief (GPR), any adverse event (AE) and withdrawal owing to intolerable AE. Direct medical costs included drug acquisition and additional visits due to lack of efficacy (poor pain relief) or intolerable AE. Unit costs were taken from local sources. Adherence rates (based in number of daily doses needed) were used to estimate the expected drug costs. All costs are expressed in 2010 USD (1USD:12.50MXN Pesos). Utility values drawn from published literature were applied to health states. Proportion of patients with GPR and quality-adjusted life years (QALY) were assessed. **RESULTS:** Branded-GBP was dominated by all the other options. PGB was more costly and less effective than DUL. Compared with branded-GBP and PGB, DUL led to savings of $80,080 and $85,920 (per 1000 patients) USD. The incremental cost per QALY gained with DUL used instead of generic-GBP was $8,194. This amount is slightly lower than the estimated gross domestic product per capita in Mexico for 2010. During a second-order Monte Carlo simulation, DUL had the highest probability of being cost-effective (61%), followed by generic-GBP (25%) and PGB (14%). **CONCLUSIONS:** This study suggests that DUL provides overall savings and better health outcomes compared with branded-GBP and PGB. Administering DUL rather than generic-GBP is a highly cost-effective intervention to manage PDPN in Mexico.

PDB11

ECONOMIC EVALUATION OF TERIPATIDE IN THE MANAGEMENT OF WOMEN WITH POSTMENOPAUSAL OSTEOPOROSIS AND HIGH RISK OF FRAGILITY FRACTURES IN MEXICO

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OBJECTIVES: Fragility fractures (FF) are associated with increased mortality, deterioration in health-related quality of life and high costs. Teriparatide stimulates bone remodeling. The aim of this study was to assess the cost and health effects of teriparatide in women with postmenopausal osteoporosis (PMOP) and high risk of FF from the perspective of public healthcare system in Mexico. **METHODS:** Target population was women aged 70 years, with PMOP, T-score −4.0 and three clinical risk factors, with a recent vertebral fracture not candidates to receive bisphosphonates. Competing alternatives were: (1) daily subcutaneous injection of teriparatide 20mcg for 18 months and (2) no therapy. A Markov microsimulation model was developed with a 30 years time horizon divided into 6-month cycles and is composed by 5 health states: hip, vertebral, forearm and humerus fracture and death. The incidence of FF was obtained from the FRAX® algorithms for Mexican women. Efficacy data was gathered from placebo-controlled clinical trials of teriparatide. We analyzed acquisition costs of teriparatide and medical care costs due to FF. Frequency and location of fractures avoided and quality adjusted life years (QALYs) were estimated. All costs are expressed in 2010 USD (1USD:12.50MXN Pesos) **RESULTS:** Teriparatide avoided 324 FF per a thousand patients (hip: 43; vertebral: 164; humerus: 35; forearm: 82). The number needed to treat (NNT) to prevent one FF was 3.09. Teriparatide was slightly more expensive ($20,052 vs. $22,209 USD) but more effective, with net gains of 87 QALYs per a thousand patients. The cost per additional QALY gained with teriparatide was $24,925 (below the upper limit of 3 times the gross domestic product per capita in Mexico). Teriparatide was found to be cost-effective therapy in 80% of the simulations performed in the probabilistic sensitivity analysis. **CONCLUSIONS:** Teriparatide is a cost-effective intervention in women with PMOP and high risk of FF.

Gastrointestinal Disorders – Cost Studies

PGI1

RESOURCE UTILIZATION AND COST OF MANAGEMENT OF COMPLEX PERIANAL FISTULA IN CROHN'S DISEASE IN SPAIN

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OBJECTIVES: To assess health care resources use and costs associated with management of complex perianal fistula in Crohn's disease (CPCD) in Spain. **METHODS:** Multicenter, retrospective and observational study conducted by 13 gastroenterologists from 11 hospitals in the Autonomous Community of Madrid, Spain. Direct healthcare resources consumption (pharmacological treatments, laboratory/diagnostic tests, visits to specialists, emergency department visits and hospitalizations/surgical procedures) were recorded for 97 adult patients with CPCD active at some time between January 1, 2005 and study data collection (4.2±1.5 years). **RESULTS:** 527 treatments were recorded: 73.1% pharmacological (32.3% antibiotics, 20.5% immunomodulators, 20.3% biological therapies) and 26.9% surgical. Mean per patient-year global cost was €7821.4. Percentage cost per treatment type and [mean per patient-year cost] breakdown was 78.7% [€5773.5] pharmacological cost, 11.12% [€1027.4] hospitalizations/surgical procedures, 6.5% [€640] specialists visits, 3.4 [€350] laboratory/diagnostic tests, and 0.2%, [€30.4] emergency department visits. Mean per patient-year cost per pharmacological treatment type was: €12.5 antibiotics, €1050.6 immunomodulators, and €4710.4 biological therapies. **CONCLUSIONS:** Pharmacological treatments are the main cost driver of CPCD management in Spain, being biological therapies the main component. Study funded by Cellerix, S.A. (Spain).

PGI2

COST-EFFECTIVENESS ANALYSIS OF THE USE OF ADALIMUMAB FOR THE TREATMENT OF CROHN'S DISEASE (CD) IN MEXICO

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OBJECTIVES: To estimate the cost-effectiveness of adalimumab CD treatment versus standard care and infliximab for patients with severe active CD. **METHODS:** The model combines clinical, utility, and cost data. Four disease states (remission; moderate; severe; very severe) based on the Crohn's Disease Activity Index range are used as measures of patient disease status. For the adalimumab arm, a cohort for the proposed adalimumab regimen using actual observations from the EOW arm in a randomized controlled clinical trial (CHARM) is used. For the standard care arm, the model simulates patient disease states based on randomized controlled trial data (CLASSIC I and CHARM) and calculates the probability of individuals being in each disease state. The base-case model analyzes lifetime patient clinical status. Hospitalization costs are estimated from the hospitalization unit cost and a regression model based on CHARM trial data. Disease state specific non-hospitalization, non-anti TNF costs are summarized over time for each patient to include other direct medical costs. For the adalimumab vs. infliximab model, the adalimumab regimen is compared to infliximab 5mg/kg maintenance therapy. The percentage of patients in remission over time is used as the measure of clinical efficacy. Indirect costs are estimated based on hospitalization stays and post-hospitalization recovery times. Costs are reported in Mexican Peso. **RESULTS:** Compared to standard care, adalimumab is dominant for patients with severe CD (cost difference -$16,825, gain in QALYs 0.1045). Adalimumab is dominant, with lower costs and higher efficacy compared with infliximab when treating patients with severe disease based on a societal perspective. Cost difference (adalimumab–infliximab) were -$19,784, and including infliximab "overdosing", the costs accounted for -$42,356. Sensitivity analyses confirm the results obtained in the cost-effectiveness analysis. **CONCLUSIONS:** Adalimumab maintenance therapy is dominant over standard care. The adalimumab regimen is cost-saving over infliximab 5mg/kg maintenance therapy.

PGI3

ADAPTACIÓN DE UN ANÁLISIS DE COSTO-EFECTIVIDAD DEL ENTECAVIR VS INTERFERÓN PEGILADO ALFA A VENEZUELA

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OBJECTIVOS: Mediante la adaptación a la realidad de Venezuela de un modelo realizado por Spackman y Veenstra y previo análisis de transferibilidad, se realizó un análisis de costo-efectividad del uso de 0.5 mg/día de entecavir versus interferón pegilado en la supresión de la replicación viral y la calidad de vida relacionada con la salud en términos de QALYs en pacientes con Hepatitis B Crónica. **METODOLOGÍAS:** Para la construcción de la cohorte hipotética, Spackman y Veenstra asumieron los datos de las eficacias así como las características de los pacientes reportadas en estudios clínicos recientes. Para el análisis de transferibilidad se siguieron los criterios de transferibilidad de la Task Force on Good Research Practices on Transferability of Economic Data de la ISPOR. En la adaptación del modelo se asumieron las probabilidades de cambio entre estados reportadas en el estudio original. Los costos médicos directos y de los medicamentos fueron tomados directamente del entorno local. Adicionalmente se tomaron las tablas de expectativa de vida del observatorio de salud global de la Organización Mundial de la Salud para Venezuela actualizadas al año 2008. Los resultados incluyeron los costos de cada alternativa de tratamiento tanto con entecavir como con interferón pegilado, así como los años de vida ajustados a calidad ganados. **RESULTADOS:** El entecavir 0.5 mg/día produjo 18,25 QALYs y una relación de costo efectividad media de 5.257 BsF por QALY, en comparación con el interferón pegilado (marketshare) que produjo 18,12 QALYs y una relación de costo efectividad media de 7.055 BsF por QALY. **CONCLUSIONES:** El entecavir a dosis de 0.5 mg/día mostró índices más bajos de costo-efectividad media con respecto al interferón pegilado en la supresión viral en pacientes con infección por el virus de la hepatitis B. En Venezuela, al igual que muchos países latinoamericanos, no están establecidos umbrales de costo efectividad.

Gastrointestinal Disorders – Patient-Reported Outcomes & Preference-Based Studies

PGI4

HEALTH-RELATED QUALITY OF LIFE IMPROVEMENTS IN PATIENTS WITH ACTIVE CROHN'S DISEASE FOLLOWING TREATMENT WITH CERTOLIZUMAB PEGOL IN THE MUSIC STUDY (NCT00297648)

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OBJECTIVES: MUSIC, an open-label, 1-year study of certolizumab pegol (CZP), evaluated the efficacy of CZP in improving pathological changes in the intestinal mucosa of patients with active moderate-to-severe Crohn's disease (CD). The purpose of this posthoc study was to examine the relationship between CZP-mediated endoscopic improvement and changes in HRQoL in patients with CD. **METHODS:** Patients with active CD (CD Activity Index score >225 to <450) were treated with open-label CZP, 400 mg subcutaneously every 2 weeks for 3 doses (induction) then 400 mg every 4 weeks for up to 54 weeks (maintenance). Patients completed the Inflammatory Bowel Disease Questionnaire (IBDQ) at baseline, Week 10, and Week 54 to assess HRQoL. An exploratory analysis of the correlation between IBDQ remission (total score ≥170 points) and endoscopic remission (measured by a CD Endoscopic Index of Severity score of <6 points) was performed. **RESULTS:** Of 89 patients entering the study, 78 patients at Week 10 and 50 patients at Week 54 completed the IBDQ. At baseline, mean IBDQ total score was 120.2. At Week 10, mean change in IBDQ total score was 43.8 and the IBDQ remission rate was 43.8%. At Week 54, mean change in IBDQ total score was 44.1 and the IBDQ remission rate