SAXAGLIPTIN/METFORMIN EXTENDED-RELEASE XR FOR THE TYPE 2 DIABETES (T2DM) TREATMENT IN VENEZUELA: A BUDGET IMPACT ANALYSIS

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OBJECTIVES: To estimate the budget impact of the use of saxagliptin/metformin XR fixed-dose combination compared to the current treatment of people with T2DM, in Venezuela.

METHODS: We used an MS Excel-based budget impact model assuming coverage of one million people in the health care system of Venezuela with a 3-year time horizon. DM prevalence was obtained from published literature. Pharmaceutical expenses of oral antidiabetic agents (OADs) were analyzed excluding only the cost of OADs used on-label only in people with diabetes mellitus T2DM, estimated in Venezuelan Bolivars (VEF$) 2013 (exchange rate: 1 US-dollar = 0.63 VEF$). The market share of the different drugs was based upon QUALIDIA Database, market studies and data provided by Bristol-Myers Squibb. A progressive increase of market share was assumed for saxagliptin/metformin XR among all the OADs: 1.14% 2.65% and 3.0% for the 1st, 2nd and 3rd year, respectively. The budget impact is reported in terms of annual budget impact, per member per-month (PMPM) and per patient per month (PPPM). A Monte Carlo simulation (10,000 iterations) was done as part of the sensitivity analysis. RESULTS: the net budget impact estimated for the introduction of saxagliptin/metformin XR combined was VEF$503,807 for the first year, VEF$1,833,333 for the second year and VEF$4,353,574 for the third year; the budget impact per PMPM was VEF$2,046.703, PMPM was VEF$0.08, VEF$10 and VEF$50.11 for the first, second and third year respectively. PFP was VEF$1.67, VEF$4.0 and VEF$94.65 each year, respectively. The cumulative impact in the total oral antidiabetic agents represented an increase of 2.36%. Monte Carlo simulation showed that cumulative budget impact varied from 1.32 to 8.74.

CONCLUSIONS: incorporation of saxagliptin/metformin XR combination into the health care system of Venezuela, as a treatment option for people with T2DM, would have a minimal budgetary impact.

PDB31

BUDGET IMPACT ANALYSIS OF UTILIZING CANAGLIFLOZIN (CANA) FOR THE TREATMENT OF TYPE 2 DIABETES MELLITUS (T2DM) IN AN UNITED STATES HEALTH PLAN

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OBJECTIVES: CANA, a SGLT2 inhibitor, is a recently approved oral antihyperglycemic agent (AHA) for the treatment of adults with T2DM. As the prevalence and cost of T2DM continue to rise, payers seek treatments that can control DM better than existing cost. Budget impact analysis may help payers in the formulary decision-making process. To estimate the three-year budget impact of adding CANA to a hypothetical health plan formulary in place of other branded AHAs.

METHODS: The model was developed from the perspective of a US health plan with 1 million members. The prevalence of people diagnosed and treated with T2DM is based on US epidemiology statistics. Drug costs were estimated using August 2013 wholesale acquisition cost data. The market share of the branded AHAs and estimated 2013, 2014, and 2015 market shares of CANA for Years 1-3 (Year 1: 0.3%, Year 2: 1.8%, Year 3: 2.1%) were used. The base case analysis examined an increasing market share of CANA in the proportional decrease of the market share of the other branded drugs. Results are presented as the difference in pharmacy budget, overall cost and per member per-month (PMPM).

RESULTS: Prior to the introduction of CANA, the expected market share of all insulin AHAs in the theoretical plan was almost $48 MM/year. With CANA added to the formulary, the budget is forecasted to decrease by $71,902 at Year 1, $431,409 at Year 2, and $503,311 at Year 3. The PMPM expenditures decrease from $3.95 when CANA was unavailable to $3.89 at Year 3 of CANA uptake.

CONCLUSIONS: The PMPM expenditures decrease from $4.00 when CANA was unavailable to $3.95 with CANA added to the formulary. The budget impact per PMPM was $48 MM/year. With CANA added to the formulary, the budget is $48 MM/year lower than the current formulary. Results are presented as the difference in pharmacy budget, overall cost, and per member per-month (PMPM). The app version of the albiglutide BIM is a useful, comprehensive tool to the excel-based BIM. The app maintains its functionality to ISPOR and AMCP recommendations.

PDB34

SOMATOTROPIN DOSE ANALYSIS FOR TREATMENT OF HYPOTHYROIDISM IN PUBLIC BRAZILIAN HEALTH SYSTEM (SUS)

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OBJECTIVES: This analysis aims to determine, in International Units (IU), the somatotropin volume waste of presentations with 4 IU and 12 IU compared to 16 IU, 36 IU, and 120 IU, when used for treatment of Turner Syndrome and for children with growth disorders due to deficiencies of growth hormone. METHODS: The amount waste per month was analyzed, in IU, from the dosage indicated in the Project of Clinical Protocol Guideline (PCG) for Hypothyroidism in the Brazilian Health Ministry and a comparative analysis was done between presentations of 4 IU, 12 IU (approved by Ministry) and 16 IU, 36 IU and 120 IU. RESULTS: The average loss per treatment/month (Turner Syndrome and children with growth disorders) are 18.36 IU, 12.0 IU, 0.38 IU and 2.01 IU presentations with 4IU, 12IU, 120IU and 36IU respectively. CONCLUSIONS: If the SUS uses the 36 IU, that could be reduce the losses in an average of 97.5% and 87% respectably in month/patients, minimize the cost, optimize doses number and achieve more patient adherence, which is, at the same time, it is important to that because they take up less space for storage and for transportation.

PDB35

IMPACT OF DIABETES IN FAMILY HEALTH SPENDING IN BRAZILIAN POPULATION

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OBJECTIVES: To estimate the impact of the cost of diabetes mellitus (DM) in Brazil based on the ratio (“K”) of health care expenses of households with at least one person using medication for diabetes to those without diabetes medication use. METHODS: We utilized data from the Family Budget Study (POF – Pesquisa de Orçamentos Familiares), a representative sample of 59.548 households investigated in 2008-2009 by the Brazilian Institute of Geography and Statistics (IBGE). The data were analyzed using Microsoft Excel and R (version 3.0.2). Households were categorized based on the purchase (or no cost receipt) of diabetes medications by family members. Expenses included those for hospitalization, medical consultations, health insurance, drugs and medical supplies. Analyses were conducted for Brazil, for regions and for those with and without health insurance coverage. Results are weighted so as to represent the Brazilian population. RESULTS: Households with diabetes (6.2% of the total) more frequently (26% vs. 8.5%) had members > 60 years of age. Expenses increased with increasing household income. Overall, for Brazil, the ratio “K” adjusted through regression analyses for the age and sex distribution of the Brazilian population was 1.81 (95%CI 1.69-1.95), indicating that expenses were 81% greater in households where diabetes was present than in those without. The expenses with the purchase of medicines to treat DM increase with increasing income. CONCLUSIONS: Health care expenses are notably greater in Brazilian households having family members with diabetes.

PDB36

DIET MODIFICATION IN PATIENTS WITH DIABETES AND ITS ASOCIATION WITH HEALTH CARE UTILIZATION AND EXPENDITURE

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OBJECTIVES: To evaluate the correlates of diet modification in Brazilian adults with diabetes and its association with health care utilization and expenditure. METHODS: This study used data from the Brazilian Longitudinal Study of Adult Health (ELSA-Brasil), a national representative probability sample of 17,946 adults aged 35 to 64 years. Diet modification was defined as a change in diet over the past year. Results were adjusted for sociodemographic variables, income, education, and health status using logistic regression models. The average annual health care utilization and expenditure were calculated using individual data on health care utilization and expenditures for each year. RESULTS: The prevalence of diet modification was 32.4% in the past year, reaching 32.5% in the past 12 months. Diet modification was associated with lower health care utilization and expenditure, as indicated by a lower number of doctor visits, hospital admissions, and outpatient visits. CONCLUSIONS: Diet modification in patients with diabetes is associated with lower health care utilization and expenditure.
OBJECTIVES: Patients who do not incorporate diet modifications in their therapy regimen may result in an undesired escalation in blood glucose levels or even hyperglycemia and chronic complications. The objective of this study is to investigate the prevalence of diabetic patients who incorporate diet modification in their therapy, and its association with health care utilization and expenditures for the US managed care population. Our study was a retrospective study with a quasi-experimental design approach. Subjects included were patients who were diagnosed with diabetes and reported the treatment of diabetes with diet modification twice daily (exenatide), or liraglutide (LIRA). METHODS: This administrative claims-based retrospective cohort study included patients if they had T2DM, were GLP-1RA-naïve, initiated a GLP-1RA between 2/1/2012-6/30/2012 (initiation date), and had continuous enrollment for 12 months before and after the index date (baseline) to 6 months after index (follow-up). Outcomes included health care costs (Total=Diabetes-related/GLP-1Rs) and hospitalizations (Total=Diabetes-related). Diabetes-related outcomes included those associated with antibiotics, insulin or insulin without bolus insulin. The study measured the patients’ demographic and clinical characteristics, as well as their health care utilization and medical costs in their therapy. For total health care expenditures, those who did not include diet modification had more expenditure ($2545.66, SE = 254.45), revealed a significant difference between the groups; p = .0001. Moreover, total inpatient expenditure for those who did not include diet modification (M = $8,033, SE = 497.3) and patients who included diet modification (M = $5,972, SE = 252.1) were different. CONCLUSIONS: The study findings indicated that diabetic patients who did not modify their diet had significant lower utilization and expenditures. Regulating diet is extremely important for people who have diabetes. It can be very effective in preventing or postponing the progression of diabetes, and subsequently managing the cost and utilization associated with it.

PDB37
TREATMENT OF BRAZILIAN CHILDREN WITH GROWTH HORMONE DEFICIENCY AND TURNER SYNDROME: IMPLICATIONS OF A DATA-DRIVEN APPROACH TO GUIDE DECISIONS
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OBJECTIVES: To compare the doubly robust estimation and propensity score methods in a diabetes-related comparative health economics study. METHODS: A model was adapted to derive medical encounter costs. Multivariate regression analyses were used to account for the variables associated with health care use and expenditures. All analyses were accomplished by taking into consideration MEPS patient sample adjustments using SAS 9.3. RESULTS: Mean estimated 2.18 million dollars in the pre-baseline period. The propensity score method indicated the two cohorts (mean age 17.2 years, percentage male 50%). Existing data-driven methods had aged 2.18 million dollars in the presence or absence of data-driven treatment decisions. The proportion of patients for whom height outcome could be improved or GH use could be reduced was estimated using a cohort model from the Pfizer International Growth Database (KIGS). This model was adapted to Brazilian patients, for both private and public perspectives, resulting in 4 scenarios: (i) Genotropin 16IU private, (ii) Genotropin 36IU private, (iii) Genotropin 16IU public, and (iv) Genotropin 36IU public. Eligible patients were the ones that calculated the treatment and impact on height outcome when a data-driven approach is used, compared to conventional treatment approach based on experience, in pre-pubertal patients with growth hormone deficiency (GHD) and Turner syndrome (TS). RESULTS: A model was adapted to derive medical encounter costs. Multivariate regression analyses were used to account for the variables associated with health care use and expenditures. All analyses were accomplished by taking into consideration MEPS patient sample adjustments using SAS 9.3. RESULTS: The propensity score method was less robust against unobserved confounders than the doubly robust estimation (cost ratios vs. exenatide QW ranging from 0.762 [p < 0.001] for GLP-1RA costs to 0.908 [p < 0.001] for Total costs among initial adherers). LIRA 1.8mg was generally associated with the highest adjusted health care costs (cost ratios vs. exenatide QW ranging from 1.039 [p < 0.080] for Total costs to 1.157 [p < 0.001] for GLP-1RA costs among initial adherers). LIRA 1.2mg was generally associated with the highest adjusted costs savings vs. exenatide QW ranging from 3.192 [p < 0.001] for diabetes-related hospitalizations to 5.128 [p < 0.036] for total hospitalizations among initial adherers). CONCLUSIONS: Among patients newly initiating exenatide QW, exenatide, or LIRA, differences existed in health care costs and hospitalization in 6 months of treatment. LIRA 1.8mg and 1.2mg were generally associated with the highest adjusted health care costs and odds of hospitalization, respectively.

PDB40
COMPARATIVE COST ANALYSIS FOR TREATING GROWTH HORMONE DEFICIENCY IN BRAZIL: PEN VERSUS SYRINGES
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OBJECTIVES: To compare costs of two delivery systems (pen vs. syringes) of recombinant human growth hormone (GH) in Brazilian GH deficient patients. METHODS: A budget impact model was developed to calculate total health care costs based on product waste (difference between prescribed dose and actual delivered dose), based on dosing increments for pens [Pfizer Gocquiup 16IU and 36IU – P16 and P36, respectively] and a fixed-percent waste described in the literature for vials [Lura 1.2mg]. Sensitivity analyses were performed to examine the impact of varying various parameters. RESULTS: The analysis estimated that the data-driven treatment approach could reduce total cost of GH therapy by 7.1% over 4 years for the treatment of Brazilian patients with GHD and by 6.7% for patients with TS, representing a reduction of 7.0% for all subjects. Total costs for all scenarios, when the conventional treatment approach was used (P36) were: $1,963.66 (P16) and $214.00 (TS), $1,874.66,165.95.35 (P36), $2,789.53,217.78 and $4,922.58,626,760, 21.2, with the data-driven approach, total costs were: ($2,274,327,729,748.47, $1,913,218,511,951.60, $2,599,094,188.81 and $0.317, for P16, P36, V4 and V12, respectively. Despite the reduction in treatment costs, the average height remained unaffected. CONCLUSIONS: In Brazil, the data-driven approach could be a useful tool to guide treatment decisions for children with GHD and TS. Total costs of GH treatment could be reduced, without having an impact on growth outcome.

PDB38
COMPARISON OF THE DOUBLY ROBUST ESTIMATION METHOD TO THE PROPENSITY SCORE METHOD IN A DIABETES-RELATED COMPARATIVE HEALTH ECONOMICS STUDY
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OBJECTIVES: To compare the doubly robust estimation and propensity score methods as a diabetes-related comparative health economics study. METHODS: We used large US claims databases that covered 315 million patients between 2000 and 2011. Patients with type 2 diabetes with continuous health insurance were selected into the intensification cohort or non-intensification cohort depending on whether they intensified basal insulin with insulin aspart or remained on treatment with basal insulin without bolus insulin. The study measured the patients’ demographic and clinical characteristics, as well as their health care utilization and medical costs in a 6-month pre-baseline period and a 12-month post-baseline period. Doubly robust estimation and propensity score methods were used to examine the impact of intensification on direct medical costs per patient per month (PPFM). RESULTS: The study included 26,016 qualified patients with 2,860 in the intensification cohort and 23,156 in the non-intensification cohort. Baseline characteristics were similar across the two cohorts (mean age=58 years, percentage male=52%). Both cohorts also had similar prevalence rates of diabetes-related conditions, and similar utilization and medical costs during the baseline period. The propensity score method indicated that the intensification cohort spent $297.44 PPFM less in the post-baseline period than the non-intensification cohort (p<0.05), while the doubly robust estimation method estimated a $399.0 PPFM cost reduction due to treatment intensification (p<0.01). However, the doubly robust estimation method was able to control all confounding factors also controlled by the propensity score method, as well as additional confounding factors not controlled by the propensity score method. CONCLUSIONS: Although both the propensity score and doubly robust estimation methods revealed cost savings due to treatment intensification with insulin aspart ($297.44 v. $399.0 PPFM), the propensity score method was less robust against unobserved confounding factors than the doubly robust estimation method.