ESTIMATION OF STUDY POPULATION SIZE FOR EFFECTIVENESS OUTCOMES AT 6 AND 12 MONTHS VIA ELECTRONIC MEDICAL RECORDS

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The lag between product launch and prescribing impacts research timing. This will describe methods applied to a population treated with a new antidiabetic agent, exenatide, to project patient counts for 6 months and 12 months real-world outcomes analyses. Patients prescribed exenatide via the General Electric Electronic Medical Record (EMR) database by March 31, 2007 were identified. The proportions of patients remaining active 6 months and 12 months on March 31, 2007 and with baseline and follow-up hemoglobin A1C values were identified. Starts for 2Q07 were estimated based on 4Q06 to 1Q07 growth, and the number of patients who would have started exenatide at least 6 months or 12 months before December 31, 2007 was projected. Rates and portions with A1C values were applied to these counts to project how many would be active at least 6 months and 12 months on December 31, 2007 and have outcomes data. Exenatide was prescribed for 8372 patients through March 31, 2007. A total of 5392 and 2240 started exenatide at least 6 months or 12 months prior to March 31, 2007. A total of 2853 (52.9%) had 6 months and 1152 (51.4%) had 12 months activity. Of these 1721 (60.3%) and 789 (68.5%) had baseline and follow-up A1C readings. The rate for 1Q07 was 20%; thus the estimated number prescribed exenatide by the end of 2Q07 was 10,043. Thus, 10,043 and 6946 would be prescribed exenatide at least 6 months and 12 months before December 31, 2007. Of these, 3207 and 2447 would be active and have baseline and follow-up A1C values. Estimates based on prescribing growth and patient retention was used to estimate patient counts for outcomes analysis. This facilitates research and planning for research on a new product. A validation of estimates will be conducted and reported when available.

WITHDRAWN

COMPARISON OF CLINICAL EFFECTIVENESS AND SAFETY OF GLULISINE VersUS INSULIN LISPRO, ASPART AND REGULAR HUMAN INSULIN IN PATIENTS WITH TYPE 1 AND 2 DIABETES

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OBJECTIVE: The aim of this analysis was to compare clinical effectiveness of insulin glulisine versus insulin lispro, aspart and regular human insulin in patients with type 1 and 2 diabetes.

METHODS: The clinical effectiveness was analyzed according to guidelines of Cochrane Collaboration and HTA Agency in Poland (AOTM). The comparison of insulin glulisine with comparators was performed as direct comparisons. RESULTS: Patients with type 1 diabetes: There was no statistically significant difference between insulin glulisine and insulin lispro, aspart and regular human insulin in patients with type 1 and 2 diabetes.

DEFINING HYPOGLYCEMIA AND ASSESSING ITS AFFECT ON OUTCOMES IN THE HOSPITAL SETTING

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Quantify the impact of hypoglycemia on outcomes of hospitalized diabetic patients and determine how variations in the definition of hypoglycemia affect outcomes. This study used an EMR database of inpatient and ED encounters for adults with diabetes treated at 70 hospitals during 2000–2006. Patients presenting to