Results: The follow up monitoring of members receiving these mental health drugs demonstrated a significant savings in pharmaceutical expenditures with no adverse effect of total health care expenditures or utilization. The measures employed (i.e. prior authorization, stepped therapy, and co-pay differentials) did not appear to adversely affect persistence with these medications. Additionally, disenrollment from Medicaid due to incarceration did not increase among this group of members during the observation period.

Lessons Learned: The inclusion of mental health drugs in a pharmacy benefit design is a controversial effort. Allowing continuation of established therapy and requiring members new to therapy with these mental health agents to go through a prudent, clinically appropriate process to utilize the most cost-effective medication available has the potential to decrease the cost of pharmaceuticals without adversely affecting the utilization of other more costly health care resources. When embarking on the inclusion of mental health medications in a pharmacy design benefit that includes prior authorization and step therapy, it is imperative that stakeholders have complete understanding of the reason for inclusion, the process to assure access to necessary medications, as well as feedback regarding the outcomes measured.

CASE 3
APPLICATION OF COST-EFFECTIVENESS ANALYSIS TO EVALUATE THE PROPOSED FORMULARY STATUS OF A NOVEL ANTIDIABETIC DRUG IN A U.S. COMMERCIAL HEALTH PLAN
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Organization: Premera Blue Cross Pharmacy and Therapeutics Committee (P&T). Premera is a 1.6 million member regional commercial health plan in the Pacific Northwest of the U.S.
Problem or Issue Addressed: Need to determine formulary status of Exenatide (Byetta), a recently marketed novel biologic agent for the treatment of Type 2 Diabetes.
Goals: To test the usefulness of manufacturer-provided disease-based cost-effectiveness models in helping formulary decision makers to determine the value and appropriate place in therapy for a new drug used to treat a chronic disease, when long-term outcomes data for the new product are unavailable due to the time required for long term sequelae of diabetes to be observed in clinical trials.
Outcomes items used in the decision: Reduction in hemoglobin A1c levels (A1c) and body mass index (BMI) observed in patients receiving exenatide.
Implementation Strategy: Using the AMCP Format for Formulary Submission (v2.1), Premera requested detailed information from Amylin regarding the clinical and economic value of exenatide in a commercial health insurance population. Upon learning that Premera was requesting disease-based cost-effectiveness modeling, Amylin purchased Web-based access to the CORE Diabetes Model (CDM) for Premera staff. Amylin personnel arranged training in the use of the model by CORE but no one from Amylin participated in planning the modeling exercise, choosing the input data and assumptions, or specifying the analytic scenarios. An informal Premera work group evaluated various model scenarios and included a summary of the results in the formulary recommendations to the P&T Committee.
Results: The model predicted reduced long-term treatment costs in obese patients, driven by 11% decrease in cardiovascular disease burden over a 30-year period. The incremental cost-effectiveness ratio (ICER) for adding exenatide over 3 years was $35,000/QALY. Using a 30-year horizon, ICER values were $13,000/QALY versus insulin, $32,000 versus generic glyburide and $16,000 versus no additional treatment. Exenatide dominated pioglitazone. By comparison, the 30-year ICER for exenatide versus insulin in the non-obese cohort was $33,000. This is a large longitudinal extrapolation based on relatively short term trials, but it did help to confirm the hypothesis that the drug would benefit a subgroup of obese patients. The P&T committee found this information useful and accepted staff recommendation to add exenatide to formulary, with prior authorization restrictions; however, due to limitations in the logistics of implementation, the restrictions did not limit use to obese patients.
Lessons Learned: Predicting long-term clinical outcomes of a new drug from the results of short-term trials is challenging. Good disease-based pharmaco-economic models help payers project costs, identify populations most likely to benefit from therapy, and perhaps craft restrictions that improve the potential for use of the drug in these populations, reducing the numbers needed to treat and improving incremental cost-effectiveness. In this context, a Format-compliant economic model can facilitate communication between manufacturer and health plan about the drug’s value.

PODIUM SESSION II: CASE STUDIES II

CASE 4
IMPLEMENTATION AND EVALUATION OF AN EVIDENCE-BASED CONTINUUM FOR HIP AND KNEE REPLACEMENTS IN ALBERTA
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Organization: Alberta Province [A new evidence-based continuum (referral to recovery) for hip and knee replacements was piloted in Alberta within the Calgary Health Region, the David Thompson Health Region and Capital Health Region.]
Problem or Issue Addressed: Redesigning an evidence based continuum for hip and knee replacements.
Bone and joint related conditions place a heavy burden on health care systems and can significantly impact patient quality of life. As the population ages and new technologies are emerging, there is profound concern about the sustainability of care for patients with bone and joint related conditions. The demand for hip and knee replacements is increasing due to changes in patient demographics (e.g., obesity) and an aging population. This increasing demand coupled with the current burden on health care resources and increasingly long wait times emphasized the urgency for health reform.
Goals: The three participating regional health authorities (Capital Health, Calgary Health Region, David Thompson Health Region) in conjunction with the Alberta Bone and Joint Health Institute and other partners designed and tested a new evidence based continuum of care for hip and knee replacements. The goals of this new continuum included significant improvement in the areas of access, quality and cost. This newly designed continuum coordinated the patient’s journey from referral to recovery. Standardized clinical paths, patient education and accountability, clinic care teams, and dedicated operating rooms and inpatient units were examples of how the continuum was redesigned. To evaluate the new continuum, a randomized controlled evaluation was applied to ensure robust results that