PODIUM SESSION I

HEALTH CARE DECISION-MAKER’S CASE STUDIES I

CASE 1

AN INTEGRATED PILOT PROJECT UTILIZING AN INTERNAL HTA PROCESS TO SET MEDICAL AND PAYMENT POLICY IN A U.S. COMMERCIAL HEALTH PLAN

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Organization: Premera Blue Cross is a 1.6 million member regional commercial health plan in the Pacific Northwest.

Problem or Issue Addressed: Need to perform more rigorous assessments of new medical technologies that present budgetary and utilization management challenges to our health plan.

Goals: (1) Develop and demonstrate a health technology assessment process for non-pharmacologic new medical technologies, utilizing plan medical and pharmacy staff, students and contractors as reviewers, including economic evaluations where data are available. (2) Apply these assessments to inform development of specific medical necessity policies and payment policies and implement the policy changes at Premera.

Outcomes items used in the decision: Clinical efficacy/effectiveness, safety, clinical utility and cost-effectiveness/cost-utility (when sufficient data were available).

Implementation Strategy: A cross-functional strategic planning group of Premera staff, with advice from University of Washington faculty, designed a comprehensive process to assess the value of new medical technologies (medical devices, diagnostics and novel procedures using existing devices) and apply the results to policy development. To strengthen our business case, we conducted a pilot implementation beginning in September 2006. The process involves pipeline surveillance, technology assessment, review by an independent panel of clinical experts, policy development and approval by an internal committee, and policy implementation. Since Premera has a high quality Pharmacy and Therapeutics Committee that meets the above description, we utilized this group as an external review committee, adding one such technology review to each meeting agenda.

Results: Between September 2006 and January 2008, 8 new medical technologies were evaluated using this process and one review was underway at the end of this period. Subjects of the completed reviews consisted of 2 diagnostic scanning modalities, 2 genetic diagnostic tests, 1 other diagnostic modality, 1 robot-assisted surgical procedure and 2 image-guided radiotherapy procedures. Strength of evidence was generally unimpressive with only 1 case having good evidence, 2 fair and 5 poor. Medical policies were impacted by 6 reviews: medically necessary without prior authorization (1), medically necessary with prior authori-

zation (1), investigational with certain exceptions (2) and investigational without exceptions (2). Payment policies were established by 2 reviews, in each case determining that the new procedure would be reimbursed at the same rate as its comparator, since the published studies had failed to demonstrate additional incremental value.

Lessons Learned: Regional private payers can establish a rigorous health technology assessment process incorporating cost-effectiveness analysis, with modest assistance from health outcomes faculty at a nearby university. These clinical and economic evidence assessments are useful to create medical and payment policies and to refine existing policies. Having a rigorous and transparent process strengthens credibility with providers and other external stakeholders. In addition, standardizing processes for assessing value for medical products informs manufacturers with regard to evidence expectations. Methodology developed for reviewing pharmaceuticals can be adapted to review non-pharmacologic entities, but lack of good quality evidence from clinical trials is a serious limitation. Medical innovations delivering sufficient high-quality evidence require a comprehensive format to optimize opportunities for scientific communication among payers, industry, and academia. Efforts to establish higher evidence standards for devices and diagnostics should be encouraged.

CASE 2

DRUG ELUTING STENTS—AN EXAMPLE OF THE TRANSITION FROM EVIDENCE TO POLICY THROUGH THE ONTARIO COMPREHENSIVE APPROACH TO THE DIFFUSION OF HEALTH TECHNOLOGIES

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Problem or Issue Addressed: In 2002, the Ontario Ministry of Health and Long-Term Care (MOHLTC) was advised that drug eluting stent (DES) would present a diffusion pressure since approximately 10,000 stents were being used per year and the differential cost between bare metal stents (BMS) and DES was $2200–$3840 per stent. An initial review of the literature by the Medical Advisory Secretariat (MAS) found that in low-risk patients the restenosis rates for BMS were 20–30% compared to 0–5% for DES. However, issues of generalisability to the Ontario health system were raised in the MAS analysis, and a concern that there would be creep to off-label use in high-risk patients.

Goals: Establish through a pragmatic study whether results published from randomized controlled trials on DES are generalizable to Ontario and to use this as a basis for long-term funding decision.