Outcomes items used in the decision: The following data was collected: the number of patients; the dose amount; the number of doses; the number of cycles; the purchase cost, the charge amount; and the reimbursement amount. The institutional annual budget impact analysis was done using direct medical costs, in 2007 United States Dollars.

Implementation Strategy: A pre-approval model was built based on the FDA approved indication of third-line treatment of MCRC. Assumptions regarding cetuximab’s use included: dose estimate/m2, number of doses per cycle per patient, median number of cycles per patient, and direct medical cost per dose patient. These data were based on information from published clinical trials, clinical use estimates and published cost data. Annual budget impact for the expected MD Anderson population of 125 MCRC patients was calculated to be $6,728,000. This model, along with a clinical monograph, was presented to the P&T Committee in April 2004 at the vote for cetuximab’s inclusion onto the institutional Formulary. Subsequently, cetuximab was added to the formulary as an add-on drug for metastatic colorectal cancer patients with two prior therapies, and with the recommendation that physicians use discretion for use outside the FDA-indication.

Results: During the time between the pre-and post approval, Cetuximab was FDA-approved for second-line treatment of MCRC (February 2004). It was also FDA-approved for head and neck (H&N) cancer in March 2006. For post-approval analysis, we reviewed the use in all patients (excluding investigational) receiving cetuximab at MDACC from June 2006 to May 2007. During this time period, we had a total of 233 patients on cetuximab. Of these, 114 (49%) were MCRC patients who had prior therapies, 83 (36%) were head and neck patients with prior treatments, and 36 (15%) patients received cetuximab for non-FDA-approved indications. We also reviewed charges and reimbursement data collected for the drug from June 2006 to December 2006. For the duration of the study period, we had a positive margin and our reimbursement to charge ratio for MCRC was 58%, the overall reimbursement to charge ratio for cetuximab was 56%. Actual annual budget impact was $4,854,230. Based on this analysis, there were some differences between the model assumptions and our findings from actual data. Our model had predicted 100% usage for the FDA approved indication of third-line MCRC treatment in an estimated patient population of estimated 125 patients versus 114 actual patients. Overall, actual data collected showed that we had more than expected number of patients on cetuximab; we had additional usage for the new FDA indication where none was previously estimated, and 15% use in non-approved indications. Also, our original model assumed a total of 8 cycles of cetuximab therapy per patient, whereas actual average number of cycles per patient was between 4 and 5. We did not have data to determine whether patients obtained other cycles of therapy from other providers outside of the institution.

Lessons Learned: Annual budget impact analysis helped estimate the cost to the institution for adding cetuximab to the formulary. Performing an annual budget impact evaluation before addition of a drug to an institution’s formulary, and comparing it with the annual budget impact after a few years of the drug being on the formulary, is an essential process in determining the best use of expensive resources. We also learnt the importance of including non-FDA usage in our initial model. Future studies will focus on calculating the estimated cost-effectiveness of therapies for the institution’s patient population. This would take into account the cost of treatment and patients’ outcomes; important in allocating resources in this era of rising costs.

Using in-house strategies to overcome inconsistencies between expenditures and budgeting

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Goals: Constraining or decreasing laboratory and pharmacy budgets while maintaining quality of medical care and introducing new technologies.

Outcomes items used in the decision: Measures used in the decision process, its monitoring and analysis were cumulative follow up budgetary and epidemiological data including: total laboratory and pharmacy budgets, Daily Defined Doses (DDD), standardized average daily and length of stay, standardized patient medication expenditures, laboratory test ordering utilization rate, average length of stay and overall mortality and re-hospitalization rate.

Implementation Strategy: Two fields of high expenditure production floors (laboratories and pharmacy), accounting for 25% of the purchasing budget were identified. A prospective drug and laboratory test utilization evaluation was conducted to profile consumption, ordering and prescribing behavior patterns. The results were formulated into two intervention programs (IPs): laboratory organization and institutional test ordering (LOTO) and drug use process (DUP).