Approximately 2.7 million Americans have active Hepatitis C infection. Combination therapy with ribavirin and interferon alfa-2b has emerged as the treatment of choice for Hepatitis C. **OBJECTIVES:** To determine if the prescribing of combination therapy differed among ethnic groups in Hepatitis C-infected members during calendar year 1999 in a Medicaid MCO. **METHODS:** Hepatitis C-infected patients were identified from a database of continuously enrolled members of an inner-city Medicaid MCO in Philadelphia using ICD-9 codes indicative of Hepatitis C (070.41, 070.44, 070.51, 070.54, 571.40, 571.41, V02.60, V02.62). From this population, members who received combination therapy with ribavirin and interferon alfa-2b were identified and demographic information was obtained. Variation in the prescribing of combination therapy among ethnic groups was assessed using a Chi-square test. **RESULTS:** From a cohort of 73,869 members, 395 members (0.535%) had an ICD-9 code for Hepatitis C. Of those, 60 members had pharmacy claims for combination therapy during 1999. These members aged from 23 to 64 years (mean age = 45.0 yrs; SD = 7.6). Based on the ethnic distribution of the 395 members with an ICD-9 code for Hepatitis C, 8.4% (16/191) of African-Americans were prescribed combination therapy compared with 23% (28/122) of Caucasians, 22.7% (15/66) of Latinos and 14.3% (1/7) of Asian-Americans. A statistically significant difference in the prescribing of combination therapy was noted among ethnic groups ($p < 0.05$). **CONCLUSIONS:** Within this Medicaid MCO, a disproportionately low percentage of African–American members received combination therapy for Hepatitis C during 1999. It is unknown whether this was due to a disproportionate number of contraindications in this group, inequitable prescribing habits of physicians, cultural barriers preventing consent for treatment, or noncompliance with obtaining the medication. Further investigation is needed to determine why this disparity exists so that differences in treatment among ethnic groups may be minimized.

**HP2**

## THE ROLE OF OUTLIER PAYMENTS IN MEDICARE PATIENTS WITH SEVERE SEPSIS

Cooper LM[1], Linde-Zwirble WT[2]
[1]Eli Lilly and Company, Indianapolis, IN, USA; [2]Health Process Management, Owings Mills, MD, USA

**INTRODUCTION:** Medicare is required to set outlier threshold so that outlier payments are between 5 and 6 percent of total DRG payments to offset extraordinarily high-cost cases. Severe sepsis (SS) is a condition affecting patients in many DRGs. High mortality and resource use in SS patients increases the likelihood of reimbursement under the outlier mechanism. We explore the role of outlier payments for SS in Medicare. **METHODS:** We examined all 1999 Medicare discharges age 65+ in prospective payment hospitals. Cost, reimbursement, and outlier payments were identified for each discharge. SS was identified by the presence of ICD-9-CM codes for acute organ failure and bacterial or fungal infection. DRGs were classified into six groups by post-operative status (medical and surgical) and by frequency of SS (high risk, high volume, remaining). **RESULTS:** Of 9,248,277 records, 384,680 (4%) were reimbursed through the outlier mechanism, reflecting 6% of total payments. SS patients represent 25% of all outliers, with an average cost per outlier case of $44,724. The average cost for non-sepsis outliers per case is $35,098. Twenty-two percent of all sepsis cases are reimbursed as outliers. While overall cases are reimbursed at 95% of reported costs, SS cases are reimbursed at only 85% of costs. SS outliers are reimbursed at only 70% of reported costs with especially low reimbursements for high volume medical SS outlier cases (54%). Overall, SS high risk medical and surgical cases are reimbursed at higher levels (103% and 78% respectively). **CONCLUSIONS:** While severe sepsis cases are only 4.7% of all Medicare discharges, almost one in four are outliers. Current outlier payments do not adequately compensate for the cost of care of most SS patients.

**HP3**

## INCORPORATING CLINICAL OUTCOMES AND ECONOMIC CONSEQUENCES INTO DRUG FORMULARY DECISIONS: EVALUATION OF 30 MONTHS OF EXPERIENCE

Atherly DE[1], Sullivan SD[1], Fullerton DS[2], Sturm LL[2]
[1]University of Washington, Seattle, WA, USA; [2]Regence BlueShield, Seattle, WA, USA

**BACKGROUND:** In January 1998, Regence BlueShield, a 1.2 million-member health plan, implemented a novel formulary submission process intended to improve clinical decision-making. The process requires pharmaceutical manufacturers to submit dossiers that include clinical and health outcomes data as well as an economic model that will demonstrate the impact of introducing the product to the health plan. Since implementation, the process has not been evaluated. **OBJECTIVE:** To evaluate the scope and content of submission dossiers received from January 1998 to June 2000. **METHODS:** All dossiers received from January 1998 to June 2000 were collected and reviewed. They were evaluated for compliance with the Regence Formulary Submission Guidelines. Data were entered into a spreadsheet for analysis. **RESULTS:** A total of 50 dossiers were reviewed. 25 (50%) were received in year 1, 16 (32%) in year 2, and 9 (18%) in the first six months of year 3. An economic model was provided in 31 dossiers, increasing from 55% to 78% of dossiers over the three years. Only 10 models were cost-effectiveness analyses. The remaining models were budget impact analyses. Complete clinical information was included in 48%, 63% and 78% of submissions in years 1, 2 and 3 respectively. Dossiers were prepared by one of three sources: Staff at the manufacturer's headquarters (68%), an outside vendor (10%) or a local manufacturer's representative (22%). Unpublished studies, which were specif-

ically requested, were included in 18 dossiers, and off-label information was included in 7. Of the 50 products submitted, 24 (48%) were added to Formulary. **CONCLUSIONS:** Compliance with the guidelines has improved over the past 30 months. Overall, a majority of the submissions included complete clinical information and some type of economic analysis. There remains, however, significant opportunity for improvement, particularly in the presentation of economic evaluation data and the dissemination of unpublished studies.

**HP4**

## ASSESSING LIFESTYLE DRUGS FOR DRUG BENEFIT FORMULARIES: A COST-UTILITY ANALYSIS OF ORLISTAT AND SIBUTRAMINE FOR THE TREATMENT OF OBESITY IN ADULTS

Trakas K[1], Oh PI[2], Leiter L[3], Shear NH[2]
[1]University of Toronto, Toronto, ON, Canada; [2]Sunnybrook and Women's College Health Science Centre, Toronto, ON, Canada; [3]St. Michael's Hospital, Toronto, ON, Canada

Obesity is now recognized as a chronic health condition instead of a cosmetic or lifestyle issue. Orlistat and sibutramine are effective weight-loss/weight-maintenance agents. Insurers argue that the high prevalence of obesity (i.e., body mass index (BMI)[3] 30kg/m[2]), questionable long-term health benefits, and cost of these drugs make it unfeasible to cover them. Proponents claim decreases in obesity's comorbidities would offset acquisition costs. **OBJECTIVES:** To provide evidence for a rational reimbursement policy for pharmacological treatments of obesity in adults. **METHODS:** A Markov decision analytic model was used to evaluate the cost-effectiveness of orlistat (120mg TID) and sibutramine (5–20mg QD) relative to diet and exercise alone. The model analyzed a hypothetical population of obese, but otherwise healthy 30 year olds over their lifetime. Estimates of efficacy and tolerance were derived from a meta-analysis of randomized, placebo-controlled trials of orlistat and sibutramine. The Framingham Study was used to derive risk-adjusted equations for the incidence of hypertension, dyslipidemia, and DM as well as the incidence of CV events, CV-attributable death, and non-CV death. Equations were adjusted for known risk factors, including BMI. The reference case analysis used the societal perspective and included both direct and indirect costs (discount rate, 3%). Costs were derived from the literature and inflated to year 2000 Canadian dollars (CDN$). Utilities were derived from a Canadian health survey and from the literature. Decision index: incremental cost per quality adjusted life year ($/QALY). A Monte Carlo simulation will be used to perform a sensitivity analyses around: estimated weight-loss, estimated dropout rates, estimated weight regain, cost of treatment, and major clinical events. **RESULTS:** Results for the base case (i.e., societal viewpoint) and third party payer (i.e., Ministry of Health) perspectives will be presented and discussed. Emphasis will be placed on the decision model approach for informing formulary decisions on "lifestyle" drugs.

# CANCER

**CN1**

## UTILITIES OF METASTATIC BREAST CANCER PATIENTS (PT) TREATED WITH TAXANES COMPARED TO UTILITIES OF ONCOLOGY NURSES (NUR)

Hauser R[1,3], Theriault R[2], Wilson J[3], Shepherd M[3], Lawson K[3], Koeller J[3]
[1]Abt Associates Clinical Trials, Cambridge, MA, USA; [2]University of Texas M.D. Anderson Cancer Center, Houston, TX, USA; [3]University of Texas, Austin, TX, USA

Cost-utility analysis is rapidly becoming the standard pharmacoeconomic measure in oncology. In a recent report (JCO, 2000;18:3302), data from 40 published cost-utility studies were presented in a league table format. Most of those studies utilized nurses or physicians as proxies for the pt. in determining utility. **OBJECTIVE:** To determine if there is a difference between utility scores obtained from metastatic breast cancer pt. and oncology nurses. **METHODS:** Using eight modified Markov modeled health states (Pharmacoeconomics, 1996; 60:504) describing metastatic breast cancer; the standard gamble procedure was utilized to obtain utility scores from 45 patients and 57 oncology nurses. Utility values were measured on a scale between 0.0 and 1.0. Independent t-tests were used to test for differences between groups using an alpha level of 0.05 (2-sided). **RESULTS:** Significant differences were found on all eight modeled health states:

| Modeled Disease State | Mean Utility Score (SD) Patients/Nurses (n = 45; n = 57) | P Value | 95% Confidence Intervals |
|---|---|---|---|
| Partial Response (PR) | .84 (.11)/.71 (.22) | .0001 | .06–.20 |
| PR with Severe Peripheral Edema | .78 (.17)/.63 (.24) | .0001 | .08–.24 |
| PR with Severe Peripheral Neuropathy | .76 (.13)/.56 (.24) | .0001 | .12–.28 |
| Before Second Line Treatment Begins | .73 (.16)/.59 (.22) | .0001 | .06–.22 |
| Stable Disease | .72 (.15)/.54 (.22) | .0001 | .11–.26 |
| Late Progressive Disease | .63 (.18)/.45 (.25) | .0001 | .10–.27 |
| Terminal Disease | .40 (.26)/.19 (.21) | .0001 | .13–.31 |
| Sepsis | .39 (.25)/.20 (.23) | .0001 | .09–.28 |

**CONCLUSION:** These results show that patients have a higher utility for health than perceived by nurses. These data leads to the question of whose utility values should be used for cost-utility analysis in oncology.

**CN2**

## EFFECT OF INCLUDING (VERSUS EXCLUDING) FATES WORSE THAN DEATH ON UTILITY MEASUREMENT

Franic DM[1], Pathak DS[2]
[1]The University of Georgia, Athens, GA, USA; [2]The Ohio State University, Columbus, OH, USA