(1.690 to 6.852); doxorubicin/congestive heart failure (1.154 to 5.004); and carmustine/leukopenia (3.796 to 5.650) and thrombocytopenia (3.796 to 5.644). Furthermore, the percentage of AERS reports associated with outcomes of hospitalization increased as follows: melphalan causing leukemia (0% to 37%, p<0.001), chromosomal aberrations (0% to 15.55%, p<0.001), bone marrow suppression (4.0% to 40.9%, p<0.001), or hypersensitivity (30.77% to 50.0%, p<0.01). The mortality outcome increased only for melphalan/leukemia (8.9% to 54.8%, p<0.001). Life-threatening outcomes increased for melphalan/leukemia (0% to 17.7%, p=0.016), melphalan/chromosomal aberrations (0 to 8.7%, p<0.001), carmustine leukopenia (0 to 17.7%, p=0.016), and carmustine/thrombocytopenia (0-20.3%, P=0.045). **CONCLUSIONS:** Prior to the BBWs, health professionals do not appear to associate the ADRs with the drug and/or do not report the events to the FDA. Issuance of BBWs appears to result in increased awareness and reporting. Since pre-marketing research may not identify rare ADRs and voluntary post-marketing reporting may be inadequate, proactive pharmacovigilance programs should be implemented.

PCN24

FACTORS ASSOCIATED WITH LATE-STAGE PROSTATE CANCER SURVIVAL IN FLORIDA

Adunlin GB, Xiao H
Florida A&M University, Tallahassee, FL, USA

OBJECTIVES: 1) Examine survival of late stage prostate cancer patients; and 2) Determine factors associated with survival at both the patient and neighborhood levels. **METHODS:** Prostate cancer cases were obtained from the Florida Cancer Data System. Men aged 40 years and above diagnosed with late prostate cancer in 1995 were followed through 2000. Demographics, health insurance and vital statistics were extracted for individual patients and linked with Florida Census 2000 data with education and poverty level information. Data was analyzed using a multilevel logistic regression to examine the relationship of prostate cancer survival with both patient-level characteristics and area-based measures of socioeconomic status. **RESULTS:** A total of 1,101 men were diagnosed in Florida with late stage prostate cancer in 1995 with an average age of 69 years. Patients with the following characteristics were more likely to die from prostate cancer than their counterparts: unmarried, Medicaid recipient, and older. Men residing in neighborhood with higher percentage of high school education and surprisingly men without health insurance were more likely to live longer than five years. **CONCLUSIONS:** Although survival has improved over time due to early detection of prostate cancer, there are still differences in survival among men diagnosed with late stage based on different marital status, health insurance and neighborhood characteristics.

Cancer – Cost Studies

PCN25

BUDGET-IMPACT OF ERIBULIN FOR THIRD-LINE TREATMENT OF METASTATIC BREAST CANCER IN A UNITED STATES MANAGED CARE SETTING

Tao C[1], Taylor D[1], Parthan A[2], Faria C[3], Choe Y[3]
[1]*i3 Innovus, Medford, MA, USA,* [2]*i3 Innovus, San Francisco, CA, USA,* [3]*Eisai, Inc., Woodcliff Lake, NJ, USA*

OBJECTIVES: Eribulin is a non-taxane microtubule dynamics inhibitor that has demonstrated improved overall survival in a phase III study relative to commonly used therapies in late-line metastatic breast cancer (MBC). This budget impact model (BIM) was developed to help US payers make informed decisions regarding addition of eribulin for the management of MBC. **METHODS:** From the perspective of US commercial payers, an Excel-based BIM was constructed upon a hypothetical plan of 1 million members. 600 women are estimated to be newly diagnosed with breast cancer; of these 5% with MBC and 24% are initiated on 3rd-line chemotherapy, 47% of these on monotherapy. A Markov decision-analytic model was used to trace movement of patients receiving eribulin or another 3rd-line single-agent chemotherapies through different MBC states (treatment initialization, stable, response, progression, death). The model used a two-year time horizon with one-week Markov cycle lengths. The efficacy, market shares, and medical and drug costs were derived using published and internally available data sources. Model probabilities were based on discontinuation, progression free survival, and overall survival rates from the EMBRACE trial. Market share of eribulin was assumed to be 5% in year-one and 10% in year-two of the model. Model outcomes included: total costs over 2 years pre- and post-inclusion of eribulin, net costs, cost per member per month (PMPM), cost per patient per month (PPPM) and median overall survival. **RESULTS:** Of the 1 million plan members, approximately 3 incident cases of MBC requiring 3rd line treatment were identified each year. Budgetary impact PMPM was estimated to be <$0.01 in year-one and year-two, and PPPM $118 and $252, respectively. Overall net budgetary impact for year-one and year-two was $4,880 and $10,450, respectively. **CONCLUSIONS:** Based on this analysis adding eribulin does not exhibit a significant overall cost increase when taking into account medical and drug expenditures.

PCN26

BUDGET IMPACT MODEL OF DENOSUMAB FOR SKELETAL RELATED EVENT (SRE) PREVENTION IN PATIENTS WITH BREAST AND PROSTATE CANCER

Northridge K[1], Richhariya A[2], Halperin M[1], Chung K[2], Danese MD[1]
[1]*Outcomes Insights, Inc., Westlake Village, CA, USA,* [2]*Amgen, Inc., Thousand Oaks, CA, USA*

OBJECTIVES: Skeletal complications from bone metastases can be debilitating and costly. Denosumab was recently approved in the US for SRE prevention in patients with bone metastases from solid tumors. This study evaluated the three-year budget impact of denosumab compared to zoledronic acid (ZA) for breast and prostate cancer using the US managed care perspective. **METHODS:** Excel-based models compared denosumab (120 mg) to ZA (4 mg) administered every four weeks for the patient lifetime. Inputs included the US population age and gender distribution, Medicare managed care enrollment rates, the prevalence of bone metastases (estimated from literature-based epidemiological simulations), and 2010 costs for therapy and SREs. Utilization estimates assumed that 66% of breast and 48% of prostate cancer patients with bone metastases would receive anti-resorptive therapy and that for years one to three 20%, 35% and 45% of these patients would use denosumab. Trial-based SRE rates per patient-year were 0.488 and 0.631 (denosumab and ZA) for breast cancer and 0.746 and 0.947 for prostate cancer. The expected incremental adverse event cost was nominal and therefore excluded. Sensitivity analyses were conducted to identify influential variables on the incremental costs per member per month (PMPM). **RESULTS:** The incremental PMPM costs for years one to three were $0.02, $0.04, and $0.05 ($0.11 total) for breast cancer and $0.01, $0.02, and $0.03 ($0.06 total) for prostate cancer. For both tumor types, influential variables included costs for denosumab and ZA, prevalence rates of each cancer and of bone metastases, utilization rates of denosumab and ZA, and underlying SRE rates. The younger breast cancer age distribution results in a larger incremental cost burden for managed care organizations when compared to prostate cancer. **CONCLUSIONS:** The real-world financial impact to US health plans from using denosumab should be relatively modest and will vary depending on prevalence and utilization patterns.

PCN27

COMPARATIVE BUDGET IMPACT OF FORMULARY INCLUSION OF ZOLEDRONIC ACID AND DENOSUMAB FOR PREVENTION OF SKELETAL-RELATED EVENTS IN PATIENTS WITH BONE METASTASES

Bell MJ[1], Miller JD[2], Namjoshi M[3], Russell MW[2]
[1]*RTI Health Solutions, Manchester, UK,* [2]*RTI Health Solutions, Waltham, MA, USA,* [3]*Novartis Oncology US, East Hanover, NJ, USA*

OBJECTIVES: Skeletal complications from bone metastases impose a significant clinical and economic burden on patients and health systems. Zoledronic acid (ZA) has been the mainstay for prevention of skeletal related events (SREs) in patients with bone metastases. In 2010, FDA approved denosumab for prevention of SREs in patients with solid-tumor bone metastases. We assessed the financial impact to a managed-care plan of adding denosumab to a ZA-only formulary for this indication. **METHODS:** We developed an Excel-based model to evaluate the trajectory of spending over 1-3 year time horizons in a hypothetical managed care plan with 1 million members and 688 patients with solid-tumor bone metastases. The model considered use and associated costs of drug acquisition and administration, SRE management, and adverse event (AE) treatment under two scenarios: (1) *Base Case*—ZA-only formulary; and (2) *Restricted Formulary*—denosumab limited to second-line treatment in patients failing ZA. SREs included pathologic fracture, therapeutic radiology, spinal cord compression, and orthopaedic surgery. AEs included osteonecrosis of the jaw, renal problems, acute phase reactions, and hypocalcemia. Model parameters were derived from published literature, product labels, clinical trial data, and administrative cost databases. Drug costs were based on published wholesale acquisition cost minus copayments. Costs were stated as 2010 US dollars. **RESULTS:** In the *Base Case* scenario (ZA only), total costs were $10.8 million per year. Allowing restricted access to denosumab was associated with total costs of $11.4, $11.6, and $11.7 million over 1, 2, and 3 years ($0.05, $0.06, $0.08 incrementally per-member per-month). The corresponding incremental cost of adding denosumab was $69, $94, and $115 per ZA-treated member per month. **CONCLUSIONS:** With an acquisition cost nearly twice that of ZA, restricted use of denosumab adds considerably to patient management costs. Incremental benefits should be weighed carefully against these costs before considering coverage.

PCN28

COST SAVINGS WITH FERRIC CARBOXYMALTOSE THROUGH ITS IMPACT ON ERYTHROPOÏESIS-STIMULATING AGENTS AND BLOOD TRANSFUSION IN CHEMOTHERAPY-INDUCED ANEMIA OF BREAST AND GASTROINTESTINAL CANCER: FRENCH HEALTH CARE PAYER PERSPECTIVE

Luporsi E[1], Mahi L[2], Moore C[3], Wernli J[4], Bugat R[5]
[1]*Centre Alexis Vautrin, Vandoeuvre-Les-Nancy, France,* [2]*Vifor Pharma AG, Neuilly sur Seine, France,* [3]*JNBD-Développement, Paris, France,* [4]*Vifor Pharma AG, Glattbrugg, Switzerland,* [5]*Institut Claudius Regaud, Toulouse, France*

OBJECTIVES: To evaluate the economic impact of intravenous iron (ferric carboxymaltose; Ferinject) in chemotherapy-induced ferriprive anemia in breast and gastrointestinal cancer. **METHODS:** We used an economic model which compared the usual therapeutic strategies of anemia with or without intravenous iron. Costs related to anemia treatment by ESA, blood transfusion and intravenous iron were estimated and compared. Cost savings were calculated from the French healthcare payer perspective. Data included in the economic model were obtained from scientific literature, public health agencies and medical experts. Impact of Ferinject on the decrease of the number of blood transfusions at hospital and the decrease of ESA dosing was evaluated. **RESULTS:** Patients treated with 2000 mg of Ferinject during chemotherapy treatment and 1000 mg at home concomitantly with ESA once every two month during 4 months. Based on the estimated decreased of the 25% ESA dosing when administered with Ferinject, and a decrease of 10% of patients receiving ESA after chemotherapy (expert opinion), the most prominent annual cost savings were observed in chemotherapy-induced anemia in breast cancer (€881 and €319 by patient for metastatic and non-metastatic breast cancers, respectively); global cost saving is estimated to €29 millions. Regarding blood transfusion the cost saving is estimated to €1.6 millions. Impact of Ferinject on the decrease of ESA dosing in gastrointestinal cancer was evaluated on the same basis. The annual cost saving is estimated to €6.6 millions. Analysis showed that strategies including intravenous iron remained cost-effective even with wide variations