The DDI results indicated small declines in medication adherence for cancer survivors relative to beneficiaries without a cancer diagnosis in all three drug classes (3 to 5 percentage points), whereas longer term cancer survivors had much better adherence to all three drug classes (10 to 12 percentage points higher) relative to beneficiaries with cancer who had a poor prognosis.

**CONCLUSIONS:** A diagnosis of cancer increases the reasons of medication adherence with evidence-based medications recommended in diabetes treatment guidelines.

**PCN166**

**REGIONAL VARIATIONS IN HEALTH CARE EXPENDITURES AMONG MEDICARE BENEFICIARIES WITH COLORECTAL CANCER**

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**OBJECTIVES:** To examine total health care expenditures in the initial phase-of-care among Medicare beneficiaries with colorectal cancer (CRC) from a rural setting and compare them with "national" estimates.**METHODS:** A population-based retrospective cohort-study was conducted on fee-for-service Medicare beneficiaries aged ≥66 years diagnosed with CRC between 2003-2006 identified from the West Virginia Cancer Registry (WVCR)-Medicare linked database (n=2,114). Similarly, a comparative cohort was identified from Surveillance, Epidemiology, and End Results (SEER)-Medicare (n=38,172). Medicare claim payment-amounts were used to calculate total average health care, inpatient, outpatient, physician-visits, and other health care-utilization expenditures. To control for geographic variation in cost-of-living across the different counties, health care-expenditures were expressed using county-specific cost-of-living indices (COLI).**RESULTS:** After COLI-adjustment, the average total health care expenditures in the initial phase-of-care for beneficiaries from the WVCR-Medicare linked database were estimated at $46,644. The average total health care and inpatient expenditures in initial phase-of-care were found to be lower (9% and 4%, respectively) for those from SEER-Medicare as compared to those from SEER-Medicare. However, they had a higher co-morbidity burden, and significantly higher (45%) outpatient expenditures as compared to their "national" counterparts. Total expenditure results were further stratified by the presence of chronic-conditions, which have a higher prevalence in the WVCR-Medicare group as compared to those from SEER-Medicare. Further, the differences in total health care-expenditures between beneficiaries from WVCR-Medicare and SEER-Medicare ranged from $2,892 to $898, and remained no longer significant in a multivariable setting after controlling for receipt of minimally-appropriate CRC-treatment (MCT) and presence of chronic-conditions.**CONCLUSIONS:** This study highlights the importance of providing preventive health care services and better co-management of CRC and chronic-conditions, to control the higher outpatient expenditures among beneficiaries with CRC from a rural population. This study also showed that the differences in total health care-expenditures between rural and non-rural beneficiaries were likely to be partially explained by the receipt of MCT and comorbidity-burden.

**PCN167**

**TREATMENT AND SURVIVAL PATTERNS AMONG ELDERLY MEDICARE BENEFICIARIES WITH COLORECTAL CANCER: A COMPARATIVE ANALYSIS BETWEEN A RURAL STATE CANCER REGISTRY AND NATIONAL DATA**

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**OBJECTIVES:** To examine colorectal cancer (CRC) treatment patterns in the initial phase-of-care, the extent of receipt of minimally-appropriate CRC-treatment (MCT) and the associated survival in a three-year period following a CRC-diagnosis in Medicare beneficiaries from West Virginia (WV) compared to those from SEER-Medicare. This study hypothesized that CRC beneficiaries from WV had poorer CRC-survivorship with adjusted hazards ratios (AHR) = 1.26; 95%CI=[1.20, 1.32]. This poorer survivorship may be due to a lower likelihood of targeted therapy.

**METHODS:** Patients from WVCR-Medicare linked database (n=2,114) were compared to those from SEER-Medicare (n=38,172). A comparative "national" cohort was identified from Surveillance, Epidemiology, and End Results (SEER)-Medicare (n=38,168). CRC-treatment received was ascertained from beneficiaries’ Medicare claims by following them for 12-months from their CRC-diagnosis date or until death. Receipt of MCT was defined based on National Cancer Institute CRC-treatment guidelines. All cause and CRC-specific mortality in the 36-month period following CRC-diagnosis were examined after accounting for selection bias using inverse probability treatment weights.**RESULTS:** Although a higher proportion of beneficiaries from WVCR-Medicare were diagnosed in the earlier stages of CRC (when it can still be treated effectively) as compared to their SEER-Medicare counterparts, they had poorer CRC-survivorship with adjusted hazards ratios (AHR)=1.26; 95%CI=[1.20, 1.32]. This poorer survivorship may be due to a lower likelihood of targeted therapy.

**CONCLUSIONS:** This study highlights the need for an increased emphasis on adoption, and adherence to surgical guidelines and the use of evidence-based CRC-treatment guidelines, and improving access to CRC-care for those from rural settings. Further research needs to be conducted to determine if similar rural-urban differences in receipt of MCT exist in the elderly in other rural-areas of the nation.

**PCN168**

**FIRST TWO YEARS OF HEALTH SYSTEM RESOURCES AND COSTS FOLLOWING A STAGED DIAGNOSIS OF BREAST CANCER: A POPULATION BASED APPROACH**

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**OBJECTIVES:** To determine the publicly funded health care costs associated with the diagnosis, treatment, and follow-up of breast cancer (BC) patients in two time periods (before and after diagnosis) and the usage of publicly funded health care services used were stratified by disease stage over the first two years following diagnosis. BC cases were matched to controls (women without cancer). Overall average costs (2008$CAN) and costs per person were compared across the two periods. The time horizon was determined.

**METHODS:** Incident cases of female invasive BC (ICD-9-C30) were identified from the Cancer Care Ontario database linkage, SEER-18 database, and the Canadian Institute for Health Information (CIHI) database. The study cohort (n=39,655) was stratified by disease stage and the first two years of diagnosis. BC cases were matched to controls (women without cancer). Overall average costs (2008$CAN) and costs per person were compared across the two periods. The time horizon was determined.

**RESULTS:** There were 39,655 BC cases and 190,520 controls in our cohort study. The average age was 61.1 years old and 60.9 years old, respectively. Of the BC cases with staging information, the majority of cases were Stage I (34.4%) and Stage II (31.8%). Eight percent of the entire cohort died within the first two years of diagnosis. The overall mean cost per BC case from a public payer perspective in the first two years following diagnosis was $41,686 based on the study cohort of 39,655 BC cases. The mean cost increased by stage: Stage I ($29,938), Stage II ($46,893), Stage III ($65,369) and IV ($66,627). When compared to controls, the net cost for BC cases was $31,732. Cost drivers for the entire cohort were cancer care, physician billing, and inpatient hospitalizations.

**CONCLUSIONS:** This study will allow for planning and decision making around limited health care resources.

**PCN169**

**TREATMENT PATTERNS AMONG PATIENTS WITH BREAST CANCER: DOES INSURANCE STATUS MATTER?**

**Component:** Sun W1, Gu G1, Yi Y2

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**OBJECTIVES:** The study aims to systematically review the efficacy, safety and cost-effectiveness of trastuzumab in metastatic gastric cancer treatment in China.

**METHODS:** A systematic review method was performed. We searched all national and international clinical, cost-effectiveness and disease burden studies finally recruited for the analysis. Clinical results showed that trastuzumab in combination with chemotherapy were effective and well tolerated in advanced gastric cancer patients. One cost effectiveness study revealed that from the perspective of the payer, trastuzumab treatment was cost-effective than the comparator, which was consistent with the results of other studies.

**CONCLUSIONS:** The net cost for BC cases was $31,732. Cost drivers for the entire cohort were cancer care, physician billing, and inpatient hospitalizations. This study will allow for planning and decision making around limited health care resources.

**PCN171**

**EFFICACY, SAFETY AND COST-EFFECTIVENESS OF TRASTUZUMAB IN METASTATIC GaSTRIC Cancer TREATMENT IN CHINA**

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**OBJECTIVES:** The study aims to systematically review the efficacy, safety and cost-effectiveness of trastuzumab in metastatic gastric cancer treatment in China.

**METHODS:** A systematic review method was performed. We searched all national and international clinical, cost-effectiveness and disease burden studies finally recruited for the analysis. Clinical results showed that trastuzumab in combination with chemotherapy were effective and well tolerated in advanced gastric cancer patients. One cost effectiveness study revealed that from the perspective of the payer, trastuzumab treatment was cost-effective than the comparator, which was consistent with the results of other studies.

**CONCLUSIONS:** The net cost for BC cases was $31,732. Cost drivers for the entire cohort were cancer care, physician billing, and inpatient hospitalizations. This study will allow for planning and decision making around limited health care resources.
PCN172
A CALL TO MONITOR DRUG SHORTAGES AND THE ROLE OF MARKET ATTRACTIONNESS IN EUROPEAN COUNTRIES
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OBJECTIVES: Drug shortages are a global problem. While extensively studied in the United States, numbers about drug shortages in European countries are scarce. This study aims to investigate publically available data about drug shortages in European countries in order to reveal a typology of drug shortages in Europe. METHODS: A standardized reporting template was designed based on a literature search to collect and structure information. Countries offering an online reporting system for drug shortages such as Belgium, The Netherlands, England, Italy, France, Germany and Spain were included in this study. The online reporting systems were consulted in May 2015. Typology and causes of drug shortages are mapped and a sub-analysis is performed for essential medicines and oncology drugs. RESULTS: Majority of drugs reported (n=671) had a preclinical stage of out-of-market status (n=671), 31% (208) preclinical drugs, 43% (496) active substances and 56% (567) medicines, which equally affect different disease domains. When considering essential medicines (n=200) and oncology drugs (n=71), generics (55% for essential drugs, 64% for oncology drugs) and injectables (52% for essential drugs, 79% for oncology drugs) are more impacted. The causes for drug shortages are underreported, as the cause is not known in 66% of the cases (n=671). Production problems are reported in 27% of the cases (n=671). Results are subjected to the different scopes of the considered reporting systems. CONCLUSIONS: Reporting of drug shortages in Europe needs to be standardized and more transparency about the reasons for drug shortages is required to understand the problem. A link between production problems and market attractiveness and market capacity is recognized to be at the root of drug shortages in the EU. A clear insight lacking in Europe is the strength and interdependencies of the oncologic and European health policies on the sustainability of the drug market is required to present fundamental solutions for the problems for drug shortages in Europe.

PCN173
DOWNSHALLS OF THE FDA ACCELERATED APPROVAL PATHWAY – STRINGENT CONTROLS MIGHT BE REQUIRED TO ENSURE PROMPT SUBMISSION OF FOLLOW-UP CONFIRMATORY TRIAL DATA
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OBJECTIVES: The 2011 FDA decision to make it temporary to withdraw a drug in October 2013 following safety concerns arising from its Phase III trials. This drug had previously been approved under the accelerated approval pathway. Three other oncologics have been withdrawn under similar conditions, further adding to concerns with this pathway. This research aims to provide an up-to-date systematic analysis of all oncologics approved under this pathway and analyse the time delay in obtaining regular approval. METHODS: Publically available assessments of any oncologic approved under the FDA accelerated approval pathway and the dates of accelerated approval and conversion to regular approval were extracted. RESULTS: 41 oncologics across 50 indications have been assessed under the FDA accelerated approval pathway, all but two of which have been approved. Of the approved indications, 50% (29/67) have been converted to regular approval with an average delay of 53 months (range 13-151 months). 6% (3/48) have been withdrawn from the market due to lack of efficacy and/or safety concerns arising from Phase III data. 44% (21/48) have not been withdrawn, completion of confirmatory data should become a strict, non-negotiable requirement with a defined time limit by which the data must be submitted. A failure to do so should be seen the FDA automatically withdrawing their license.

PCN174
EVIDENCE FOR A LOWERED THRESHOLD FOR FDA APPROVAL ON ONCOLOGICS BASED ON SINGLE-ARM PHASE II DATA, COMPARED TO THE EMA
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OBJECTIVES: The European Medicines Agency (EMA) approved 19 oncologics across 25 indications on the basis of pivotal Phase II data lacking an active comparator (Macaulay, ISPOR Dublin 2013). Approval was typically granted for indications in which there was no therapeutic alternative where a response rate of ≥35% was demonstrated. This research aims to define the circumstances under which the Food and Drug Administration (FDA) will approve oncologics on the basis of pivotal Phase II data and compare to those of the EMA. METHODS: A systematic search was undertaken for FDA oncologics submissions based on pivotal Phase II data and the acceptance decision, indication, and level of benefit were extracted. RESULTS: 31 oncologics across 38 indications were submitted to the FDA on the basis of pivotal Phase II data. All of which were non-comparative and 36 were approved. This included drugs approved by the FDA in 2013 based on this basis except trabectedin. 32 indications were approved under the accelerated approval pathway, only 47% (15/32) of which have been converted to regular approvals. Two of these drugs have been subsequently withdrawn from the market. In the case of gefitinib and gemtuzumab, neither of which were EMA-approved for these indications. 72% (23/32) were FDA designated orphan indications. 78% (25/32) indications were for lines of therapy or diseases that had no relevant therapeutic alternatives. The average time to approval was 140 days (range 0-357 days). Median length of pre-index continuous enrollment was 779 days. The majority resided in the southern (51.6%) and midwestern (26.0%) U.S. and most patients had Medicare Advantage (26.0%) or Medicare Part D (9.3%) coverage. The percentage of patients met all inclusion/exclusion criteria. Median time to approval from initial submission was 130 days. The lower threshold enables more drugs for severe diseases to become available earlier in their development cycle but risks approving ineffective and/or unsafe drugs.

PCN175
A RETROSPECTIVE STUDY OF PATIENTS OUT-OF-POCKET COSTS FOR ORAL ONCOLOGY MEDICATIONS FOR MULTIPLE MYELOMA
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OBJECTIVES: To study patient’s out-of-pocket expenditures in patients taking oral oncology medication for the treatment of Multiple Myeloma who are enrolled in a specialty pharmacy program. METHODS: A retrospective analysis of pharmacy claims and reimbursement data for oncology medications purchased in a specialty pharmacy from January 1, 2011 through October 31, 2013 was conducted. Patients with a primary diagnosis of Multiple Myeloma (ICD-9 CM: 203.xx) prescription data were included. There were no exclusion criteria. The cost per prescription or per patient was compared and a chi square test performed comparing average co-pay responsibility per prescription after insurance to average patient co-pay per prescription after funding assistance. RESULTS: A total of 22,566 prescriptions were included. The average patient co-pay responsibility after insurance was $435.00 per prescription and the average patient-co-pay after funding assistance was $81.00 per prescription. This resulted in 12,822 (91.17%) of the prescriptions had a patient co-pay of under $10.00 after funding assistance. The patient’s insurance type was as follows: private insurance was 59%, Medicare was 25%, Pharmacy Benefit Manager was 10%, Tricare was 1%, and Medicaid was 5%. CONCLUSIONS: In this retrospective analysis of pharmacy and financial claims data, Multiple Myeloma patients significantly reduced their out-of-pocket expenditures, from an average of $435.00 to $81.00 by the specialty pharmacy gaining funding assistance for the patient.

PCN176
ASSESSMENT OF IMAGING UTILIZATION AND TREATMENT PATTERNS FOR HEAD AND NECK CANCER PATIENTS IN THE UNITED STATES
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OBJECTIVES: To assess imaging and treatment patterns in head and neck cancer (HNC) patients using a large commercial-insurance database from the United States (U.S.). METHODS: We used the Marketscan® Research Databases (2007-2011) to identify adult, parotid (oral pharynx, paranasal sinus) cancer using ICD-9 codes. We evaluated three periods of imaging and treatment patterns: 1) three months pre-diagnosis, 2) diagnosis-to-treatment initiation, and 3) post-treatment initiation. Patients receiving single-imaging modalities and multiple-imaging modalities were assessed. RESULTS: Imaging and treatment intensity and variability by cancer types and geographic regions (Northeast, North Central, South, and West) were assessed using univariate and multivariate logistic regression. RESULTS: 80,987 patients were analyzed (39% female, mean age: 60 years). During pre-treatment, comparing all cancer types to oral cancer, pharynx cancer patients had the greatest likelihood of single-modality imaging and multiple-modality imaging. Patients with higher comorbidities and index scores were more likely to receive more invasive prior to treatment. Pre-treatment imaging was more likely to occur in other regions compared to West (OR range: 1.07-1.29), with consistent imaging patterns versus the West. CONCLUSIONS: Head and neck imaging and treatment patterns are affected by patient geographic location and geographic region. Imaging and treatment intensity and variability by cancer types and geographic regions (Northeast, North Central, South, and West) were assessed using univariate and multivariate logistic regression. RESULTS: 80,987 patients were analyzed (39% female, mean age: 60 years). During pre-treatment, comparing all cancer types to oral cancer, pharynx cancer patients had the greatest likelihood of single-modality imaging and multiple-modality imaging. Patients with higher comorbidities and index scores were more likely to receive more invasive prior to treatment. Pre-treatment imaging was more likely to occur in other regions compared to West (OR range: 1.07-1.29), with consistent imaging patterns versus the West. CONCLUSIONS: Head and neck imaging and treatment patterns are affected by patient geographic location and geographic region.