PCN59
REAL WORLD DATA ON COLONY-STIMULATING FACTORS (CSF) IN ONCOLOGY: PATTERNS OF USE IN BRAZIL
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OBJECTIVES: Incorrect use of colony stimulating factors (CSF) can add unnecessary cost to cancer treatments and adverse events to patients. We conducted an epidemiological study to assess the correlation between CSF use recommendations issued by the Brazilian Regulatory Agency of Health (ANS) and technical recommendations stated by international guidelines. We also analyzed the main reasons for not recommending the use of CSF, in patients during chemotherapy. **METHODS:** Data on patients treated with CSF during 2014 was retrieved from Evidências - Kantar Health database of administrative claims, which comprises more than 4 million people and 46 Private Health Insurance Companies (PHIC) in Brazil. Demographic assessment, types of tumor, number of patients, treatment purpose, technical recommendation, ANS recommendation, reason for not recommending and class of requested CSF were assessed. **RESULTS:** We retrieved 440 CSF requests corresponding to 322 patients. 188 requests were recommended both technically and by ANS. In 200 claims, CSF use was not recommended by either guidelines or ANS; and only 30 claims were in discordance, as CSF use was recommended by guidelines but not by ANS. Reasons for technical non-recommendation were: requests for primary prophylaxis on chemotherapy regimens with risk of febrile neutropenia below 20% and no complicating factors (37.5%), secondary prophylaxis in palliative care setting (26%) or request based on complete blood count (CBC) collected at the nadir of chemotherapy. **CONCLUSIONS:** Administrative recommendations from ANS are in close agreement with the scientific literature. Nevertheless, despite clear international guidelines and ANS recommendation, there is still a gap in physicians' knowledge about the correct indications for CSF. Continual medical education on this topic should emphasize the following of protocols to ensure proper CSF use.

PCN60
REGULATORY APPROVAL FOR ONCOLOGY PRODUCTS IN BRAZIL: A COMPARISON BETWEEN THE FDA AND ANVISA APPROVAL TIMELINES
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INTRODUCTION: Inequitable access to oncology care between the USA and Brazil is frequently attributed to delays in regulatory approval by ANVISA. **OBJECTIVES:** The purpose of this research was to estimate the differences in regulatory approval timelines between the FDA (USA) and ANVISA (BRA) for oncology therapies, while distinguishing between delays in manufacturer application submissions and ANVISA regulatory processes, to understand how these delays may create inequitable patient access to care. **METHODS:** A basket of twenty-three oncology products approved by ANVISA after 2002 were surveyed to evaluate the differences in regulatory submission and approval dates between the USA and Brazil The ANVISA and FDA regulatory approval timelines were calculated by obtaining the difference between submission and approval dates of each product's regulatory applications; comparisons between the FDA and ANVISA timelines were drawn by taking the difference in each of the regulatory bodies' average approval time for all products Delays in the manufacturers' submission for regulatory approval in Brazil were calculated by comparing the FDA and ANVISA application submission dates for each product. **RESULTS:** The analysis revealed that on average there was a difference of 8.6 months between ANVISA and the FDA's regulatory approval process, with ANVISA averaging approximately 449 days and the FDA 186 days from submission of an application to regulatory approval On average, between Brazil and the USA, the products surveyed demonstrated a delay in the manufacturers' submission for regulatory approval of 1.1 years (393 days). **CONCLUSIONS:** The results of this study indicate that there are significant differences in the regulatory approval timelines between the FDA and ANVISA which raise significant concerns over access to equitable treatment for oncology patients in these two countries. Importantly, although delays in ANVISA approval are significant, the manufacturer's submission timing has also considerably contributed to delayed patient access to new oncology therapies in Brazil.

PCN61
THE IMPACT OF THE U.S. ODAC DECISION ON AVASTIN PRESCRIBING FOR METASTATIC BREAST CANCER
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OBJECTIVES: Breast cancer is the second most common cause of cancer-related death. Women with metastatic disease have low survival rate due in part to the lack of effective treatments. In 2008, the U.S. Food and Drug Administration (FDA) granted an accelerated approval of Avastin to treat metastatic breast cancer (MBC) in combination with paclitaxel. In July 2010, the Oncologic Drug Advisory Committee (ODAC) voted unanimously to withdraw the approval. This decision was contested by many including the European Medicine Agency (EMA) and the National Comprehensive Cancer Network (NCCN). Despite this disagreement, the FDA revoked the approval by the end of 2011. This study examined the impact of ODAC's decision on prescribing practices in 2011. **METHODS:** Truven MarketScan™ claims data from 2006 – 2011 was used as the data source. The sample included women ≥18 years who received specific chemotherapy agent listed in the NCCN treatment guidelines for MBC. A difference-in-difference model compared Avastin use before/after the 2010 ODAC decision using colorectal cancer to form the control group. **RESULTS:** Providers were about 41% (p<0.00) less likely to prescribe Avastin after 2010. Region impacted this associated. Prescribers in North central, South and West were approximately 3.3 – 10.0% (p<0.00) more likely to prescribe Avastin than prescribers in the Northeast. **CONCLUSIONS:** The magnitude of the utilization decrease in 2011 is higher than expected. However, we speculate that conflicting information on Avastin's effectiveness led to greater reliance on the ODAC decision by providers. Only one other study has examined the impact of ODAC and our results are consistent with their findings. The impact of region on prescribing practices may be due to the high concentration of academic medical centers in the North east. The FDA needs to fully understand the impact of their advisory bodies on influencing providers when considering the public's health needs.

PCN62
EVOLUTION OF TREATMENT PARADIGMS IN METASTATIC CASTRATE-RESISTANT PROSTATE CANCER
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OBJECTIVES: The treatment landscape for metastatic castrate-resistant prostate cancer (mCRPC) has changed following the introduction of new agents abiraterone, denosumab and cabazitaxel in 2011, and enzalutamide in 2013. The objective of this study was to quantify treatment trends for mCRPC. **METHODS:** Chart audit data from patients with mCRPC was collected quarterly from 2012 to 2014 from a physician panel of urologists, uro-oncologists and medical oncologists. Data included patient demographics, disease characteristics, and treatment details. Treatment regimens were categorized into: ADT, new oral agents, or chemotherapy. The use of bone-targeted agents (BTAs) was also noted. **RESULTS:** The percentage of mCRPC patients being treated with oral treatments increased from 9% in 2012 to 15% in 2013 to 61% in 2014 across all lines of treatment. The usage of BTA in order to reduce the risk of skeletal related events increased from 61% to 69% to 80% over the three years. In addition, patients are initiating treatment with BTA sooner after confirmation of bone metastases on bones can. The percentage of patients initiating treatment upon confirmation of bone metastases increased by 93% from 2012 to 2014. **CONCLUSIONS:** There has been a strong uptake of new oral agents for the treatment of mCRPC. A greater proportion of patients are receiving BTA as compared with 2012, and physicians are now less likely to delay initiating BTA treatment.

PCN63
ANÁLISIS DEL COMPORTAMIENTO DEL CÁNCER DE MAMA EN UNA ASEGURADORA COLOMBIANA
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OBJECTIVOS: analizar el comportamiento de pacientes con cáncer de mama a partir de la información de gastos y costos reportada en el 2013 en una aseguradora colombiana del régimen contributivo. **METODOLOGÍAS:** a partir de la información de uso de servicios reportados y consolidados en el año 2013, se desarrolló un análisis descriptivo de los pacientes identificados con cáncer de mama afiliados a Coomeva-EPS, los pacientes fueron identificados por los diagnósticos según el código CIE-10. Se estimó, caracterizó e identificaron los costos de atención de cada paciente y sus variaciones por características epidemiológicas, discriminando los resultados por departamento. En el análisis solo se incluyen costos reconocidos dentro del plan de beneficios colombiano. **RESULTADOS:** se identificaron 2692 pacientes únicos con cáncer de mama que correspondería a una prevalencia de 0,092% del total de afiliados, siendo el 98% mujeres con una edad promedio de 55 +/-12,7 años. El costo promedio anual por paciente fue de $10.385.724 con variaciones importantes por regiones, siendo la población atendida en Bolívar la de mayor costo ($19.408.590). Desde el punto de vista de distribución geográfica la mayor cantidad de pacientes se encuentran en Valle del Cauca y Antioquia, pero en proporciones similares según la cantidad de población afiliada. Desde el punto de vista de intervenciones, el 11,92% recibió tratamiento quirúrgico durante ese mismo año. El 49,69% del costo es hospitalario y los medicamentos ambulatorios corresponden al 24,32% del total. **CONCLUSIONES:** el costo promedio por paciente con cáncer de mama equivale a 18,25 veces la unidad de pago por captación para el año 2013 y su alta prevalencia impacta en los costos, siendo el 2,08% del costo total de la prestación en salud para el año y el 46,03% del total de los gastos en cáncer. Con este análisis se justifica el diseño de estrategias de gestión específica.

PCN64
EXPLORATORY ANALYSIS OF APAC VALUES VERSUS RECOMMENDED TREATMENT GUIDELINES FOR METASTATIC NON-SMALL CELL LUNG CANCER (MNSCLC) IN THE BRAZILIAN PUBLIC HEALTHCARE SYSTEM
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OBJECTIVES: Reimbursement of oncology treatments by Brazilian Public Health System (SUS) is controlled by the Authorization for High Complexity Procedures (APAC) system. Each treatment line has an APAC code associated with a specific reimbursement value that should cover all drug expenses in one month. However, with innovation and more expensive drugs that have been launched, these fixed values may not be enough to cover drug expenses. In this context, our objective was to compare costs of recommended treatments with values reimbursed by the APAC system. **METHODS:** We reviewed NCCN (National Comprehensive Cancer Network) guidelines for mNSCLC and analyzed recommended chemotherapy regimens. Regimens costs were calculated and compared to the APAC value for metastatic NSCLC which reimburses only 1,100.00BRL (~343.75USD) per month. Drugs maximum sales price for government without taxes were used. For the drugs that already have generics, calculations were made in two different ways: mean price or the lowest price. The following parameters were used to calculate regimens costs by milligrams approach: age 65, weight 70kg, and body surface 1,70m2. **RESULTS:** Ten different regimens are recommended for metastatic NSCLC, two target therapies, four bevacizumab and two pemetrexed based regimens, and other 3 older regimens. By considering mean costs of drugs whose patents expired, the APAC value does nt cover any regimen. Costs ranged from 574BRL (~179,30USD) to 14,204BRL (~4,439USD). With