to reimbursements, causing a significant growth in costs. Expenses for oncology in 2003-2011 increased by 718% (from €15.4 billion). In December 2011, a cost/QALY threshold was introduced to legislation, creating a barrier to the inclusion of oncology drugs to the Reimbursement list. Following adoption of this legislation, of the 12 drugs registered by the EMA, only 3 oncology drugs were included. The other 9 were rejected. Czech and Slovak patients with limited number of patients by way of individual exceptions, or by participation in clinical trials. CONCLUSIONS: In Czechia, the willingness to pay for an additional unit of care at an average price of €22,553 (2012) was associated with the availability of innovative oncological treatment. The health system in Czechia needs to introduce efficient and transparent mechanisms that enable the treatment of oncology patients in line with the latest medical findings, while keeping expenses for treatment within economic possibilities.

PCN229

INNOVATION MAY DRIVE STREAMLINED ACCESS TO NEW BIOPHARMACEUTICALS ACROSS SOME EU/EMA MARKETS

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OBJECTIVES:timelines with different outcomes. There are some countries that may obtain access to new biopharmaceuticals through early access schemes. Breakthrough and innovative products that are thought to have a profound impact on current standard of care are often eligible for quicker routes to access. This research sought to investigate how these schemes worked, where they were prevalent, and the outcomes of such schemes. METHODS: The research was conducted through in-depth interviews with payers and clinicians across 10 EU/EMA markets. RESULTS: Of the 10 markets studied, 5 countries were identified to have either easier or quicker routes to access for new biopharmaceuticals (e.g., ATU in France or 648/96 in Italy, not mandatory referral in Italy; the “white list” in Norway). Most often, these routes were reserved for products with orphan indications or products that were believed to significantly impact current standards of care. Biopharmaceutical companies need to leverage the opportunity for streamlined access to products. Physicians grasp at the opportunity to use efficacious products as early as possible and companies need to leverage the opportunity for streamlined access to products.

PCN230

HEALTH ECONOMIC IMPACT OF VOLUME DOUBLING TIME AS BIOMARKER IN LUNG CANCER-DIAGNOSIS

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OBJECTIVES: Lung cancer has a continuously bad prognosis in terms of survival and quality of life, usually because of late detection of malignancies. Given an expected increase in the incidence, overall mortality will increase. Early detection and efficient diagnostic planning may offer additional gain in survival. The objective of this study is to estimate the health economic impact of diagnostic procedures and the expected gain by volume-doubling time on low-dose CT as biomarker in suspected lung cancer. A state-transition model is created to simulate the pathway of lung cancer diagnostic procedures, including x-ray, diagnostic CT, PET-CT, bronchoscopy, mediastinoscopy and more. Hospital registries and data from the National Cancer Registry were used to estimate the amount of diagnostic procedures in a cohort of lung cancer patients. Systematic literature search was performed to estimate the diagnostic performance of different modalities. Patient cohort is defined and the pre-test probability for malignancy is estimated through the Swenssen criteria. Probabilistic sensitivity analysis is performed using Monte Carlo Simulations. RESULTS: Diagnostic procedures for patients with suspected lung cancer can count up to almost €3,000 per patient. Pathway was modeled in a microsimulated cohort through Swenssen criteria, leading to a mean chance of malignancy of 40%. Costly steps in the pathway include cervical mediastinoscopy and mutational analysis. Inclusion of NELSON protocol can lead to a reduction in costs. Decision making per patient can reduce overuse of diagnostic modalities. CONCLUSIONS: The diagnostic procedure for suspected lung cancer patients is a costly pathway and can be improved with use of the NELSON screening protocol or personalized selection of diagnostic procedures.

PCN231

HOW SUCCESSFUL HAVE PEDIATRIC INVESTIGATION PLANS BEEN IN STIMULATING RESEARCH FOR PEDIATRIC CANCERS?

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OBJECTIVES: The Drug and Pediatric Medical devices was created in 2007 to encourage further drug development for pediatric diseases, by requiring pharmaceutical companies to submit pediatric investigation plans (PIPs) when submitting the marketing application for a new drug. The objective of this study was to determine how successful this legislation had been in stimulating research in pediatric cancers. METHODS: Current oncology PIPs were manually extracted from the EMA website. A primary indicator for investigator initiated mechanotranslational indication, applicant, decision, decision date, and date of expected completion. Indications for approved PIPs were classified into five categories: brain tumors, diagnostics, leukemias/lymphomas, side effects, and solid tumors. RESULTS: A total of 105 PIPs were found for 110 orphan indications of which 34% (37) of approved PIPs were indicated for solid tumors, including melanomas and malignant tumors; 30% (21) of approved PIPs were indicated for leukemias or lymphomas (12) of approved PIPs were indicated for side effects, such as anti-nausea and neurotoxicity medications; 12% (8) of approved PIPs were indicated for brain tumors; and one oncology diagnostic PIP was also approved. The ramp-up of the PIP program was significant. PIPs approved in 2013 and the first half of 2014 accounted for 34% (37) of all PIPs approved during the study period. CONCLUSIONS: Approved PIPs covered a wide range of pediatric cancers, and the number of approved PIPs increased significantly over time. While the ramp-up of the PIP program indicates that it was successful, it should be stressed that in this area, serious concerns remained regarding the feasibility of the program. For example, there were currently four trials planned for completion between 2015-2020 for extremely rare high grade gliomas. This limitation may compromise the integrity of the PIP program.

PCN232

TREATMENT PATTERNS AND OUTCOMES OF PATIENTS DIAGNOSED WITH OVARIAN CANCER IN THE NETHERLANDS: A REGISTRY STUDY

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OBJECTIVES: Among 1,645 patients treated with chemotherapy for metastatic ovarian cancer (OC) in the Netherlands, the data for the years 2012-2014 was extracted. The study found that 39% (27) of approved PIPs were indicated for solid tumors, including melanomas and malignant tumors; 30% (21) of approved PIPs were indicated for leukemias or lymphomas (12) of approved PIPs were indicated for side effects, such as anti-nausea and neurotoxicity medications; 12% (8) of approved PIPs were indicated for brain tumors; and one oncology diagnostic PIP was also approved. The ramp-up of the PIP program was significant. PIPs approved in 2013 and the first half of 2014 accounted for 34% (37) of all PIPs approved during the study period. CONCLUSIONS: Approved PIPs covered a wide range of pediatric cancers, and the number of approved PIPs increased significantly over time. While the ramp-up of the PIP program indicates that it was successful, it should be stressed that in this area, serious concerns remained regarding the feasibility of the program. For example, there were currently four trials planned for completion between 2015-2020 for extremely rare high grade gliomas. This limitation may compromise the integrity of the PIP program.

PCN233

THE FDA BLACK BOX WARNING DOES NOT REDUCE THE USE OF ERYTHROPOIETIN STIMULATING AGENTS AND INCREASES BLOOD TRANSFUSIONS IN INSURED, LOW INCOME CANCER PATIENTS

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OBJECTIVES: Erythropoietin stimulating agents (ESAs) are useful drugs for treating chemotherapy related anemia to reduce the number of blood transfusions. However, there were unrecognized toxicities of ESAs. These toxicities were finally recognized in 2007 when the FDA issued a black box warning for ESAs. The objective of this study is to determine the effect of the FDA black box warning on ESA use patterns and associated outcomes in insured, low-income cancer patients in South Carolina. METHODS: The merged South Carolina Central Cancer Registry-Medicaid dataset was used to determine the trend of ESA use from 2001-2010. Female Breast, Colon, Rectal, Non-Small Cell Lung cancer patients were identified from the registry. Of those, their chemotherapy status was identified along with ESA use from Medicaid medical claims. The major outcome measures were claims for use of ESAs after chemotherapy and the blood transfusion rate. Logistic regression was used as a quantitative method to determine if the likelihood of receiving ESA treatment was reduced after FDA black box warning. RESULTS: Among 1,645 patients treated with chemotherapy from 2002-2010, the proportion of chemotherapy patients receiving ESA treatment from 56.47% before black box warning to 51.44% after black box warning (p < 0.001). The blood transfusion rate per year during 2002-2007 remained around 10-15% and increased to 31% in 2009. The likelihood of ESA use was reduced by 181% after black box warning issued by FDA after adjusting for demographic and clinical variables. CONCLUSIONS: The black box warning may have been effective in reducing overall ESA utilization in cancer patients taking chemotherapy.

PCN234

TREATMENT PATTERNS AND COSTS OF NEOADJUVANT SYSTEMIC THERAPIES (NAT) FOR EARLY BREAST CANCER (BEC): A RETROSPECTIVE CLAIMS ANALYSIS IN THE U.S.

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OBJECTIVES: Among 1,645 patients treated with chemotherapy for metastatic ovarian cancer (OC) in the Netherlands, the data for the years 2012-2014 was extracted. The study found that 39% (27) of approved PIPs were indicated for solid tumors, including melanomas and malignant tumors; 30% (21) of approved PIPs were indicated for leukemias or lymphomas (12) of approved PIPs were indicated for side effects, such as anti-nausea and neurotoxicity medications; 12% (8) of approved PIPs were indicated for brain tumors; and one oncology diagnostic PIP was also approved. The ramp-up of the PIP program was significant. PIPs approved in 2013 and the first half of 2014 accounted for 34% (37) of all PIPs approved during the study period. CONCLUSIONS: Approved PIPs covered a wide range of pediatric cancers, and the number of approved PIPs increased significantly over time. While the ramp-up of the PIP program indicates that it was successful, it should be stressed that in this area, serious concerns remained regarding the feasibility of the program. For example, there were currently four trials planned for completion between 2015-2020 for extremely rare high grade gliomas. This limitation may compromise the integrity of the PIP program.