for BSC were consistent in the validation MAICs for both OS and PFS. **CONCLUSIONS:** Based on ITCs, evidence suggests nivolumab demonstrates greater overall survival compared to regorafenib, cabozantinib and BSC. Limitations of indirect comparisons without common comparators are acknowledged. As this analysis did not consider comparisons on safety, these findings should be confirmed with real-world evidence evaluating both effectiveness and safety outcomes.

PCN18

TREATMENT OF POST-MENOPAUSAL ADVANCED BREAST CANCER: NETWORK META-ANALYSIS USING SECOND-ORDER FRACTIONAL POLYNOMIALS MODELS

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OBJECTIVES: A multi-dimensional approach to evidence synthesis has previously been explored as an alternative to analysis of hazard ratios (HR) frequently used for time-to-event data. The objective of this study was to explore and compare results using a more complex approach to network meta-analysis (NMA) with those using conventional methods. The methods were applied to an evidence base previously identified to evaluate comparative efficacy for the treatment of advanced breast cancer in postmenopausal women following failure of prior endocrine therapy. **METHODS:** Data were identified from a published systematic literature review previously conducted in this population; these data were synthesised within a Bayesian NMA utilising fractional polynomial models to estimate relative efficacy between different interventions for overall survival. Kaplan–Meier curves reported by all studies were digitised to recreate virtual individual patient data. Extrapolated long-term survival profiles, expected (mean) survival and ranking probabilities were also estimated for each intervention. **RESULTS:** Seven trials were identified, which assesed seven comparators of interest. Fulvestrant 500 mg was found to be the most effective intervention; mean survival was over 3 years and there was around a 40% chance of fulvestrant 500 mg being ranked as the best treatment over a 10-year time horizon. Findings and trends were consistent with previously published NMAs utilising conventional methodology, synthesising HRs. **CONCLUSIONS:** A comprehensive approach to evidence synthesis may yield more informative, robust and reliable estimates of comparative efficacy than traditional NMA methods analysing trial-level HRs. These efficacy estimates may subsequently be incorporated into cost-effectiveness models without the assumption of proportional hazards between treatment arms that underpins the use of HRs, which have been shown to be a limited measure of treatment effect. An alternative approach to synthesis, utilising fractional polynomials models, may lead to more informed decision-making, which is critical when there are budget constraints associated with reimbursement of new interventions.

PCN20

CONTRIBUTION OF TRASTUZUMAB TO THE PROGNOSTIC IMPROVEMENT OF HER2-POSITIVE EARLY BREAST CANCER IN SPAIN

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OBJECTIVES: The primary objective is to estimate the benefit of adjuvant trastuzumab in the treatment of patients with HER2-positive early breast cancer (HER2+ eBC) in terms of life years gained (LYG) and disease-free life years gained (DFLYG), since its approval in Spain in 2006. The secondary objective is to estimate the incremental cost for the healthcare system, and to compare both parameters. **METHODS:** An epidemiological model that compared two scenarios (with and without trastuzumab) was developed to estimate the benefits and costs associated with adjuvant trastuzumab in HER2+ eBC patient cohorts from 2006 to 2017, with a time horizon until 2035 and a 3% discount rate for both parameters. The effectiveness data used to model the survival curves were obtained from the T (trastuzumab)+CT (chemotherapy) and CT arms of the phase-III BCIRG-006 study. The analysis included direct costs related to the adjuvant treatment (pharmacological, administration and monitoring) and disease recurrence management. **RESULTS:** A total of 35,851 women make up the cohorts from 2006 to 2017. The sum of life years (LY) in the T+CT scenario was 605,358 (525,964 DFLY) versus 564,137 (489,916 DFLY) in the CT scenario, resulting in an estimated 41,221 LYG (36,048 DFLYG) provided by trastuzumab. The general population for the same age range would have generated 704,331 LY. The estimated incremental cost was 880.43 million€ (€24,558.13 per patient) from 2006 to 2035. The incremental cost-effectiveness ratios obtained were €20,644 and €23,960 per LYG and DFLYG, respectively. **CONCLUSIONS:** Our estimations show that adjuvant trastuzumab has substantially improved the survival of patients with HER2+ eBC, contributing over 41,000 LYG to the Spanish society (over 36,000 DFLYG) in an acceptable cost-effective manner. However, the sum of LYG with trastuzumab is still far from the LY estimated for the general population, supporting the need of further advances in HER2+ eBC therapy.

PCN21

COMPARATIVE EFFICACY OF NIVOLUMAB±IPILIMUMAB VERSUS STANDARD OF CARE (SOC) FOR THIRD-LINE (3L) PATIENTS WITH RECURRENT SMALL CELL LUNG CANCER (SCLC) USING POPULATION-ADJUSTED INDIRECT COMPARISON

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OBJECTIVES: To estimate comparative efficacy of nivolumab±ipilimumab versus SOC for SCLC patients treated with two prior lines of chemotherapy/chemo-radiotherapy using a population-adjusted indirect comparison. **METHODS:** A systematic literature review identified no randomized controlled trials evaluating 3L SCLC patients. Therefore, real-world data for this population were obtained from Flatiron Health electronic health record database from Jan-2011 to Sep-2017. The overall survival (OS) Kaplan Meier curve was constructed for a subgroup of SCLC patients who received a 3L treatment, at least one platinum-based regimen, and no immune-oncology agents (SOC n=78) with inclusion/exclusion criteria matched to patients in CheckMate 032. Individual patient data from CheckMate 032 for patients who received 3L nivolumab (n=78) or nivolumab+ipilimumab (n=43), respectively, were used to predict OS controlling for Eastern Cooperative Oncology Group performance status, platinum sensitivity, disease stage (i.e. extensive versus limited), and gender. These covariates were centered using the Flatiron target population. Constant and time-varying hazard ratios (HRs) were explored for the comparisons of interest using fractional polynomial models. **RESULTS:** SCLC chemotherapies (predominantly topotecan) evaluated in Flatiron for the 3L population delivered poor survival outcomes (median=3.8 months [95%CI: 2.8, 4.9]). OS HRs (95% credible intervals) from the naïve unadjusted indirect comparison were: nivolumab versus SOC 0.62 (0.42-0.90); and nivolumab+ipilimumab versus SOC 0.43 (0.27-0.69). Based on the population-adjusted indirect comparison, the HRs were: nivolumab versus SOC 0.68 (0.48-0.96); and nivolumab+ipilimumab versus SOC 0.50 (0.32-0.78). Time-varying hazard ratios were not justified based on the deviance information criteria. Estimates from sensitivity analyses using matched-adjusted indirect comparison were similar. **CONCLUSIONS:** Population-adjusted indirect comparison suggests nivolumab±ipilimumab was more efficacious than SOC for 3L SCLC in terms of OS based on real-word data. An analysis using individual patient data from routine practice observational data to better account for between-study differences in patient characteristics is ongoing.

PCN22

MARKETING AUTHORISATION PRACTICE OF THE EUROPEAN MEDICINES AGENCY (EMA) IN ONCOLOGICAL INDICATIONS

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OBJECTIVES: The objective of analysis was to determine the types of endpoints which were basis for efficacy assessment of medicines used in specific oncological indications. The paper discusses statistical significance of results included in the marketing authorisation applications (MAAs), as well as the availability of overall survival (OS), progression-free survival (PFS) and quality of life (QOL) results after marketing authorisation. **METHODS:** A database of European Public Assessment Reports (EPARs) was searched. The analysis included MAAs for medicines used in oncological indications which were approved by the EMA in 2009-2017. **RESULTS:** The detailed analysis included 125 MAAs (62% - first-time approved, 38% - extensions). The most frequently reported endpoints in the analysed trials were OS (94.4%), PFS (92.8%) and ORR (87.2%). The results of OS were not reached (NR) in 30% of MAAs, mainly in indications characterised by longer survival. The percentage of applications based on statistically significant results in OS differed significantly between hematological and oncological indications (20% vs 65%). There were no available data regarding OS, PFS, QOL in 47.2%, 20.8% and 41.6% of MAAs. The main reason was reporting NR data (for OS) and the lack of results presented in EPAR (for QOL). Post-marketing OS data have been identified for 25.4% of MAAs. In 44 of 125 (35.2%) MAAs, a significant benefit in OS was demonstrated, with a median follow-up of 2.36 year. **CONCLUSIONS:** The choice of endpoints reported in clinical trials depends on the indication and subpopulation. The heterogeneity of oncological indications, in particular in terms of the length of patient survival, is noteworthy. The median follow-up of the analysis was relatively short, in 27 MAAs (21.6%), results still have not been reached (especially in hematological indications), which suggests that an increase in the percentage demonstrating a benefit in OS can be expected in the long-time follow-up.

PCN23

EFFICIENCY OF NIVOLUMAB TREATMENT AFTER PLATINUM CHEMOTHERAPY IN RECURRENT OR METASTATIC SQUAMOUS CELL CARCINOMA OF THE HEAD AND NECK (R/M SCCHN) IN SPAIN

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OBJECTIVES: Over 50% of patients with SCCHN have a recurrence within 2 years. Patients whose disease had progressed within 6 months after platinum-based chemotherapy are eligible for nivolumab therapy in Spain. This analysis aims to explore alternative methods of assessment to capture the full value of nivolumab and comparators in R/M SCCHN. **METHODS:** The relative value assessment (RVA) tool on clinical and economic value of SCCHN therapies is based on results from pivotal trials such as CM-141 (nivolumab vs investigators choice (IC) of SCCHN patients post-platinum) and, in absence of other after platinum-based relevant treatments, EXTREME (cetuximab + platinum + fluorouracil vs platinum-fluorouracil QT), the standard of care (SoC) in untreated R/M SCCHN in Spain. The