meant these patients had greatest propensity for quality-of-life improvements and QALY gains, resulting in the public subsidy recommendation in this patient subgroup by the PBAC in Australia. **CONCLUSIONS:** Patients using MOCS with a baseline ACQ-5 ≥2.0 or AQLQ ≤5.0 are those in whom OM shows optimal cost-effectiveness in the Australian healthcare environment.

PRS31

ECONOMIC EVALUATION OF INDACATEROL IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) FROM THE PUBLIC PAYER PERSPECTIVE IN BRAZIL

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OBJECTIVES: To assess the cost-effectiveness of indacaterol in comparison to tiotropium and formoterol from Brazilian public healthcare system perspective. **METHODS:** A Markov model was designed to project costs and outcomes associated with disease progression of patients with COPD over 3-years time horizon. The model health states are divided by severity of COPD (mild, moderate, severe and very severe) with each of these states divided into three states: no exacerbation, non-severe and severe exacerbations. The target population consists of patients with moderate or severe COPD, and the health states for mild and very severe COPD are included to account for those who improve in first cycle to the mild state and those who progress to very severe state over time. Efficacy data and exacerbation rates were obtained from the pivotal trials. Mortality data for COPD-specific states are based on study by Rutten-van Mölken et al. COPD related medical resource utilization patterns were assessed through clinical experts' panel. Unit costs were extracted from Brazilian official lists. Outcomes are expressed as life years gained (LYG). One-way sensitivity analysis was performed. Annual discount rate of 5% was applied both to costs and outcomes. **RESULTS:** Base case analysis estimated incremental LYG for indacaterol of 0.010 vs. formoterol and 0.006 vs. tiotropium. Indacaterol was cost-saving as compared to tiotropium (incremental cost of -2,667BRL). Comparing to formoterol, the projected ICER was 25,458BRL per LYG. The variables that most influenced the results were time horizon, mortality rates and baseline population. **CONCLUSIONS:** Indacaterol is a valuable alternative for COPD patients, being a cost-saving treatment vs. tiotropium with incremental clinical benefits and lower costs. Versus formoterol, indacaterol has incremental benefit, at a reasonable incremental cost.

PRS32

COST-EFFECTIVENESS OF OMALIZUMAB IN SEVERE UNCONTROLLED ALLERGIC ASTHMA USING RCT AND REAL-WORLD EVIDENCE IN THE DUTCH SETTING

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OBJECTIVES: The objective of this analysis was to compare results of two cost-effectiveness analyses for omalizumab added to standard therapy in severe allergic asthma patients using an RCT (INNOVATE) compared to a real-world, prospective observational study (EXPERIENCE). **METHODS:** A Markov model was developed to examine the cost-effectiveness of add-on omalizumab versus standard care from the perspective of the Dutch health care system over a patient's lifetime. Efficacy data for clinically significant (CS) exacerbations and resource use (hospital admissions, unscheduled physician visits and emergency visits) were derived from INNOVATE or Dutch patients enrolled in EXPERIENCE. Data from each were projected to lifetime with discounted future costs (4%) and outcomes (1.5%). **RESULTS:** For the EXPERIENCE study, the modelled direct medical costs for patients on standard therapy were €77,615, of which 75% was for exacerbation control versus €133,475 for standard therapy + omalizumab, of which 38% was for exacerbation control. Patients on omalizumab had more QALYs than those on standard therapy alone, 12.05 versus 10.47. The resulting ICER was €35,257/QALY for the EXPERIENCE study. The INNOVATE costs were lower in both treatment arms: €22,499 for standard therapy and €58,666 for standard therapy + omalizumab. Costs were lower due to lower rate of CS exacerbations in the RCT where patients had been under best possible control at trial entry. QALYs were similar to the EXPERIENCE study 12.05 and 10.91, respectively; resulting in €31,802/QALY. **CONCLUSIONS:** Decision-makers are often presented with cost-effectiveness evidence from RCTs although they prefer to base decisions on real-world data are preferred. This study is one the first to include both in a re-evaluation dossier. It showed differences in patient characteristics (exacerbation rates and resource use) between the RCT and observational study. However it confirmed the value of omalizumab with similar ICERs, indicating that omalizumab is cost effective in both settings.

PRS33

A COST-EFFECTIVENESS ANALYSIS OF VARENICLINE VERSUS BUPROPRION AND NICOTINE REPLACEMENT THERAPY IN GREECE

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OBJECTIVES: To evaluate the cost-effectiveness of varenicline compared to bupropion and nicotine-replacement therapy (NRT) from a third-party payer (Social Insurance Fund) perspective in Greece. **METHODS:** The Benefits of Smoking Cessation on Outcomes (BENESCO) Markov model was applied to calculate the long-term health and economic benefits of smoking cessation, simulating the incidence and outcomes of smoking-related morbidities to a hypothetical cohort of patients (age- and gender-representative of the Greek population) making a single quit attempt. Demographic, epidemiological, treatment efficacy and economic inputs for the modelled cohort were obtained from the literature and publicly available data from public healthcare databases. The model calculated costs and outcomes for a lifetime perspective, discounted at a 3% discount rate and reported in year 2011 fees and prices. Extensive probabilistic sensitivity analysis was performed to test the robustness of the results. **RESULTS:** The cohort consisted of 819,709 current smokers making a quit attempt. The respective 1year continuous abstinence rates were 22.5%, 15.5% and 15.4% for quitters under varenicline, NRT and bupropion. For a lifetime horizon, varenicline prevented in total 7652 and 7609 additional cases of smoking-related disease (coronary heart disease, stroke, lung cancer, chronic obstructive pulmonary disease) versus NRT and bupropion, respectively. Moreover, varenicline led to a gain of 21,219 QALYs (16,955 life years) and 21,099 QALYs (16,859 life years) for the cohort, compared to NRT and bupropion. Taking direct costs into account, varenicline produced cost-savings against both comparators for the lifetime as well as for shorter (20year) timeframes of analysis. The probabilistic sensitivity analysis corroborated the study outcomes. **CONCLUSIONS:** Taking into account the Social Security perspective in Greece, varenicline was a dominant smoking cessation strategy compared to NRT and bupropion, reducing both treatment costs and smoking-related morbidity.

PRS34

COST-EFFECTIVENESS OF ROFLUMILAST (DAXAS®) IN THE TREATMENT OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) IN SPAIN

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OBJECTIVES: To estimate the cost-effectiveness of roflumilast (Daxas®) versus the most prescribed drug combination in Spain in the treatment of adult patients with severe chronic obstructive pulmonary disease (COPD) with a history of frequent exacerbations. **METHODS:** A Markov model was constructed to estimate the life time cost-effectiveness of roflumilast plus a long acting muscarinic antagonist (roflumilast + LAMA) versus the combination of LAMA with a long-acting beta agonist plus and an inhaled corticosteroid (LAMA+LABA/ICS). Outcomes were expressed as the incremental cost per exacerbation avoided from the Spanish National Health System perspective using a life-time horizon (30 years). Other health outcomes in the model include quality-adjusted life year (QALY) gained and life years (LY) gained. The key inputs to the model are based on roflumilast pivotal clinical trials and published epidemiological and population data. Uncertainty in the model's parameters was examined by sensitivity analysis. **RESULTS:** The results of the economic analysis have demonstrated that over the lifetime of the treatment of patients with severe COPD and associated chronic bronchitis with a history of frequent exacerbations, the roflumilast + LAMA strategy will cost 3468 € less than using LAMA + LABA/ICS. Over a lifetime a patient treated with a roflumilast + LAMA is estimated to have 1.23 exacerbations less and 0.129 more QALYs that a patient treated with LAMA + LABA/ICS. Therefore, the roflumilast treatment arm appears to be the dominating option. The sensitivity analyses showed that the variable that has the most impact on the ICER results is the relative risk of exacerbations. **CONCLUSIONS:** Roflumilast + LAMA offers a cost-effective option for the maintenance treatment of severe COPD associated with chronic bronchitis in patients with a history of frequent exacerbations compared with LAMA + LABA/ICS.

PRS35

ECONOMIC EVALUATION OF INDACATEROL VERSUS TIOTROPIUM OR FORMOTEROL FOR PATIENTS WITH MODERATE TO SEVERE COPD IN GREECE

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OBJECTIVES: Evaluate the cost-effectiveness of indacaterol (Onbrez Breezhaler, 150μg & 300μg) against tiotropium (Spiriva, 18μg) or formoterol (Foradil, 12μg twice daily) respectively. **METHODS:** A Markov model was developed describing each COPD disease severity stage based on pre-bronchodilator FEV_1 measurements reported in the indacaterol clinical trials (INVOLVE & INHANCE). The outcomes assessment criteria were Quality-Adjusted Life-Years (QALYs), Life Years Gained (LYG) and exacerbation rates. A 3-year time horizon was used for the cost-utility analysis (CUA) and a lifetime (25 year) time horizon was used for the cost-effectiveness analysis (CEA). Discount rates of 3.5% were set for both costs and outcomes and univariate sensitivity analyses were conducted. Resource utilization was based on Greek published data and relevant costs on official NHS prices. **RESULTS:** The mean number of QALYs per patient in the three-year CUA was 2.152 in the indacaterol 150μg arm and 2.144 in the tiotropium arm, resulting in 0.0078 QALYs in favor of indacaterol; the total costs per patient were €9,717 in the indacaterol arm and €9,853 in the tiotropium arm, resulting in €136 savings in favor of indacaterol, gaining the dominant position (lower total costs, better outcomes). The CEA over the lifetime is similarly dominant with 10.213 LYG for indacaterol and 10.119 LYG for tiotropium and a lower cost per patient for indacaterol. The CUA comparing indacaterol 300μg and formoterol also resulted in indacaterol dominating formoterol with an incremental QALY of 0.017 (2.149 and 2.132 respectively) and a cost saving of €48.23 compared to formoterol over 3 years. Similarly, indacaterol dominates the CEA over a life time. Regarding exacerbation rates, although very similar outcomes appeared among treatments, COPD treatment was less costly with indacaterol against all other comparators. **CONCLUSIONS:** For patients with moderate to severe COPD, indacaterol represents a cost-effective treatment and is potentially cost saving for the Greek NHS.

PRS36

THE COST-EFFECTIVENESS OF STEP DOWN FROM HIGH DOSE ICS/LABA COMBINATION THERAPY IN ASTHMA IN THE UK SETTING

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OBJECTIVES: According to international guidelines on the management of asthma (GINA), step down to the lowest dose of treatment that maintains control should be considered for controlled patients. The aim of this analysis was to estimate the costs and health outcomes associated with step down of controlled patients on high dose fluticasone/salmeterol (FP/S 1000/100μg daily) dry powder to either extrafine beclometasone/formoterol (BDP/F 400/24μg) pMDI or medium dose FP/S (500/100μg) dry powder in the UK setting. **METHODS:** A patient-level simulation Markov model was defined to perform the simulation of a cohort of patients along three comparative arms (FP/S 1000/100, FP/S 500/100, BDP/F 400/24). Transition probabilities and healthcare resources costs were derived from patient-level data of a recent multinational clinical trial comparing the three treatments. Direct costs and health state utilities were sourced from published literature and UK current prices and tariffs. The analysis was conducted from the UK National Healthcare System perspective, over a six–month time horizon. Probabilistic sensitivity analysis was conducted. **RESULTS:** The analysis showed an ICER (Incremental Cost-Effectiveness Ratio) of 57,300 GBP/QALY (Quality Adjusted Life Year) associated with high dose FP/S 1000/100μg versus extrafine BDP/F 400/24μg and an ICER of approximately 86,300 GBP/QALY associated with medium dose FP/S 500/100μg versus BDP/F 400/24μg. **CONCLUSIONS:** International guidelines recommend that when asthma control is achieved and stabilized, treatment can be stepped down to the lowest possible dose maintaining control. This analysis shows that maintaining controlled patients on high dose FP/S is not a cost-effective strategy. Extrafine BDP/F 400/24μg daily can be considered to be a cost-effective option in the UK to maintain control of asthmatic patients stepped down from high dose FP/S 1000/100μg daily.

PRS37

THE IMPACT OF REGIONAL DATA ON COST-EFFECTIVENESS RESULTS OF SALMETEROL/
FLUTICASONE PROPIONATE (SAL/FP) + FENOTEROL/IPRATROPIUM BROMIDE (FEN/IB) VERSUS FEN/IB ONLY IN COPD TREATMENT

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OBJECTIVES: In order to assess cost-effectiveness of SAL/FP + Fen/IB versus Fen/IB only in chronic obstructive pulmonary disease (COPD) treatment in different Russian regions we developed PHACTOR pharmacoeconomic model. **METHODS:** Our model was based on the constant disease-specific data such as number of COPD exacerbations and health care resource utilization data obtained from PHACTOR (multicenter observational research of severe and very severe COPD). The methodology of PHACTOR research was published in 13th ISPOR Annual European Congress (Research Abstract #PRS31). The following region-specific input data were taken into account: drug prices (from the List of Vital and Essential Pharmaceuticals), medical tariffs (from regional government regulations), gross domestic product (GDP) per capita and average salary (from statistics service). SAL/FP + Fen/IB was compared with Fen/IB only. ICERs (cost per COPD exacerbation avoided) were calculated for all 83 Russian regions. Regional willingness to pay (WTP) was assumed as three regional GDP per capita. **RESULTS:** Average yearly drug costs varied from 29,539 RUR (Belgorod) to 35,264 RUR (Yakutia) for SAL/FP + Fen/IB treatment and from 7,877 RUR (Altai Republic) to 9,442 RUR (Yakutia) for Fen/IB treatment. Estimated yearly costs of COPD exacerbation treatment significantly varied from 6,552 RUR (Evreyskaya AO) to 63,053 RUR (Chukotka) for SAL/FP + Fen/IB treatment and from 12,592 RUR (Evreyskaya AO) to 109,019 RUR (Chukotka) for Fen/IB treatment. SAL/FP + Fen/IB treatment was cost-saving (dominating) in 9 regions and cost-effective in 74 regions (ICER < WTP; in this regions ICERs were from 74 RUR to 4,605 RUR per COPD exacerbation avoided). **CONCLUSIONS:** This analysis demonstrated that regional data had the biggest impact on final cost-effectiveness results. In general case SAL/FP + Fen/IB treatment was cost-effective in most Russian regions and cost-saving in some regions.

PRS38

THE COST-EFFECTIVENESS OF ROFLUMILAST FOR COPD IN SWEDEN

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OBJECTIVES: Daxas (roflumilast) is a new PDE4-inhibitor which targets the underlying inflammation in COPD. It is indicated for treating severe and very severe COPD associated with chronic bronchitis and a history of frequent exacerbations. The objective was to assess the incremental cost-effectiveness of using roflumilast in a Swedish health care setting.The clinical trials for roflumilast have shown that it consistently reduces exacerbations by approx. 20% and that it also provides a lung function benefit of between 46-81 mL in addition to long-acting bronchodilators. **METHODS:** A Markov model with a life time time horizon, one month cycles and a discount rate of 3% was constructed using Treeage and an Excel interface. The model uses comparator treatments relevant to Swedish guidelines including long acting β-2 agonist (LABA), inhaled corticosteroids (ICS) and long-acting muscarinic antagonists(LAMA). All input parameters on costs and epidemiology were from Swedish sources. Clinical effectiveness was based on results from clinical trials along with indirect comparisons to address other comparators relevant to the reimbursement authorities. The analysis had a societal perspective and included lost productivity using a human capital approach. Outcomes were measured in QALYs. Uncertainty was addressed both through probabilistic sensitivity analysis and one-way analyses of central variables. **RESULTS:** Treatment with roflumilast (ROFL) as an add-on to LABA resulted in an incremental gain of 0.35 QALY. From a societal perspective the ICER for LABA+ROFLU versus LABA was €18,000 per QALY. The probability that LABA+ROFLU was cost-effective using a €50 000 threshold was 97%. The ICER for LABA+ROFLU vs LABA+ICS was €14,500. ROFLU+LAMA+LABA+ICS vs LAMA+LABA+ICS was €19,000. **CONCLUSIONS:** The ICERs calculated were all well below commonly accepted willingness to pay for a QALY in Sweden for all different comparator scenarios. The results were stable when central variables were varied. Roflumilast is a cost-effective treatment for severe and very severe COPD.

PRS39

COST-EFFECTIVENESS OF ROFLUMILAST IN COMBINATION WITH BRONCHODILATOR THERAPIES IN PATIENTS WITH SEVERE AND VERY SEVERE COPD IN SWITZERLAND

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OBJECTIVES: Chronic obstructive pulmonary disease (COPD) represents a considerable burden on patients and health systems. Frequent exacerbations in patients with COPD result in high healthcare costs. Roflumilast, an oral, selective phosphodiesterase-4 inhibitor, has been shown to reduce exacerbation rates and improve lung function in patients with severe COPD. The objective of this analysis is to estimate the long-term cost and outcomes of roflumilast added to several bronchodilator regimens in management of severe COPD from a health payer perspective in Switzerland. **METHODS:** A Markov cohort model was constructed to simulate the progression of disease, mortality, and exacerbation rates in patients with COPD. Transition probabilities between severe and very severe COPD were determined from the published literature. Background mortality was expressed through the risk of death in the general population and standardised mortality ratios (SMR); hospital mortality was based on the published literature. A cost-effectiveness analysis was conducted for roflumilast as add-on treatment to LAMA, LABA/ICS and LAMA+LABA/ICS, with the relative ratios of exacerbations rates derived from a recently published multiple-treatment-comparison. Direct costs were sourced from published Swiss data; utilities and disutilities of exacerbations were based on published data. Analysis was conducted from the payer perspective in Switzerland, for a lifetime horizon, with costs and outcomes discounted at 2.5% pa. A range of sensitivity analyses were conducted. **RESULTS:** The added quality-adjusted life years (QALY) and exacerbations avoided were: (0.275 and 2.56); (0.289 and 2.69); and (0.278 and 2.59) for roflumilast added to LAMA, LABA/ICS, and LAMA+LABA/ICS respectively. The incremental cost-effectiveness ratios (ICER) were CHF 18,512 per QALY in LAMA+roflumilast vs. LAMA, CHF 17,083 per QALY in LABA/ICS+roflumilast vs. LABA/ICS, and CHF 19,470 per QALY in LAMA+LABA/ICS+roflumilast vs. LAMA+LABA/ICS. **CONCLUSIONS:** For patients with severe COPD who continue to exacerbate in clinical practice in Switzerland roflumilast can be a cost-effective treatment option.

PRS40

COST-UTILITY OF FLUTICASONE COMPARED WITH BECLOMETHASONE AND BUDESONID IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) IN POLAND

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OBJECTIVES: To evaluate cost-utility of fluticasone compared with beclomethasone and budesonide in COPD treatment in Poland. **METHODS:** A discreet event simulation (DES) model was used to estimate utilities and costs of treatment (medicines, standard hospitalization, ambulatory visit cost for patients with COPD) on fluticasone therapy in comparison to beclometasone and budesonide. Analysis was performed from public payer's perspective with a time horizon of 10 years. Measures of medical effects of the therapies were obtained from a systematic review of RCTs. The range of possible outcomes in the model included: exacerbation, death, FEV_1. Based on the systematic review fluticasone is more effective than beclomethasone and budesonide in terms of FEV_1 improvement. Differences in costs and effects are presented per individual patient, described as statistically significant (SS) or non-significant (NS) and discounted at 5% and 3.5% respectively. Probabilistic sensitivity analysis was performed to estimate the probability that fluticasone is cost-effective in Polish conditions (threshold about 105,000 PLN/QALY). **RESULTS:** The QALY difference between fluticasone and beclomethasone was 0.136 QALY (SS), and the cost difference was 4544 PLN (NS). In deterministic analysis incremental cost per QALY for fluticasone compared with beclometasone was 33,333 PLN. The probability of fluticasone being cost-effective was 88.1%. The QALY difference between fluticasone and budesonide in 10 years perspective was 0.071 (NS). The cost difference was 9,027 PLN (SS). In deterministic analysis incremental cost per QALY for fluticasone compared with budesonide was 127,190 PLN and exceeded the threshold. There was 44.9% chance that the fluticasone therapy was cost-effective in comparison with budesonide therapy. **CONCLUSIONS:** Fluticasone therapy is more effective than beclomethasone (SS) and budesonide (NS). It offers to patients with COPD an additional, pay-off therapeutic option.

PRS41

COST-EFFECTIVENESS ANALYSIS OF IMMUNOTHERAPY IN PATIENTS WITH GRASS POLLEN ALLERGIC RHINITIS

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