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## COST-UTILITY OF RANIBIZUMAB VERSUS AFLIBERCEPT FOR TREATING VISUAL IMPAIRMENT DUE TO DIABETIC MACULAR EDEMA IN GREECE

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**OBJECTIVES:** To conduct a cost-utility analysis of ranibizumab versus aflibercept for the treatment of patients with visual impairment due to diabetic macular edema (DME) in the Greek setting. **METHODS:** A Markov model was adapted to compare the use of ranibizumab 0.5mg (pro re nata-PRN and treat & extend-T&E) to aflibercept 2mg (every 8 weeks after 5 initial doses) in DME. Patients transitioned at a 3-month cycle among nine specified health states (including death) over a lifetime horizon. Transition probabilities, utilities as well as DME-related mortality incorporated in the model were extracted from relative clinical trials, a network meta-analysis and other published studies. The drug acquisition and administration costs as well as the costs of blindness and laser surgery were also incorporated in the analysis. The analysis was conducted from payer perspective and as such only costs reimbursed by the payer were considered (year 2014). Treatment costs and health outcomes were discounted by 3.5% annually. The incremental cost per quality-adjusted life year (QALY) gained and the net monetary benefit was the main outcome measures. Sensitivity analysis was conducted to test robustness of the model. **RESULTS:** The use of PRN and T&E ranibizumab regimens were shown to be cost saving comparing to aflibercept by €2,824 and €22, respectively, and more beneficial in terms of QALYs gained (+0.05) and time without visual impairment (0.031 and 0.034 years), thereby dominating aflibercept. Moreover, ranibizumab used as PRN or T&E resulted in a net monetary benefit of €3,984 and €1,278, respectively. Sensitivity analysis revealed that the net monetary benefit for each regimen remained positive for all tested scenarios. **CONCLUSIONS:** Both PRN and T&E ranibizumab regimens were more beneficial and less costly compared to aflibercept for the management of DME. Hence, ranibizumab seems to be a dominant option for the treatment of visual impairment due to DME in the Greek setting.

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## COST-UTILITY ANALYSIS OF INGENOL MEBUTATE VERSUS IMIQUIMOD 5% FOR ACTINIC KERATOSIS TREATMENT IN SPAIN

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**OBJECTIVES:** To estimate the incremental cost utility ratio (ICUR) for ingenol mebutate vs imiquimod 5% for actinic keratosis (AK) patient's treatment on the face and scalp, in Spain. **METHODS:** A Markov model was used to simulate AK patient treatment evolution for a 5-year horizon from the Spanish National Health System (NHS). Duration of ingenol mebutate treatments was 3 days and 12 days for imiquimod 5%. Effectiveness measure was total clearance rate obtained from indirect mixed comparisons (42.24% for ingenol mebutate and 44.54% for imiquimod) and adjusted according compliance (90% for ingenol mebutate and 60% for imiquimod). Annual recurrence rate (20%) derived from literature. Annual discount rate of 3% was applied for costs and outcomes. Total cost estimation (€,2015) included: drug (retail price VAT included with mandatory deduction), and dermatology visits cost (for adverse events and disease management).Utilities values (0.986 for AK and 1 for clearance) were used to derive quality-adjusted-life years (QALY). Probabilistic and deterministic sensitivity analyses were performed to confirm the robustness of the obtained results. **RESULTS:** Ingenol mebutate showed higher effectiveness than imiquimod 5%, 0.535 vs 0.503 total gained clearances and 4.451 vs 4.449 total QALYs and accounted higher total costs, €551.50 (46% drug cost) versus €527.89 (36% drug cost) compared to imiquimod 5%. Estimated ICUR was €10.906/QALY gained with ingenol mebutate vs imiquimod 5%. In probabilistic sensitivity analysis performed, 78% of simulations yielded an ICUR below €30,000/QALY for ingenol mebutate versus imiquimod. **CONCLUSIONS:** Ingenol mebutato vs imiquimod 5% was an efficient alternative for NHS for patients with AK, on face and scalp, considering an acceptable threshold of €30,000/QALY.

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## HEALTH AND ECONOMIC OUTCOMES RELATED TO DELAY BETWEEN MEDICAL INDICATION AND TREATMENT WITH RANIBIZUMAB IN AGE-RELATED MACULAR DEGENERATION IN GREECE

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**OBJECTIVES:** To examine the impact of delay between indication to treat and injection of ranibizumab for the management of age-related macular degeneration (wAMD), in Greece. **METHODS:** A Markov model was developed to estimate, in a lifetime horizon, the clinical and cost outcomes related to treatment with ranibizumab 0.5mg on a pro re nata protocol: a) "without delay" and b) "with delay" between medical indication and treatment administration. At monthly cycles, patients' visual acuity could increase by 3 lines, remain the same, or decrease by 3 lines. As for the "without delay" arm, the number of injections and transition probabilities were obtained from the CATT trial, while for the "with delay" arm, a one-month delay at first treatment was assumed, based on local experts estimation, and then the delay at re-treatment was indirectly modeled by applying number of injections and transition probabilities as obtained from clinical trials evaluating the efficacy of a quarterly protocol of injections (i.e. PIER trial).The model assumes that patients discontinue treatment after the second year of treatment. Costs related to drug acquisition, administration, monitoring costs and blindness were considered in the analysis (2015).This model predicted: blind-years, quality-adjusted life-years (QALYs), and the direct costs from a payer perspective. **RESULTS:** Treatment without delay was found to be more beneficial compared to "with delay" treatment in terms of QALYs (4,487 vs. 4,190) and blind-years (1,084 vs. 1,511). The total lifetime cost was calculated to be €235 higher in patients treated without any delay, resulting in an ICER of €790 per QALY gained (well-below the threshold of €17,000).The higher drug acquisition cost observed in "without delay" arm was partially offset by the increased non-medical direct cost related to the "with delay" arm. **CONCLUSIONS:** Ranibizumab treatment of wAMD without delay seems to be a strongly cost-effective strategy in Greece.

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## COST-UTILITY OF OMALIZUMAB COMPARED WITH STANDARD OF CARE FOR THE TREATMENT OF CHRONIC SPONTANEOUS URTICARIA (CSU)

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**OBJECTIVES:** Chronic spontaneous urticaria (CSU) is characterised by rapid appearance of wheals, angioedema or both, with no obvious cause and with symptoms lasting for more than six weeks; CSU has a demonstrable negative impact on patient quality of life and societal productivity. The objective of this study was to assess the cost-utility of omalizumab compared with continued standard of care (SOC) for the treatment of patients with moderate or severe CSU with an inadequate response to SOC, from the UK societal perspective. **METHODS:** A Markov model was developed, defined by five disease severity health states and three additional states for relapse, spontaneous remission and death. The model considered 6 month courses of omalizumab treatment, with re-treatment upon relapse (relapse definition: UAS7≥16) and early discontinuation of non-responders (definition of response: UAS7≤6). Clinical and cost inputs were derived from omalizumab trials and published sources; productivity inputs were informed by a non-interventional study and average earnings data. The base case considered a 20-year time horizon, and cost-utility was expressed as an incremental cost-effectiveness ratio (ICER). Scenario analyses included no early discontinuation of non-responders and an altered definition of response (UAS7<16). **RESULTS:** In the base case analysis, the deterministic ICER was £3,183, with omalizumab being associated with increased costs and increased benefit relative to SOC. Probabilistic sensitivity analysis supported this result. Individual scenarios without early discontinuation of non-responders and adjusting the definition of response had little impact on Results(ICERs £4,409 and £5,304, respectively). Further sensitivity analyses demonstrated robustness of Resultsto changes in key model parameters and inputs. **CONCLUSIONS:** To our knowledge, this is the first economic evaluation of omalizumab in CSU from a UK societal perspective. Omalizumab was associated with consistently low ICERs across a range of different scenarios, demonstrating omalizumab to represent a treatment option with societal benefit for CSU in the UK.

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## COST-EFFECTIVENESS OF OMALIZUMAB IN CHRONIC SPONTANEOUS URTICARIA IN THE NETHERLANDS

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**OBJECTIVES:** Chronic spontaneous urticaria (CSU) is a skin disease, with itchy hives that last for at least 6 weeks without an obvious external trigger. Omalizumab has been shown to diminish clinical symptoms and signs. The objective of this study was to determine the cost-effectiveness of omalizumab relative to cyclosporine and standard of care (up to 4 times the daily dose of H1-antihistaminics) for the Netherlands. **METHODS:** A Markov model was used in this study. The model's settings and characteristics of the Dutch patient population were based on an online survey among clinical experts. These values were validated during a clinical expert committee meeting. The GLACIAL trial was used to describe transition probabilities. Data on health care consumption, quality of life and productivity losses were derived from medical records and a survey among 93 Dutch CSU patients. Health care consumption was valued using prices from the Dutch costing manual. Utilities were derived from EQ-5D and calculated using Dutch tariffs. Productivity losses were valued using Dutch wage rates. Comparator treatments were cyclosporine and standard of care. Uncertainty was assessed by one-way sensitivity analyses and probabilistic sensitivity analyses. **RESULTS:** Omalizumab was more effective than cyclosporine (incremental QALYs: 11.3). Incremental costs for omalizumab were €51.052, resulting in an ICER of €4.510 per QALY gained. Compared to standard of care, incremental QALYs for omalizumab were 9.2 and incremental costs were €161.342 (ICER of €17.502/QALY gained). Productivity costs played an important role in the value of the ICER. Probabilistic sensitivity analyses resembled the Resultsfrom the deterministic analyses. **CONCLUSIONS:** Omalizumab is cost-effective compared to both cyclosporine and standard of care. The ICER is well below the implicit cost-effectiveness threshold in the Netherlands, which ranges from €20.000-80.000 per QALY.

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## COST-UTILITY ANALYSIS OF INGENOL MEBUTATE VERSUS DICLOFENAC 3% FOR ACTINIC KERATOSIS TREATMENT IN SPAIN

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**OBJECTIVES:** To estimate the incremental cost-utility ratio (ICUR) for ingenol mebutate vs diclofenac 3% for actinic keratosis (AK) patient's treatment on the face and scalp, and trunk and extremities, in Spain. **METHODS:** A hypothetical cohort of 73 aged AK patients was simulated for a 5-year time horizon with a Markov model. Duration of treatments was 3 days (face-scalp) and 2 days (trunk-extremities) for ingenol mebutate and 90 days (face-scalp and trunk-extremities) for diclofenac. Total clearances rates (42.24% and 34.07% for ingenol mebutate and 24.64% and 25.07% for diclofenac on face-scalp and on trunk-extremities, respectively) obtained from indirect mixed comparisons and adjusted according compliance were used as effectiveness measure. Annual recurrence rate (20%) derived from literature. The perspective of the Spanish National Health System (NHS) was choosen. Total cost estimation (€,2015) included: pharmaceutical cost (retail price VAT included with mandatory deduction), and dermatology visits cost (for adverse events and disease management).A 3% annual discount rate was applied for costs and outcomes. Utilities values (0.986 for AK and 1.00 for clearance) were used to derive quality-adjusted-life years (QALY). Several sensitivity analyses were performed to test model robustness. **RESULTS:** Ingenol mebutate showed higher effectiveness, with 0.192 incremental clearances and 0.011 incremental QALYs (face-scalp), and 0.129 incremental clearances and 0.007 incremental QALYs (trunk-extremities) compared to diclofenac. Total costs accounted were €551.50 and €622.27 (46% drug cost) for ingenol mebutate, compared to €849.11 and € 844.93 (54% drug cost) for diclofenac (for face-scalp and trunk-extremities, respectively). Ingenol mebutate versus diclofenac 3% was dominant on face-scalp and trunk-extremities AK treatment. Further, ingenol mebutate remained a dominant option in 96% (face-scalp) and 91% (trunk-extremities) of the 1,000 MonteCarlo simulations of probabilistic sensitivity analysis. **CONCLUSIONS:** Ingenol mebutate was a dominant strategy for Spanish NHS, compared to diclofenac 3%, for treatment of patients with AK both, face-scalp and trunk-extremities.

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**A COST-EFFECTIVENESS ANALYSIS OF SECUKINUMAB 300 MG VS CURRENT THERAPIES FOR THE TREATMENT OF MODERATE TO SEVERE PLAQUE PSORIASIS IN ITALY**

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**OBJECTIVES:** Secukinumab (SEC300), an IL-17A antibody, was recently approved as highly effective therapy for moderate-to-severe plaque psoriasis (PSO). We examined the cost-effectiveness of SEC300 compared against other systemic biologic drugs: adalimumab (ADA), etanercept (ETA), infliximab (INF), ustekinumab (UST) 45 and 90 mg, and standard of care (SOC - cyclosporine and methotrexate) for plaque psoriasis, in the Italian National Health System (NHS) setting. **METHODS:** A previous cost-effectiveness model was adapted to the Italian healthcare setting. The model was designed to consider the clinical benefits, resource use and costs related to SEC300. A decision tree reflecting response to treatment (PASI change <50, 50-75, 75-90, 90-99, 100) fed into a long-term Markov model with health states related to treatment continuation, dropout, and death. Clinical data (PASI change scores, percentage of adverse events, discontinuation rate) and utility scores were derived from clinical trials as well as from published evidence on Italian patients. The perspective of the model is the Italian NHS, therefore only direct medical costs (drug prices, inpatient and outpatient hospital tariffs, etc.) were taken in account. Both costs and benefits were discounted at 3% according to Italian National Guidelines for Health Economics Evaluations. Incremental cost-effectiveness ratios (ICERs) were calculated. **RESULTS:** At 10 years, SEC300 is a dominant (less costly and more effective) option compared with UST45 and UST90. It is a cost-effective option – with a threshold <€50,000/QALY gained as per National Health Economics Evaluation Guidelines – vs. ADA, IFN, ETA, and SOC with an ICERs of €37,252, €48,949, €21,943 and €41,896, respectively. The sensitivity analysis demonstrated the robustness of model results. **CONCLUSIONS:** The model shows that SEC300 is a costTeffective option when compared to other biologic agents and SOC currently funded by NHS in Italy for the treatment of moderate-to-severe plaque psoriasis.

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**COST-EFFECTIVENESS ANALYSIS OF SECUKINUMAB COMPARED TO USTEKINUMAB IN THE TREATMENT OF MODERATE TO SEVERE PLAQUE PSORIASIS IN THE CZECH REPUBLIC**

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**OBJECTIVES:** Secukinumab (SEC), an IL-17A antibody, is a new highly effective therapy for moderate-to-severe plaque psoriasis (PSO). Ustekinumab (UST) is reimbursed in the Czech Republic under the condition of ≥PASI50 response at week 16. We estimated the cost effectiveness of SEC vs. UST based on different PASI response (dis/continuation) criteria; PASI≥75 for SEC and PASI≥50 for UST. **METHODS:** A decision tree reflecting response to treatment (PASI change <50, 50-75, 75-90, 90-99, 100) fed into a long-term Markov model with health states related to treatment continuation, dropout, and death. Responders at week 16 (defined as PASI≥75 for SEC, PASI≥50 for UST) continued on biologic treatment. Non-responders and drop-outs were switched to standard-of-care (MTX, CyA, emollients). A health-care system perspective with 3% discount rate was adopted. Dosing schedule for maintenance treatment for SEC and UST as 12.0 and 4.35 doses per year was calculated. Baseline patient characteristics and efficacy data were derived from the CLEAR study, a head-to-head 52-week superiority trial (SEC 300 mg vs. UST 45/90 mg). Long-term treatment resistance and dropout were modelled by assuming a 20% annual discontinuation rate. Utility weights for each health state were calculated from EQ-5D measures from the SEC clinical program. **RESULTS:** With a 10-year time horizon, SEC treatment gains 0.05 QALYs and 0.80 years in PASI≥90 with €144 in cost savings vs. UST, reflecting dominance of SEC vs. UST. Absolute (discounted) QALYs, years in ≥PASI90 and costs (discounted) for SEC and UST were 6.84, 2.87, €54,428 and 6.79, 2.08, €54,572, respectively. Probabilistic sensitivity analysis indicated robustness in the Conclusionsof dominance/highly cost-effective approach for SEC vs. UST. **CONCLUSIONS:** Applying stricter criteria for response (i.e., PASI≥75 instead of PASI≥50) for treatment dis/continuation for highly efficacious PSO therapy (SEC) Resultsin overall greater QALYs and cost savings for the health-care system.

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**HEALTHCARE RESOURCE UTILISATION AMONG CHRONIC SPONTANEOUS/IDIOPATHIC URTICARIA PATIENTS– FINDINGS FROM THE FIRST INTERNATIONAL BURDEN OF ILLNESS STUDY (ASSURE-CSU)**

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**OBJECTIVES:** There are limited data on healthcare resource utilisation associated with inadequately controlled chronic spontaneous (idiopathic) urticaria (CSU/CIU) patients. ASSURE-CSU is an observational, multinational study conducted to identify and quantify burden of illness in these patients. Data on resource utilisation for Canada, Germany, UK and the Netherlands are summarised. **METHODS:** This study included a 1-year retrospective medical record abstraction and a cross-sectional patient-reported outcomes survey. Adult CSU/CIU patients with disease persisting for ≥12 months despite treatment were assessed. Data on resource utilisation were extracted from patient medical records, and reported descriptively. **RESULTS:** Medical records were abstracted for 99 patients each in Canada and the Netherlands, 100 in Germany and 83 in the UK. In Canada, 83% patients had one or more visits to a health care professional (HCP) with a total mean (SD) of 3.1 (2.57) annual visits. In the prior 12 months, visits to allergists and dermatologists were reported by 72% and 11% patients. In Germany, 52% patients visited HCPs [annual visits: 3.3 (3.81)]. Hospitalisations and emergency room (ER) visits were reported by 18% and 15% patients. Allergists and dermatologists were visited by 33% and 31% patients. In UK, 86% patients visited HCPs [annual visits: 3.7 (2.68)]. Dermatologists were seen by 54% patients, allergists by 30% and hospital nurses by 10%. HCPs were visited by 87% patients in the Netherlands [annual visits: 4.1 (3.87)]. Visits to dermatologists, allergists and other consultants were reported by 51%, 42% and 13% patients. ER visits and hospitalisations were less frequent in Canada, the UK and the Netherlands compared with Germany. **CONCLUSIONS:** This is the first study to quantify resource utilisation associated with inadequately controlled CSU/CIU. The types of medical resources differ among the countries depending on the local healthcare specificities. Resource utilisation pattern was primarily outpatient but varied across countries.

## SENSORY SYSTEMS DISORDERS – Patient-Reported Outcomes & Patient Preference Studies

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**ECONOMIC BURDEN OF CHRONIC SPONTANEOUS URTICARIA AND PSORIASIS: PATIENTS PERSPECTIVE FROM EUROPE**

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**OBJECTIVES:** Chronic urticaria (CU) (or chronic hives) can be inducible or spontaneous (also known as idiopathic urticaria) (CSU/CIU). Data supporting the impact of CSU/CIU on patients and comparison with other dermatological diseases are scarce. This study evaluated economic burden associated with CU relative to psoriasis (PsO) overall and different severity levels of PsO among the adults in 5 European (France, Germany, Italy, Spain and UK) countries. **METHODS:** Data from patients diagnosed with chronic hives (proxy for CSU) and PsO were collected in the National Health and Wellness Survey (NHWS). Outcome measures included the Work Productivity and Activity Impairment (WPAI) questionnaire and self-reported healthcare use in prior 6 months. Generalized linear models with different link functions were used to compare patients with CU vs. overall PsO (includes all severity levels) and CU vs. moderate-severe-PsO, controlling for patient characteristics. **RESULTS:** Study included 769 CU patients and 7,857 PsO patients (26.9% moderate-severe). CU patients reported non-significant higher rate ratio (RR) of absenteeism (RR=1.31), presenteeism (1.15) and overall work impairment (1.15) than overall PsO, however, activity impairment was significantly higher among CU patients (1.21; p<0.05). The rates of work and activity impairment were similar between CU and moderate-severe-PsO patients (RR: absenteeism; 0.99, presenteeism; 0.97, overall work impairment; 0.97 and activity impairment; 1.08) (all p=NS). Rate of healthcare visits were higher among CU than overall PsO (RR: HCP visits; 1.16, ER visits; 2.13, Hospitalizations; 1.94, all p<0.001) and also than moderate-severe-PsO patients (RR: HCP visits;1.07, ER visits;1.77, Hospitalizations;1.47, all p<0.001). **CONCLUSIONS:** Patients with CU and PsO report a similar negative impact on work ability. Compared to overall PsO patients with CU have a significantly higher impact on daily activities and non-significant higher impairment on work components. The impact on work and activities is similar among CU and moderate-severe PsO. CU patients report significantly higher use of medical resources than Pso.