body weight less or equal to 100 kg who received 45 mg. Additionally, PASI responses from ACCEPT between ustekinumab and etanercept were used. Costs in the model included drug acquisition costs only. RESULTS: In the weight-based efficacy analysis, ustekinumab 45 mg treatment had the highest PASI 75 response. Under a fixed budget of $75,000 per responder, it is possible to treat more patients successfully (achieving a PASI 75) with ustekinumab 45 mg than with etanercept 50 mg biweekly. In both the first year of therapy and in the maintenance year, ustekinumab 45 mg is more cost-effective compared to etanercept 50 mg biweekly. CONCLUSIONS: According to the results of the cost per responder model, ustekinumab 45 mg is more cost-effective than etanercept 50 mg biweekly and therefore a preferable alternative in the treatment of moderate to severe plaque psoriasis in Turkey.

EFFICIENCY (COST/EFFICACY) OF BIOLOGIC AGENTS IN THE TREATMENT OF MODERATE TO SEVERE PSORIASIS

Lázaro P1, Blasco AJ1, Ferrándiz C2, García A3, Liso J4

1Advanced Techniques in Health Services Research (TAISS), Madrid, Spain, 2Universidad Autónoma de Barcelona, Badalona, Barcelona, Spain, 3Universidad Autónoma de Madrid, Madrid, Spain, 4Complutense Hospitalario de Badajoz, Badajoz, Spain

OBJECTIVES: To estimate the cost/efficacy ratios of biologics authorized in Spain in 2009 (adalimumab, etanercept, infliximab and ustekinumab) in the management of moderate-severe psoriasis. METHOD: A model for economic evaluation (decision tree) was built for the treatments according to the available scientific evidence. The payer perspective (National Health System) was used, only considering drug cost and assuming zero cost for placebo. In the case of weight-dependent dosing, the weight of patients was adjusted by age and sex and the standard Spanish population was corrected by the weight increment in individuals with psoriasis. The Psoriasis Area and Severity Index (PASI) 75 criterion (improvement of 75% from baseline PASI) was used as indicator of efficacy. The incremental cost (calculated as the proportion of patients responding with PASI 75 criterion in the biologic group minus the proportion who respond in the placebo group) was assigned according to the outcomes of clinical trials at the period of time defined in the primary efficacy outcome. When more than one trial was available per treatment, a meta-analysis was undertaken (DerSimonian-Laird method). Uncertainty was tested by deterministic sensitivity analysis, building scenarios with the confidence intervals at 95% for costs and efficacy. RESULTS: The incremental cost in the baseline scenario ranged from 31.19% (etanercept: 25 mg twice a week at 12 weeks of treatment) to 78.33% (infliximab: 5 mg/Kg at 24 weeks of treatment). The efficiency in terms of cost/efficacy, in the baseline scenario, ranged from $8,013 (adalimumab at 16 weeks) and $17,981 (ustekinumab: 90 mg at 12 weeks) per PASI 75 responder. In the sensitivity analysis, adalimumab remains as the most efficient biologic on the most and least favourable scenarios. CONCLUSIONS: Of the biologic agents authorized in Spain for treating moderate-severe psoriasis, the most efficient in terms of cost/efficacy is adalimumab.

COST PER RESPONDER OF USTEKINUMAB VERSUS ETANERCEPT IN PATIENTS WITH MODERATE-TO-SEVERE PLACSE PSORIASIS: ANALYSIS FROM THE ACCEPT TRAIL

Feldman SR1, Augustin M2, Martin S3, Stapley P4, Schadel B5

1Wake Forest University, Winston-Salem, NC, USA, 2University Clinics of Hamburg, Hamburg, Germany, 3Centocor Ortho Biotech Services, LLC, Horsham, PA, USA, 4Centocor Research & Development, Inc, Malvern, PA, USA, 5Johnson & Johnson Pharmaceutical Services, LLC, Horsham, PA, USA

OBJECTIVE: To compare the cost per responder of ustekinumab (UST) versus etanercept (ETN) based on head-to-head data from the ACCEPT trial, which demonstrated greater efficacy of two doses of UST, 45 mg and 90 mg at weeks 0 and 4, versus ETN, 50 mg twice weekly through week 12, in patients with moderate-to-severe plaque psoriasis (PsO). METHODS: Efficacy results (proportion of patients achieving at least 75% improvement in the Psoriasis Area and Severity Index [PASI75]) were obtained from the ACCEPT trial (n = 903). Given the unique dosing of UST, 45 mg at weeks 0 and 4 and 90 mg at weeks 0, 4, and 12, we determined the cost per PASI75 response at week 16, the appropriate decision point for determining whether to proceed with a third dose. Week 16 PASI75 results were assumed to be equal to week 12 efficacy from ACCEPT; previously published randomized controlled trials have reported similar observations for both drugs. Dosing through week 12 was per ACCEPT. Dosing for weeks 13–16 was assumed to be per labeled indication in PsO. US wholesale acquisition cost (WAC) was used for calculating costs. The analyses used weight-based efficacy results for UST (45 mg ±100 kg and 90 mg ±100 kg) and overall efficacy for ETN to align with the respective approved labels for each drug. RESULTS: In ACCEPT, 209 patients received UST 45 mg, 347 received UST 90 mg, and 347 received ETN. Baseline demographics and disease characteristics were comparable between groups. Twenty-eight percent of patients were >100 kg. The PASI75 responses at week 12 were 72% for UST 45 mg in patients ≤100 kg and 65% for UST 90 mg in patients >100 kg, compared with 57% for the ETN group. At week 16, the WAC per PASI75 response was $17,909 for UST-treated patients and $19,140 for ETN-treated patients. CONCLUSIONS: WAC per PASI75 response was lower for UST relative to ETN through 16 weeks in PsO patients.

SOMATOTROPHIN DEFICIENCY IN INDIVIDUALS WITH MODERATE TO SEVERE ATOPIC DERMATITIS

Verma S1, Dharmarajan S2, Yang Y3

1University of Mississippi, University, MS, USA, 2University Clinics of Hamburg, Hamburg, Germany, 3Centocor Ortho Biotech Services, LLC, Horsham, PA, USA

OBJECTIVE: To determine the cost-effectiveness of ustekinumab in patients with moderate-to-severe psoriasis in comparison with Etanercept from third-party payer perspective. METHODS: A cost-utility analysis was performed using a Markov model which compared cost per QALY of Ustekinumab (45 mg at week 0 and 4, then every 12 weeks thereafter) and Etanercept (50 mg twice weekly on week 0, then once a week). The probabilities of treatment response were taken from the ACCEPT trial (which compared both the drugs); while utility values for different stages were obtained from published studies. A 12 week paradigm for the base case of each agent was developed on the basis of dosage administration, laboratory monitoring utilized in the Randomized Clinical Trials and manufacturer’s published guidelines. The cost of therapies included 2009 AWAP (average wholesale price) of both the drugs, and cost of physician visits and lab were inflated to 2009 from 2006 Medicare clinical laboratory fee schedule and physician reimbursement schedule (which included mean US reimbursement). Since the time frame of the analysis was only 12 weeks, the costs of long-term side effects and adverse events were not included. Extrapolations were made to evaluate the cost-effectiveness of two drugs over a period of five years, with costs and benefits discounted at 3.3% per annum. Various sensitivity analyses were carried out to test the robustness of the model. RESULTS: The QALYs gained by Ustekinumab in comparison to Etanercept over a period of 5 years were 0.23, at an incremental cost-effectiveness ratio (ICER) of $63,493.59 per QALY gained. Further sensitivity analysis confirmed the robustness of results. CONCLUSIONS: Although as per the present analysis, Ustekinumab might not appear to be more cost effective than Etanercept, but it may be recommended due to modest increase in QALYs and convenient dosage pattern over 12 weeks.
assessed using Cronbach's alpha and intra-class correlation. RESULTS: The mean age was 76.3 (8.9) years, majority of the subjects were female (55.1%), residing in the United States (77.5%) and Caucasian (92.8%). The mean utility value calculated with the VQ-U was 0.68 (0.11), compared to the EQ-SD: 0.88 (0.12), HUI2: 0.81 (0.13), and HUI3: 0.84 (0.11). The VQ-U is associated with HUI2 ($r = 0.22, p < 0.05) but not significantly associated with the EQ-SD or the HUI3. There was no significant correlation between VQ-U and visual acuity in the study eye. The VQ-U varied by known groups using a combination of study and fellow eye visual acuity; the more impaired visual acuity the lower the utility value (more disability and less functioning). Internal consistency reliability for the VQ-U was 0.76 and the intra-class correlation was 0.84. CONCLUSIONS: Utility values calculated from the VQ-U demonstrated greater visual function impairment compared to the HUI and HUI-U. The VQ-U showed good convergent validity with the HUI2, good discriminant validity with visual acuity known groups and good internal consistency and test-retest reliability in individuals with AMD.

**VALIDATION OF THE EYELASH SATISFACTION FOLLOW-UP QUESTIONNAIRE FOR FOLLOW-UP SELF-ASSESSMENT OF EYELASH SATISFACTION**

Burgess S1, Wei T2, Yang MF3, Hansen JF4, Beddington FC5, Hammond G4, Cole J5
1Allergan, Irvine, CA, USA, 2Allergan, Inc, Irvine, CA, USA, 3QualityMetric Incorporated, Lincoln, RI, USA, 4Independent Consultant, Torrance, CA, USA

OBJECTIVES: The Eyelash Satisfaction Questionnaire (ESQ), a static measure, has been previously validated for the assessment of eyelash-specific patient-reported outcomes (PROs). We evaluated its ability to detect changes occurring after a therapeutic intervention. METHODS: The ESQ was initially examined in a 909-person validation sample consisting of online respondents. Confirmatory factor analysis (CFA) was initially used to test the measurement structure of the questionnaire. Item- and scale-level psychometric properties such as item-total correlations, internal consistency, and convergent and discriminant validities were reviewed. The ESQ was then used in a clinical population receiving botulinum ophthalmic solution 0.03%, a product that improves eyelash prominence, during a 16-week randomized, controlled, masked, clinical trial. RESULTS: Initial CFA results revealed a “good fit” based on hypothesized similarity with the factor structure identified in the ESQ. A model using 9 indicators (3 per factor), similar to the structure of the ESQ, was chosen as the optimal method. The final model showed good internal consistency along with convergent and discriminant validities. However, the alpha-removed statistic for the length, fullness, and overall satisfaction (LFOS) construct showed a significant increase in scale consistency with the removal of item 8 (Compared to your first visit, overall, how satisfied are you with your eyelashes now?). Despite this, the model structure was retained to better facilitate comparisons between the ESQ and ESFQ and to provide sufficient measures to properly evaluate the construct. CONCLUSIONS: The 9-item ESQ appears to be a valid measure to assess changes in eyelash-specific PROs. The factor structure showed near equivalence with the ESQ. Future research will involve further validation of the ESQ in response to variations in hypotrichosis etiologies and clinical treatment paradigms.

**COMPARISON OF THE PRO ENDPOINTS FOUND IN LABELING CLAIMS OF PRODUCTS FOR THE TREATMENT OF PSORIASIS WITH THOSE RECOMMENDED BY THE CORRESPONDING EMEA GUIDANCE**

Caron M1, Emsy MP1
1MAP Research Trust, Lyon, France

OBJECTIVES: Our objective was to compare the PRO endpoints recommended by the EMEA for guidance on the clinical investigation of medicinal products indicated for the treatment of psoriasis (CHMP/EWP/24345/2002) published in November 2004, with those used for the approval of medicinal products for psoriasis. METHODS: The EMEA website was searched for identification of all medicinal products approved specifically for psoriasis since 1999. PROlabels was searched to identify the products with a PRO labeling claim. RESULTS: The EMEA guidance specifies that “Patient-assessed drug efficacy may be a secondary or tertiary endpoint in pivotal clinical trials. These measures correspond both to efficacy evaluated by patients and to health-related quality of life (HRQL) scales validated in dermatology.” The guidance quotes simple measures such as symptom improvement, tolerability, cosmetic acceptability, ease of use, patient’s assessment of global improvement, and patient-reported outcome (PRO) measures, including depression, quality of life and patient’s global assessment of disease activity. Conclusions: The EMEA endpoints are generally consistent with the regulatory requirements and scientific literature on psoriasis treatment recommendations. The end result of the PRO endpoints recommended by the EMEA is a compromise between regulatory requirements and scientific evidence on psoriasis treatment.

**SUSTAINED IMPROVEMENT IN SKIN DISEASE-SPECIFIC QUALITY OF LIFE IN PATIENTS WITH MODERATE TO SEVERE PSORIASIS RECEIVING USTERKINUMAB MAINTENANCE THERAPY: LONG TERM OUTCOMES FROM A 52-WEEK, 2-ARM, FREE-CHOICE STUDY**

Leonardi C1, Papp K2, Schenkert B3, Zhao N4, Yalding N4, Kimball A1
1St. Louis University, St. Louis, MO, USA, 2Probi Medical Research, Waterloo, CAN, 3Johnson & Johnson Pharmaceutical Services, LLC, Horsham, PA, USA, 4Centor Research & Development, Inc, Malvern, PA, USA, 5Harvard Medical School, Boston, MA, USA

OBJECTIVES: To assess the long-term impact of ustekinumab (UST) on quality of life (QoL) among patients responding to therapy at wk40. METHODS: In PHOENIX, a psoriasis patient was randomized to UST45 mg (n = 255), UST90 mg (n = 256), or placebo (n = 255). Placebo patients crossed over to receive UST45 mg or 90 mg at wk12. At wk40, UST PASI75 responders were re-randomized to continue the same dose of UST q12 wks or be withdrawn from treatment. After losing 30% of the improvement gained while on UST, patients withdrawn from treatment re-initiated UST at the same dose previously received. The DLQI assessed skin disease-specific QoL (lower scores indicating better QoL) through 3 y results of >5 points was defined as a clinically meaningful change and a score of 10 was considered no effect on patient’s life. RESULTS: 162 patients were re-randomized to UST at wk40 (n = 77.45 mg; n = 85.90 mg; 320 patients were withdrawn from UST at wk40 (n = 141.45 mg; n = 179.90 mg). Among patients re-randomized to UST, mean change from baseline in DLQI score for the 45 mg and 90 mg groups [mean(SD)] was: -9.1(7.0) and -12.0(7.1) at wk76 and -8.6(6.9) and -9.7(6.2) at Year1, respectively. Among re-randomized patients withdrawn, mean change from baseline in DLQI score for those re-randomized to UST at wk76 and Year1 was: -14.5(8.4) and -42.2(7.4) at wk76 and -9.2(2.2) and -28.0(9.3) at Year3, respectively. At wk76 and Year3, 64.0% and 74.7%, and 64.6% and 65.4% of patients in the 45 mg and 90 mg groups, respectively, achieved a DLQI score of 101 at wk76 and Year1, 10.9% and 19.2%, respectively, achieved a DLQI score of 101 at wk76 and Year3, 10.9% and 19.2%, respectively, achieved a DLQI score of 101 at Year3. CONCLUSIONS: The mean DLQI score at wk40 was 25.8% and 20.9% for patients with withdrawal and, 10.8% and 13.9% of patients withdrawn from 45 mg and 90 mg, respectively, achieved these results. In those re-randomized to UST, the proportion of patients in the 45 mg and 90 mg groups who experienced a ≥5 point improvement in DLQI was 73.3% and 78.5% at wk76, and 70.8% and 72.3% at Year3, respectively. CONCLUSIONS: Clinically meaningful QoL improvements are sustained through Year3 among patients responding at wk40 who continued to receive UST q12 wks.