with CZP in workplace and household productivity, and social participation was sustained until 96 wks in PsA patients.

**MUSCULAR-SKELETAL DISORDERS – Health Care Use & Policy Studies**

**PMS5 MARKET ACCESS OF IMPLANTABLE MEDICAL DEVICES - PART II: DECISION MAKERS IN the BIO-MARKETS**

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OBJECTIVES: With rising pressures on health care budgets, health technology assessment (HTA) agencies are increasingly scrutinizing medical devices (MDs) for economic and clinical value. The objective of this study was to identify the level of scrutiny that resulted in many unfavorable recommendations from agencies and only a small proportion of unconditionally favorable reviews. As an extension of our work reported at 2013 ISFOR Annual Congress (Dublin, Ireland), this study aims to: 1) Identify key criteria cited by HTAs to make a favorable or unfavorable decision, as opposed to criteria that were only correlational. 2) Analyze temporal or geographic trends among decision drivers. METHODS: A review of 68 HTAs and reimbursement decisions of implantable MD with a variety of indications was conducted, focusing on decisions published from 2008-2013 identified by Quintiles’ HTA Watch from North America, Europe, and Australia. Clinical, economic, and other factors noted as pivotal to HTA and reimbursement decisions were registered and compared. Importantly, care was exercised to note only the criteria that triggered a HTA to make a favorable or unfavorable decision, as opposed to criteria that were only correlational. RESULTS: Key product attributes affecting HTA decisions include 1) sufficiency and quality of evidence, 2) cost offsets and budget impact, 3) adverse event profiles, and 4) comparison to existing alternatives where available. Notably, 33% of HTA decisions were negative, with many decisions citing insufficient evidence. Additionally, a majority of favorable HTA decisions were reserved in their recommendations, citing a need for additional evidence to uphold the initially favorable recommendation. The relative importance of economic considerations varied across countries. CONCLUSIONS: HTA agencies’ scrutiny of sufficiency of evidence, among other factors, may significantly impact access to medical devices. As such, manufacturers need careful planning to align evidence development, pricing and access plans with HTA agency, payer and pricing authority requirements.

**PMS6 ANTI-TNF BIOSIMILARS INDICATED FOR RHEUMATOID ARTHRITIS ARE INCREASINGLY AVAILABLE IN EUROPE: HOW DO Payers AND Key Stakeholders PERCEIVE THEM?**

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OBJECTIVES: The process of bringing a biosimilar to market in Europe is quicker, easier and cheaper than developing a new biologic. As a class, rheumatoid arthritis (RA) has the greatest number of anti-TNF biosimilar molecules in development, with more expected to follow. This research was focussed on the key issues reported by stakeholders on access plans with HTA agency, payer and pricing authority requirements. As such, manufacturers need careful planning to align evidence development, pricing and access plans with HTA agency, payer and pricing authority requirements.

**PMS7 COMPARISON OF CLINICAL CHARACTERISTICS OF PATIENTS WITH RHEUMATOID ARTHRITIS (RA) RECEIVING BILOGIC MONOTHERAPY AND BILOGIC-CONTAINING COMBINATION THERAPY IN EUROPE**

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OBJECTIVES: To assess the clinical characteristics of patients with RA who received biologic monotherapy (“Mono”) or biologic-containing combination therapy (“Combo”) in Europe. METHODS: A multi-country, multi-center medical chart review study of patients with RA was conducted in 4Q2011 among patients receiving biologic therapy across six European countries. Data were collected from patients participating in a large, randomized clinical trial as well as through the collection of historical data from medical records. RESULTS: 1534 eligible RA patients were assessed; Mono: 428 (28%), Combo: 1106 (72%). Patient characteristics (Mono/Combo) included: age 51.8/51.7; female 71%/75%; weight 68.6/68.5 Kg; top three comorbidities: dyslipidemia (16%/19%), depression/ anxiety (9%/13%), obesity (8%/12%). Time since diagnosis: 68.6/78.2mo. Current line of biologic therapy: first-line 86%/75%, second-line 11%/18%, >third-line 3%/6%. Top three biologics used across countries were: infliximab (28%)/etanercept (66%)/adalimumab (13%); tocilizumab (9%)/certolizumab pegol (7%). Current lab values/disease severity measures: ESR (mm/h) 21/72.2; CRP (mg/l) 10.3/10.3; rheumatoid factor (positive) 84%/87%; anti-CCP (positive) 70%; tender joint count: median 25/9; swollen joint count: median 52/21; Mean DAS 28 3.6/3.3; mean tender joint count 3.5/4.1; mean swollen joint count 2.4/2.6. CONCLUSIONS: In this cohort of RA patients in Europe, the majority of patients on monotherapy and combination therapy had mild disease per physician judgment and were on first-line biologic therapy. Lab measures and joint counts indicated only slightly higher disease burden among combination therapy patients. The relatively high disease burden of patients in the Combo line of therapy may be due to the introduction of more biologics into the market and the need for therapeutic sequencing may warrant further research.

**PMS90 RPPREVENTING THE BURSTING OF THE KNEE ARTHROPLASTY REVIVAL OVER A 20 YEAR HORIZON**

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OBJECTIVES: Knee arthroplasty is the most frequently performed orthopaedic procedure in developed countries, with around 200,000 cases/year in Spain. Despite a decrease after the economic crisis, the number of annual procedures increased recently. Patients with severe knee osteoarthritis (OA) have a high functional disability, pain and costs. The aim of this study was to assess the costs, the functional improvement and the durability of knee arthroplasty in a cohort of patients with OA in a university hospital in Barcelona, Spain.

METHODS: A prospective, longitudinal cohort study was performed on 50 consecutive patients who underwent primary total knee replacement surgery between January 2017 and December 2018. The primary outcome was the cost of the procedure, defined as the total expenses for hospitalization, surgery, medications, and follow-up visits, obtained from the patient's medical records. The secondary outcomes were: functional improvement measured by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and the Knee Injury and Osteoarthritis Outcome Score (KOOS), and durability defined as the number of revisions required within 2 years. The costs were adjusted to the 2018 values using the Spanish consumer price index.

RESULTS: The mean age of the patients was 73 ± 9 years, with 72% women and 28% men. The mean WOMAC score decreased from 79 ± 19 to 39 ± 27 points (p < 0.001), and the mean KOOS score improved from 35 ± 19 to 75 ± 16 points (p < 0.001). The mean number of revisions was 0 ± 0.1 procedures per patient, with no statistically significant differences between the sexes. The mean hospitalization cost was €18,800 ± 7,700, the mean surgery cost was €4,300 ± 2,200, the mean medication cost was €220 ± 100, and the mean follow-up cost was €370 ± 200. The total cost per patient was €23,700 ± 7,800. The mean cost per knee replacement was €29,600 ± 10,600.

CONCLUSIONS: This study demonstrates that knee arthroplasty is an effective and durable treatment for patients with severe OA. However, the high costs of this procedure require careful planning and management to ensure its sustainability in the long term.