with CZP in workplace and household productivity, and social participation were sustained up to 96 wks in PsA patients.

MUSCULAR-SKELETAL DISORDERS – Health Care Use & Policy Studies

PMS55

MARKET ACCESS OF IMPLANTABLE MEDICAL DEVICES - PART II: DECISION DRIVERS AND ACROSS 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 justification. This project focuses on specific biologic devices in terms of level of societal benefit and in many unfavorable recommendations from agencies and only a small proportion of unconditionally favorable reviews. As an extension of our work reported at 2013 ISPOR Annual Congress (Dublin, IR), this study aims to (1) identify key criteria cited by HTA agencies in unfavorable recommendations, (2) note common criteria among reviews that were positive, negative, or positive with reservations, and (3) 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 correlative. 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 things, 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.

PMS63

ANTI-TNF BIOSIMILARS INDICATED FOR RHEUMATOID ARTHRITIS ARE INCREASINGLY AVAILABLE IN EUROPE: HOW DO PAYERS AND KEY STAKEHOLDERS PERCEIVE THEM?

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Objective: 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 focused on the key issues reported by payers and key stakeholders (KOLs) in 2013 in France, Germany, Italy, Spain, and the UK. Method: By Qualitative survey of payers across national, regional and local levels in France, Germany, Italy, Spain, the UK and Netherlands. Collection and analysis of data on (1) current and future attitudes relative to expected biosimilar purchasing systems; and (2) the tools that payers expect to use to drive biosimilar use, assuming this is a payer goal. Results: 1) The method of biosimilar purchase in the short term will vary by the majority of payers and KOLs. 2) Payers are more likely to procure these products, whereas KOLs are more likely to restrict use of biosimilars due to current and future concerns about quality and efficacy. 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 correlative. CONCLUSIONS: Anti-TNF biosimilars are expected to rapidly change in a short timeframe. Anti-TNF biosimilars, this is expected to rapidly change in a short timeframe. Anti-TNF biosimilars, this is expected to rapidly change in a short timeframe.