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MUSCULAR-SKELETAL DISORDERS – Health Care Use & Policy Studies

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THE INTRODUCTION OF BIOSIMILAR MONOCLONAL ANTIBODIES INTO DEVELOPED MARKETS: WHAT ARE PAYERS CONCERNED ABOUT?

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OBJECTIVES: The introduction of biosimilar monoclonal antibodies into the market is thought to be eagerly awaited by payers. This is motivated by the need to constrain prescribing costs due to the ever burdening pressure on health care budgets. The objectives of this research were to explore payers' attitudes towards the introduction of biosimilars into the UK National Health Service, and to identify the key concerns of payers towards the entry of biosimilars into the market. As the UK is widely recognised as a leading health care market the outputs from this research can be applied to other developed markets. **METHODS:** A thorough literature review was carried out identifying the current regulatory stance and other national guidance on the introduction of biosimilar monoclonal antibodies. From this a series of value messages were formulated around four themes: the manufacture of biosimilar monoclonal antibodies, extrapolation of clinical data, generic substitution and interchangeability and pharmacovigilance. These value messages were then tested with national payers to identify key priority areas. **RESULTS:** Payers identified that interchangeability and pharmacovigilance were the priority areas which needed to be addressed at both a national and local level to manage the entry of biosimilar monoclonal antibodies. In particular they identified immunogenicity as a key area of concern due to the long acting nature of biosimilar monoclonal antibodies. They also recommended a greater emphasis on the use of electronic prescribing systems to ensure that the appropriate recording of the originator product or biosimilar is documented and can be traced back to an individual patient. This should be mandated at a national level supported by local hospital protocols. **CONCLUSIONS:** Payers are aware of the introduction of biosimilar monoclonal antibodies into the market. They recognise that a managed entry assisted by the regulatory authorities alongside locally agreed guidance will be crucial to a successful roll-out

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COMPARISON OF CLINICAL CHARACTERISTICS OF PATIENTS WITH RHEUMATOID ARTHRITIS (RA) RECEIVING THEIR FIRST BIOLOGIC IN UK, GERMANY, FRANCE, ITALY AND SPAIN (5EU)

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OBJECTIVES: To assess the clinical characteristics of patients with RA receiving their first biologic in 5EU. **METHODS:** A multi-country multi-center medical chart-review study of RA patients was conducted among physicians (rheumatologists:97%) in hospitals and private practices to collect de-identified data on patients who were recently treated with a biologic as part of usual care. Physicians were screened for duration of practice (3-30 yrs) and patient volume (incl. >2RA biologic patients/week) and recruited from a large panel to be geographically representative in each country. Eligible patient charts (>5) were randomly selected from a sample of prospective patients visiting each center/practice during the screening period. Physicians abstracted patient diagnosis, treatment patterns/dynamics and patient symptomatology/disease status. **RESULTS:** In 1Q2012, 2208 eligible RA patient charts were abstracted; 1562 (71%) patients were on their first biologic (mean-age:50.7yrs, female:71%). Geographic distribution of patients were - UK:19%, Germany:18%, France:22%, Italy:23%, Spain:18%. Time-to-1stbiologic from diagnosis (range:31mo (Italy)-52mo (France)) and time-on-current biologic (range:17month (Italy)-27month (France)) differed within 5EU. The top-3 reasons for biologic treatment initiation were consistent across 5EU ('mechanism of action', 'improve signs/symptoms', 'prevent structural damage'), whereas the next 2 reasons differed (UK/Germany: 'disease worsened' & 'positive personal experience'; France: 'inhibits disease' & 'mode of administration'; Italy: 'frequency of administration' & 'positive personal experience'; Spain: 'positive personal experience' & 'inhibits disease progression'). Key lab measures documented were: ESR (range:20.8mm/h (France)-29.1mm/h (Italy)) and CRP (range:6.9mg/dl (Spain)-15.0mg/dl (UK)). Current disease severity per physician-judgment (mild/moderate/severe) in 5EU were: UK-58%:29%:13%, Germany-50%:44%:7%, France-39%:48%:12%, Italy-47%:49%:4%, Spain-59%:36%:5%. Among patients with available data, current HAQ (range: 0.7(Spain)-1.5(Germany)), DAS28 (range:3.0(Spain)-3.8(Germany)), 100mmVAS (range:23.3(France)-34.8(Italy)) and Total Sharp (range:0.9(France)-3.6(Germany)) differed within 5EU. **CONCLUSIONS:** Among RA patients receiving their first biologic, disease severity differed within 5EU, with patients in Germany with relatively higher burden. Impact of specific biologic treatments on the observed patterns warrants further scrutiny.

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A MULTI-COUNTRY PHYSICIAN SURVEY ON PATIENT ELIGIBILITY AND USE OF BIOLOGICS IN RHEUMATOID ARTHRITIS (RA), ANKYLOSING SPONDYLITIS (AS) AND PSORIATIC ARTHRITIS (PSA) IN EUROPEAN UNION (EU)

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OBJECTIVES: To assess physician assessment of patient eligibility and eventual use of biologics in RA, AS and PsA in EU. **METHODS:** A multi-country physician survey was conducted in 5EU (UK, Germany, Spain, France, Italy) in RA, AS and PsA. Physicians were screened for experience (3-30yrs) and biologic patient

volume (>2RA biologic patients/week, >5AS biologic patients/month, >5PsA biologic patients/month) and recruited from a large physician-panel to be geographically representative in each country. Practice characteristics, patient-volume, physician perceptions and practice patterns were assessed; physicians' target patient population was grouped into 2 categories, based on physician input: Group1 – patients perceived to be eligible for biologics, Group2 – patients who ended up receiving biologics within Group1. Summary statistics across 5EU are reported. **RESULTS:** In the first quarter 2012, 434 physicians (rheumatologists: 97%; internist: 3%) participated in the study. Mean age: 45yrs; female: 35%; exclusively hospital-based practice:71%. Geographic distribution of physicians was: UK-18%, Germany-19%, Spain-19%, France-22%, Italy-22%. Patient volume per physician was: total-1065, RA-207, AS-80, PsA-88. Average frequency of patient encounters were: RA-11wks, AS-12wks, PsA-11wks. Physician global assessment of patient disease severity were (average across patients): RA mild: 35%/moderate: 41%/severe: 23%, AS – mild: 37%/moderate: 39%/severe: 24% and PsA-mild: 37%/moderate:39%/severe: 24%. Physician assessment of patient eligibility and use of biologics were: within RA-mild-patients – Group1: 18%/Group2: 10%, within RA-moderate-patients-Group1: 45%/Group2: 33%, within RA-severe-patients-Group1: 76%/Group2: 66%; within AS-mild-patients-Group1: 20%/Group2: 11%, within AS-moderate-patients-Group1: 48%/Group2: 37%, within AS-severe-patients-Group1: 77%/Group2: 69%; within PsA-mild-patients-Group1: 22%/Group2: 12%, within PsA-moderate-patients-Group1: 51%/Group2: 37%, within PsA-severe-patients-Group1: 76%/Group2: 66%; Among patients who received biologics, Enbrel, Humira and Remicade were the top-3 prescribed medications across RA/AS/PsA. **CONCLUSIONS:** Across the markets, approximately one-tenth of biologic eligible patients (per physician perception) within corresponding disease severity groups did not end up receiving a biologic, across RA/AS/PsA, with the discordance slightly more pronounced within moderate patients. Reasons behind these patterns and the impact on subsequent patient outcomes warrants further scrutiny.

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VALUE-BASED INSURANCE DESIGN INFORMED BY GOVERNMENT RESEARCH: A CASE STUDY OF OSTEOPOROSIS FRACTURES

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OBJECTIVES: To use a mixed-treatment meta-analysis and simulation model to estimate fracture reductions and cost savings achievable from switching osteoporosis patients to more efficacious treatments in a large health plan. **METHODS:** We populated the Bayesian mixed-treatment meta-analysis using studies identified within a recent AHRQ systematic review of anti-osteoporosis agents. We considered anti-osteoporosis drugs included in a health plan's pharmacy benefit, i.e., alendronate, ibandronate, raloxifene, risedronate, and teriparatide and these drugs' effect upon the clinical endpoints of vertebral, hip, and other fractures. We used the results of the meta-analysis to populate a stochastic simulation model to examine a cohort of 13,337 individuals with an osteoporosis diagnosis in a large private health plan. We compared the expected number of vertebral, hip, and other fractures and cost of care (drug and hospitalization costs) between the existing distribution of treatments as identified by claims data and a distribution optimized in accordance with the mixed-treatment meta-analysis. We obtained drug costs from claims data and hospitalization costs from the literature. **RESULTS:** Results from the mixed-treatment meta-analysis suggest that ibandronate and raloxifene are associated with worse outcomes than alendronate, risedronate, and teriparatide across the considered endpoints. Therefore, our simulation switched patients from ibandronate and raloxifene and increased the proportion of patients treated with alendronate, risedronate, and teriparatide. Results suggest a substantial reduction in clinical events and economic savings (18% reduction of clinical events, including a 30% reduction in new hip fractures, a 5% in vertebral fractures, and a 9% reduction in other fractures). We estimate total economic savings to the health plan of over \$750 per covered patient, over \$10 million in aggregate. **CONCLUSIONS:** Opportunities to leverage existing research can help inform value-based pharmacy benefit design. The optimized allocation of treatments can increase the health of beneficiaries while providing savings for payers.

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HIP AND KNEE ARTHROPLASTY: HOW MUCH THESE PROCEDURES IMPACTS IN THE BRAZILIAN HEALTH CARE EXPENDITURES?

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OBJECTIVES: The number of hip and knee arthroplasty has been growing steadily over the last decade because they are effective procedures that improve quality of life and functional capacity and decrease pain. They have been proven to be cost-effective procedures in different countries. The objective of this study is to quantify the number and expenditure with these procedures in Brazil. **METHODS:** We used for the public health care system data from the hospital information system (SIH/SUS) database and for the private health care data from the BI2IM database that has 5 million lives. We used the codes for each of these two procedures as search base. All values are in 2010 Brazilian reais (US\$1.00=R\$ 2.00). **RESULTS:** A total of 20,116 hip and 6,320 knee arthroplasties were performed in the public system and 20,212 hip and 16,206 knee arthroplasties were performed in the private health system. The total expenditure to the Brazilian health system generated by these procedures was R\$ 584,6 millions. For hip procedures the expenses for the public and private systems were respectively R\$ 60,8 millions and R\$ 280 millions. For knee procedures the expenses for the public and private systems were R\$ 15,3 millions and R\$ 228, 5