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ACCESS TO BIOLOGIC TREATMENT IN RHEUMATOID ARTHRITIS IN CENTRAL AND EASTERN EUROPEAN (CEE) COUNTRIES

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OBJECTIVES: To assess and compare patients' access to biologic anti-RA drugs in selected CEE countries (Bulgaria, Croatia, Czech Republic, Estonia, Hungary, Poland, Romania, Russia, Serbia, Slovakia, Slovenia) and to analyse the determinants of differences between countries. **METHODS:** This is a multi-country survey study, based on a combination of desk research and direct contact with national RA stakeholders. Data was collected using a pre-defined questionnaire. Affordability was measured using affordability index, calculated comparing the health care expenditures index to the price index, using Poland as an index of 1. A higher index indicates more limited affordability. **RESULTS:** The percentage of patients on biologic treatment in 2009 was highest in Hungary (5%), followed by Slovenia (4.5%), Slovakia (3.5%), Czech (2.92%), Romania (2.19%), Estonia (1.8%), Croatia (1.4%) and Serbia (1.3%), lowest in Poland (1%). Infliximab, etanercept, adalimumab and rituximab are included in the reimbursement system in all countries (latest in Bulgaria), abatacept and tocilizumab—only in Slovakia. In Slovenia public payer covered 75% of the price, 25% was covered by supplementary health insurance; in Bulgaria public payer covered 50% of etanercept and adalimumab costs, and 75% of rituximab cost. In other countries biological drugs were reimbursed in 100%. Affordability index for biologic drugs was lowest in Slovenia (0.4), followed by Hungary (0.6), Czech Rep. (0.7), Estonia (0.9), while countries with health care expenditures below 500 USD/capita (Bulgaria, Romania and Serbia) had the highest indexes (1.4–1.9). In each country national guidelines defined which patients were eligible for biologic tretament, and some also defined the sequence in which drugs should be used. DAS28 of over 5.1. and failure of 2 or more disease-modifying anti-RA drugs, including methotrexate, are commonly used criteria. **CONCLUSIONS:** The most important factors of limited access to biologic anti-RA treatment CEE region are macroeconomic conditions and restrictive treatment guidelines.

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EVIDENCE APPRAISAL FOR THE TREATMENT OF FIBROMYALGIA: COMPENDIA, GUIDELINES, AND A REVIEW OF CLINICAL TRIALS

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OBJECTIVES: Payers may employ utilization management tools that restrict access to FDA-approved therapies in favor of off-label therapies for treating disorders such as fibromyalgia (FM). It is appropriate to review the body of evidence that exists to support these decisions. We assessed the quality and quantity of published randomized clinical trials (RCTs), as well as reviewed the trial evidence presented in compendia and guidelines, for commonly prescribed FM treatments. **METHODS:** A literature review was conducted using MEDLINE, Cochrane Library, and EMBASE for FM RCTs published January 2000 to June 2009. Two raters reviewed the quality of each RCT using the Jadad Quality Score. RCTs published prior to 2000 and cited in systematic reviews with published Jadad scores supplemented the review. Trial evidence cited in Drugdex and AHFS-DI compendia and the 2005 American Pain Society (APS) guideline were also reviewed. **RESULTS:** The 2000–2009 literature review yielded 19 RCTs; the supplemental review yielded an additional 14 RCTs. When comparing across FM treatments, the FDA-approved therapies reported high-quality scores and had many more study subjects reported in published RCTs compared to off-label therapies. A review of compendia showed pregabalin was the only FM therapy cited in both Drugdex and AHFS-DI. However, the APS guideline, last updated in 2005, recommended off-label therapies and cited gabapentin and the FDA-approved pregabalin as "experimental" treatments for FM. The off-label therapies nortriptyline and cyclobenzaprine were not listed as treatments for FM in either compendia, and many off-label and FDA-approved therapies were not specifically cited in the guideline. **CONCLUSIONS:** Formulary decision-makers should carefully consider the currency and quality of the body of evidence cited in compendia and guidelines, and should compare listings to recent high-quality published RCTs when considering utilization management tools for the treatment of FM.

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HEALTH STATUS, PHYSICIAN, DAY PROCEDURES AND HOPITALIZATION COSTS ASSOCIATED WITH RHEUMATOID-ARTHRITIS IN ONTARIO

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OBJECTIVES: Little is known about the burden of rheumatoid-arthritis (RA). The study objectives were to present an overview of the burden of RA in Ontario using survey and administrative data. **METHODS:** Records of all Ontarians who participated in the Canadian Community Health Survey (CCHS), cycle 1.1 (2000/2001) and provided consent to data linkage were linked to the Ontario Health Insurance Program (OHIP) physician claims database and the Discharge Abstract Database (DAD) In-Patient (i.e. hospitalization) and Day-Procedure databases. Two criteria were used to identify RA patients (N = 233): 1) self-reported physician-diagnosed RA in CCHS; and 2) ICD-9 diagnosis code of RA in OHIP. A control group matched by age and gender was created (N = 688). Socio-demographic variables, medical characteristics, health-related quality of life and one-year physician, day procedures and hospitalization costs were determined. CCHS sample weights were applied to represent the Ontario population. Logistic regressions, Tobit and Generalized Linear Model models were used to identify predictors of medical characteristics, utility and cost data, respectively. Bootstrap techniques were applied for the cost analyses. **RESULTS:** The mean age of the population was 59 years old and 75% were female. Compared to the control group, RA Individuals were statistically more likely to: be obese, reside in an urban community, be female, have more comorbidities and a lower HRQoL. No statistical differences were observed in terms of costs even after covariate adjustment. **CONCLUSIONS:** Although drug costs were not included, these results indicate that the burden of RA is considerable.

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A RETROSPECTIVE STUDY OF INCIDENCE, PREVALENCE, TREATMENT PATTERNS AND COST OF RHEUMATOID ARTHRITIS'S IN TAIWAN USING THE NATIONAL HEALTH INSURANCE DATA

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OBJECTIVES: The aim was to estimate the prevalence of rheumatoid arthritis (RA) between 2003 and 2007, examine the real-life treatment patterns, and estimate the cost of managing RA in Taiwan. **METHODS:** A retrospective analysis of the medical claims data from the National Health Insurance Research Database (NHIRD) from years 2003–2007 was conducted. Eligible patients were defined as having 1) an outpatient visit with ICD9 code = 714.0; 2) an inpatient admission with the ICD9 code = 714.0; or 3) a catastrophic card for RA. Medication records were extracted. Information on treatment with NSAIDs, DMARDs, and bio-DMARDs was extracted from the recorded diagnosis. **RESULTS:** The prevalence rate of RA in Taiwan was found to be around 0.4%. Majority of the patients identified were on NSAIDs (~81%), while the proportion of patients treated with DMARDs increased from 26% to >35% during the study period. In the first year from initial diagnosis, 13% to 17% patients were treated with DMARDs and 75% with NSAIDs. Etanercept was the first bio-DMARD approved for use in RA in Taiwan in 2003; since its introduction, both the number and proportion of RA patients treated with etanercept increased sharply to 2284 by the end of 2007. Out of 2284, TB was reported in 55 patients, 45 of which were new cases. The average duration from starting etanercept to the date of a TB diagnosis was 461 days. The mean cost per person increased from 379 in 2003 to US$703 in 2007, i.e. nearly doubled. **CONCLUSIONS:** The findings provide an estimate of RA prevalence and show the significant medical cost of managing RA to the national health care system in Taiwan. A key limitation of the study is that the claims data do not have biological information on disease status and the medical reasons for treatment failure or discontinuation.

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UTILIZING HEALTH SURVEY AND ADMINISTRATIVE DATA TO ESTIMATE THE BURDEN OF OSTEO-ARTHRITIS IN ONTARIO

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OBJECTIVES: Little is known about the health status and costs of individuals with osteo-arthritis (OA) in Ontario. The study objectives were to estimate the burden of OA in Ontario using health survey and administrative data. **METHODS:** The records of all Ontarians who participated in the Canadian Community Health Survey (CCHS), cycle 1.1 (2000/2001) and provided consent to data linkage were linked to the Ontario Health Insurance Program (OHIP) physician claims database and the Discharge Abstract Database (DAD) In-Patient (i.e. hospitalization) and Day-Procedure databases. OA individuals (N = 4,331) were identified using CCHS 1.1. A control group matched by age and gender was created (N = 1,477). Socio-demographic variables, medical characteristics, health-related quality of life (HRQoL) and one-year physician, day procedures and hospitalization costs were determined. CCHS sample weights were applied to the data to represent the Ontario population. Logistic regressions, Tobit and Generalized Linear Model models were used to identify predictors of medical characteristics, utility and cost data, respectively. Bootstrap techniques were applied for the cost analyses. **RESULTS:** The mean age of the population was 66 years old and 74% were female. Compared to the control group, OA individuals were statisti-