attributable to the institution of Medicare Part D, a national prescription drug benefit program for the elderly instituted at the end of 2005 in the United States. METHODS: We implemented retrospective analyses of pharmacy claims of beneficiaries aged 67–79 years from 2005 to 2006, from a large pharmacy chain in the United States. Subjects aged 61–63 were used a control group in a differences-in-differences approach to account for trends not related to Part D. The final sample represented approximately 2.4 million unique beneficiaries aged 67–79. The main outcomes are: 1) Changes in proportion of total days of therapy dispensed as generics, and 2) changes in prescription utilization for each therapeutic class. RESULTS: Prescription drug use by these beneficiaries increased by 11% from 2005 to 2006. After adjustment for secular trends and other potential confounders, utilization of each therapeutic class was similar in 2005 and 2006. Small increases in drug utilization occurred for several drug classes, ranging from 0.66 pill days (0.46%) for users of nonsteroidal anti-inflammatories (NSAIDs) to 4.64 pill days (1.78%) for users of angiotensin-converting enzyme (ACE) inhibitors. Decreases occurred for anti-diabetic drugs (–2.06 pill days, –0.58%), beta-blockers (–1.24, –0.49%), and benzodiazepines (–5.96 pill days, –3.57%). Overall, beneficiaries were slightly less likely to fill prescriptions for generic drugs vs. brand-name drugs in 2006 compared to 2005 (OR 0.98, 95% CI 0.97–0.98). CONCLUSION: Small increases in prescription drug utilization occurred across numerous drug classes for these Medicare seniors following the implementation of the Medicare Part D Prescription Benefit, while overall market share by drug class did not change significantly. Further analyses are needed to explore the degree to which these changes reflect moral hazard versus beneficial expansions of coverage.


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OBJECTIVES: To quantify and characterize economic-content in pharmaceutical advertisements, and its supporting evidence, in leading American medical journals from 1990-2006. METHODS: Two researchers reviewed all pharmaceutical advertisements in three leading general medical (New England Journal of Medicine, JAMA, and Annals of Internal Medicine) and specialty journals (Circulation, Gastroenterology, Neurology) in three specified months each year for 2000 through 2006. Using a standardized data collection form, we investigated economic claims (e.g., ads using the words “value”, “price”, “savings”, “hospitalization,” etc.), as well as the supporting evidence. This work builds upon our previous research of economic claims from 1990-1999, adding new data and content. RESULTS: We reviewed 3,516 pharmaceutical advertisements (2,144 from 1990-1999 and 1372 from 2000-2006). Economic content occurred in 11.1% of ads in the 1990s, and 7.6% of ads in 2000-2006 (p = 0.0007). From 1997 to 2002, economic advertisements declined (p < 0.0001), and increased again from 2003–2006 (p = 0.0006), with a peak in 1997 at 16.2% and a nadir of 3.9% in 2002. Economic claims appeared with similar frequency in the specialty journal ads across time periods (1990s: 8.6% vs. 2000-2006: 8.5%; p = 0.91), but declined in the general medical journal ads (1990s: 13.0% vs. 2000–2006: 6.4%; p < 0.0001). The presence of supporting evidence for economic claims was similar in the 1990s and 2000s (63.7% vs. 61.5%, p = 0.70), but over time derived less from the Red Book (1990s: 38.7% vs. 2000-2006: 15.6%) and average wholesale price listings (1990s: 51.1% vs. 2000–2006: 6.3%) and more from data on file (1990s: 9.5% vs. 2000–2006: 29.7%) and published studies (1990s: 6.6% vs. 2000-2006: 23.4%). From 2000–06, a small number of ads mentioned patient compliance (2.6%) or persistence (2.0%). CONCLUSION: Drug companies continue to promote health economic messages in medical journal advertisements. Mention of supporting evidence underlying economic claims has not changed over time, though more ads reference published studies.

Podium Session III: Musculoskeletal Disease

MD1

Impact of Anti-Tumor Necrosis Factors on Health Care Resource Utilization in Patients with Immune-Mediated Inflammatory Diseases

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OBJECTIVES: To evaluate the impact of anti-tumor necrosis factor (anti-TNF) therapy on real world health care resource utilization in patients with immune-mediated inflammatory diseases (IMIDs). METHODS: Three groups of patients were identified using claims data from Blue Cross Blue Shield health plans: IMID (rheumatoid arthritis, ankylosing spondylitis, Crohn’s disease, psoriatic arthritis, psoriasis or ulcerative colitis) patients receiving anti-TNF therapy between January 1, 2003 and June 30, 2005 (Group 1); IMID controls without anti-TNF therapy (Group 2); and non-IMID controls (Group 3). The groups were matched for gender, age and geographic region in a 3:1 ratio. All patients had >= 6 months continuous plan enrollment before and >= 12 months after the index date. Health care resource utilizations per patient per month (PPPM) were calculated for the 6-month pre- and 12-month post-index periods. Differences from baseline were compared among three groups. RESULTS: After matching, 27,006 patients (3,970 Group 1; 11,718 Group 2; and 11,318 Group 3) were analyzed. Of these, 61% were female and the average age was 46 years. Group 1 had higher pre-index PPPM resource utilization for all categories than the 2 control groups. However, compared with pre-index utilization, all post-index resource utilization categories, except emergency room visits, showed a significant decrease for Group 1 that was not consistently observed for controls. Inpatient admissions were reduced in Group 1 (~16.28%), versus no change in Group 2, and +4.17% for Group 3. Physician visits were reduced in Group 1 (~5.11%) versus +2.73% in Group 2, and +6.24% for Group 3. Non-anti-TNF prescriptions were reduced in Group 1 (~6.70%) versus +6.75% in Group 2, and +8.02% for Group 3. CONCLUSION: Anti-TNF therapy appears to be associated with a decrease in health care resource utilization. Additional analyses to determine the effectiveness of anti-TNF therapies in patients with IMIDs through clinical, economic, and humanistic assessments are recommended.

Economic Consequences of Providing Rituximab as a Treatment Alternative for Rheumatoid Arthritis in the Netherlands

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OBJECTIVES: A pharmacoeconomic analysis was performed to determine the cost implications of providing rituximab (RTX, a
selective B cell therapy) + methotrexate (MTX) as an alternative for the treatment of patients with an inadequate response to anti-tumour necrosis factor (TNF) therapies in rheumatoid arthritis (RA) in The Netherlands [NL]. This analysis was performed as part of a reimbursement request. Currently RTX is reimbursed according to the Dutch Expensive Hospital Drug Act.

METHODS: A cost-effectiveness model was developed to evaluate the societal costs and clinical outcomes of a standard Dutch treatment sequence either with or without RTX + MTX. The model uses Monte Carlo simulation to generate 10,000 random RA patients who start with 2nd line treatment after an inadequate response to TNF therapy + MTX. Baseline patient characteristics were taken from the RTX registration study, REFLEX. Efficacy data were taken from published literature and were placebo-adjusted to minimise bias from cross-trial comparisons. Dutch observational data were collected in order to determine local treatment patterns and resource utilisation data. Both direct and indirect medical costs were based on official price lists (2005). Costs and benefits were discounted at 4% and 1.5%, respectively. RESULTS: The average lifetime treatment costs per patient in NL were €131,531 for the current treatment sequence and €141,544 when RTX + MTX was added. QALYs gained were 3.76 for the current treatment sequence and 4.4 when RTX + MTX was added. The incremental cost-effectiveness ratio for inclusion of RTX + MTX in the current treatment sequence was €13,903/QALY. CONCLUSION: Adding RTX + MTX to the current treatment sequence is predicted to increase QALYs with a slight increase in overall lifetime costs for the society. These favourable outcomes are driven by the lower annual drug therapy costs compared with other biological alternatives.

OBJECTIVES: To profile the weight change observed in rheumatoid arthritis (RA) patients receiving infliximab, in order to understand the expected change in their dosing requirements over time on treatment. METHODS: A total 3211 RA patients (2436 males [24%], 775 females [76%]) with valid bodyweight and follow-up measurements from the BSRBR were analysed. Weight change was initially modelled by follow-up (FUP) number using ordinary least-squares linear regression adjusted for sex and patient's total number of visits. Standard errors were adjusted for clustering on study ID. RESULTS: The main analysis modelled FUP as a categorical variable. This analysis showed that the change in average bodyweight did not follow a steady slope, but rather was characterized by a rapid, statistically significant increase of about 1 kg on the first visit after baseline followed by a slow, uneven and statistically nonsignificant upward trend over subsequent follow-up visits. This modelling technique gave a significantly better fit (p = 0.006) over that possible if treating follow-up number as a continuous variable. To test for possible biases attributable to drop-out, the analysis was repeated in several subsets of patients who had all completed the same number of follow-up visits. Despite statistically nonsignificant or statistically borderline estimates in these subsets, the findings were similar to those reported in the main results. CONCLUSION: Translating observed bodyweight into an expected number of vials required at each visit using basic 3 mg/kg dosing shows that the observed weight gain in the BSRBR's infliximab patients does not correspond to a statistically significant change in the total number of vials of infliximab required. Although the dosing in real-life clinical practice tends to vary, the results of this analysis demonstrate that the weight gain observed during infliximab treatment of RA patients is unlikely to have an independent, critical impact on the resource implications for these patients as their treatment continues.

MD4
COST-EFFECTIVENESS OF BONE DENSITOMETRY SCREENING COMBINED WITH ALENDRONATE THERAPY FOR THOSE WHO HAVE OSTEOPOROSIS
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OBJECTIVES: To evaluate the cost-effectiveness of bone densitometry screening for Belgian women aged 55 and older combined with 5 years Adalimumab therapy in osteoporotic women (femoral neck t-score ≤−2.5) versus no screening and no treatment. METHODS: A microsimulation Markov model was developed. The model used a lifetime horizon, a Belgian societal perspective and recorded the full patient history by the use of tracker variables. Each prior fracture had an impact on transition probabilities, costs and QALY level. All the model parameters were selected from Belgian literature when available and from systematic literature review otherwise. Analyses were realized at the ages of 55, 60, 65, 70, 75, 80 and 85 years and for women with 0 to 4 clinical risk factors. Sensitivity analyses were run on persistence level. RESULTS: Costs per QALY gained for the screen and treat strategy versus no intervention with optimal persistence and no clinical risk factor were €49,711, €25,392 and €10,487 for the ages of 55, 65 and 75 years respectively. With realistic persistence, these values were respectively €61,373, €35,780 and €14,302. With one clinical risk factor and optimal persistence, these values were €31,320, €11,507 and cost-saving. And with two clinical risk factors, these values were €18,206, €2,588 and cost-saving. CONCLUSION: Universal bone densitometry followed by Alendronate treatment in the presence of osteoporosis seems highly cost-effective (cost per QALY gained ≤€30,000) for women aged 65 and older (with optimal persistence), for women aged 70 and older (with realistic persistence) and for women with at least one clinical risk factor aged 60 or older (even under realistic persistence assumption). We concluded that screening individuals with or more clinical risk factors is more cost-effective than universal screening and should be recommended.

MD3
CHANGES IN BODYWEIGHT AND ASSOCIATED DOSING REQUIREMENTS FOR RHEUMATOID ARTHRITIS PATIENTS RECEIVING INFliximAB—RESULTS FROM ANALYSIS OF THE BRITISH SOCIETY FOR RHematology’s BIologics REgister (BSRBR)
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OBJECTIVES: To understand the expected change in their dosing requirements for the treatment of patients with an inadequate response to infliximab (MD3) therapy [TNF] therapies in rheumatoid arthritis (RA) patients in The Netherlands [NL]. This analysis was performed as part of a reimbursement request. Currently RTX is reimbursed according to the Dutch Expensive Hospital Drug Act.

METHODS: A cost-effectiveness model was developed to evaluate the societal costs and clinical outcomes of a standard Dutch treatment sequence either with or without RTX + MTX. The model uses Monte Carlo simulation to generate 10,000 random RA patients who start with 2nd line treatment after an inadequate response to TNF therapy + MTX. Baseline patient characteristics were taken from the RTX registration study, REFLEX. Efficacy data were taken from published literature and were placebo-adjusted to minimise bias from cross-trial comparisons. Dutch observational data were collected in order to determine local treatment patterns and resource utilisation data. Both direct and indirect medical costs were based on official price lists (2005). Costs and benefits were discounted at 4% and 1.5%, respectively. RESULTS: The average lifetime treatment costs per patient in NL were €131,531 for the current treatment sequence and €141,544 when RTX + MTX was added. QALYs gained were 3.76 for the current treatment sequence and 4.4 when RTX + MTX was added. The incremental cost-effectiveness ratio for inclusion of RTX + MTX in the current treatment sequence was €13,903/QALY. CONCLUSION: Adding RTX + MTX to the current treatment sequence is predicted to increase QALYs with a slight increase in overall lifetime costs for the society. These favourable outcomes are driven by the lower annual drug therapy costs compared with other biological alternatives.

METHODS:

RESULTS: The main analysis modelled FUP as a categorical variable. This analysis showed that the change in average bodyweight did not follow a steady slope, but rather was characterized by a rapid, statistically significant increase of about 1 kg on the first visit after baseline followed by a slow, uneven and statistically nonsignificant upward trend over subsequent follow-up visits. This modelling technique gave a significantly better fit (p = 0.006) over that possible if treating follow-up number as a continuous variable. To test for possible biases attributable to drop-out, the analysis was repeated in several subsets of patients who had all completed the same number of follow-up visits. Despite statistically nonsignificant or statistically borderline estimates in these subsets, the findings were similar to those reported in the main results. CONCLUSION: Translating observed bodyweight into an expected number of vials required at each visit using basic 3 mg/kg dosing shows that the observed weight gain in the BSRBR’s infliximab treatment of RA patients is unlikely to have an independent, critical impact on the resource implications for these patients as their treatment continues.

CV5
FONDAPARINUX (FOND) VERSUS Enoxaparin (ENOX) FOR PREVENTION AND TREATMENT OF VENOUS THROMBOEMBOLIC EVENTS (VTE) IN PATIENTS UNDERGOING MAJOR ORTHOPEDIC SURGERY OF THE LOWER LIMBS (MOSLL) IN GERMANY: ECONOMIC EVALUATION FROM THE HOSPITAL PERSPECTIVE
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OBJECTIVES: To estimate, from the hospital perspective, the cost effectiveness of FOND versus ENOX for prevention and treatment of VTE in MOSLL patients in Germany (42% with total hip replacement, 33% with total knee replacement, 25% with hip-fraction surgery). METHODS: The incremental cost-effectiveness ratio "additional cost for FOND per clinical VTE