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PEGINTERFERON BETA-1a IN THE MANAGEMENT OF RELAPSING-REMITTING MULTIPLE SCLEROSIS IN ITALY: ELEMENTS OF HEALTH TECHNOLOGY ASSESSMENT

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Introduction: Multiple sclerosis (MS) is a condition with a significant economic and social burden that affects young adults in their active working phase. The most recent evaluations show an annual average social cost of €38,000–39,000 per patient. Peginterferon beta-1a, injected every two weeks, is the first approved pegylated interferon beta-1a for the treatment of relapsing remitting multiple sclerosis (RRMS), the most common form of MS. The efficacy and safety of peginterferon beta-1a was demonstrated in the placebo-controlled ADVANCE trial.
Objective: The objective of this study was the cost-effectiveness and the budget impact analysis of peginterferon beta-1a as compared to injectable first-line treatments for RRMS in Italy.
Methods: The cost-effectiveness analysis was developed through a Markov model with lifetime simulation in the perspective of the Italian National Healthcare Service (NHS). An additional scenario analysis was developed to take into account the Italian societal perspective. Outcomes were measured in terms of life years (LYs), quality adjusted life years (QALYs), lifetime costs and incremental cost-effectiveness ratio (ICER). The efficacy of treatments was simulated as reduction of disability progression and relapse rate. A 3.5% discount rate was applied to costs and outcomes. One-way and probabilistic sensitivity analyses were developed and cost-effectiveness acceptability curves generated. The budget impact analysis was conducted with a three-year time horizon with the support of a simple decision-analytic model adopting the perspective of the Italian NHS. Healthcare costs sustained by the Italian NHS to manage the RRMS population (drug treatment, monitoring, relapse management, adverse events management) were calculated over 3 years and compared in two scenarios: the base scenario, based on a mix of interferons-beta and glatiramer acetate to treat RRMS patients, was compared with an alternative scenario where peginterferon beta-1a had an estimated market share of about 4%, 9%, and 13%, in the three years of analysis. The efficacy of treatments was simulated as a reduction of relapse rates. A one-way sensitivity analysis was developed. For both, the cost-effectiveness and the budget impact analyses, efficacy data were derived from a published network meta-analysis and unit costs were based on current prices, tariffs, and the published literature.
Results: In the cost-effectiveness analysis, peginterferon beta-1a was more effective than the comparators in terms of survival (19.94 vs.19.68 to 19.81 discounted LYs, respectively), and QALYs (9.07 vs. 8.06 to 8.55 discounted QALYs, respectively). In the perspective of the Italian NHS, peginterferon beta-1a dominated interferon beta-1a 44 µg and the ICER was € 11,111/QALY vs. interferon beta-1a 30 µg, € 12,604/QALY vs. interferon beta-1a 22 µg, € 10,580/QALY and € 16,702/QALY vs. interferons beta-1b 250 µg and € 22,023/QALY vs. glatiramer acetate 20 mg. In the societal perspective, peginterferon beta-1a was dominant, being more effective and less costly than first-line injectable treatments (interferon beta -1a, interferon beta-1b, glatiramer acetate) for RRMS. The results of the sensitivity analyses confirmed the trend of the base case results. In the budget impact analysis it was estimated that the adoption of peginterferon beta-1a would result in a decrease of total costs. In the base scenario (no peginterferon beta-1a) the total cost to treat Italian RRMS patients was estimated to be approximately € 321.5, € 339.7 and € 357.8 million in years 1, 2, and 3, respectively. In the alternative scenario (adoption of peginterferon beta-1a), the same costs resulted in about € 321.1, € 338.6 and € 356.2 million, respectively. The cumulative budget impact over the three year period resulted in an approximate cost saving of € 3.1 million (about 0.3%). The sensitivity analysis confirmed the robustness and reliability of the base-case results.
Conclusions: Peginterferon beta-1a showed a favourable pharmaco-economic profile versus the first line injectable therapies for the treatment of RRMS, being both cost-effective and financially sustainable, and thus represents an efficient treatment option for RRMS patients in Italy.
Keywords: Cost-Effectiveness Analysis, Budget Impact Analysis, Peginterferon beta-1a, Multiple Sclerosis
Disclosures
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Conflict of interest: S.I., L.G. have received consulting fees from Biogen Italia for analysis conduction; L.S., C.S., E.P., G.V. are employees of Biogen Italia; P.L.C. has received research grants, contributions and fees by Biogen; D.C. is an Advisory Board member of Biogen.

COST MINIMIZATION ANALYSIS OF BoNT-As IN THE TREATMENT OF UPPER LIMB SPASTICITY AND CERVICAL DYSTONIA

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Introduction: Botulinum toxin type A (BoNT-A) injections are recommended for the management of upper limb spasticity (ULS) and cervical dystonia (CD).
Objective: The main aim of this cost minimization analysis (CMA) was to compare the annual cost per patient for three BoNT-As (Botox®, Dysport® and Xeomin®) in the treatment of ULS or CD in Italy. A budget impact analysis (BIA) was also conducted.
Methods: The CMA was conducted from the perspective of the Italian National Health Service. Only direct medical costs (BoNT-A and standard therapy) were considered. By using a Delphi panel of twelve Italian Experts in the treatment of ULS and CD, data was collected about BoNT-As (dose, number of administrations and acquisition prices) and standard therapy (concomitant medications, visits, Day-Hospital, hospitalizations, etc.). Costs were assessed in Euros 2014. A BIA was conducted to evaluate the pharmaceutical expenditure for the three BoNT-As on a five-year time horizon. A sensitivity analysis was also conducted.
Results: The mean annual cost per patient with ULS was €1,840.20 with Dysport®, €2,067.12 with Botox® and €2,171.05 with Xeomin®. The mean annual cost per patient with CD was €1,353.79 with Dysport®, €1,433.12 with Botox® and €1,503.60 with Xeomin®. In the time horizon considered, the substitution process of Botox® and Xeomin® by Dysport® would result in a total saving of €620,000 when treating ULS and a total saving of €481,000 in the case of CD. Sensitivity and probabilistic analyses showed the robustness of results.
Conclusions: From the Italian National Health Service perspective, Dysport® appears to be the cost-saving therapeutic option compared with Botox® and Xeomin® in the treatment of ULS or CD.
Keywords: BoNT-A, Cervical dystonia, Cost-minimization analysis, Upper limb spasticity
Disclosures
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Conflict of interest: P.M.C. is an employee of Ipsen SpA, while the other authors declare that they have no conflict of interest related to the article.

RESOURCE UTILIZATION AND RELATED COSTS OF BIOLOGICS IN REAL LIFE: RESULTS OF A RETROSPECTIVE ANALYSIS

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Introduction: Anti TNF alpha drugs are used to treat immune-mediated inflammatory diseases (IMIDs) such as rheumatoid arthritis (RA), inflammatory bowel disease (IBD), psoriatic arthritis (PsA), psoriasis, and ankylosing spondylitis (AS). In order to have a realistic picture of resource utilization in this setting and to compare therapy costs across different TNF-inhibitors, it is important to take into account the indication and to distinguish between naive, maintenance and switch patients.
Objective: The purpose of this study was to perform a descriptive analysis of patient divided into different therapeutic indications and patient groups (naive, switch and maintenance) in order to provide a real world picture of drug use and costs of anti TNF alpha therapies at hospital level.
Methods: A real-world, retrospective, observational study based on data was performed through administrative database analysis of Messina Hospital on a cohort of 906 patients diagnosed with chronic inflammatory diseases treated between January 1st 2014 and December 31st 2014. Both a pooled analysis and a specific analysis for each indication and disease area (adult rheumatology, pediatric rheumatology, adult gastroenterology, pediatric gastroenterology and dermatology) were performed. In addition, also an economic analysis on treatment drug costs across indications was carried out.
Results: One hundred six (106) patients out of 906 patients were not included in the analysis because of lack of data at follow-up (e.g. due to discontinuation or other causes). The pooled analysis, performed on patients admitted in 2014, showed that of the 800 patients included in the analysis: 190 (23.8%) were treatment-naive patients, 550 (68.8%) were maintenance patients and 60 (7.5%) were switching patients. The average monthly cost was € 778. A huge heterogeneity in average values was recorded across indications and disease areas. The proportion of treatment-naive patients ranged from 17% (in pediatric rheumatology) to 47% (in gastroenterology area). The same variability was found in the switch rates (ranging from 4% in pediatric rheumatology to 15% in adult rheumatology). Similarly, the economic analysis showed that also average monthly costs vary from €1,054 in dermatology (highest monthly cost) to € 729 in adult rheumatology (lowest monthly cost). Finally the economic analysis showed that in general the highest costs were observed achieved in the maintenance group.
Conclusions: The analysis shows high variability across different areas and indications. This is mainly due to patients' characteristics, type of disease, available treatments and their mix. The huge heterogeneity in monthly costs is due to the fact that costs are collected from a real world administrative database, therefore the annual costs depend on real patients' exposure time to treatments. In fact it is important to address this issue in order to correctly assess results of the data analysis, providing evidence based data to appropriately support policy and decision makers choices.
Keywords: Economic burden, Biologic drugs, Real world evidence
Disclosures
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Conflict of interests: D.C. and M.A.V. are employees of MSD Italia. The authors report no other conflicts of interest in this work.

WHAT SIZE MATTERS? MINIMUM CLINICALLY IMPORTANT DIFFERENCE FOR EQ-5D, EQ-5D-VAS AND SF-6D

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Introduction: There is increasing use of health-related quality of life (HR-QoL) measures in clinical trials. However, there is often limited evidence available on the importance of treatment effects observed from generic HR-QoL measures from the perspective of patients. The minimal clinical important difference (MCID) represents the smallest amount of benefit that the patient can recognize and value.
Objective: This working paper is aimed at estimating the Minimum Clinical Important Difference (MCID) of EQ-5D, EQ-5D-VAS and SF-6D in patients with chronic widespread pain.
Methods: Data comes from a previous randomized controlled trial, including patients with chronic widespread pain. Anchor based methods were applied to estimate MCID: Global Change Impression (GCI), patient self-reported statement of improvement and a disease specific scale and Chronic Pain Grade (CPG), were utilized as anchors. The selection of anchors was based on Spearman's correlation coefficient and ANOVA analysis.
MCID estimates were computed by means of regression analysis and ROC curves. Moreover, several non-analytical methods were also applied. Coherent with existing literature, triangulation was used to provide a range of MCID estimates for each HR-QoL measure.
Results: For EQ-5D index, MCID was 0.10 [0.03-0.16]. These estimates were robust with respect to the anchor utilized in the analysis; self-reported improvement and CPG yielded a MCID estimate of 0.09 [0.03-0.13]and 0.10 [0.01-0.14], respectively.
For EQ-5D-VAS score, MCID was 9.56 [0.16-13.51] using GCI as an anchor and 6.48 [2.76-16.09] and 9.37 [9.16-13.81] with self-reported improvement and CPG, respectively. However, in EQ-5D-VAS score analysis CPG was a weak anchor and gave raise to not statistically significant estimates when applying regression analysis.
Finally for SF-6D score, MCID was 0.06 [0.03-0.09]. Estimates were most robust for SF-6D score, for which sensitivity analysis gave 0.06 [0.03-0.08] and 0.05 [0.02-0.09], with self-reported improvement and CPG, respectively.
Conclusions: Overall, MCID estimates for SF-6D were lower than those obtained for EQ-5D index and EQ-5D-VAS.
Keywords: Health-related quality of life, Minimum clinically important difference, Minimum important difference, Smallest worthwhile effect
Disclosures
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Conflict of interest: None.

COST EFFECTIVENESS ANALYSIS OF CEFTOLOZANE-TAZOBACTAM IN COMPLICATED URINARY TRACT INFECTIONS (cUTI) AND COMPLICATED INTRA-ABDOMINAL INFECTIONS (cIAI) SUSTAINED BY GRAM NEGATIVE PATHOGENS

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Introduction: Antibiotic resistance, especially in the case of Gram-negative pathogens, is an important global public health issue and is responsible for many hospital infections and related mortality. According to ECDC data, antibiotic resistance impact is expected to grow in the next few years especially in Italy where a significant increase of Klebsiella strains resistant to carbapenems has been recorded between 2006 and 2013 (from 1% to 34%). This increasing trend is a particularly alarming phenomenon as carbapenems represent the last-line antibiotics for treatment of infections with multidrug-resistant Gram-negative bacteria - including those producing an extended-spectrum beta-lactamase (ESBL). Complicated urinary tract infections (cUTIs) and complicated intra-abdominal infections (cIAIs) sustained by gram negative pathogens have been demonstrated to have significant epidemiological and economic burden. In order to prevent the further development of antibiotic resistant strains (strategy "carbapenem-sparing") there is an urgent need for new antibiotics active against prevalent multidrug-resistant bacteria such as ceftolozane-tazobactam.
Objective: To perform two cost-effectiveness analyses of ceftolozane-tazobactam vs piperacillin-tazobactam (current standard of care) in patients affected by cUTI and cIAI from the perspective of the Italian national health care service (NHS). A lifetime horizon was considered in order to evaluate in a comprehensive way both costs and related effects in the long run.
Methods: Two cost effectiveness analyses in which ceftolozane-tazobactam was compared with piperacillin-tazobactam in patients with cUTI and cIAI were adapted to the Italian context from the National Health Service perspective and applied to a hypothetical cohort of 5000 patients affected by cIAI and cUTI. The analysis time horizon was lifetime. On the basis of the current clinical practice, it was assumed that patients are treated empirically either with ceftolozane-tazobactam or with piperacillin-tazobactam. Data about survival, efficacy, costs were collected through national and international literature. Only direct medical costs (related to drug and hospitalization costs) were considered. The unit costs were obtained from the national tariff lists.
A one way sensitivity analysis on key parameters was performed in order to assess base case results robustness, by varying significant parameters.
Results: In the base case, ceftolozane-tazobactam was cost-effective vs piperacillin-tazobactam in cUTI as it was associated with higher costs and life years (LYs) gain (+0,078 LYs). The analysis performed on a cohort of patients affected by cIAI shows that ceftolozane-tazobactam is dominant as it is leads to lower costs and higher LYs gained compared to piperacillin-tazobactam. These results are confirmed by the one way sensitivity analyses performed.
Conclusions: The analysis shows that the new antibiotic combination represents a sustainable and cost saving alternative compared to the current standard of care. Furthermore, the use of ceftolozane / tazobactam, to support the "carbapenem sparing" strategy, would generate positive externalities that, in the long run, could have a positive impact by leading to a potential decrease in antibiotic resistance in the general population. Thence, the potential value associated with ceftolozane / tazobactam is not just related to direct benefits but also to indirect benefits for the whole community, considering the current increase of the antimicrobial resistance phenomenon recorded at national level.
Keywords: Economic burden, Antibiotic resistance, Cost effectiveness
Disclosures
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REDUCING CD4+ LYMPHOCYTE CELL MONITORING IN HIV-1 STABLE PATIENTS: A FORECAST OF THE COST SAVING

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Introduction: In the clinical management of HIV infection, CD4 cell counts and HIV-RNA copies counts have proved to be the best predictors of disease progression and combined antiretroviral therapy (cART) efficacy.
However, several studies have recently shown that in patients on cART with CD4 >200 cell/mm^3 and HIV-RNA <50 copies/mL frequent (generally quarterly) CD4 cell count monitoring results in limited (or null) clinical relevance.
Objective: The study, based on data referring to all HIV-infected patients > 18 years being treated at two infectious diseases units located in the metropolitan area of Genoa, is intended to investigate whether performing quarterly CD4 cell counts in stable patients is worthwhile and provides a forecast of the cost saving that could be achieved by reducing CD4 monitoring.
Methods: Patients with HIV-RNA <50 copies/mL and CD4 >500 cell/mm^3 throughout 2011 were enrolled and defined as "stable patients". The set of stable patients was observed during a one-year time period, from January to December 2012.
The probability of CD4 cell count dropping below the threshold value of 350 cells/mm^3 was assessed using confidence intervals and Kaplan-Meier survival estimates. Multivariate Cox analysis and logistic regression were implemented in order to identify factors associated with CD4 cell count fall below the threshold value.
The economic consequences of less frequent CD4 cell counts in stable patients were estimated assuming two alternative scenarios: in the first it was assumed that all stable patients were monitored once per year, while in the second scenario stable patients were divided on the basis of the results of the econometric analysis and it was hypothesized CD4 cell counts twice a year for patients characterized by higher risk and CD4 cell counts once a year for the group of "safe" patients.
Results: The results of the statistical analysis indicate that among stable patients the probability of maintaining CD4 >350 cell/mm^3 is more than 98%. Econometric models reveal that HCV co-infection is associated with CD4 fall below 350 cells/mm^3.
Economic evaluation suggests that if all stable patients are monitored once per year the total expenditure would be reduced by 63%, whereas it would be decreased by 50% by monitoring once annually stable patients without HCV and twice a year those patients with HCV co-infection (in the Italian context cost saving is estimated in the range from about € 400,000 to € 500,000 per year).
Moreover, during the period of observation none of the patients have reached the critical value of 200 cells/mm^3 (which is usually considered as the threshold under which to start a prophylaxis against opportunistic infections) and no change in the therapies, as consequence of CD4 decline, has been necessary in the sample at stake. Consequently, the hypothesis of a less frequent monitoring of CD4 cell counts would not have had any consequence in terms of patient prognosis and therapies.
Conclusions: Empirical findings seem to confirm that routine CD4 examinations are unnecessary for stable patients. Indeed, the research supports a recommendation for annual CD4 monitoring in such patient category.
Keywords: Cost, HIV, CD4 monitoring
Disclosures
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REAL WORLD DATA: BIOLOGIC TREATMENT FOR NAIVE PATIENTS IN THE LAZIO REGION

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Introduction: Immune-mediated inflammatory disease (IMID) is a term used to describe a wide array of chronic disorders resulting from an immune-mediated inflammatory pathogenesis. The introduction of new biologic treatments has radically changed the management of these diseases. Due to the high costs of the treatments a strong control and monitoring of claims databases could help decision makers to understand the consequences of their decisions.
Objective: The objective of this work was to identify the cohort of patients starting treatment with biologics in the years 2012-2013 using the claims databases of Lazio region in order to investigate the parameters influencing the biologic treatment expense at regional level.
Methods: Patients were enrolled based on data drawn from the File F and H-OSP (Administrative database) of the Lazio region. Treatment-naive patients were defined as subjects who did not have a prescription in the two years before the index prescription. Patients that switch biologic therapy were defined as those who had an Anatomical Therapeutic Chemical classification (ATC) prescription different than the one at enrolment within one year of the index date. Biologic drug, hospitalization and concomitant drug costs have been included in the analysis. The information sources were linked with a deterministic record linkage and the pathological condition was inferred from the treatment plan prescription of the Lazio region. Treatment adherence was estimated as the number of doses actually prescribed as compared to the number indicated in the Summary of Product Characteristics (SPC); the result from such comparison was divided into 3 groups: low (<60%), adherent (60-110%) and dose increase (>110%). Logistic regression were performed in order to investigate switch predictors.
Results: From a total number of 33027 patients treated with biologic drugs between 2010-2014 in the Lazio region, 3002 were estimated as treatment naive patients (43% male). The most frequently were etanercept (974 patients, 32%), adalimumab (898 patients, 30%) and infliximab (524 patients, 17%). Considering the disease treatment distribution, 857 patients were treated for rheumatoid arthritis (28.55%), 811 for psoriatic arthritis (27.02%), 421 for psoriasis (14.02%) and the remaining patients for other diseases (i.e. ankylosing spondylitis, ulcerative colitis). 332 patients switched biologic therapy, of which 86 (25.8%) within the first 120 days, 97 patients (29.22%) between 120 and 210 days, 82 patients (24.70%) between 210 and 300 days, 67 patients (20.18%) between 300 and 365 days. Total mean adherence was estimated in 87.7%: 21.5% of patients showed a low adherence, 60.4% were adherent and 18.1% were estimated as dose increase patients (11.4% for rheumatic diseases, 32.3% for dermatological diseases and 26.9% for IBD-Inflammatory Bowel Disease). Regression analysis demonstrated that age, sex and total costs are the main driver for switch therapy during the first year of treatment.
Conclusions: The present study provides a map of the current treatment setting with biologics in the Lazio region considering disease, adherence and prescribed treatments.
Keywords: Adherence, Biologic, Claims databases, Dose increase
Disclosures
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Conflict of interest: No conflict of interest.

COST-EFFECTIVENESS OF THE EXTENSION OF SOFOSBUVIR AND LEDIPASVIR BASED REGIMEN TO HCV PATIENTS WITH METAVIR CLASSIFICATION F1 AND F2 AND TO HIV/HCV CO-INFECTED PATIENTS

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Introduction: The new drugs for hepatitis C characterized by direct antiviral action represent a step forward in the treatment of hepatitis C, assuring the nearly total viral eradication. However, priority in the access to the new treatments is currently given to patients with fibrosis F3 and F4 and cost effectiveness in the former stages of the disease is still uncertain.
Objective: To investigate the cost-effectiveness of different treatment strategies where sofosbuvir e ledipasvir are combined in the following patients subgroups: Strategy 1 (F1, F2, F3 and F4 patients) vs. Strategy 2 (only F3 and F4 patients). Such a comparison is performed also for HCV/HIV co-infected patients.
Methods: The economic evaluation has been performed through a Markov Model, populated with two cohorts of 1000 patients each, from the Italian National Health Service (NHS) perspective. The model has a lifetime horizon with annual cycles. The economic evaluation assumes four different price levels for both drugs (€15,000, €30,000, €40,000, €50,000). Costs and utilities are discounted at a 3% rate. A probabilistic sensitivity analysis has been performed to test the robustness of the results. Results, expressed in terms of incremental cost-effectiveness ratio (ICER) have been computed also for a shorter time horizon, namely 30 years.
Results: In the cohort of patients with HIV only, the base case analysis showed that when the drug price is €15,000, Strategy 1 is dominant exhibiting a greater benefit in terms of QALYs gained in the long run. If the price ranges between €30,000, €40,000 and €50,000 ICERs are equal to €3,507/QALY, €8,523/QALY and €13,540/QALY, respectively. The Monte Carlo simulation highlighted that, at the lowest price, ICERs stay under the threshold of € 30,000/QALY gained in almost all the scenarios hypothesized (99.9%). A similar trend has been observed for patients with HIV/HCV co-infection.
Conclusions: The study results show that extending sofosbuvir and ledipasvir treatment to all classes (F1, F2, F3 and F4) of affected patients represents a recommendable investment, and improves the efficiency and the equity of the NHS.
Keywords: Cost-effectiveness analysis, Anti-HCV therapy, Markov Model, Cost/QALY
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