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VP99 Economic Impact Of rpFVIII In The Management Of Acquired Hemophilia A

AUTHORS:

Valentina Lorenzoni, Isotta Triulzi, Giuseppe Turchetti (giuseppe.turchetti@santannapisa.it)

INTRODUCTION:

Acquired hemophilia A (AHA) is a rare coagulation disease characterized by frequent bleeding episodes treated with plasma-derived products and bypassing agents as rFVIIa and aPCC. Similar to the previous plasma-derived porcine FVIII and without its side effects, pFVIII (Obizur®) is a porcine recombinant factor VIII produced with the recombinant DNA technique. The study analyzes the economic impact of pFVIII compared to the other available therapies in order to manage the bleeding episodes in AHA patients.

METHODS:

To assess the impact of the introduction of pFVIII in the market-mix of products for the management of AHA a budget impact analysis was conducted from the perspective of the Italian National Health System (INHS) and considering a three-year time horizon. Consumption of products, products' wastage, needs for additional treatment in case of failure of first line therapy, laboratory tests, hospitalization and drug wastage were considered for cost estimation. Model inputs were derived from literature, preliminary experience with the use of pFVIII for compassionate use, and from the updating of previous evidence by data collected among a panel of clinical experts. Univariate sensitivity analysis was performed to explore overall uncertainties in input parameters.

RESULTS:

The management of a bleeding episode considering conventional treatment is EUR8,229,621 per year, with an overall cost over three years equal to EUR24,688,864. The introduction of pFVIII leads to an overall costs saving ranging from EUR2,253,938 and EUR1,196,985 when the treatment duration is varied between 5 and 6.5 days, according to data from compassionate use or literature, respectively.

CONCLUSIONS:

The model outlined a significant reduction of all the components of direct costs for the INHS when Obizur® is introduced into the market with an ex-factory unit price equal to EUR2.32/IU.

VP100 Disease Modelling Approaches In Multiple Sclerosis

AUTHORS:

Paolo Cortesi, Nilhan Uzman, Matteo Ferrario (matteo.ferrario@roche.com), Lorenzo Giovanni Mantovani

INTRODUCTION:

In the past decades the cost-effectiveness of new effective disease-modifying therapies (DMTs) for Relapsing Remitting Multiple Sclerosis (RRMS) form was assessed through decision analytical models. Recently, new treatment option for the Primary Progressive (PPMS) form was developed. Aim of this work was assessing the similarities and differences of PPMS and RRMS and their impact in the development of decision analytical model for PPMS.

METHODS:

Literature review was performed to retrieve information on natural history of PPMS and RRMS and impact of

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DMTs agents on the progression of these conditions. Further, a review of the published cost-effectiveness models for RRMS was performed. Based on these data, an analysis on the difference and similarities between the two MS forms that could have an impact on the development of decision analytical model for PPMS was performed.

RESULTS:

Based on the analysis, similar structure model used for RRMS could be applied for PPMS. Health states of the model could be based on Expanded Disability Status Scale score as already done for RRMS. The relapse events considered for RRMS should not be included in PPMS model, and no possibility to develop another form, as the Secondary Progressive, should be included. While RRMS models should include at least a second line treatment option due to alternative DMTs available, only first treatment line should be considered for PPMS. Assessing data available to populate the model, poor data on the natural history, utility and cost associated to PPMS were available and assumption or expert opinions will be needed to overcome the lack of robust data.

CONCLUSIONS:

A decision analytical model for PPMS can use a similar structure used in the models for RRMS. However, more robust data on PPMS and some structural change are needed to provide a good tool to assess cost-effectiveness of DMTS in PPMS.

VP101 Medical Devices For Treatment-resistant Hypertension: Health Technology Assessment Report

AUTHORS:

Tom Jefferson, Iosief Abraha, Anna Maria Vincenza Amicosante, Mirella Corio, Antonio Migliore, Roberto Cioni, Stefano Taddei, Corrado Vassanelli, Marina Cerbo (cerbo@agenas.it)

INTRODUCTION:

While optimal medical therapy (OMT) represents the current standard of care for treatment-resistant hypertension, non-pharmaceutical therapeutic approaches, such as renal denervation and carotid baroreceptor stimulation therapy, have been proposed. The present Health Technology Assessment (HTA) project was aimed at assessing benefits and risk of those approaches versus OMT.

METHODS:

A systematic review of evidence on effectiveness and safety was performed together with a review of economic studies. A contextual analysis of market availability and use of the technology in Italy was also performed.

RESULTS:

In Italy, ninety-nine renal denervation procedures were performed in 2014. Ten studies from six trials were included in the review and meta-analysis. No evidence of dominance or increased harms of renal denervation compared to OMT were found. Four economic evaluations were included and reported dominance of renal denervation. These were based on short-term clinical data and three evaluations used the same Markov model assuming dominance of renal denervation. Estimated average prospective cost of the procedure was EUR6,129.90 (range EUR3,821.15 – EUR9,714.23). We updated the results of an earlier assessment published by an Italian Regional agency on carotid baroreceptor stimulation therapy (1). None of the three studies identified as ongoing in 2015 were completed or had published preliminary results and the technology was not assessed further within the present HTA project.

CONCLUSIONS:

Even if follow-up was limited to 6 months, randomised evidence showed no benefits of the procedure. Economic evaluations were unreliable, based on unrealistic assumptions of effectiveness and contrived therapy regimes. Further investment in renal denervation should await the results of well-designed and adequately followed-up trials assessing the impact

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