efficacy outcome versus comparators was 0.74 for first-line or refractory disease therapies and 0.42 for drugs used in maintenance therapy when patients had not progressed after first-line therapy.

**Conclusion and relevance** The health technology assessment processes analysed were heterogeneous. Drug approvals must be balanced between clinical trials and real world evidence. For innovative drugs, clinical trial extensions must be published promptly after efficacy outcome modifications, leading to review of the reimbursement evaluations.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

No conflict of interest.

**1ISG-008 COST EFFICACY ANALYSIS OF ABIRATERONE IN NEWLY DIAGNOSED HIGH RISK METASTATIC CASTRATION SENSITIVE PROSTATE CANCER**

A Soares, A Alcobia*. Hospital García De Orta, Pharmacy Department, Almada, Portugal

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**Background and importance** Abiraterone was recently proved by the EMA for addition to androgen deprivation therapy (ADT), associated with prednisone (P), in metastatic castration sensitive prostate cancer. The economic impact could be important.

**Aim and objectives** The aim of this study was to evaluate the cost efficacy of abiraterone in newly diagnosed high risk metastatic castration sensitive prostate cancer.

**Material and methods** Abiraterone efficacy outcomes are based on the LATITUDE trial. Treatment costs were calculated based on the direct costs of the drugs in 2019. This study was conducted from an institutional perspective—the hospital perspective.

**Results** Based on the LATITUDE trial, the overall survival for the abiraterone+P+ADT group was 53.3 months versus 36.5 months in the ADT group. Median treatment duration was 24 months for the abiraterone+P+ADT group and 14 months for the ADT group. Adding abiraterone+P to ADT resulted in a marginal efficacy of 1.4 years compared with ADT alone. The marginal costs associated were 70.163€.

**Conclusion and relevance** Based on this analysis, the incremental cost efficacy ratio calculated for abiraterone+P was 50.116€. The economic impact could be important.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**


No conflict of interest.

**1ISG-009 BUDGET IMPACT ANALYSIS OF A NATALIZUMAB EXTENDED INTERVAL DOSING REGIMEN**

E Piembon, A Mastrogiacomo, F Capano*, D Ielo. AOU San Luigi Gonzaga, Pharmacy, Turin, Italy

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**Background and importance** Natalizumab is a monoclonal antibody that blocks the immune reaction evoked during multiple sclerosis (MS) attacks but it could also weaken immunosurveillance, leading to an increased risk of developing progressive multifocal leucoencephalopathy (PML).

Many studies have demonstrated that extended interval dosing (EID) of natalizumab 300 mg every 6 weeks has the same efficacy as standard interval dosing (SID) every 4 weeks, but with a lower risk of PML.

**Aim and objectives** To compare the costs of SID and EID administration of natalizumab and to estimate the savings associated with EID.

**Material and methods** The analysis was carried out adopting a 3 year time horizon, the hospital perspective (corresponding to the National Health Service) and considering the direct costs of the drug’s purchase price. The population was patients diagnosed with MS and already being treated with the SID regimen at our hospital. The model used was based on real clinical data: patients were selected from September 2016 to September 2019.

The annual cost considered 12 infusions for SID and 8 for EID of natalizumab, according to the actual regional public tender, which is mandatory (no possibility of further paybacks or discounts, or planned changes to the purchase agreement in the next 3 years).

Three different scenarios were considered: 75%, 85% and 95% of patients on the EID regimen and the remaining on the SID regimen, based on the clinical judgment that almost all patients could benefit from an EID regimen, but the possibility should also be foreseen that a patient could not wait more than 4 weeks between infusions.

**Results** In the first scenario, there were 512 patients receiving EID and 171 SID, corresponding to a total cost of €10,490,101, or €13,986,802 if all patients were receiving SID. Treating 75% of patients with EID could reach a saving of €3,496,700.

The second scenario (581 vs 102) generated a cost of €10,037,875 and a saving of €3,962,927, and the third scenario (649 vs 34) a total cost of €9,557,648 with a saving of €4,429,154.

**Conclusion and relevance** The analysis underlines the large savings in direct costs if most patients are infused every 6 weeks. This also corresponds to lower administration related costs (indirect costs) that could be calculated in a future analysis.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**

No conflict of interest.

**1ISG-010 INTRODUCTION OF RITUXIMAB BIOSIMILAR: AN OPPORTUNITY TO IMPROVE HEALTH SYSTEM EFFICIENCY?**

C Pancirolli*, L Cevi, D Maizza, G Mangoni, M Dall’aglio, F Ruggiero, Ml Medaglia. Asst Grande Ospedale Metropolitano Niguarda, SC Farmacia, Milan, Italy

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**Background and importance** The introduction of a biosimilar drug represents similar efficacy at a lower cost, providing savings without compromising patient treatment. Moreover, their quality is certified by regulatory agencies and high quality clinical trials. In 2017, rituximab biosimilar (RB) was approved in Italy. At the end of 2017, our hospital implemented a new policy for using biosimilars, and decided to