SEVERE ULCERATIVE COLITIS IN CHILDREN AND ADOLESCENTS IN POLAND - IT'S TIME TO CATCH UP WITH EUROPE. BUDGET IMPACT ANALYSIS (BIA) FOR BIOSIMILAR INFLIXIMAB

Introduction

Ulcerative colitis (UC) is a chronic inflammation of the mucous membrane of the colon or rectum. Manifestation of the disease in early childhood is associated with severe clinically course. [1, 2] In Poland UC is affecting 3-6-2,2/100,000 children and adolescents annually. [1, 2, 3, 4, 5, 6, 7]

Currently Polish children and adolescents suffering from severe ulcerative colitis refractory to conventional therapies have limited access to innovative therapy recommended by clinical guideline – biological drugs.

The most common symptom of UC is diarrhea mixed with mucus and blood in the stool. Other symptoms include abdominal cramps and feeling of straining at stool. The number of bowel movements may even exceed 20 per day. In addition, weakness and weight loss is present. [8]

Treatment of UC is based on the use of immunosuppressive agents, glucocorticoids, immunomodulatory drugs, biological treatment, nutritional therapy and surgery. ( Detailed clinical guidelines with the classification, risk of hormone replacement treatment) (9)

The use of the recommended biological treatment for children and adolescents is the best way to avoiding surgery of colon removal and struggle with stoma complications.

Objectives

Polish children and adolescents suffering from severe ulcerative colitis refractory to conventional therapies have limited access to innovative therapy recommended by clinical guidelines.

Existing healthcare treatment programme (HTP) for adults financed by the National Health Fund (NHF) in Poland, should be extended for population below 18 years of age, which is the only chance to avoid or delay debilitating colectomy procedure.

The aim of this analysis was to estimate financial consequences of biosimilar infliximab (biosNF) reimbursement for pediatric population (6 to 17 years) within the HTP on the budget of NHF in Poland.

Methodology

Population and time horizon: Budget Impact Analysis (BIA) was performed for 2 years' time horizon (2016-2017). Target population qualified to the HTP were children and adolescents (age 6-17 years) with severe UC who have an inadequate response, or are intolerant, or have medical contraindications to therapy including corticosteroids and 5-aminosalicylates or thiopurines (6-mercaptopurine or azathioprine).

Perspective: Polish Health Fund (NHF).

Compared scenarios: Two scenarios were compared: present, without biosNF (100 mg powder for concentrate solution for infusion) reimbursement and new, with reimbursement of biosNF as part of HTP. Market share was based on experts’ opinion.

Included cost: Direct medical costs (costs and their administration, cost of hospitalization, colectomy and monitoring).

Outcome: The impact on the budget of a public payer (NHF).

The calculations were performed in the Microsoft Office Excel spreadsheet.

Results

Number of children and adolescents (age 6-17 years) eligible for the HTP are shown in FIGURE 1. Based on market share (FIGURE 2) number of newly treated patients with NF would be 136 in 2016 and 136 in 2017.

The impact on the budget of a public payer (NHF) is shown on TABLE 1 and FIGURE 3. NHF annual expenditures related to introduction of biosNF reimbursement would increase by €471,071 in 2016 and €474,159 in 2017 comparing with the present scenario (€1 = PLN 4.39).

Discussion

Children and adolescence with UC suffer more than adults. They more often require hospitalization because of an acute severe UC relapse in the first year after failing III.

Extending the HTP for a pediatric group of patients will have a significant impact on the disease progress. New HTP will improve the quality of life of these children and future adults, allow children to learn and play with their peers. Significantly lower price of biosNF in comparison with reference infliximab gives possibility to treat more patients within the same budget.

Conclusions

Treatment with infliximab has great success in used countries around the world, so why can’t be also successfully used in Poland?

References