INTRODUCTION

- Uremia need for the healthcare treatment programme (HTP), covering a population of children and adolescents with severe ulcerative colitis (UC) refractory to conventional therapy was topic recently raised repeatedly by the medical society, but still without success.
- Ulcerative colitis is a chronic inflammation of the mucous membrane of the colon or rectum, as yet of unknown etiology. UC is included in the group of inflammatory bowel diseases. [1]
- The occurrence of the disease in early childhood is associated with severe clinically course, refractory to conventional treatment, requiring intensive treatment i.e. mutilating surgery co-悉尼osis.[1,2]

- Despite infliximab is the only rescue treatment recommended before colectomy in Poland, access to innovative treatment, financed by Polish National health Fund (NHF) is limited.
- Infliximab is authorized for the treatment of moderate-severe active UC patients who had an inadequate response, or are intolerant, or have medical contraindications to therapy including corticosteroids and 5-Aminosalicylates or thiopurinines.

- In Poland, infliximab is reimbursed in this indication only for adults with severe UC.
- Ensuring access to a biological medicine within the HTP, covering a population of children and adolescents aged 6 to 17 years, will provide access to innovative therapy recommended by clinical guidelines.

OBJECTIVES

The aim of this study was to evaluate the cost-utility of bioINF in the treatment of severe UC children and adolescents aged 6 to 17 years, refractory to conventional therapies.

METHODOLOGY

A decision-analytical model (TreeAge) was prepared to simulate disease progression of hospitalized UC patients, refractory to intravenous corticosteroids (PRED 4), and to estimate the costs and benefits associated with bioINF compared to surgery (colectomy), over a 5-year timeframe horizon from the perspective of NHF. Cost-effectiveness was derived from systematic review. Resource use and costs were obtained from Polish data sources and experts opinion.

The primary effectiveness measure used in the analysis was quality-adjusted life years (QALYs). The analysis covered direct medical costs, i.e. cost of infliximab, cost of colectomy treatment, hospitalization, other drug administration, diagnostic and monitoring, cost of colectomy surgery and postoperative complications, cost of outpatient visits after the surgery. With the short time frame of the analysis (5 years), no discounting of costs and health effects was performed. Table 1 provides the base case model assumptions.

Population: Children and adolescents aged 6 to 17 years with diagnosed severe UC, in whom treatment with infliximab is undesirable or contraindicated: 1) with an inadequate response to conventional therapy, including corticosteroids and 5-Aminosalicylates (6-MP) or azathioprine (AZA), 6-MP PluCAL), or 2) being intolerant to corticosteroid and 6-MP or AZA treatment, or 2) having co-existing contraindication to corticosteroids and 6-MP or AZA treatment.

Intervention: Infliximab 5 mg/kg (induction therapy at 0, 2 and 6 weeks and maintenance therapy every 8 weeks).

Comparator Colectomy (C60L). Outcome: QALYs (quality adjusted life years).

RESULTS

In the INF group the biggest costs were drug (53% of total costs), whereas in the C60L group - cost of surgery (93% of total costs). Distribution of included costs from the perspective of NHF is shown in Figure 2.

The incremental cost-utility ratio (ICUR) for bioINF from perspective of NHF was €24,033 per QALY compared to colectomy (TABLE 2). Obtained results are placed below the acceptability threshold (3xGDP per capita in Poland) which is about €28,693 (€1 = PLN 4.39).

CONCLUSIONS

Analysis indicated that bioINF is a cost-effective treatment option for UC children and adolescents compared with disabling method which is colectomy. Lack of reimbursement in pediatric population is not therefore based on threshold criteria.

Financing of infliximab in the treatment of severe UC in children and adolescents aged 6 to 17 years, within the HTP, Treatment of patients with ulcerative colitis (UC) (C60L-6.5%)1 would avoid crippling colectomy in many cases.

REFERENCES
4. COST of colectomy surgery and Cost of diagnostic and monitoring surgery.
5. COST of colectomy surgery and Cost of diagnostic and monitoring surgery.
6. COST of colectomy surgery and Cost of diagnostic and monitoring surgery.
7. COST of colectomy surgery and Cost of diagnostic and monitoring surgery.
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