

OBJECTIVES: To analyze the cost-effectiveness of Omalizumab in addition to Standard of Care (SoC) in the treatment of paediatric patients (>6 yeas-old) with severe uncontrolled asthma from the perspective of the Public Health Care System in México. METHODS: A Markov model, with cycle duration of 2 weeks, was designed to analyze the cost-effectiveness of Omalizumab vs SoC. Effectiveness was evaluated by the number of exacerbations avoided. The model identifies 4 health-states, and death based on symptoms and exacerbations with and without omalizumab. Transition probabilities were obtained from two clinical studies identified after a systematic review, with approximately 627 patients. Omalizumab showed a reduction of 43% in the asthma exacerbation rate vs SoC (Lanier, 2009). Model time horizon was 20 years, with treatment duration of 6 years. A discount rate of 5% was used for costs and outcomes. Direct medical costs associated with exacerbations were elicited from an expert panel of clinicians and valuated by the unitary cost list of the Mexican Institute of Social Security. Drug costs are those from public tenders 2012. (US\$1=MX\$13.8). Probabilistic sensitivity analysis was performed using Monte Carlo technique. RESULTS: The expected 20-year costs and number of exacerbations per patient with each treatment were: Omalizumab US\$96,483/31.52; and SoC US\$49,857/39.84. It represents 8.3 exacerbations avoided with an incremental cost-effectiveness ratio of US\$5,617 per exacerbation avoided for omalizumab versus SoC, below the Mexican threshold of 1GDP per-cápita=US\$8,586. Probabilistic sensitivity analysis showed omalizumab was below the threshold 95% of the times, according to the acceptability curve. The model is more sensitive to changes in efficacy than price. CONCLUSIONS: For paediatric patients with severe uncontrolled asthma, treatment with omalizumab is a cost-effective option compared with current SoC in the health system. The higher drug acquisition cost of Omalizumab is off-set by the lower rate of exacerbations seen with patients on omalizumab and their related costs.

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ECONOMIC EVALUATION OF OMALIZUMAB IN PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA FROM THE PUBLIC PAYER PERSPECTIVE IN BRAZIL

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OBJECTIVES: To assess the cost-effectiveness of adding omalizumab to standard therapy (ST) alone in patients with uncontrolled severe allergic asthma from Brazilian public health care system perspective. METHODS: A Markov model comparing lifetime ST with omalizumab add-on therapy was developed based on efficacy data from INNOVATE (Phase III trial, N=419, 28 weeks). Outcomes are expressed as clinically significant exacerbation (CSE) and clinically significant severe exacerbation (CSSE) avoided. A CSE is defined in INNOVATE as worsening of asthma requiring treatment with rescue systemic corticosteroids and a CSSE is defined as PEF/ FEV1 <60% of personal best, in addition to requiring rescue treatment with corticosteroids or requiring emergency room treatment or hospitalization. Resources use data (physician consultations, laboratory tests, emergency rooms visits, hospitalizations, drug treatments) was obtained from INNOVATE and valued from the perspective of health care payer. In the model, subjects move back and forth between daily symptoms (optimized asthma control) and the CSE or CSSE states, as they have exacerbations and then recover. Patients can have several CSE sequentially, or can remain with no exacerbation for a long period, determined by the transition probabilities. The death states are separated into deaths from all causes and asthma-related deaths due to severe exacerbations. One-way-sensitivity-analysis (OWSA) was performed. Annual discount rate of 5% was applied both to costs and outcomes. RESULTS: Base case analysis showed that more CSE and CSSE were avoided with omalizumab add-on therapy than ST alone (incremental of 17.57 and 9.27 respectively) with additional cost of BRL 122,392. Hence, omalizumab ICERs are BRL 6,967/CSE avoided and BRL 13,198/CSSE avoided (1BRL=0.487USD). OWSA confirms the favorable results of base case for omalizumab. CONCLUSIONS: The pharmacoeconomic evaluation confirms that omalizumab add-on therapy is very cost-effective versus ST in the treatment of patients with uncontrolled severe allergic asthma (i.e. <1GDP per capita or BRL 19,000; WHO threshold).

ONE-YEAR COST-EFFECTIVENESS OF MONTELUKAST IN 2-6-YEAR-OLD CHILDREN WITH MILD-MODERATE PERSISTENT ASTHMA IN BELARUS

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OBJECTIVES: To estimate cost-effectiveness of montelukast in 2 - 6-year-old children with mild-moderate persistent asthma in Belarus. METHODS: A one-year decision tree model of asthma for a hypothetical cohort of 100 patients taking either montelukast (4 mg/day) or budesonide inhalation suspension (0,5mg/day) or lack of basis therapy has been constructed on the basis of the results of randomized clinical studies and local data. The number and duration of asthma exacerbations, the number of days with use of short-acting β_2 -receptor agonist (salbutamol) inhaler, the number of salbutamol puffs per day have been calculated. Direct and indirect costs have been calculated (U.S. \$, 2012). The cost-effectiveness ratio (CER) for montelukast, budesonide inhalation suspension or lack of basis therapy per \ll number of days without asthma attacks, exacerbations, use of short-acting β_2 receptor agonists >>> has been quantified. Sensitivity analysis has been performed. The duration and severity of asthma exacerbations, various types of pharmacotherapy were taken into consideration when sensitivity analysis was being made. RESULTS: In 2 – 6-year-old children with mild-moderate persistent asthma the CER of oral montedukast use was \$4.1 per ≪day without asthma attacks, exacerbations, use of short-acting β_2 -receptor agonists \gg , CER of budesonide inhalation suspension use by nebulizer was \$5.6, CER of lack of basis therapy was \$6.9. The resulting trend persisted during the sensitivity analysis. CONCLUSIONS: In Republic of Belarus the use of oral montelukast is considered to be cost-effective in comparison to budesonide inhalation suspension or a lack of basis therapy in 2 -6-year-old children with mild-moderate persistent asthma.

COST-EFFECTIVENESS ANALYSIS OF MONTELUKAST IN 6-14-YEAR-OLD CHILDREN WITH MILD-MODERATE PERSISTENT ASTHMA IN BELARUS

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OBJECTIVES: Global strategy for the prevention and treatment of bronchial asthma (GINA) recommends antileukotriene drugs as second-line therapy, also while treating children. The cost-effectiveness analysis (CEA) of montelukast in 6-14-year-old children suffering from mild-moderate persistent asthma has been performed to determine economic advisability of its applying in Republic of Belarus. METHODS: On the basis of the results of randomized studies and local data, the model of asthma process for a hypothetical cohort of 100 patients taking either montelukast (5 mg/day) or fluticasone - aerosol (250 mcg/day) has been constructed. The number and duration of asthma exacerbations, the number of days with the use of shortacting β_2 -receptor agonist (salbutamol) inhaler, the number of salbutamol puffs per twenty-four hours have been chosen as important criteria influencing the process of the disease and economic burden. RESULTS: In children older than 6 with mildmoderate persistent asthma the priority medicine is an inhaled corticosteroid (ICS) ($CER_{fluticasone}$ – 1, 45\$ per day without attacks, aggravations, use of salbutamol as compared to $CER_{montelukast}$ – 2, 62\$). The trends obtained in the main analysis remain unchanged (CEA_{fluticasone} - 1, 67\$ for one day without attacks, aggravations, use of salbutamol as compared to $CEA_{montelukast}$ – 2, 98\$) even if changes in the period of hospitalization of the patients occur (an increase up to 14.7 days) as well as in case of extension of exacerbation treatment or severity of exacerbation and additional medical aid in the emergency room for one or two days. If indirect costs caused by one of the parents' absence at work are excluded from the analysis, the priority medicine is an ICS: (CEA $_{\rm fluticasone}$ – 1, 19\$ as compared to CEA $_{\rm montelukast}$ – 1, 95\$). CONCLUSIONS: In the Republic of Belarus inhaled corticosteroid is the priority medicine in children older than 6 years who are able to master the technique of inhalation

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QUEUING STATISTICAL MODEL - A NEW TOOL FOR PRELIMINARY COST-EFFECTIVENESS ASSESSMENTS

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OBJECTIVES: We hypothesized that one central laboratory would be more costeffective than several local laboratories because price of single Chlamylege test depends on number of simultaneous tests performed. Incidence of pneumonia requiring hospitalization in Poland is app.4/1000 persons/year. For hypothetical population of one million people 4 000/ year will require hospitalization for pneumonia (VIP). We established seasonal incidence using clinical database of Military Medical Institute Warsaw. New statistical method (Queuing Model)was used. METHODS: Two simulation models were constructed for one million inhabitants: one, where four hospital laboratories exist, performing 10-50 tests. Second, where large central laboratory exists performing 50-200 tests. Three scenarios of morbidity were established: 1) 3000 outpatients, 1000 inpatients, equal number of patients over year; 2) 3000 outpatients, 1000 inpatients, number of patients/month related to seasonality (4 seasons specified); 3) increased influx of patients: 12000 outpatients and 4000 inpatients; number of patients/month related to seasonality. RESULTS: 1) in central laboratory significantly smaller number of samples were tested (mean 0.25vs0.75); 2) quarter 1 (increased patients influx) % tested in central laboratory was significantly higher but still smaller than in the local labs (0.92vs.0.95) whereas in quarter 3 (decreased patients influx) less tests performed(0.2777 vs. 0.0005); and 3) % of tests made in central lab is much higher, but still not exceeding number of tests performed in local labs (0.82vs.0.83). Central laboratory performed less tests comparing to local labs and periods of inactivity were noted which significantly increased cost of a single test. CONCLUSIONS: According to Queuing Model it was confirmed that creation of the central laboratory is not reasonable in terms of costs. We conclude that Queuing Statistical Model can be a useful tool for preliminary assessment ofthe cost-effectiveness of hypothesized research methodology.

COST-EFFECTIVENESS ANALYSIS OF 100% WHEY-BASED PARTIALLY HYDROLYZED INFANT FORMULA USED FOR PREVENTION OF ATOPIC DERMATITIS IN GERMANY

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OBJECTIVES: Clinical evidence shows that fewer infants fed for up to 4 months with 100% partially hydrolyzed whey formula (pHF-W) subsequently develop atopic dermatitis (AD) over up to 6 years than infants fed standard formula (SF) or extensively hydrolyzed whey formula (eHF-W). The present study assessed the cost-effectiveness of pHF-W compared to SF and eHF-W for the prevention of AD in Germany. METHODS: A Markov cohort model was used to assess over a period of 6