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Severe Allergic Asthma and Biological Therapy in the Treatment of Severe Asthma

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Severe asthma is present in 3-10% of the adult population. Asthma could be well-controlled disease. The adequacy of therapy and disease control are followed at the primary level by asthma control questionnaires.

Severe Asthma is a subtype of difficult-to-treat asthma that remains uncontrolled asthma despite administration of high doses of inhaled corticosteroids along with long-acting beta-2 agonists, leukotrienes modifiers or theophylline during the previous year, or asthma requiring systemic corticosteroids during the previous 6 months. It is important to note that these are patients who regularly and correctly use the recommended therapy and whose therapy and comorbidity control are adequate.

Type 2 inflammation is found in almost 50% of patients with severe asthma. It is characterized by the presence of cytokines (interleukin IL-4, IL-5 and IL-13) as part of the response to the presence of allergens. It can be activated by viruses, bacteria and irritants that stimulate the immune system and cause secretion of IL-33, IL-25 and thymus stromal lymphopoetin (TSLP). Type 2 inflammations are characterized by elevated eosinophils level or FeNO and may be accompanied by atopy. The main characteristics of patients with severe asthma and type 2 inflammation are: blood eosinophils ≥ 150 / mcl and / or FeNO ≥20ppb and / or eosinophils in sputum ≥2% and / or asthma that clinically worsens after exposure to the allergen and / or exists the need for the occasional administration of oral corticosteroids (OKS).

Patients with severe asthma and type 2 inflammation should be considered for usage of one of the modalities of biological therapy: anti-IgE, anti IL5 / 5R, or anti-IL4R. Currently, anti-IgE therapy is available in our market.

Anti-IgE (omalizumab, Xolair®) binds to the Fc fragment of free IgE, thus preventing IgE binding to its receptors (FCεR1) leading to down-regulation of the receptor.

Omalizumab (Xolair®) is available to patients under Article 9 of the „Rule book On the content and scope of the health care rights from compulsory health insurance and on participation for 2020" if they meet the following criteria, according to the approved indication and the Summary of Product Characteristics:

o Persistent allergic asthma in adults and children over 6 years of age population
o Positive skin test for perennial aeroallergens (dermatophagoides, fungi, pet hair, cockroaches, etc.) or in vitro-proven reactivity to perennial aeroallergens
o Reduced lung function (FEV1 <80% and FEV1 / FVC less than 12% compared to normal)
o Frequent night and day symptoms despite high-dose IKS / LABA therapy (ACT less than 20, ACQ greater than 1.5)

o At least one exacerbation treated in hospital or 2 verified exacerbations outpatient treated (lasting at least 3 days) in the last year
o Total IgE between 76-1500 IU / ml

Omalizumab (Xolair®) is administered according to the body weight and serum IgE values of the patient according to the table for dosiging of the drug given in SmPc. It is administered subcutaneously every 2-4 weeks.

Patients with blood eosinophilia ≥260μl have a good response to anti-IgE therapy, if FENO is ≥20ppb, if allergen-induced symptoms and childhood asthma began.

This therapeutic treatment reduces exacerbations by 50-65%, improves quality of life and reduces the required dose of OKS by 40-50%. In order to achieve successful asthma treatment, well control and the patient satisfied, good coordination is needed between the pulmonologists/allergologists, the GP physician, the medical staff and the patient.

References:
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2. Chung KF et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. European Respiratory Journal 2014; 43: 343-373.

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4. Rule book On the content and scope of the health care rights from compulsory health insurance and on participation for 2020 (Official Gazette of the Republic of Serbia No. 13/2020) / Pravilnik o sadržaju i obimu prava na zdravstvenu zaštitu iz obaveznog zdravstvenog osiguranja i o participaciji za 2020. godinu ("Sl. glasnik RS", br. 13/2020) https://www.rfzo.rs/index.php/pravilnici

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