

14 December 2018

**Benralizumab in the treatment of extremely severe eosinophilic asthma
Approved in COHERE meeting on 9 October 2018**

<p>Recommendation by CO-HERE</p>	<p>Benralizumab belongs to the publicly funded range of services of the Finnish health care system for the treatment of extremely severe eosinophilic asthma in adult patients at the discretion of a specialist familiar with the treatment of asthma in cases where first-line therapy has not produced a good response or if significant adverse effects prevent the use of glucocorticoids in tablet form. The most typical patient cases in which the treatment is considered are:</p> <ul style="list-style-type: none"> o The current adverse effects of a tablet form glucocorticoid prevent its efficient use or the required dose is continuously so high that adverse effects are likely to appear. o A patient who cannot be treated with a regularly administered tablet glucocorticoid has had frequent, reliably verified periods of exacerbation of asthma, whose treatment has required a glucocorticoid in tablet form (at least 5 courses of medication per year) o An intractable obstructive reduction of pulmonary function is discovered during the follow-up of a patient who cannot be treated with a regularly administered tablet glucocorticoid. <p>COHERE is of the opinion that treatment can be implemented with the drug that has the lowest cost at the time, taking into account the cost of procurement and administration.</p>	
<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Grounds</p>	<p>Severity and prevalence of the health issue</p>	<p>This recommendation applies to the treatment of extremely severe eosinophilic asthma in adults. A systemic (tablet form) glucocorticoid is needed for treating the most severe forms of asthma. In particular, the periods of exacerbation can affect the patient's quality of life and ability to work and function, and they also cause sickness absences and costs to the health care system. It is estimated that approximately 5% of adults suffering from severe eosinophilic asthma might be suitable for treatment with a biologic drug. This means that benralizumab, mepolizumab or reslizumab therapy would be started on approximately 60 new patients each year.</p>
	<p>Treatment options</p>	<p>If severe eosinophilic asthma cannot be controlled with a systemic corticosteroid or systemic corticosteroids are contraindicated, the only remaining treatment options are mepolizumab, reslizumab and benralizumab.</p>
	<p>Effectiveness</p>	<p>The therapeutic effects of benralizumab are systematic, but modest compared to placebo. Benralizumab seems to somewhat reduce the periods of exacerbation and use of tablet form glucocorticoids. The effects on the quality of life and symptoms of asthma cannot be considered clinically significant. Patients who experience frequent periods of exacerbation might benefit from the therapy more than others. There is no research evidence that benralizumab, mepolizumab or reslizumab differ in their therapeutic effectiveness and their effectiveness is generally regarded as similar.</p>
	<p>Safety</p>	<p>The most common adverse effects reported with benralizumab treatment are exacerbation of the asthma, nasopharyngitis and upper airway infection. Reslizumab, mepolizumab and benralizumab can be considered fairly safe and their safety is generally considered similar.</p>
	<p>Costs and impact on the budget</p>	<p>The costs of reslizumab, mepolizumab and benralizumab are not significantly different. The adoption of these drugs will increase the overall costs of health care, i.e. the savings attained by the treatment will be materially smaller than the pharmaceutical costs of the treatment.</p>
	<p>Ethical and financial aspects as a whole</p>	<p>Studies show that the therapeutic effects of mepolizumab are modest compared to a placebo, but its price is significantly higher compared to other drugs used for treating asthma. Therefore, it is ethically justified to restrict the use of the drug to patients whose asthma cannot be controlled with conventional medication or for whom the conventional medication is unsuitable.</p>
<p>Collection of further evidence</p>	<p>More evidence should be collected on the use, costs, treatment results and safety of benralizumab. The effects of the recommendation can be assessed when the number of patients treated, duration of treatment and outcomes by hospital district (as far as possible) are known.</p>	
<p>Diagnosis (ICD-10) codes</p>	<p>Eosinophilic asthma J45.0</p>	
<p>Background information and references</p>	<p>COHERE memorandum: Reslitsumabi, mepolitsumabi ja benralitsumabi -lääkkeet vaikean eosinofiilisen astman hoidossa. (Reslizumab, mepolizumab and benralizumab in the treatment of severe eosinophilic asthma). Pharmaceutical assessment report by Fimea: Benralitsumabi vaikean eosinofiilisen astman hoidossa (Benralizumab in the treatment of severe eosinophilic asthma).</p>	