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POLATUZUMAB-VEDOTIN IN COMBINATION WITH BENDAMUSTINE AND RITUXIMAB IN THE TREATMENT OF DIFFUSE LARGE B-CELL LYMPHOMA

According to the recommendation of the Council for Choices in Health Care in Finland (COHERE Finland), polatuzumab-vedotin in combination with bendamustine and rituximab (pola-BR) is not included in the national range of services for the indication for use compliant with its marketing authorisation.

According to its marketing authorisation, polatuzumab-vedotin is meant for use in combination with bendamustine and rituximab in the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) when the patient is ineligible for haematopoietic stem cell transplantation.

The antibody contained in the drug binds to B-cells and the drug enters the cell, where the released drug inhibits cell division and initiates apoptosis. The drug is administered intravenously every three weeks together with the pharmaceuticals included in the combination.

The benefit of pola-BR treatment compared to the combination of bendamustine and rituximab (BR treatment) has been shown in one phase Ib/II study. This study is an open and partly randomised study that is unfinished and preliminary in nature. The aim of the study was to investigate the safety, tolerability and efficacy of combination therapy containing polatuzumab-vedotin, and only a limited number of patients took part in the study.

There are considerable limitations to the marketing authorisation research. BR treatment, to which pola-BR treatment is compared, is not commonly used in Finland for the treatment of DLBCL. In randomised patient groups, there are differences in favour of the pola-BR group that can affect the disease prognosis. Therefore, although research results suggest that pola-BR treatment has better efficacy than BR treatment, on the basis of the results it remains uncertain whether the efficacy of pola-BR treatment is as good as or better than other treatment options used in Finland.

In about four out of five patients, pola-BR treatment is associated with a severe or life-threatening adverse event. Pola-BR treatment is associated with low blood cell counts as a common adverse effect, and also fever and infections as severe adverse effects. According to a randomised cohort of the study, adverse effects other than severe adverse events leading to death or life-threatening adverse events were more common with pola-BR treatment than with BR treatment.

Compared to treatments in line with Finnish treatment recommendations, pola-BR treatment causes an additional cost of about EUR 40,000–55,000 per patient if the duration of treatment is 4.4 to 6 treatment cycles. The additional costs are almost entirely due to the price of polatuzumab-vedotin. In Finland, about 20 to 30 patients a year could receive pola-BR treatment. Although the group of patients is small, the introduction of pola-BR treatment may result in an additional cost of EUR 0.8–1.6 million, calculated at the public wholesale price.

Meritullinkatu 8, Helsinki.
PO Box 33, 00023 Government
www.palveluvalikoima.fi

Phone 0295 16001

e-mail:
palveluvalikoima@stm.fi

DLBCL is a fast-growing lymphocyte cancer and the most common subtype of non-Hodgkin lymphomas. Approximately 600 new DLBCL cases are diagnosed in Finland each year. First-line treatment cures about 60–70% of patients with DLBCL. An estimated 10–15% of patients do not respond to first-line treatment, and the disease relapses among 20–30%. For these patients, the primary treatment option is stem cell transplantation. However, not all patients are eligible for stem cell transplantation, for example because of old age or comorbidities. The prognosis for recurrent or refractory disease after first-line treatment is poor and life expectancy is often less than six months.

COHERE Finland works in conjunction with the Ministry of Social Affairs and Health and its task is to issue recommendations on which healthcare methods should be included in healthcare services financed from public funds. You can read more about the range of healthcare services on COHERE Finland's website www.palveluvalikoima.fi