Summary and Overall Assessment (Knowledge Base TLA)

Introduction

This evaluation is based on the Swedish Dental and Pharmaceutical Benefits Agency (TLV) commission from the government to conduct health technology assessments of medical devices. An evaluation at the national level can shed light not only on the individual care providers, but also on society as a whole through the utilisation of the ethical platform. It is very important that decisions and recommendations do not rely only on the principle of cost-effectiveness, but also take into account the other prevailing principles, namely the principles of human dignity and of need and solidarity, in accordance with the Health and Medical Services Act (1982:763).

Method and target group

This knowledge base evaluates treatment with *temperature controlled laminar airflow (TLA)*. The fundamental principle of this treatment is to minimise the inhalation of airborne allergens at night, which can combat inflammatory reactions and the stress on an allergic asthmatic's hyperreactive airways. TLA treatment is intended for patients with moderate to severe perennial allergic asthma whose disease control is deficient, despite high doses of the recommended medication.

The current guidelines recommend the addition of oral steroids or anti-IgE (Xolair) for patients who have an incomplete controlled allergic asthma, despite optimised drug treatment. The patients for whom these drugs do not provide the expected or a sufficient effect are those who it may appropriate to treat with TLA. The treatment can also be relevant for those patients who, for whatever reason, cannot or should not be treated with the above medications.

There is currently one TLA device for the treatment of allergic asthma on the market in Sweden, Airsonett.

Disease severity

Patients with an incomplete controlled allergic asthma are treated with daily and/or high doses of several drugs in order to ease the symptoms and limit the number of times their condition deteriorates. Despite intensive drug treatment, certain patients are affected by very severe asthma attacks. These patients probably have a worse prognosis, with higher morbidity and mortality, compared with the rest of the patient group. In addition, these patients have a poorer quality of life as a result of the serious limitations to their daily lives, higher number of deteriorations in their condition, hospital stays and unplanned visits to the doctor. They are also at risk of permanent disabilities such as reduced lung function.

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Treatment with Airsonett should be reserved for patients whose asthma is incompletely controlled, despite optimised drug treatment. The scientific studies that form the basis of this knowledge base have not included patients with frequent exacerbations or those patients with the highest treatment intensity with regard to number of drugs and dosage regime. The TLV thus assesses, based on the studies available, that the severity of the condition is moderate.

Patient benefit

The positive effect of the treatment, which it has been possible to demonstrate, applies primarily to asthma-related quality of life. For patients with incompletely controlled asthma, however, all improvements in quality of life are significant as the disease constitutes a barrier to productivity, family life and social functions. The risk for serious, unwanted side effects is judged to be very low as the treatment is neither pharmacological nor invasive.

The TLV assesses, based on the studies available, that the benefit to patients is greater than the alternative used for comparison (pharmacological treatment alone) for those patients who suffer the most from allergic asthma. This is because the treatment improves quality of life for individuals with serious limitations to their daily lives. In this assessment, the TLV draws its conclusions based on randomised, double-blind controlled trials that are of an acceptable quality. Despite the seriously limited number of patients, the knowledge base is larger than is normally available within the medical devices field. The limited data does, however, mean that there is a high level of uncertainty with regard to the treatment effectiveness and primary target group.

In cases of incompletely controlled allergic asthma, an improvement to quality of life as a result of a more effective treatment can mean better sleep, a lower rate of absence due to illness, an increased ability to concentrate and a more active life. If the treatment is provided as a complement to optimised drug treatment, the ethical consequences are minimal. Before treatment is started, patients should be informed about the limitations to the knowledge about the treatment's effectiveness, as well as the drawbacks the method may involve in terms of comfort.

Cost-effectiveness

Two health economic evaluations of treatment with TLA have been published in which the cost-effectiveness of Airsonett has been evaluated, but which both use the same model. The result of this evaluation indicates moderate cost-effectiveness. In addition, the manufacturer has produced two health economic models, one for the Swedish market and one for the British market. Both of these indicate a moderate cost-effectiveness ratio, even though the cost data from the British model is not directly transferable to Swedish circumstances. Each of the three models has a different base and are therefore hard to compare with one another. Even though the

bases are different, the analyses of the models still gives an idea of the size of the cost-effectiveness ratio.

The TLV has also conducted its own sensitivity analyses of the Swedish model that the manufacturer produced. These analyses indicate that the cost-effectiveness ratio is sensitive to a change in the initial parameters. When using a conservative assumption, no healthcare cost savings, there is a cost-effectiveness ratio of SEK 405,000 per quality-adjusted life year (QALY). That is to say, the TLV judge the cost-effectiveness ratio to be moderate. The model is relatively sensitive to the price of the device, with an increase in the monthly cost by SEK 500 leading to an increase in the cost-effectiveness ratio of SEK 50,000 per QALY. A change in quality of life also has a relatively large impact on the result, with a 20 per cent reduction in quality of life leading to a cost-effectiveness ratio of SEK 635,000 per QALY.

The data used in the health economic model is uncertain as there is a prevailing uncertainty surrounding both the effectiveness of the treatment and the costs associated with it. None of the models reports on the cost to society as a whole, which probably underestimates the cost-effectiveness of the treatment.

Follow-up and evaluation
Follow-up and registration of the effectiveness of the treatment is of great importance. It is appropriate to conduct an evaluation of the effects on the individual patient, as well as to make a decision on whether to continue treatment following three months of treatment.

Overall assessment
The treatment appears to be cost-effective based on the best available data. This is conditional on the use being limited to certain specific patients. These patients should have comparable problems and circumstances to those patients for whom the treatment has been shown by the available studies to have an effect.

The organisations responsible for healthcare may thus consider whether or not to introduce this method. However, it is advantageous to refer patients for whom this may be appropriate to a specialist physician/allergist for individual assessment.