
Triobe excluded from pharmaceutical benefits system

Pharmaceutical reimbursement review

THE DECISION COMES INTO FORCE 2010-08-01

Triobe excluded from benefits system

The TLV is excluding Triobe from the reimbursement system. It is not reasonable to reimburse a medicine which is exclusively used to prevent a deficiency in vitamin B. The treatment of more severe diseases holds a higher priority. Furthermore, other more cost-effective treatment alternatives to Triobe are available. The decision comes into force from the 1st of August, 2010.

Triobe contains a combination of the vitamins B6, B12 and folic acid. Vitamin B is necessary for a number of different processes in the body, such as cell division including the formation of red and white blood cells. Common symptoms of vitamin B deficiency are anaemia, dizziness, memory disturbances, loss of feeling and abnormal tiredness.

Triobe has been approved for prevention of symptoms caused by the lack of vitamins B6, vitamin B12 and folic acid on insufficient intake of food or malabsorption, primarily for older people.

Lessened absorption from intestine common cause of vitamin B12 deficiency

A deficiency in vitamin B can appear when food intake is not varied enough, when the functional ability to absorb the vitamin is disturbed or when the need is increased. The most common cause of vitamin B deficiency is chronic stomach ulcers (atrophic gastritis). Atrophic gastritis is relatively common in older people as is a deficiency in vitamin B12. This deficiency often develops slowly over a number of years. Some medicines also affect the body's ability to utilise vitamin B. Patients on long-term treatment with proton pump inhibitors or metformin may also experience a lessened ability to absorb vitamin B12.

Preventive treatment only in isolated cases

For many patients a nutritional diet suffices. Only in isolated cases and for specific risk groups can preventive treatment with vitamin B substances be considered motivated.

Treatment of severe diseases prioritised

Triobe is not intended to treat deficiencies, but to prevent deficiencies. And a deficiency in Vitamin B is a condition which is treatable. A medicine which is exclusively to be used for the prevention of vitamin B deficiency is not urgent enough to be reimbursed with taxpayer's funds. Patients with severe diseases where needs are greater shall receive more of health-care resources than other patient groups.

Triobe is not cost-effective

The vitamins in Triobe are available at higher doses and at a lower cost in other reimbursed medicines. For this reason Triobe is not cost-effective.

Other reimbursed vitamin B substances hold, in contrast to Triobe, also an indication for the treatment of vitamin B deficiency.

Our task is to extract as much health as possible for funds expended on medicines. For this reason we also revisit previous decisions. We also review the reimbursement of medicines which were part of the benefits system already when the agency was formed, as is the case with Triobe.

Triobe turned over 35 million crowns in the benefits system in 2009

In total Triobe turned over 53 million crowns in 2009 of which 35 million crowns were within the benefits system.

The decision to exclude Triobe from the benefits system comes into force on the 1st of August 2010.

Why the TLV carries out reviews of the positive list of pharmaceuticals

Our task is to decide on pricing and reimbursement for medicines and medical devices in order to extract as much health as possible for tax funds expended on reimbursement. Besides making decisions on new medicines we carry out reviews of the positive list of pharmaceuticals and decide if medicines should retain their reimbursement status.

We exclude the medicines which do not provide enough utility in relation to their cost. But this does not mean we shall only have cheap medicines in the reimbursement system. If a medicine has positive enough effects on the health and quality of life and on society as a whole, then it may also be expensive.

Three principles for decisions

When making reimbursement decisions we must decide if a medicine is cost-effective. This means that we weigh the utility of a medicine against the cost. The cost-effectiveness principle we apply must also be balanced with two other principles. Namely, the

needs and solidarity principle meaning that those with the greatest medical need should get more of healthcare's resources, and the human value principle meaning that the equal value of all people shall be respected

Investigations and analysis before decisions made

Before we make a decision we carry out a comprehensive analysis of data on medical effect and cost-effectiveness which we request companies to submit about their medicines. We also go through the medical and health economic scientific literature available for the group to be reviewed.

We publish all material on www.tlv.se. We also direct some information so that doctors and nurses who prescribe medicines receive information on our decisions so that their patients can review their medications in good time.

Information on www.tlv.se (in Swedish)

Decision on TrioBe - www.tlv.se/triobe

Decisional criteria - www.tlv.se/principer

User council - www.tlv.se/brukare

Pharmaceutical reviews - www.tlv.se/genomgang

This is the TLV

The Swedish Dental and Pharmaceutical Reimbursement Agency (TLV) is a State agency responsible for deciding if a medicine or dental care procedure shall be reimbursed by society. We also have responsibilities on the reformed pharmacy market. Our task is to contribute to good service and access at pharmacies without costs rising for patients and county councils.

We work to extract as much health as possible for tax funds expended on medicines and dental care.

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