
Hyaluronic acid excluded from the reimbursement system

Interim decision from the review of painkillers and anti-inflammatory medicines

THE DECISIONS COME INTO FORCE on 2010-06-15

Hyaluronic acid leaves reimbursement system

The TLV is excluding medicines containing hyaluronic acid from the pharmaceutical reimbursement system. Hyaluronic acid is used for the treatment of mild to moderate knee osteoarthritis. The companies selling these products have not been able to prove to a sufficient degree that there is a clear relation between cost and utility. The decisions will free up at least 16 million Skr annually. Money which can be used for other urgent areas within the healthcare system. The decisions come into force from the 15th of June 2010.

The cartilage in the joints of the body lends stability and allows the bones of the skeleton to meet each other and provide flexibility. Osteoarthritis is caused by a degradation in the natural balance in the cartilage. This means that the cartilage is thinned out and that the ends of the bones grate against each other creating pain and stiffness. Osteoarthritis can appear in different joints in the body, such as for example in the knees, hip joints, thumbs and big toes. It is most common for patients to be afflicted by osteoarthritis from the age of 50 and up.

Many medicines against pain

This patient group often needs pain-alleviating medicines as pain is the most common symptom of osteoarthritis. There are many different types of medicines to treat arthritis. Hyaluronic acid is one of the substances approved here for the indication of treatment of symptoms for mild to moderate osteoarthritis of the knee. There are three different products containing hyaluronic acid: Artzal, Hyalgan and Synvisc.

Collaboration with the National Board of Health and Welfare

There are three medicines in the reimbursement system which contain hyaluronic acid. They are part of our more comprehensive review of painkillers and anti-inflammatory medicines. This review is carried out in collaboration with the National Board of Health and Welfare within their remit of producing the national guidelines for treatment of musculoskeletal diseases. As enough evidence exists already today to examine if the three hyaluronic acid products in the reimbursement system shall continue to be reimbursed we have fast-tracked the decisions to this effect.

Utility does not match the cost

Hyaluronic acid occurs naturally in cartilage in the joints and synovial fluid and gives the synovial fluid a certain viscosity assumed to protect the joint itself. When suffering from osteoarthritis of the knee the levels of hyaluronic acid decrease in the fluid and the probable protection afforded disappears.

The companies selling these medicines have not demonstrated the utility value of the efficacy in relation to the cost. Our conclusion is that it is not sufficiently proven that use of medicines containing hyaluronic acid is cost-effective. For this reason the products shall no longer be part of the reimbursement scheme.

Frees up 16 million crowns annually

Medicines containing hyaluronic acid turn over approx. 20 million Skr per year, of which almost 16 million is reimbursed. The decision to exclude hyaluronic acid from the benefits system will therefore free up almost 16 million crowns per year. These are funds which can be used in other urgent areas in healthcare.

These medicines are excluded from the reimbursement system from 15th June, 2010:

Medicines

Artzal

Hyalgan

Synvisc

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, 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

Comprehensive investigations

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)

Decisions on hyaluronic acid - www.tlv.se/hyaluronsyra

Decision 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.