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## Cymbalta (duloxetine) receives restricted reimbursement

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Cymbalta is reimbursed only for patients suffering from depression or general anxiety disorders who have not reached their treatment objectives with at least two other antidepressants. One of these should be venlafaxine unless there are strong reasons to the contrary.

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THE DECISIONS COME INTO FORCE ON 2010-07-01

## Cymbalta receives restricted reimbursement

The TLV is restricting the reimbursement of the antidepressant Cymbalta (duloxetine). It is to be reimbursed only for patients suffering from depression or general anxiety disorders who have tried at least two other antidepressants and not reached their treatment objectives. One of these medicines should be venlafaxine unless there are very specific reasons against this. Expensive medicines should not be reimbursed as a first or second line alternative when there are cheaper ones with a similar effect. The TLV's task is to extract as much health as possible for taxpayer's money expended on medicines. The decision comes into force from the 1st of July, 2010.

### Deterioration in quality of life and wide-ranging societal costs

Depression is one of the most common causes of loss of health and productivity and inability to work. The disease entails a stark decrease in quality of life for those afflicted and their nearest ones. Depression also leads to large societal costs due to sick leave and early pension retirements. Approximately one out of every twenty adult persons in Sweden is estimated to suffer from depression.

### Treatment and range of medicines

There are a number of methods to hand to treat depression and anxiety. Medicines are an alternative, psychotherapy such as CBT is another. In pharmaceutical treatment there are different classes of medicines to choose between. One of them is the class of SSRIs which stand for more than half of the sales of antidepressants. Another is SNRIs. The two substances duloxetine (Cymbalta) and venlafaxine (Efoxor and generic venlafaxine) are part of this group.

The pharmaceutical treatment of depression is often initiated with an SSRI substance. This is also the most cost-effective treatment alternative according to the TLV's review of antidepressants which was presented in December 2008. Some of the patients who do not receive sufficient effect from this treatment may instead try an SNRI substance.

Less than half of patients achieve sufficient effect from the first antidepressant they try. For some the effect does not set in, for others the medicine may produce an effect but the side-effects can lead to the patient ceasing medication. For this reason a range of medicines are needed in the high-cost threshold to treat depression.

### Patent expiry for Efoxor affects the cost-effectiveness of Cymbalta

Based on the active mechanism and its place in the treatment ladder venlafaxine is the nearest alternative to Cymbalta. Cymbalta was approved for reimbursement in 2005, primarily based on a head-to-head comparison with Efoxor (venlafaxine). The DDD for treatment with Efoxor was then approximately 20 Skr while the cost for Cymbalta was estimated at approximately 13 Skr

Patent protection for Efoxor expired in 2008 and the product left the reimbursement system in the middle of 2009. For this reason today only generic venlafaxine is prescribed under reimbursement. The DDD for this treatment is 1.25 Skr which is a tenth of the cost for the comparable treatment with Cymbalta. During 2009 the costs for Cymbalta within the reimbursement system was approximately 80 million Skr .

With this in mind the TLV has reviewed the reimbursement of the medicine.

When it comes to the treatment of most patients suffering from depression or anxiety disorder there is no decisive difference between Cymbalta and venlafaxine in terms of effect or side-effects. For this reason Cymbalta is not a cost-effective alternative to venlafaxine on treatment of depression or generalised anxiety disorder.

Neither are there any studies which support Cymbalta being a cost-effective alternative as a first or second-line treatment for a specific sub-group of patients diagnosed with depression or generalised anxiety disorder. For example, Cymbalta is not more effective than an SSRI medicine for the treatment of patients suffering

from depression and painful physical symptoms.

However, Cymbalta is probably still cost-effective for patients suffering from depression and who have not responded to a number of other antidepressants. In particular if we consider that this group of patients have a great need and also an increased risk of relapse.

#### Reimbursement of Cymbalta restricted

The TLV has decided that Cymbalta shall only be reimbursed for patients suffering from depression or generalised anxiety disorder who have not achieved their treatment objectives using at least two other

antidepressants. One of the antidepressants should be venlafaxine unless there are specific reasons against this.

In order to make this restriction clear for prescribers and to enable follow up, Cymbalta is no longer reimbursed for patients suffering from diabetes neuropathy. For these patients duloxetine has been available since 27 March 2010 when it was granted reimbursement in the form of the medicine Ariclim.

The TLV will follow up how the restriction of Cymbalta's reimbursement status is adhered to in the healthcare system.

## The TLV and pharmaceutical reviews

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

#### 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](http://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](http://www.tlv.se) (in Swedish)

Decision on Cymbalta - [www.tlv.se/cymbalta](http://www.tlv.se/cymbalta)

Decisional criteria - [www.tlv.se/principer](http://www.tlv.se/principer)

User council - [www.tlv.se/brukare](http://www.tlv.se/brukare)

Pharmaceutical reviews - [www.tlv.se/genomgang](http://www.tlv.se/genomgang)

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## This is the TLV

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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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