

Review of medicines against asthma, COPD and coughs

Summary

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TLV

TANDVÅRDS- OCH
LÄKEMEDELSFÖRMÅNSVERKET

The LFN has changed name to the TLV

On the 1st of September 2008 we changed name to the TLV,
the Dental and Pharmaceutical Benefits Agency

We decide if pharmaceutical products and dental care procedures shall be subsidized.



Why is the LFN conducting a review?

On adopting new reimbursement rules in October of 2002, it was not practically possible to review all medicines according to the new rules. Therefore, the LFN is now conducting a review of approximately 2,000 medicines to see if they should continue to be given reimbursement status in the future. Each of the medicines will be tried according to the new rules and will either retain or lose reimbursement status.

More health per tax crown

The purpose of the new reimbursement rules is to allow the Swedish population to extract as much health value as possible for every tax crown allocated to medicines. We eliminate those medicines that do not show sufficient effectiveness in relation to what they cost. However, this does not mean that we aim only to have inexpensive medicines in the medical reimbursement system. If a medicine has positive effects on a person's health and quality of life, and on a socio-economic level as a whole, then it may also be worth paying for.

Three principles for making decisions

In reimbursement decisions for a medicine, we shall, among other things, evaluate whether or not it is cost-effective. This means that we weigh the effectiveness of the medicine against its cost. We also incorporate other principles into our evaluation: the needs and solidarity principle, which means that those who have the greatest medical needs shall receive more of our healthcare resources than other patient groups; and the human value principle, which means that we must respect the equal value of all individuals.

49 groups to be reviewed

In this review we are testing medicines in one therapeutic area after another. The review encompasses a total of 49 groups of medicines and the order in which they are tested is determined by how large the sales figures were for each respective group in 2003. The medicines that sold the most will be reviewed first. However, the first two groups – medicines against migraine and medicines against diseases caused by stomach acid – were pilot groups selected on the basis of other criteria. The review of these two groups was presented in 2005 and 2006.

Extensive research and groundwork

Before any decision is made, we perform a comprehensive investigation and analysis of data on medical effect and cost-effectiveness which we request from pharmaceutical companies in regard to their medicines. We also review the scientific, medical, and health economic literature available for the group of medicines to be reviewed. In addition, we sometimes need to construct our own health economic models. We publish each completed review in a final report. The report documents the existing body of scientific knowledge for the group in question. Where possible, the agency also reports on an evaluation of each medicine's cost-effectiveness. We also prepare a synopsis of the report to be printed separately.

Assessment by independent external experts

The assembled knowledge in regard to medical effect and health economic documentation which we present in the final report has been assessed by independent external medical experts. The report has also been circulated for comments to the SBU (The Swedish Council on Technology Assessment in Health Care), Medical Products Agency and the National Board of Health and Welfare. The companies and patient organisation groups concerned, as well as the county councils' pharmaceutical reimbursement group, have also had the opportunity to give input.

If you are interested in the entire report then it is available for download in Swedish at www.lfn.se. You can also order it from the LFN. The English version of the entire report will be available shortly.

The review of medicines against asthma, COPD and coughs

In this review the LFN (Läkemedelsförmånsnämnden) has evaluated medicines used to treat asthma, chronic obstructive pulmonary disease (COPD) and coughs. The review also covers medicines used to treat cystic fibrosis. In total the review comprises approximately forty medicines which were, prior to the review, reimbursed in the Swedish reimbursement system. This review is part and parcel of our review of the entire list of medicines in Sweden which have been accorded reimbursement status. In this we rule on the continued reimbursement, or otherwise, of medicines included in the reimbursement system. Each and every medicine is evaluated and will either lose or retain its reimbursement status. The purpose of the exercise is to extract as much health as possible for every tax crown which is expended on healthcare. This is the third therapeutic group to be presented. Previously we presented the review of medicines against migraines as well as medicines against diseases caused by stomach acid.

Medicines against asthma, COPD, cystic fibrosis and coughs

The treatment of asthma, COPD, cystic fibrosis and coughs involves using medicine to open the airways, decrease swelling and inhibit the production of mucus. The same medicine is often used to treat different diseases, in particular for medicines against asthma and COPD. The same medicine can also be in different pharmaceutical forms. It can for example be available as a tablet, in liquid form, for use in a nebuliser (a device designed for inhaling medicines) and as powder for inhalation. For inhalable medicines there are a number of different aids for inhaling the medicine. A number of the medicines are also available as a double action medicine. Medicines against coughs are an older type of medicine, often lacking in scientific documentation which backs up the medical effect of the medicines in question.

Nine medicines to leave the reimbursement system

In total 34 medicines have retained their reimbursement status. Nine medicines have lost their status as a reimbursed medicine while limited reimbursement has been granted for one medicine. Of these ten medicines, six are cough medicines and four are medicines against asthma. For asthma medicines there are a number of alternatives still in the reimbursement system with as good as, or better, medical effect. Coughing and mucus production as a result of a common cold cause such short-term and relatively minor discomfort that it is not reasonable to reimburse medicines for the treatment of these symptoms. And

furthermore, the effect of these medicines is rather weak and poorly documented.

The Swedish reimbursement system is product-centred, meaning that reimbursement is contingent on the product. There are two possible routes to reimbursement; General and limited reimbursement. General reimbursement means that a medicine is reimbursed for the whole range of its therapeutic uses. Limited reimbursement means that a medicine is only reimbursed for a specific therapeutic area or patient group.

Table 1: Medicines granted general, limited or no reimbursement from the 1st of October 2007.

General reimbursement granted:

- | | |
|---------------------------|--------------------------------------|
| • Acetylcystein | • Mucomyst |
| • Aerobec | • Oxis Turbuhaler |
| • Aerobec Autohaler | • Pulmicort |
| • Airomir | • Pulmicort Turbuhaler |
| • Airomir Autohaler | • Pulmozyme |
| • Atrovent | • Salbutamol Arrow |
| • Bambec | • Seretide Diskus |
| • Beclomet Easyhaler | • Seretide Evohaler |
| • Becotide | • Serevent Diskus |
| • Bricanyl | • Singulair |
| • Bricanyl Depot | • Spiriva |
| • Bricanyl Turbuhaler | • Symbicort Turbuhaler |
| • Budenonid Arrow | • Teofyllamin Ipex |
| • Buventol Easyhaler | • Teovent (oral and rectal solution) |
| • Combivent | • Ventoline |
| • Flutide Diskus | • Ventoline Diskus |
| • Flutide Evohaler | • Ventoline Evohaler |
| • Foradil | • Ventoline Depot |
| • Giona Easyhaler | • Viskoferm |
| • Ipramol | • Xolair |
| • Ipratropiumbromid Arrow | |

Limited reimbursement:

- Bisolvon

Bisolvon has been granted reimbursement only for patients with cystic fibrosis or primary ciliary dysfunction.

No reimbursement granted:

- | | |
|---|---------------------|
| • Efedrinhydroklorid APL (oral solution) | • Mollipect |
| • Efedrinhydroklorid i Quilla Simplex APL | • Teovent (tablett) |
| • Lepheton - Desentol APL | • Theo-Dur |
| • Lomudal (powder for inhalation) | |

Appealed decisions:

- | | |
|----------------------|------------------------------------|
| • Asmanex Twisthaler | • Efedrinhydroklorid APL (capsule) |
|----------------------|------------------------------------|

The companies have appealed the LFN's decision to remove these medicines from the reimbursement list. These medicines will because of this retain their reimbursement until the courts have ruled otherwise.

Decisions free up to 40 million Skr per year

The decisions in this review are estimated to save approximately 40 million Skr per year. This money can be used for other more urgent treatments within the healthcare system.

The decisions enter into force on the 1st of October, 2007, unless appealed. Following this date the medicines which have been excluded from the reimbursement system will no longer be reimbursed. This means that patients have approximately four months to contact their doctor and change their treatment. For those decisions that have been appealed, the medicine will continue to be reimbursed until the courts rule otherwise. A list of appealed decisions is available at the LFN website.

Sales value of 1.8 billion Skr

The medicines in this review have a combined sales value of 1.8 billion Skr. The patients themselves pay approximately a quarter of the costs in a so-called "own fee". Sales are dominated by inhaled medicine in powder form which stands for 60 percent of the sales.

This is used mainly for treating asthma, but also for COPD. Over the past five years there have been some changes across the composition of the sales. Sales for double action medicines have exhibited strong growth. Simultaneously, it is possible to discern some decline in the sales of anti-inflammatory drugs for inhalation and long-acting bronchodilators, both of which are the key components of double action drugs. It is however clear that the increase cannot only be explained by a matching decrease in the sales of these two groups. One probable contributing factor is the usage of double action drugs for COPD.

There are a number of medicines against coughs. Many are OTC and only a few are included in the reimbursement system. Sales within the reimbursement system consist mainly of two medicines: Molipect and Acetylcysteine.

Table 2: Composition of sales for medicines in the asthma, COPD and coughs review.

Pharmaceutical group	Sales value 2006 (M Skr)
Bronchodilators for inhalation	966
Anti-inflammatory substances for inhalation and anticholinergics	536
Bronchodilators in other dosage forms	14
Others	88
Expectorant	120
Cough reduction substances	12
Cough reduction substances in combined forms	58
Total	1 794

Socio-economic costs run to many billions

Treatment of a disease does not only comprise the cost for the medicine. Diseases can also cause other costs for society. For asthma and COPD these costs

run into the billions. These diseases cause costs within both out and in-patient care in the form of extra visits to the doctor, emergency visits and hospital stays. Other costs such as absence from work can be placed on top of this.

Coughing and other problems probably cause costs both directly in the healthcare system and through decreased productivity at work. The total socio-economic costs of coughing are however not known.

Reasons for decisions

When judging whether a medicine should be included in the reimbursement system we take into account three principles from the Act on Pharmaceutical Benefits etc. The three principles cover:

- cost-effectiveness
- needs and solidarity
- human value

We are to evaluate whether a medicine is cost-effective, meaning we weigh the value of the medicine against the cost. We shall also utilise the other two principles in our evaluations. The needs and solidarity principle means that those with the greatest medical need should have more healthcare resources than other patient groups. The human value principle means that healthcare should respect the equal value of all people.

Treatment of asthma and COPD is cost-effective

Asthma and COPD are diseases which can have a huge impact on patient quality of life. They also carry a risk of premature death, although the risk has decreased considerably since the introduction of anti-inflammatory medicines (steroids) and bronchodilators. If the medicines are used in accordance with the current recommendations then there is evidence in the scientific literature that the steps used in the treatment ladder for asthma are cost-effective.

The health economic evidence in support of medicines used for treating COPD is somewhat weaker. We judge the long-acting bronchodilators and anticholinergics to be cost-effective compared to no treatment, and the same is true for inhaled steroids. All medicines in this area are, however, not cost-effective.

Cystic fibrosis is a serious disease

Excess mucus in the airways can be a product of various diseases, everything from the common cold to the constant overproduction of mucus in cystic fibrosis. Cystic fibrosis is a difficult and chronic disease leading to huge losses in quality of life and a greatly increased risk of a premature death. That is why it is crucial that expectorant medicine be reimbursed for these patients.

Coughing is not a serious disease

Coughing and mucus production as a result of a common cold cause such short-term and relatively minor discomfort that it is not reasonable to reimburse medicines for the treatment of these symptoms. And furthermore, the effect of these medicines is rather weak and poorly documented. Therefore, patients who wish to use these medicines should stand for the costs themselves.

Decisions for the various medicines in this review

This review covers 43 medicines in total. Here is a summary of the main points in the decisions made.

Short and long-acting bronchodilators for inhalation retain reimbursement

All bronchodilators have retained their reimbursement status. These medicines are used mainly for treating asthma and COPD, but they are also used in standard treatment for cystic fibrosis.

We believe it is important with a broad range of medicines in this group. Short-acting bronchodilators are used in an emergency situation to reverse narrowing of the airways, and it is therefore important the patient can choose between different active ingredients and various inhalers.

We have not located any clinical studies which show any difference in effect between the medicines. We can however say that there are differences in price. We find the difference in price to be acceptable considering this is an emergency treatment.

The short-acting bronchodilators which remain in the reimbursement system are: Airomir (sabutamol), Airomir Autohaler (sabutamol), Bambec (bambuterol), Bricanyl (terbutaline), Buventol Easyhaler (salbutamol), Ventoline (salbutamol), Ventoline Diskus (salbutamol) and Ventoline Evohaler (salbutamol).

Long-acting bronchodilators will also remain in the reimbursement system and are mainly used for maintenance treatment.

A large number of health economic studies point towards the cost-effectiveness of these substances in maintenance treatment of asthma in combination with steroids for inhalation. There are differences in price between the substances. For these medicines we find the price difference to be acceptable as it gives the patients access to a number of active ingredients and inhalation devices. The long-acting bronchodilators which remain in the pharmaceutical reimbursement system are: Foradil (formoterol), Oxis Turbuhaler (formoterol) and Serevent Diskus (salmeterol).

Anti-inflammatory substances for inhalation – Not reasonable to reimburse Asmanex

Inhaled steroids have a well-documented effect and an accepted place in therapy. Treatment with inhaled steroids as a group can also be considered cost-effective. However, this does not mean that all inhaled steroids are cost-effective.

We find anti-inflammatory substances, at directly comparable doses, to produce similar effects in regard to asthma. At these doses there is a big difference in price between the products. The price difference varies depending on which doses you compare. The most expensive substances are between 30 and 70 percent more expensive than the cheapest. For Asmanex Twisthaler (mometasone) we find the cost in relation to the effect does not merit inclusion in the pharmaceutical reimbursement system.

Therefore there is no reason for Asmanex to retain its reimbursement status.

The pharmaceutical company marketing Asmanex has not shown that the increased cost the treatment incurs adds any value compared to other inhaled steroids. Asmanex is 60 to 70 percent more expensive than the cheapest alternative. We do not believe the price difference to be justified and it to be worth paying so much for yet another product in a range of products which is already large.

The company has appealed the decision and as a result Asmanex will retain its reimbursement until the courts have ruled otherwise.

The other six anti-inflammatory steroids retain their reimbursement status. Also, the inhaled steroids in spray form and solution for nebulisers may remain in the reimbursement system. It is urgent to have these substances remain in the reimbursement system as these forms of medicine are mainly used to treat children and the seriously ill.

The anti-inflammatory medicines which retain their reimbursement status are: Aerobec (beclometasone), Aerobec Autohaler (beclometasone), Beclomet Easyhaler (beclometasone), Becotide (beclometasone), Flutide Diskus (fluticasone), Flutide Evohaler (fluticasone), Giona Easyhaler (budesonide), Pulmicort (budesonide) and Pulmicort Turbuhaler.

Anticholinergics remain in the system

The medicines in this group are used almost exclusively to treat COPD, but Atrovent (ipratropium) can also be used to treat asthma. We find that both Spiriva and all dosage forms which contain the active ingredient ipratropium shall remain in the reimbursement system.

Ipratropium has a documented effect on lung function and breathing difficulties for patients with COPD. It can also have an effect on asthma symptoms. Spiriva is somewhat more expensive than ipratropium, but there are indications that Spiriva is cost-effective for the treatment of COPD. The anticholinergics which remain in the reimbursement system are: Atrovent (ipratropium), Ipratropiumbromid Arrow (ipratropium) and Spiriva (tiotropium).

Double action drugs retain reimbursement

All double action drugs may remain in the reimbursement system. Seretide and Symbicort are combinations of a long-acting bronchodilator and an anti-inflammatory substance (steroid). There are price differences between the substances but we consider these to be reasonable. We also consider it to be important with access to both of the double action drugs and devices. It has been proven that it is cost-effective to add a long-acting bronchodilator to inhaled steroids when the medical effect has been negligible, primarily when treating asthma but also for COPD.

The cost for the pharmaceuticals becomes lower using a double action drug than if each of the medicines is bought on their own. It is however important to first arrive at the lowest effective dose for each of the medicines before migrating to the double action drugs. This is in order to avoid a too high maintenance dose of the inhaled steroid.

We consider the combination of an anticholinergic and a short-acting bronchodilator to be of value for patients who are in constant need of both of the active ingredients. The double action drugs Combivent and Imprimol are between 10 and 30 percent cheaper than each of the medicines bought on their own.

The double action drugs which retain their reimbursement status are: Combivent (salbutamol and ipratropium), Ipramol (salbutamol and ipratropium), Seretide Diskus (fluticasone and salmeterol), Seretide Evohaler (fluticasone and salmeterol) and Symbicort Turbuhaler (budesonide and formoterol).

Singulair remains in the reimbursement system

Singulair (montelukast) in granule form and as a chewable tablet is of value for children with infection-triggered asthma. The medicine is easy to take and it is considered relatively free from side-effects. We consider it to be especially valuable to have other dosage forms for children who can have difficulties with using inhalation devices in the correct way.

Singulair tablets have advantages which, despite the higher price, result in the substance being granted continued reimbursement. Singulair has an anti-in-

flammatory effect which differs from the anti-inflammatory effect of inhaled steroids. It also has a different side-effect profile compared to long-acting bronchodilators.

We underline that it is important to try treatment with inhaled steroids and long-acting bronchodilators before using Singulair due to the high cost. It is also extremely important that the effect is evaluated and that treatment be terminated if it is not giving results, in order for it to be cost-effective.

Teofyllamin for emergency treatment still in reimbursement system

Teofyllamins are used for acute and maintenance treatment for asthma. This group of medicines may to a certain extent also be used for treating COPD. But is not recommended as a general treatment option due to side-effects and the risk of interactions when used together with other medicines, as well as the risk of toxicity.

Teofyllamins, in the form of injection fluid and oral solutions and suppositories, are used primarily for emergency treatments. They are because of this most widely used within in-patient care. Experts whom we have used underline that there are patients who get the above forms of teofyllamins on prescription. This is mainly for patients with frequent asthma attacks who fail to relieve the attack through using short-acting bronchodilators. In these cases the patient can get help in stopping an attack by adding teofyllamin. Children make up part of the patient group and pediatricians therefore see a need for having the medicine within the reimbursement system.

The teofyllamins which remain in the reimbursement system are: Teofyllamin Ipex (teofyllamin), injection fluid and Teovent (choline theophyllinate) in oral solutions and suppositories.

Teofyllamins for maintenance treatment lose their reimbursement

We do not consider it proven that maintenance treatment with teofyllamins is cost-effective. Furthermore, there are more modern medicines which are better documented both in terms of effect and safety.

The medical effect from teofyllamins is difficult to judge. There is no literature showing that teofyllamins are cost-effective in comparison with more modern medicines.

The teofyllamins which lose their reimbursement status are: Teovent (choline theophyllinate) in tablet form and Theo-Dur (teofyllamin) prolonged-release tablets.

Lomudal leaves the reimbursement system

In our estimation the increased cost when using Lomudal is not compensated for by any medical or financial advantages. Lomudal should therefore not be covered by the reimbursement system. The medicine has no clear effect on asthma according to the latest studies. It may have an effect on exercise-induced asthma, but here there are cheaper treatment alternatives available.

Lomudal is available in different formulations. This review only affects Lomudal powder for inhalation. Our decision does not affect the other formulations, eye-drops, nasal spray and oral solution. These formulations will retain their reimbursement status.

Xolair retains reimbursement status

Xolair is a medicine which should only be used by people with very serious asthma. We decided in March 2006 that Xolair should be included in the pharmaceutical benefits scheme. We draw the same conclusion this time as we did then, and continued inclusion is dependent on some follow-up conditions. The company shall follow up the usage of Xolair in clinical practice. These follow ups shall be reported to us at the latest 31st of December, 2010.

Acetylcysteine retains its reimbursement

In our estimation soluble tablets with acetylcysteine shall remain in the reimbursement system. We believe it to be justified to reimburse long-term treatment with acetylcysteine for COPD patients with chronic bronchitis, as well as for patients with cystic fibrosis.

Acetylcysteine is used as a standard treatment for patients with cystic fibrosis and patients with primary ciliary dysfunction. This is a very serious disease. Furthermore, these are patients with a great medical need where other treatment alternatives are lacking or severely limited.

Acetylcysteine is also available as a solution for nebulisers. This medicine is used as a standard treatment for patients with cystic fibrosis. Acetylcysteine as a solution for nebulisers shall also retain its reimbursement status.

However, we consider coughing and mucus production as a result of a common cold to cause such short-term and relatively minor discomfort that it is not reasonable to reimburse medicines for the treatment of these symptoms. Neither is there any documentation which supports this usage of acetylcysteine.

The question is whether such a usage should be an exception for reimbursement. However, in our estima-

tion, it would be difficult to enforce such a limitation in practice.

The medicines which retain their reimbursement status are: Acetylcysteine (acetylcysteine), Muscomyst (acetylcysteine) and Viskoferm (acetylcysteine).

A number of medicines against coughing lose their reimbursement

Coughing and mucus production as a result of a cold cause such short-term and relatively minor discomfort that it is not reasonable to reimburse medicines for the treatment of these symptoms. And furthermore, the effect of these medicines is rather weak and poorly documented. Therefore, patients who wish to use these medicines should stand for the costs themselves.

Mollipect contains an expectorant (bromhexin) and a bronchodilator (ephedrine) component. The studies done show that the expectorant component (bromhexin) can have some small effect on the stickiness of the mucus, but however has no effect on coughing, shortness of breath or lung function. Ephedrine has a bronchodilator effect but has no effect on coughing unless it is due to a narrowing of the airways. There are other bronchodilators which are cheaper, better documented and have a better side-effect profile, if there is a need for a bronchodilator effect.

The effect of Lepheton-Desentol is badly documented. There is no scientific evidence showing an effect when used for treating coughing due to croup. Neither is Lepheton-Desentol recommended for treatment of croup in the Swedish pharmaceuticals book (Läkemedelsboken) There, instead, cortisone in inhaled or tablet form is recommended. There is also scientific evidence for this recommendation. The medicines Lepheton and Desentol have not either been reimbursed in Sweden as free-standing medicines.

The medicines which, according to the LFN, should lose their reimbursement status are: Mollipect (bromhexin/ephedrine), Lepheton-Desentol (ephedrine/ethylmorphine/diphenhydramine), Efedrinhydroklorid APL, oral solution and capsules (ephedrinehydrochloride) and Efedrinhydroklorid in Quilla Simplex APL (ephedrinehydrochloride).

The decision to exclude Efedrinhydroklorid APL capsules from the reimbursement system has been appealed. As a result the medicine will retain its reimbursement until the courts have ruled otherwise.

Pulmozyme retains reimbursement

Pulmozyme is used for treating cystic fibrosis. There is no comparable medicine on the market. Cystic

fibrosis is a serious, chronic disease which leads to great losses in quality of life and a greatly increased risk of an early death. It is therefore crucial that mucus-reducing medicines be reimbursed for these patients.

Limited reimbursement for Bisolvon

Patients with cystic fibrosis and primary ciliary dysfunction should get this medicine reimbursed. Most of these patients use Bisolvon for inhalation, but they should also get reimbursement for Bisolvon tablets as this treats diseases which lead to great losses in quality of life.

Coughing and mucus production as a result of a cold cause such short-term and relatively minor discomfort that it is not reasonable to reimburse medicines for the treatment of these symptoms. And furthermore, the effect of these medicines is rather weak and poorly documented. Therefore, patients who wish to use these medicines should stand for the costs themselves.

Reimbursement for Bisolvon in tablet form will therefore be limited to those who have cystic fibrosis or primary ciliary dysfunction.

What constitutes a cost-effective medicine?

When the LFN decides whether or not a medicine should be given reimbursement status, we shall, among other things, evaluate whether or not the medicine is cost-effective. Or, put more simply, if the medicine is worth its price, if treatment with the medicine costs an amount of money that is reasonable for society in relation to the healthcare benefits that the medicine delivers. The size of the cost of a medicine is therefore not a good measure of whether or not we are using the right medicine or even a sufficient amount of it. What is important, on the other hand, is that use of a medicine is cost-effective, not just for healthcare, but for society as a whole. To investigate how cost-effective a medicine is gives us a foundation for being able to prioritize and therefore use resources in the best way.

Benefits weighed against costs

What then, does it mean, for use of a medicine to be cost-effective? First of all, it does not mean that all inexpensive medicines are cost-effective, while more expensive ones are not. When determining whether or not a medicine is cost-effective, all the expenses associated with the medicine being used must first be totaled. There is, first and foremost, the cost of the medicine. But costs can also arise if the patient has to visit a doctor to receive the medicine, or if any other additional healthcare assistance is needed, as well as any side-effects that the medicine might cause.

This total cost is weighed against the benefit that the medicine provides, primarily in the form of healing, alleviation,

and increased quality of life for the patient. One must also account for the fact that use of the medicine may also entail savings in other areas of healthcare, in that the patient does not need to visit the doctor as often, avoids hospitalization, operations, etc. However, all this is still not enough to gain a societal perspective. We also have to account for whether or not a medicine allows a patient to work and earn a living and contribute to our common welfare instead of being on medical leave or even being placed on early retirement. In this case, benefits go to the individual in production, and to the state, who then avoids fees for sick leave and early retirement. If the patient is older, it is possible that use may lead to the individual's being able to take better care of himself or herself and thereby require less assistance from elderly care services or relatives. This is also a socio-economic benefit on the plus side of a cost-effectiveness analysis.

Does not need to lead to cost-savings

It sometimes happens that the positive effects of a medicine are so great that they entirely compensate for the medicine's costs. Then it can be said that the treatment is cost-saving. But we do not make such high demands to consider use of a medicine to be cost-effective; in other words that it has a reasonable cost when seen in relation to the effect and therefore should be given reimbursement status. That people are healthy, without pain, and able to live a more normal life by taking a medicine, has a great value for which we are prepared to pay.

