The Dental and Pharmaceutical Benefits Agency
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Version 2.0

Handbook – reviewing the reimbursement status of pharmaceuticals

Denna handbok kommer att uppdateras. Information om uppdateringar kommer att finnas på Tandvårds- och läkemedelsförmånsverkets hemsida www.tlv.se . Version 2.0. Publiceringsdatum 2012-10-19.

Contents

This handbook will be updated. Information on updates will be made available at the TLV's website at www.tlv.se . Version 2.0. Date published 2012-10-19.

1 Introduction

The Dental and Pharmaceutical Benefits Agency (TLV) has the remit of reviewing reimbursement status for the medicines within the pharmaceutical benefits system and determining if these medicines should remain within the high cost threshold or not.

We prioritise reviewing medicines in areas where we judge there to be the greatest reason to query if the use of a medicine or medical device is cost-effective. Our objective is to extract the greatest possible health for the tax funds expended on the reimbursement of medicines and medical devices.

This handbook is aimed at those wanting to know more about review activities undertaken by the agency and also how we work with reviews. The handbook is available online at www.tlv.se.

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2 Reviewing pharmaceuticals

2.1 Our review remit

The Dental and Pharmaceutical Benefits Agency, TLV, makes decisions on which pharmaceuticals and medical devices shall be included in the high cost threshold and thereby besubsidized, as well as evaluating the existing positive list.

We evaluate and review reimbursement on a continual basis for products which are part of the reimbursement system.

Our overall objective is ”most health possible for the tax funds expended on the reimbursement of medicines and medical devices”. Our activities shall contribute to having cost-effective and suitable medicines and medical devices within the high cost threshold system.
Nowadays we initiate a number of smaller reviews, rather than routinely reviewing entire therapeutic areas, and put the spotlight on individual products or limited groups of medicines which do not have a cost-effective or suitable usage.

Previously the review remit meant a review of the approximately 2000 medicines which were part of the high cost threshold system, as part of the shift to the new rules and regulations for reimbursement which took place in 2002. Then all medicines were divided into 49 therapeutic groups which would be reviewed one by one. The order in which these groups would be reviewed was based on sales volume for the calendar year of 2003.

In the budget proposition leading up 2010 the Government proposed that the TLV would get increased funds to increase the rate the reviews were carried out at. Due to the new directives in the appropriation directions for 2010[1] we have transitioned to working in a more effective process where we abandon the previous order of prioritisation from 2003 to instead carry out continual internal mappings and prioritisation analyses when choosing which areas to review.

The current working method with smaller reviews and annual prioritisation analyses means that we can rationalise our work and respond more flexibly to changes on the pharmaceutical market.

2.2 New rules for medical devices

During 2010, and in connection with our review of cannula pens, we tightened the requirements for when a medical device shall be included in the pharmaceutical benefits system. In general we now make the same demands for medical devices as we make for medicines. This means that the cost of

[1] S 2009/1010 SK (partly) Appropriation directions for the 2012 budget year in regard to the Swedish Dental and Pharmaceutical Benefits Agency

treatment for a medical device shall be compared with the cost of treatment using the most cost-effective alternative.

3 Regulatory framework

3.1 Criteria for the reimbursement of pharmaceuticals

Within the TLV the Board for pharmaceutical benefits has been appointed by the Government to make decisions on reimbursement status and prices for medicines and medical devices. The board also makes decisions on reviews, that is to say makes decisions on exclusions, limited reimbursements or continued general reimbursement status.

The criteria on which the board base their decisions on reimbursement for medicines are in article 15 § in the Ordinance (2002:160) on pharmaceutical benefits etc. A prescription medicine shall, in accordance with this regulation, be covered by the pharmaceutical benefits system and purchase price and sales price shall be be set for the medicine on the condition

> 1. that the costs of using the drug, with observation of the provisions of Section 2 of the Health and Medical Services Act (1982:763), appear reasonable from the medical, humanitarian and economic aspects, and
>
> 2. that there are no other available drugs or treatment methods which after overall consideration of the intended effects and harmful effects as referred to in Section 4 of the Medicinal Products Act can be judged as significantly more suitable for the purpose.

In the preparatory work it is clear that our analysis shall have a holistic perspective where medical, humanitarian and socio-economic aspects should be weighed up.

”Medicines are proposed to only be included in the pharmaceutical benefits system if they fulfil certain criteria indicated in law. Basic starting points in this case are the objectives outlined for the healthcare system and indicated in the Health and Medical Services Act (1982:763), namely the human value principle and the needs and solidarity principle. Using these principles the Pharmaceutical Benefits Agency shall try medicines against the criterion of cost-effectiveness stated in the Ordinance on pharmaceutical benefits etc. Also, the criterion of marginal utility is applied.”[2]

Before the TLV was founded, an effective mechanism was lacking to make it possible to systematically carry out evaluations of medicines from a societal and health economics perspective .

3.2 Reimbursement of medical devices

In accordance with article 18 § 3 of the law on pharmaceutical benefits the benefits shall also cover medical devices which are needed in order to administer medicine to the body or to check one’s own medication.

The decision criterias stated for medicines in article 15 § of the benefits law are not directly suitable for medical devices. Set against this backdrop of the general purpose with the current regulations of

[2] Prop. 2002/03:163 page 1

the pharmaceutical benefits system and society's interest in having a State-controlled price level also for medical devices, the starting point for the TLV's evaluation of medical devices must also be grounded in which extra value a medical device brings compared to other similar products in relation to the cost they carry.

3.3 The TLV's right to initiate a review

We can, on our own initiative, decide that a medicine or product which is included in the pharmaceutical benefits system should be excludedand we can also, if there are specific reasons for it, decide that a medicine or product shall only be considered part of the pharmaceutical benefits system for a restricted area of use. This is stated in article 10 § of the law on pharmaceutical benefits.

We have the right to initiate a review of an indivdual medicine or group of medicines within the pharmaceutical benefits system, if we judge the cost-effective or suitable usage of the medicine to be absent. A requirement to carry out reviews in a specific order does not exist.

Decisions on the order in which reviews are carried out are based partly on the size of the resources which can be freed up through the reviews, and partly on the work inputs needed in order to carry out the review. The larger the work inputs needed to carry out the review the more it is necessary that the findings from the review have a considerable impact on the use of resources. The opposite is also true that the reviews which with a limited work input can provide a considerable impact on the cost-effective use of medicines within the high cost threshold will be given priority. A change in the pricing situation within an area can mean that the order in which reviews are carried out is impacted.

Also, our right to initiate a new review does not require changed conditions in any other way than that a medicine, on being newly evaluated, is no longer considered to fulfil the conditions required by 15 § in the law on pharmaceutical benefits. In principle the cost-effectiveness of a medicine can be changed immediately after we have made a decision in regard to reimbursement. This can be the case if there is a rapid change in the pharmaceutical market and the pricing within an area is changed by, for example, a new medicine being launched on the market or the expiry of a patent. The same medicine can for this reason be reviewed more than once.

4 Selection of medicines for review

4.1 Overview mapping

Prior to starting a new calendar year of activities we map which medicines are prominent when it comes to sales volumes and cost within the pharmaceutical benefits system. In our overview mapping we look at aspects such as sales volumes, reimbursement costs and cost per defined daily dose (DDD).

In connection with the mapping we also initiate a dialogue with the county councils who have the opportunity to make suggestions in regard to which medicines or therapeutic areas we should review.

4.2 Choice of prestudies

After the overview mapping we decide which areas which should become studied. The prestudy is a rapid study to give more information to be able to make suitable prioritisations in the next stage.

Some of the information contained in our prestudies is:

- The market, analysis of the market in regard to sales, number of patients etc.
- Usage and use recommendations
- Previous decisions
- Activities from other agencies in the form of national treatment guidelines, reports from the SBU etc.
- Expanded indications
- Other events in the area such as new studies, introduction of new medicines etc.
- Pending patent expiries

4.3 Starting a review

We make internal prioritisations and discuss which areas we should continue with based on our prestudies. When making our choice we weigh various factors up such as the degree of severity for a disease as well as the potential for improvement, in other words how much resources can be freed up and used in other urgent areas within the healthcare system. The decision to initiate a new review is formally taken by the Unit Head for the Unit for reviews of pharmaceutical reimbursements.

We take three ethical principles into account which apply for prioritisations within the healthcare system:

- The human value principle which means that care should be given with respect for the equal value of all people and for the dignity of the individual
- The needs and solidarity principle which means that those in the greatest medical need shall also get more of the resources allocated to healthcare. For prioritisations within healthcare the urgency of a treatment is of huge importance.

- The cost-effectiveness principle, which demands a reasonable relationship between the cost and effect of a treatment (measured in improved health and increase in quality of life), must be considered in the choice between various treatments.[3]

In regard to medical devices we make our selections based on the sales volumes and benefits costs relative to the need for a broader choice of alternatives.

4.4 External information on our prioritisations

The TLV endeavours to be open in regard to our activities and for this reason informs companies and other stakeholders of ongoing reviews online. This information contains details of which areas we intend to review and which prestudies we plan to carry out.

We update information on our reviews on an ongoing basis online in Swedish at www.tlv.se/lakemedel/omprovning-av-lakemedel/. The prioritisation order which we communicate externally on our web may come to change during the year however due to, for instance, changes on the pharmaceutical market .

[3] Prop. 1996/97:60 page. 19 and prop. 2001/02:63 page. 44

5 Case process for reviews

5.1 Information to the companies concerned

When we commence a review we inform the companies concerned in writing where we take up which products will be part of the review and ask a number of medical and health economics questions. The make-up of the questions vary and depend on the particular conditions which apply for the review in question.

When it refers to medical documentation this can be:

- Treatment efficacy, effect on the quality of life for patients or expected length of life,
- Side-effects or,
- Benefits relative to comparable treatments.

When it refers to the health economics documentation this can be:

- Which factors are most crucial for the cost-effectiveness of the medicine or,
- how the medicine's cost-effectiveness varies based on for example the severity of the disease, gender, age, primary or secondary prevention and other risk factors.

The written communication also contains an approximate timescale for the process. As a rule the companies get at least three weeks (longer if the questions asked require more time) to submit their answers. Communication between the TLV and companies concerned should, during the entire handling of the case, be written. This increases the possibility for everyone to receive the same information during the process and improves our ability to collate the informaiton which is appended to the case. For any verbal communications we will encourage companies to also submit anything added to the case in written form.

The investigators responsible for a review at the TLV is in general a project group comprising a medical investigator, health economist and a legal expert. The project group produces the documentation on which the Board for pharmaceutical benefits makes its decisions.

When it comes to reviews for the reimbursement of medical devices the reviews follow the same process in general.

5.2 Our investigation

Reviewing the investigative material

For each individual review an investigation and analysis of data on the products in question, their medical efficacy and cost-effectiveness is carried out.

We compile both medical and health economic overviews of the state of knowledge within the scientific literature for the area in question. In some cases we collaborate with the SBU on compiling this documentation and/or with the Swedish National Board of Health and Welfare. When compiling the documentaion on the area we also consider treatment recommendations from the Medical Products Agency, prioritisation documents from the Swedish National Board of Health and Welfare and documentation submitted from pharmaceutical companies. Sometimes we conduct our own meta analyses and construct our own health economic models.

Our analysis is based on a holistic perspective where medical, humanitarian and socio-economic aspects are weighed up.

Scientific advicors

We have contact with a number of scientific advisors within the medical field. These have long clinical experience and are available so that we can easily consult them during our investigations. The fields these scientific advisors represent today are general practice, internal medicine, oncology, psychiatry, diabetes and ostomy.

Experts

We are also assisted by other medical experts in complex issues. Via these experts we receive information on how specific medicines are used in everyday clinical reality. As a rule we utilise two medical experts in each investigation, of which one is often a general practitioner and the other is a specialist in the area.

When we start a new review we gather suggestions for experts from a number of instances such as the Swedish Society of Medicine, the Medical Products Agency, the Swedish National Board of Health and Welfare, the SBU and the county councils pharmaceutical benefits group (LFG).

For our decisions to fulfil the requirement of being objective we check experts before they are utilised in a project. In order to participate they must be impartial and without conflicting interests. As a basis for our evaluation we use a declaration of non-conflicting interests detailing engagements with pharmaceutical companies, share holdings or other relationships which could impact their impartiality when working on the case with us.

The experts do not however take the role as investigator in a case. They are not responsible for penning the documentation to base decisions on and do not make any decisions.

Collecting opinions and input from other agencies, the county councils' pharmaceutical benefits group and user organisations

When our investigators have produced a proposed decision then we gather input on the investigative material and the proposal from:

- The Swedish National Board of Health and Welfare, Medical Products Agency and the SBU
- County councils' pharmaceutical benefits group, LFG
- Relevant patient and user organizations

Our collaboration with patient and user organisations is primarily with organisations which receive state grants and besides those organisations also the Swedish Consumers Organisation, the National Pensioners Organisation (PRO) and the Swedish Pensioners Association (SPF) These organisations must also submit a declaration of non-conflicting interests accounting for any connections to the pharmaceutical industry.

The period in which replies may be submitted is as a rule three weeks and input is gathered on an ongoing basis, meaning that our draft proposed decision is not publicly available at this stage. The LFG is always invited to consultation with the Board.[4]

Communication to the companies concerned

When we've received input from other agencies, the LFG and user organisations a base documentation is written in the form of a memorandum proposing a course of action and decision. Here we detail the input received from the various instances and to what degree we've taken these inputs into account.

The memorandum is sent to the companies concerned who are given the opportunity to comment on it. Normally companies are given a period of at least three weeks to reply.They are also invited to a consultation with the Board where they have the opportunity to present their view of the proposal. As a rule a presentation is carried out to the Board before the Memorandum is sent out to the companies concerned.

If the proposal means a change in reimbursement status for a medicine (restriction or exclusion from the scheme) the company may sometimes be given the opportunity to submit a price decrease. On occasions such as this we inform the companies of the terms and time window which applies.

Quality assurance

After our investigator has taken a stance on the company's opinions and written a decision memorandum it is quality-assured by a different group to the project group but with the same skill set and competences. Based on their specific areas of competence they judge if the memorandum is of quality to function as documentation to make decisions on.

The presentation memorandum is finally sent to the members of the Board for pharmaceutical benefits. This takes place normally at the latest one week before the Board meets. The companies concerned are informed via e-mail of the final proposal

[4] 9§ law (2002:160) on pharmaceutical benefits etc.

5.3 The process when we make our decisions

The TLV's decision-making organ, the Board for pharmaceutical benefits, meets once a month and comprises a chairperson and six members of the board as well as six substitutes. The members of the board represent the public in their role and shall therefore be free of any prejudicial interests.

At board meetings the TLV's investigators present the review case with a proposed decision. If a representative from a company or a representative from the county councils pharmaceutical benefits group (LFG) has come for deliberation then this takes place after the TLV's investigator has presented the case. Representatives from companies or LFG each have 30 minutes at their disposal to present their opinions and answer questions from the board.

In a review case the board must decide if the medicines which are part of the case shall retain their reimbursement, receive restricted reimbursement or lose their reimbursment status completely.

5.4 Communicating our decisions externally

In accordance with the law on pharmaceutical benefits all decisions within the pharmaceutical benefits system shall apply immediately, if not otherwise stipulated (27 § law on pharmaceutical benefits, prop. 2006/07:78) but when the board rules on a change to the benefits system they are simultaneously ruling, under normal circumstances, that the decision shall come into force at the earliest three months after being announced.

Information on how the board has ruled on a case and date for the coming into force of that decision is not communicated to the companies at the meeting of the board, and is instead communicated a couple of weeks later. The decisions are sent by post and e-mail to the companies concerned the day after they have been made public.

Informational material

In connection with a review we produce informational material in the form of a fact sheet comprising an analysis of the current state of medical knowledge, our evaluation of the cost-effectiveness of the medicine as well as our conclusions in regard to which medicines or medical devices should continue or not continue to be a part of the pharmaceutical reimbursement system. In some cases we also produce supplementary information in the form of a Powerpoint presentation and an FAQ sheet.

Companies and other stakeholders who have followed an investigation receive information by e-mail on the date for the publication of a decision approximately one week before we make the decision public. The day before the publication we distribute informational material and decisions.

We inform many players of our decisions via e-mail in the healthcare area: the companies representative associations, user organisations, other agencies, pharmacies and representatives from the county councils and others.