LÄÄKKEIDEN HINTALAUTAKUNTA
Läkemedelsprisnämnden

29 March 2023

INSTRUCTIONS ON CONDITIONAL REIMBURSEMENT

General

There is often uncertainty about the total costs, cost-effectiveness and therapeutic value of new medicines. A method for controlling this uncertainty is conditional reimbursement. New pharmacotherapy is the primary group eligible for conditional reimbursement. In practice, this means new active substances or new significant therapeutic indications of medicinal products already approved for reimbursement.

Under chapter 6, section 6a of the Health Insurance Act, the Pharmaceuticals Pricing Board can make a conditional decision on reimbursement status and wholesale price if a special medical need for new pharmacotherapy is proven and if there is significant uncertainty relating to the costs of the treatment, to the therapeutic value of the medicinal product, to its cost-effectiveness or to other corresponding factors affecting the assessment of the reimbursement status or the wholesale price of a medicinal product. The provisions on conditional reimbursement will remain valid for a fixed term, to the end of 2025.

Procedure when a medicinal product does not yet have a conditional reimbursement status

The evaluation of a medicinal product's eligibility for a reimbursement status and of the reasonability of its wholesale price will always start on application. Eligibility for a conditional reimbursement status can be examined as part of this application process if the applicant proposes it.

The applicant may propose a conditional reimbursement status to be granted for a new medicinal product after the Pharmaceuticals Pricing Board has discussed in its meeting the application and requested additional information from the applicant. In their proposal, the applicant must show that there is a special medical need for their product and describe the key uncertainty concerning the medicinal product and propose how that uncertainty could be controlled. Moreover, the applicant must request that the processing of their application be suspended.

When the applicant proposes a conditional reimbursement status for their product, they must also supply the additional information requested by the Pharmaceuticals Pricing Board. This additional information must be submitted as a separate document.

A proposal for a conditional reimbursement status must include the following information:

Information	Specification
Special medical need / therapeutic alternatives, therapeutic value of the medicinal product	Show that there is a special medical need for the medicinal product in the indication in question. Give a brief description of the therapeutic value of the medicinal product, the current treatment practice of the illness, taking into account medicinal therapeutic alternatives as well as other therapeutic alternatives, such as surgical operation. Note. Conditional reimbursement status does not entitle to higher treatment costs of the medicinal product in situations where products with a similar therapeutic value are already used for the treatment of the same illness.
Key uncertainty concerning the medicinal product	Give a description of the key uncertainty concerning the medicinal product, such as uncertainty concerning therapeutic value, cost-effectiveness, treatment costs, patient numbers, dosage, length of therapy and/or other factors affecting the reimbursement status or reasonable wholesale price.
Proposal for controlling the uncertainty	Give a well-founded and concrete proposal for measures to control the uncertainty associated with the medicinal product. The proposal must especially address the suitability of the measures in controlling the uncertainty and their feasibility in Finland.
Request for suspension	In their proposal for conditional reimbursement, the applicant must request a suspension of the processing of their application for the duration of the process to examine the product's eligibility for a conditional reimbursement status.

The Pharmaceuticals Pricing Board will assess, case by case, whether to start the negotiations on conditional reimbursement. A notification of the Pharmaceuticals Pricing Board's decision to start negotiations will be published on the Board's website under "Kokouspäätökset" (meeting decisions). The processing of the application will be suspended for the duration of the negotiations. If the Board decides not to start negotiations, the processing of the application will continue in the normal process. The applicant has the

opportunity to provide additional information to support their application, after which the Board meeting will reach a final decision.

The practices and duration of the negotiations are case-specific. The contact person at the Pharmaceuticals Pricing Board is the presenting officer.

If the Board grants the medicinal product a conditional reimbursement status, the final decision on reimbursement status and wholesale price will include an agreement between the marketing authorisation holder and the Pharmaceuticals Pricing Board about the conditions for monitoring and controlling the uncertainty associated with the medicinal product. If no agreement is reached in the negotiations, the Board will decide to terminate the negotiations without result. The processing of the application will continue in the normal process. The applicant has the opportunity to provide additional information to support their application, after which the Board meeting will reach a final decision.

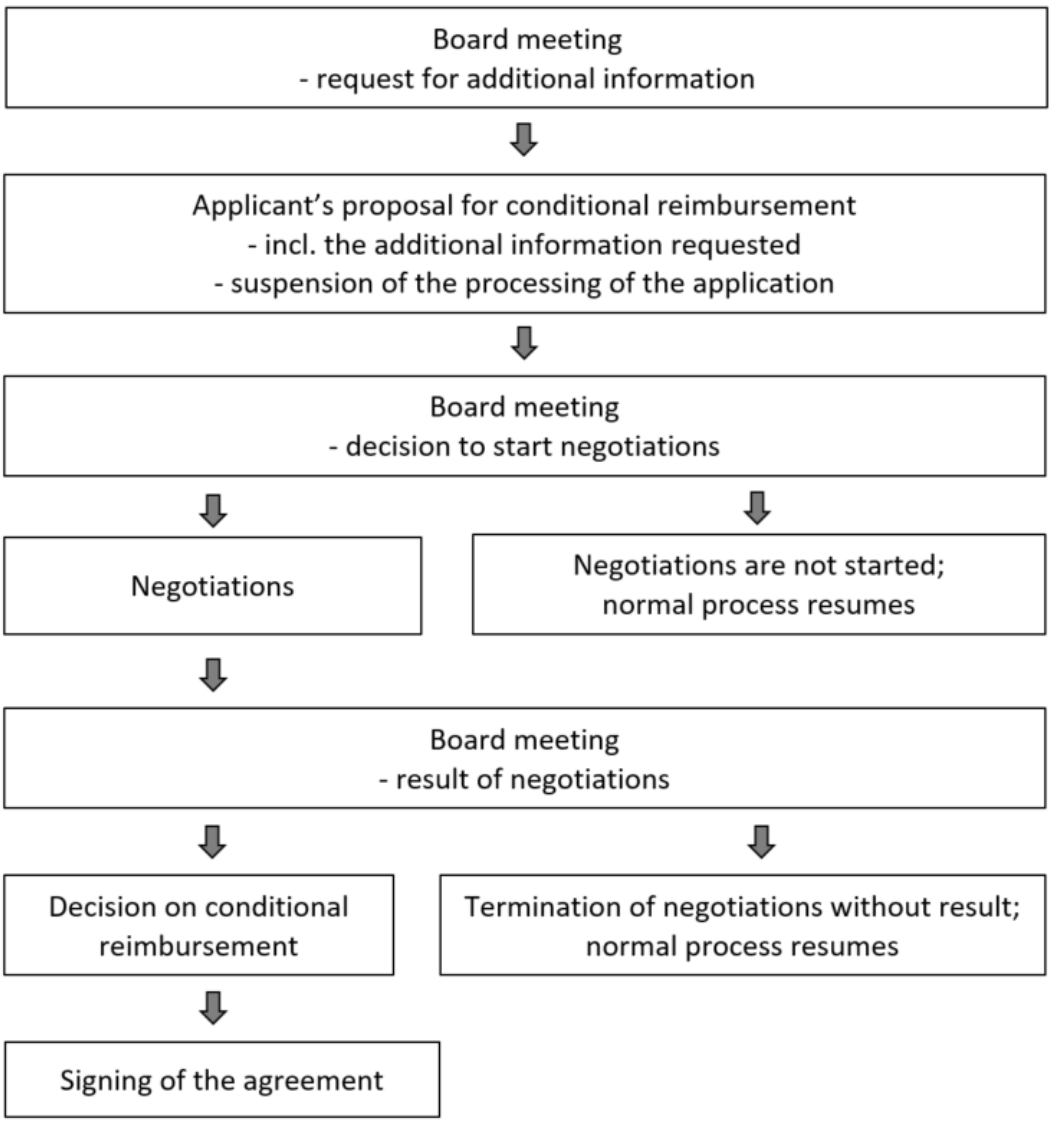

Figure 1 Procedure when a medicinal product does not yet have a conditional reimbursement status

Applications for reimbursement status and wholesale price for a product with confirmed conditional reimbursement status

The eligibility of a medicinal product for conditional reimbursement will be reassessed if the marketing authorisation holder applies for a **renewal** of the product's conditional reimbursement status or for an **extension of reimbursement status** or **special reimbursement status** during the validity of the conditional reimbursement status.

Applications for renewal, extension and special reimbursement status must be drawn up in accordance with the instructions of the Pharmaceuticals Pricing Board. If the applicant proposes a continuation of the conditional reimbursement status, the application must include in addition to the necessary ordinary application documents a separate document that includes the proposal for a conditional reimbursement status and the reasons for it. This document should be named "Confidential proposal for conditional reimbursement". If the Pharmaceuticals Pricing Board requests expert opinions on the application from the Social Insurance Institution (Kela) or from its own Expert Group, the separate document containing confidential agreement information will not be included among the consultation material. The applicant must not include any confidential agreement information in any other application document.

The application and the proposal for conditional reimbursement must take into account any changes (such as changes in research evidence, sales, market situation, clinical practice or therapeutic alternatives) that have occurred while the current decision on reimbursement status and wholesale price has been in force. They must also take into account the effects of these changes on the grounds for a conditional reimbursement status and on the proposed measures to control uncertainty.

When an application concerns a medicinal product with confirmed conditional reimbursement status, the Secretariat of the Pharmaceuticals Pricing Board can start the negotiations without a decision by the Board meeting. However, even in such cases, and especially if there are any unclear issues with the application, the decision to start negotiations can be taken by the Board meeting instead of the Secretariat.

As a rule, suspension of the processing of the application is required for the negotiations on conditional reimbursement. The applicant is requested to contact the presenting officer on this matter.

Drafting and signing of agreement

Once an agreement is reached, the Pharmaceuticals Pricing Board will draw up a draft agreement, which is sent to the applicant for comments. Both parties must approve the document before the Board meeting

can confirm the agreement. The agreement documents (one for each party) will be signed after the Board's approving decision.

The applicant must give, and if necessary later update, the contact details of the person the Pharmaceuticals Pricing Board can be in contact with concerning the agreement after the conditional reimbursement status has been granted.

Processing fee for conditional reimbursement

A separate processing fee will be charged for conditional reimbursement. Once the Pharmaceuticals Pricing Board has reached its final decision, the applicant will be invoiced for both the processing fee and the application fee. The processing fee will be EUR 6,600 when a medicinal product is granted conditional reimbursement status after negotiations. The fee will be EUR 3,300 when no conditional reimbursement status is granted.