Icelandic Medicines Agency

Reimbursement system for specialty care high-cost medicine

Procedure

The Icelandic Medicine Agency holds the authority to decide whether a Specialty Care High-Cost Medicines (SCHCM) should receive reimbursement once a review/opinion has been obtained from the Medicine Committee of the National Hospital of Iceland (MCL). The objective of the procedure is to set a defined criterion for the approval and evaluation of reimbursement for SCHCM.

Reimbursement for SCHCM

Reimbursement is requested, and an application is sent for each indication, on a form for:

1. **Each indication of medicine**
    - Application must be submitted on the form „Application for reimbursement for Licensed medicines“
2. **New pharmaceutical form or strength**
    - Application must be sent on the form ,,Application for reimbursement for Licensed medicines – New Pharmaceutical form or strength“. It is important that it is stated in the application whether it is a cost increase or not. If approved reimbursement leads to changes in treatment, then changes should be explained.
3. **Biosimilar or generic drugs**
    - If there is an approved reimbursement for a similar indication of an original drug, a simpler application is submitted on the form „Application for reimbursement for Licensed medicine – Biosimilar or generic drugs“
    - If there is not an approved reimbursement for a similar indication of an original drug, application must be sent on the form „Application for reimbursement for Licensed medicines“

In accordance with the Icelandic law of medicine nr. 100/2020 article 66. MCL should provide IMA a review/opinion on the matter before IMA makes a decision regarding reimbursement. Therefore, it is important that IMA sends an application for review to MCL as soon as possible. The review/opinion from MCL should be provided in written inclusive of argumentation on the matter alongside all other important documents. Once the IMA has received the review/opinion from MCL it can then make its decision regarding reimbursement for SCHCM.

Individual reimbursement for specialty care high-cost medicine

Individual reimbursement for a medicine is either for a single reimbursement action or for a temporary reimbursement to an individual who is insured by the Icelandic social insurance system, it is for medicines that are not part of the general reimbursement system. Reimbursement of medicine can be tied to an individual or a group of people who have been diagnosed with a symptoms or syndrome which demands a certain/specific medicine treatment.

The MCL makes decisions on individual reimbursement regarding medicine that the National Hospital of Iceland pays for. Applications for individual reimbursement must be sent directly to the MCL.

Rules, criteria and implementation of decisions regarding reimbursement for Specialty care high-cost medicine

Implementation – Reimbursement regarding SCHCM Article 18 of regulation no. 1414/2020 on pricing and reimbursement.

Once IMA has received an application for reimbursement for SCHCM the agency requests for a review/opinion on the matter from the National Hospital of Iceland. The review must address the following factors:

- What is the clinical benefits of using the particular medicine?
- Has a contract price been agreedfollowing a public procurement process?
- What is the cost impact on the budget part for specialty care high-cost medicine.

When IMA evaluates an application for reimbursement for SCHCM, the agency takes the following factors into account:

- The review/opnion on the matter from the MCL.
- Is the price of the SCHCM in accordance with its treatment value, e.g Compared to other existing medicine on the market.
- What is the estimated number of patients and is the estimated sales volume of the medicine in accordance with the provided the sales plan.
- Whether there is a reimbursement system for the SCHCM in reference countries.

If a health technology assessment does exist it should be used as a reference in the decision process for reimbursement for SCHCM in accordance to article nr. 59 in law of Medicine nr. 100/2020.

IMA has right to make limitation on reimbursement for SCHCM to certain indication, clinical guidance or specific field in medicine.

If an application for reimbursement for SCHCM is approved the IMA sends a letter to the registered agent/applicant inclusive of information when the decision takes effect. The agent/applicant can make observations or changes to the decision within two weeks of receiving the notification.

If IMA considers rejecting an application for reimbursement for SCHCM the agent is informed and given two weeks to submit his objections to the possible decision.

If the decision of the IMA is to reject an application for reimbursement for SCHCM, the decision shall be substantiated, and the applier must be informed of his right to take IMA´s decision to court.

Once IMA has approved reimbursement for SCHCM, information is added to the list: “Approved specialty care high-cost medicine” which is published on IMA website.

IMA is authorized to re-evaluate its decisions for classification medicine as SCHCM.

Implementation - Individual reimbursement for specialty care high-cost medicine - Articles 14 and 16 of Regulation no. 1414/2020 on pricing and reimbursement.

Physician shall send an application for individual reimbursement for SCHCM to MCL. The MCL makes decisions on individual reimbursement regarding medicine that the National Hospital of Iceland pays for.

Before the decision is taken regarding individual reimbursement, the IMA must have issued or agree to a maximum price for the medicine in question

Definition / Legal basis

The Medicinal Products Act no. 100/2020.

Article 3(7) Medicinal products subject to licence: Medicinal products subject to licence' refers to medicinal products that may only be used after they have been approved by Landspítali's Medicinal Products Committee, are normally expensive, require great care in their use and require some sort of expert knowledge and the involvement of healthcare workers, whether this is in connection with their administration or the monitoring of the patient or the medicinal product.

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