Reimbursement system for specialty care high-cost medicine

Procedure

The Icelandic Medicine Agency holds the authority to decide whether an indication for Specialty Care High-Cost Medicines (SCHCM) should receive reimbursement once an opinion has been obtained from the Drug and Therapeutics Committee (DTC) of the National University Hospital (NUH) of Iceland.

The DTC holds the authority to decide on individual reimbursement for SCHCM.

The objective of the procedure is to set a defined criterion for the approval and evaluation of reimbursement for SCHCM.

A. The Icelandic Medicine Agency holds the authority to decide whether an indication for Specialty Care High-Cost Medicines (SCHCM) should receive reimbursement once an opinion has been obtained from the Drug and Therapeutics Committee of the National University Hospital of Iceland (DTC).

Regulation – Criteria for reimbursement in SCHCM (Article 18 of regulation no. 1414/2023)

Once IMA receives an application for reimbursement for SCHCM, the agency requests for an opinion on the application from the DTC of NUH. The review must address the following factors:

1. What are the clinical benefits of using the particular medicine?
2. Is the price of the SCHCM in accordance with its treatment value, e.g. compared to other medicine on the market?
3. What is the estimated number of patients, treatment length and cost effect on the NUH budget?
4. If the DTC of the NUH recommends reimbursement for the applied indications of the SCHCM and what conditions if any.

When evaluating if reimbursement is approved for indication of SCHCM the IMA shall take into account:

- The review from the DCT of the NUH
- If reimbursement is approved in the indication applied for in the 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 with article nr. 59 in law of Medicine nr. 100/2020.

IMA holds the authority to make following limitation on reimbursement for SCHCM to certain indications:

a. Narrower indication
b. Clinical guidelines or treatment guidelines
c. Specific filed in medicine

d. That the most economical option of the comparable medicine should be used
e. Public procurement is finalised

If the approval of reimbursement is limited according to the above, the IMA shall inform the applicant of the limitations in the letter to the applicant.

The IMA holds the authority to revaluate a decision on reimbursement, e.g. if the price of SCHCM is higher following public procurement process than the price in the application for the reimbursement.

Application for reimbursement of SCHCM

Agents or marketing authorization holder (MAH) apply for reimbursement, one application for each indication. Application forms can be found here, for:

1. **Reimbursement for SCHCM each indication of medicine**
   - Application must be submitted on the form *„Application for reimbursement for SCHCM – New indication "*.

2. **New pharmaceutical form or strength**
   - Application must be sent on the form *"Application for reimbursement for SCHCM – 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 SCHCM – 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 SCHCM – New indication*"

The DCT of the NUH can in exemptional cases apply for reimbursement in indication of SCHCM.

The decision of IMA

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

If the IMA:

- **Approves 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. Information is added to the list: "*Approved specialty care high-cost medicine*" which is published on IMA website.
- **Considers rejecting an application** for reimbursement for SCHCM the agent is informed and given two weeks to submit his objections to the possible decision.
- **Rejects 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.

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

Public procurement and reimbursement

1. After a contract for the purchase of medicine is made:
    a. MAH or agent applies for reimbursement for the indications that do not have reimbursement approved.
2. The contract for the purchase of medicine expires:
    a. The NUH purchasing unit notifies the IMA.
    b. IMA performes price comparision to the reference countries and notifies the agent or MAH about the result.
    c. Applieer must be informed of his right of objection, two weeks.
    d. New price is published in the Price Catalogue.
    e. Reimbursement decision is not re-evaluated.

B. The DTC holds the authority to decide on individual reimbursement for SCHCM.

The Medicinal Products Act no. 100/2020, Article 44

The DCT of NUH shall make decisions on individual reimbursement for the medicines paid by the hospital, i.a. for medicines that fall under number 4. Paragraph 2 Article 66: NUH makes a decision on reimbursement of exempted medicines according to Paragraph 5 Article 44.

Applications for individual reimbursement must be sent to the Medicines Committee of Landspítala. Representatives of the DCT may not have a special and significant interest in the development, production, marketing, import, distribution, wholesale or retail sale of medicines (Pharmaceuticals Act no. 100/2020, Article 44).

Regulation no. 1414/2023 on pricing and reimbursement, Article 16

Physician shall send an application for individual reimbursement for SCHCM to DTC.

Applications and processing by the DTC of the NUH depend on the regulation on the appointment, role and activities of the DTC of the NUH and the Development Center of Icelandic Health Care.

The DTC of the NUH makes decisions on individual reimbursement regarding medicine that the NUH pays for.

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

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 DTC 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 DTC .

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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