Classification of a medicine as a Specialty Care High-Cost Medicine

Procedure

The Icelandic Medicine Agency (IMA) holds the authority to decide whether a medicine is to be classified as a Specialty Care High-Cost Medicine (SCHCM) once a review/opinion has been obtained from the Drug and Therapeutics Committee of the National Hospital of Iceland (NHL) on the matter/assessment.

The objective of the procedure is to set a defined criterion as to when a medicine should and can be classified as SCHCM inclusive of guidelines and (which) references are to be considered in the assessment.

Rules and categorization for SCHCM

IMA is the responsible authoritative body in deciding if a medicine should be classified as SCHCM if the medicine has an Icelandic marketing authorization and is marketed. In addition, the IMA may classify medicines that have been granted an exemption in accordance with Article 12 of the Medicinal Products Act no. 100/2020 as SCHCM in the same way as a medicine that upholds a marketing authorization according to Article 11 of the same act, once a review/opinion on the matter from the NHL has been obtained/received.

IMA´s evaluation if a medicine should be classified as SCHCM, is constructed by two factors:

- Is the medicine expensive?
- Does the medicine require great care in its use, expert knowledge and/or the involvement of HCPs?

Cost evaluation of the medicine

IMA cost evaluation takes the following factors into consideration:

- Will the estimated yearly cost per patient exceed 1 million ISK (retail price without VAT)?
- Will the estimated yearly total cost exceed 15,5 million ISK (number of patients or number of treatments * retail price without VAT)?
- Estimated number of patients on a yearly basis for the next three years?
- Will estimated total cost for the medicine for next three years exceed 46,5 million ISK (retail price without VAT)?

Evaluation if a medicine requires great care

If a medicine fulfils any of the following criteria, an evaluation for a classification of SCHCM is implemented:

- The usage requires special follow up or monitoring of HCP?
- The medicine requires mixing/administration at hospitals/health care clinics?
- The medicine requires biological testing?
- Is the medicine in the following ATC classification LXXXX, J05XXX, J06XXX?
- Is the medicine under any special supervision in accordance to limited marketing authorization of the medicine?

Request for changes on definition for an already classified common (general) medicine or SCHCM can be sent to the IMA from the corresponding bodies; The National Hospital in Iceland (Landspítali), the Icelandic Health Insurance agency (Sjúktratrygginga Íslands), by the agent of the medicine and or from a competing agent. The request must include a justification/argumentation for the requested changes.

Implementation:

IMA evaluation regarding if a medicine should be defined/classified as SCHCM occurs when:

1. Application for SCHCM on the corresponding form has been received by the IMA.
2. Once an application for a wholesale price of a medicine has been received by the IMA, the IMA will then estimate if the medicine should be classified as SCHMC.
3. Request for changes regarding a definition for common/general medicine or SCHCM has been received by the IMA from the appropriate applicant.

Evaluation on applications

IMA reviews all applications and if needed requests for further information.

If IMA estimates that a medicine should be classified as SCHCM, the IMA will request a review/opinion from the Medicine Committee of the national hospital of Iceland (MCL).

If IMA is to deviate from the review/opinion of the Medicine Committee of the national hospital of Iceland (MCL) the IMA is then obligated to document and publish the arguments for the deviation in minutes.

If an application for classification as SCHCM is approved the IMA, 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 classification of medicine as 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 classification 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.

Definition / Legal basis:

The Medicinal Products Act no. 100/2020.

In accordance with Article 3(7) of the Medicinal Products Act no. 100/2020 are medicinal products subject to licence those 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.

If the Icelandic Medicines Agency does not agree to a requested official price, a change of price or cost participation under the provisions of this Section, the agency shall give reasons for its decision and inform the applicant of his right to refer the agency's decision to the courts. The same applies to decisions by the Icelandic Medicines Agency to classify medicinal products as medicinal projects subject to licence in accordance with Article 66(7) of the Medicinal Products Act no. 100/2020.

Landspítali's medicinal products committee shall submit comments to the Icelandic Medicines Agency before the agency takes decisions on classifying medicinal products as being subject to licence. The committee shall also submit comments on participation in the cost of medicinal products that are subject to licence (cf. Article 66). In accordance with Article 44(4) of the Medicinal Products Act no. 100/2020 shall comments be written and backed by reasoning. Comments submitted to the Icelandic Medicines Agency shall be accompanied by all the necessary documentation.

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