

Application for Reimbursement for Specialty Care High-cost medicine (SCHCM) – New indication

- **Parts I, II and III:** MAH or agent should fill in each field on the form. Application is not considered valid unless all the fields have been filled in.
- **Part IV:** Assessment by Drug and Therapeutics Committee (DTC) at The National University Hospital (NUH) of Iceland

Part I. – Basic Information

1. Please fill in the following basic information:	
Marketing authorization holder	
Local representative	
Contact name	
Address	
Phone number	
Email address	

2. Trade name and active pharmaceutical ingredient.

3. Insert link to SmPC.

4. ATC code.

5. Indication applied for?

6. Which indications have been approved for reimbursement?

7. Dosage and pharmaceutical form?

Part II. – Clinical Evaluation

1. Clinical mechanism of action?

2. Clinical studies of which reference drugs form the basis for the approved indication?

3. Administration of the drug, and is research or special preparation needed before starting use of the drug, or during treatment?

4. Which is the target patient group?

5. Estimation of the effect on other treatments. Please cite sources of the information. Is use of the drug estimated to:

- a. Replace other treatments, if so which?
- b. Add to other treatments, if so which?
- c. Not effect other treatments?

6. Do reference countries, or other recognized organizations or specialized associations have published clinical guidelines? If so, please insert a link.

7. Overview of published studies/research

Name of study	Type of study	Indication	Sources and/or links

8. Summary of clinical publications:

9. Other aspects of clinical evaluation for consideration?

Part III. – Economical Evaluation

1. Is public procurement finalised or ongoing?

2. Please estimate the cost of treatment per individual for the indication being applied for. What is the estimated annual cost per patient treated with the drug, based on the indication applied for. What are the premises for that conclusion, what is the dosage size, duration of treatment, etc. Refer to the information on which the plan is based.

3. Please estimate the total cost for the indication being applied for. What is the estimated total annual cost for the indication being applied for the next three years, i.e. what is the number of patients, when in the year does treatment start, when does it end, what is the dosage size, etc. Refer to the information on which the plan is based.

4. Estimated cost effects on other treatments:

- Which drugs are in use today for the same indication and in which dosage sizes. Please cite sources of the information.
- Is it estimated that treatment and cost of other drugs with the same indication will be affected with the approval of reimbursement and if so how?

5. Is it estimated that approval of the drug will have direct effect on other interventions/treatments within the health care service?

6. Are other benefits or changes expected should this indication be approved, such as regarding out-patients clinics, testing, blood sampling etc.

7. Overview of submitted health economical evaluation, CEA (Cost Effective Analysis)

Name/Country	Type	Indication	Comparator

8. What effect do the results of the CEA have on the cost of treatment with the drug, and especially those that have been conducted in the reference countries?

9.a. Is the indication in the CEA consistent with the estimated use in Iceland?
9.b. Are the patient groups the same in the CEA?

10. List an overview of reimbursements in reference countries. Please state whether it is general, with conditions and if so which, or individual. Please insert links to information from reference countries.

Reference country	General reimbursement	Conditions	Individual reimbursement	Link

11. Other aspects of economical evaluation for consideration?

Part IV. – Assessment by Drug and Therapeutics Committee (DTC) at The National University Hospital (NUH) of Iceland

1. Full assessment:

2. Summary of clinical and economical evaluation:

3. Date of summary/by: