Proposal for assessment of new health technologies

**Important information – read this first!**

* Submitted proposals for national health technologies (HTAs) will be published in full. If the proposer thinks there is information necessary for filling out the form, that should not be made public, please contact the secretariat (Nye Metoder) before submission.

The proposer is aware that the form will be published in its entirety (tick): [ ]

* Proposer has filled out point 19 below «Interests and, if any, conflicts of interest» (tick): [ ]
* This form serves the purpose to submit proposals for health technology assessment (HTA) at the national level in Nye Metoder - the national system for managed introduction of new health technologies within the specialist health service in Norway. The form does not apply to proposals for research projects. A health technology assessment is a type of evidence review, and for this to be possible, documentation is required, e.g. from completed clinical trials. Lack of documentation may be one of the reasons why the Commissioning Forum (Bestillerforum RHF) does not assign a health technology assessment.
* If the proposal concerns a medical device, the proposer is familiar with the document «[Guidance criteria for management of medical devices in the National System for Managed Introduction of New Health Technologies within the Specialist Health Service in Norway](https://nyemetoder.no/Documents/Om%20systemet/Guidance%20criteria%20for%20handling%20medical%20devices%20in%20Nye%20metoder.pdf)» (link) (tick): [ ]

## Contact information:

## Name of the proposer (organization / institution / company / manufacturer):

“Click in the field and type”

**Name of proposal contact:**

“Click in the field and type”

**Telephone number:**

“Click in the field and type”

**E-mail address:**

“Click in the field and type”

**Date and locality:**

“Click in the field and type”

1. Proposer's title on the proposal: \*

\*This may be changed during the course of the process”

“Click in the field and type”

1. Brief description of the health technology proposed to be considered:

“Click in the field and type”

1. Brief description of current standard of care (SOC) (Which health technology (ies) are currently used. What is the status of the technology (ies)? Whether it provides curative treatment, life extension, etc.)

Will the proposed technology replace or be a supplement to today's SOC?

“Click in the field and type”

1. This proposal concerns: Yes No

A brand new and innovative health technology [ ]  [ ]

Anew application, or a new indication for an established method [ ]  [ ]

A comparison between several methods [ ]  [ ]

A technology that is already in use [ ]  [ ]

 If yes – technology used in clinical practice [ ]  [ ]

 If yes – technology used in research/clinical trials [ ]  [ ]

A re-evaluation of technology used in clinical practice [ ]  [ ]

The technology is relevant for disinvestment [ ]  [ ]

 “Please include further details about any use of the technology”

1. This health technology involves (Multiple ticks are possible)

Pharmaceutical [ ]

Medical device/IVD medical device that is CE-marked\* [ ]

Medical device/IVD medical device that is not CE-marked [ ]

“\*If the technology is CE-marked: What is it CE- marked as and for which indication? Please describe”

Procedure [ ]

Screening [ ]

Highly specialized services / national offers [ ]

Organization of the health services [ ]

Other (describe) [ ]

“If relevant, please include who should be responsible for developing the technology.”

1. Application of the technology:

Prevention [ ]

Assessment and diagnostics [ ]

Treatment [ ]

Rehabilitation [ ]

Specialist health care [ ]

Primary health care [ ]

“Please give a description here”

1. Responsibility for funding Yes No

Is the specialized health service responsible for financing

the technology today? [ ]  [ ]
May the specialized health service become responsible for funding the

health technology? [ ]  [ ]

“Please give a further description of responsibility for funding”

1. Is the technology mentioned in the national guidelines or action programs prepared by the Norwegian Directorate of Health? Yes No
 [ ]  [ ]

“Give more details about the relevant national guidelines or action programs.”

1. Does the technology involve the use of radiation (ionizing/ non- ionizing)? Yes No
 [ ]  [ ]

“Give a short description of type of radiation source, device and degree of radiation exposure”

1. Which discipline(s) does the health technology apply to, and which patients are affected? (Could the health technology also affect other groups (e.g. health personnel or relatives)?)

“Click in the field and type”

1. Which aspects are relevant to the assessment? (Multiple ticks are possible)

Clinical efficacy [ ]

Safety/adverse effects [ ]

Costs/resource use [ ]

Cost-effectiveness [ ]

Organizational consequences [ ]

Ethical [ ]

Legal [ ]

1. Please suggest the main scope/objective for the health technology assessment, as well as secondary scopes/objectives (in compliance with question 10). For those familiar with “PICO” (Patient, Intervention, Comparator, Outcome) – please include tentative suggestions for PICO.

“Click in the field and type”

1. Please give a brief explanation of why it is important that the health technology assessment proposed should be conducted.

“Click in the field and type”

1. Please comment on the technology that is proposed to be assessed with regard to the following points:

The severity of the disease/condition the health technology targets

“Click in the field and type”

Expected effect

“Click in the field and type”

Safety

“Briefly describe known risk factors, safety aspects/concerns and adverse effects”

Total number of patients in Norway the health technology is applicable to

“Click in the field and type”

Consequences for resource use in the public health service

“Click in the field and type”

Need for revision of existing national guidelines or preparation of new guidelines

“Click in the field and type”

1. Please provide references to documentation of the health technology’s effect and safety (i.e. previous technology assessments). (Up to 10 key references can be provided, please do not send attachments in this step of the process):

“Click in the field and type”

1. Please provide the name of the marketing authorization holder/manufacturer/supplier of the health technology (if applicable/available):

“Click in the field and type”

1. Marketing Authorization Status (MA) or CE-marking: When is MA or CE- marking expected? If possible, provide the time of planned marketing:

“Click in the field and type”

1. Additional relevant information (up to 300 words.)

“Click in the field and type”

1. Interests and potential conflicts of interests

Please describe the proposer’s relationships or activities that may affect, be influenced by, or be perceived by others to be important for further management of the health technology that is proposed assessed. (E.g. proposer has financial interests in the matter. Proposer has or has had assignments in connection with the technology or to other actors with interest in the technology)

“Click in the field and type”