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» (link) (tick): ☒

Contact information:

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

Lillehammer sykehus v/Dr. Øyvind Asak

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Date and locality:

09.12.21 Lillehammer

1. Proposer's title on the proposal: *
   *This may be changed during the course of the process"

ENDOCUFF VISION® for endoscopic investigation

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

ENDOCUFF VISION® is a class I sterile medical device with approved CE mark. This device is developed to fit the end of most of the colonoscopes and it is intended to increase visibility and accuracy of the colonoscopy. It is represented by the row of flexible "arms" which push out the mucosal folds of the colon and allow more mucosal surface to be viewed. ENDOCUFF VISION®, therefore, improves identification of adenomas and polyps, has potential to reduce the incidence of colorectal cancer (CRC) by assisting detection in pre-cancerous or early cancer stages of CRC, and lowers the cost of CRC treatment.

3. 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?

Current SOC represents the use of standard colonoscopy.

ENDOCUFF VISION® increases the visibility of standard colonoscopy and has medical evidence from the randomized clinical trials that its use significantly improves adenoma detection rate (ADR). This represents an additional clinical benefit to the SOC and can lead to lowering incidence and costs of CRC.

ENDOCUFF VISION® will be a supplement of the SOC – standard colonoscopy – it should be used together with SOC enabling better visualization.

4. This proposal concerns:

	Yes	No
A brand new and innovative health technology	☒	☐
A new 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	☐	☐

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

Pharmaceutical	☐

Medical device/IVD medical device that is CE-marked* ☒

ENDOCUFF VISION received a CE mark in August 2016 as a class I sterile medical device. It is a medical device that is attached to colonoscopes and intends to improve the visibility of standard colonoscopy. As for patient populations, it is tested in randomized clinical trials for the use in symptomatic population for CRC, and general CRC screening population.

Medical device/IVD medical device that is not CE-marked ☐

Procedure ☐

Screening ☐

Highly specialized services / national offers ☐

Organization of the health services ☐

Other (describe) ☐

6. Application of the technology:

Prevention	☐
Assessment and diagnostics	☒
Treatment	☐
Rehabilitation	☐
Specialist health care	☐
Primary health care	☐

ENDOCUFF VISION® is a medical device that should be used together with the standard colonoscopy, and represents a diagnostic tool for better visualisation of endoscopic changes.

7. 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?	☐	☐

The use of standard colonscopy (and potentially for ENDOCUFF VISION®) is covered through the DRG system to the hospital.

8. Is the technology mentioned in the national guidelines or action programs prepared by the Norwegian Directorate of Health?

Yes	No
☐	☒

The use of ENDOCUFF VISION® is not described in the national guidelines.

9. Does the technology involve the use of radiation (ionizing/ non- ionizing)?

Yes	No
☐	☒

10. 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)?)

ENDOCUFF VISION® applies in gastroenterology as an enhancement device for standard colonoscopy. It should be used in all patient population that require standard colonoscopy, and these should include at least:

- Population selected for CRC screening programmes
- All other patients where polyps are suspected

11. 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	☐

12. 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.

ENDOCUFF VISION® should be assessed for its clinical efficacy for use as an enhancement medical device for standard colonoscopy. It should be also evaluated for its effects on the cost practice in standard colonoscopies procedures as it results in better ADR and can reduce the CRC incidence and its expensive treatments.

Population that is concerned are those selected for CRC screening programmes, and patients with potential symptoms that require standard colonoscopy.

Intervention in question, ENDOCUFF VISION® added on the standard colonoscopy, increases the visibility of standard colonoscopy to obtain the better detection rates of carcinomas, precancerous lesions, adenomas, and polyps.

Comparator for the assessment is current SOC – standard colonoscopy alone.

Outcome that should be assessed given the evidence from the clinical trials is ADR (adenoma detection rate) change. Outcomes can also include the differences in costs of diagnosing with ENDOCUFF VISION® (cost of the device + cost reductions obtained by earlier detection of the disease) versus current practice without ENDOCUFF VISION®.

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

While the health technology in question increases the initial cost at the initial investigation, an evaluation by NICE in the UK has demonstrated that the technology is cost-saving. In addition it will lead to the improvement of the detection of carcinomas, adenomas, and polyps. This has potential to lower the CRC incidence given that the disease will be diagnosed earlier and, therefore, lower the high economic burden of CRC for the entire health care system.

It is important to understand if a similar benefit such as concluded by NICE would be applicable in Norway.

14. 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

Very severe disease with high mortality – colorectal carcinoma (CRC)

Expected effect

Earlier detection of CRC (improved ADR) in organized screenings and/or individual symptomatic patients

Safety

The proposed technology has comparable safety profile to the one of the SOC

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

In period between 2016 and 2020 the number of standard colonoscopies performed in Norway (relying on data on the respective codes that include colonoscopy - JUF32, JUF35, JUF 42) was relatively stable and ranged from 40,636 until 43,137 colonoscopies per year. (Source: https://statistikk.helsedirektoratet.no) With the introduction of the national screening program introduced 2022, the numbers will increase further. https://www.kreftregisteret.no/screening/kopi/Tarmkreftscreening111/aktuelt/screeningtilbud/

Consequences for resource use in the public health service

It is expected that use of ENDOCUFF VISION® will reduce resources utilisation in treatment of CRC. This will result from earlier detection of cancer and precancerous lesions, and therefore, making significant cost cuts in the expensive treatment algorithms of CRC.

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

ENDOCUFF VISION should be included in the national guidelines which recommend use of standard colonoscopy.

15. 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):

Previous health technology assessments:

1. The National Institute for Health and Care Excellence, UK. Endocuff Vision for assisting visualisation during colonoscopy. Medical technologies guidance [MTG45]. Available from: https://www.nice.org.uk/guidance/mtg45 [published in June 2019]
2. Application for registration on the List of Reimbursable Products and Services OLYMPUS ENDOCUFF VISION ™, France. Available upon request [issued in March 2021]

Published clinical trials:

1. Ngu WS, Bevan R, Tsiamoulos ZP, et al. Improved adenoma detection with Endocuff Vision: The ADENOMA randomised controlled trial. *Gut*. 2019;68(2):280-288. doi:10.1136/gutjnl-2017-314889
2. Karsenti D, Tharsis G, Perrot B, et al. Adenoma detection by Endocuff-assisted versus standard colonoscopy in routine practice: A cluster-randomised crossover trial. *Gut*. 2020;69(12):2159-2164. doi:10.1136/gutjnl-2019-319565
3. Bhattacharyya R, Chedgy F, Kandiah K, et al. Endocuff-assisted vsstandard colonoscopy in the fecal occult blood test-based UK Bowel Cancer Screening Programme (E-cap study): A randomized trial. *Endoscopy*. 2017;49(11):1043-1050. doi:10.1055/s-0043-111718
4. Rameshshanker R, Tsiamoulos Z, Wilson A, et al. Endoscopic cuff–assisted colonoscopy versus cap-assisted colonoscopy in adenoma detection: randomized tandem study—DEtection in Tandem Endocuff Cap Trial (DETECT). *Gastrointestinal Endoscopy*. 2020;91(4):894-904.e1. doi:10.1016/j.gie.2019.11.046
5. Tsiamoulos ZP, Misra R, Rameshshanker R, et al. Impact of a new distal attachment on colonoscopy performance in an academic screening center. *Gastrointestinal Endoscopy*. 2018;87(1):280-287. doi:10.1016/j.gie.2017.04.001

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

Olympus Europa SE & Co. KG (OEKG)

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

ENDOCUFF VISION® received a CE mark in August 2016 as a class I sterile medical device.

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

ENDOCUFF VISION® is supported with clinical trial evidence proving its efficacy in improvement of adenoma detection rate (ADR). There are five published controlled trials, four of which had randomization, conducted in the UK and France, and in total they included nearly 5,000 patients. Patient population consisted of symptomatic patients indicated for colonoscopy, or patients from CRC screening after positive faecal occult blood test (FOBT), or both. Across all trials increase of ADR was demonstrated for ENDOCUFF VISSION® added on standard colonoscopy in comparison to standard colonoscopy alone and was statistically significant in four out of five trials. The improvement of can affect decrease of costs and increase of health gains potentially resulting in cost savings for the health care system.

The National Institute for Health and Care Excellence (NICE) in the UK recommended ENDOCUFF VISION® for use in CRC screening population by its guidance. This report included the assessment of cost differences between ENDOCUFF VISION® and standard colonoscopy. The NICE has approved the structure of the applied cost-consequence model and estimated cost savings of £53 per patient (10 year time horizon) when ENDOCUFF VISION® is added to the standard colonoscopy in comparison to the standard colonoscopy alone.

The use of Endocuff will lead to an increased cost during the initial screening, but will lead to a long term cost saving with increased ADR detection.

19. 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)

Non