

CENTER FOR CLINICAL GUIDELINES | CANCER

Version x.y

**APPROVAL**

**Content** **approval**

DD. MM. YYYY (DMCG)

**Administrative approval**

DD. MM. YYYY (Center for Clinical Practice Guidelines | Cancer)

**REVISION**

Planned: DD. MM. YYYY

**KEYWORDS**

Insert at least 3 relevant search terms

(e.g. DMCG, cancer type, part of illness trajectory, intervention)

Insert title

-including area of disease and procedure/treatment modality

Content

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(Please update the table of contents when the document is done: highlight the table of contents, right-click to select: 'update table', select: 'update entire table').

Revisions to previous version (changelog)

The purpose of the changelog is to provide an overview of significant revisions and/or new additions to the previous version of the guideline. It is only to be filled in when a guideline is updated.

A complete or partial update is optional according to relevance.
All significant revisions to the previous version should be noted in the table below (Revisions to version x.x.)
**Please delete the rows that are not relevant.**

If the guideline has undergone critical evaluation and all content is still valid, please state the following and delete the table:
"The guideline has been critically evaluated by the working group and the content is considered valid. Changes have been made solely to the version number, approval and revision dates".

##### Revisions to version x.x

|  |  |
| --- | --- |
| **Guideline chapter** | **Description of revisions or additions***Please describe briefly the revisions made relevant to the chapters, to clarify which changes have been made and why )* |
| Title |  |
| Purpose |  |
| Patient population |  |
| Target users |  |
| Recommendations |  |
| Literature and evidence review |  |
| Patient values and preferences  |  |
| Rationale |  |
| Comments and considerations |  |
| References |  |
| Literature search |  |
| Literature review |  |
| Wording of recommendations |  |
| Stakeholder engagement |  |
| Hearing and approval |  |
| Recommendations that entail significant additional costs |  |
| Suggestions for further research |  |
| Authors and conflicts of interest |  |
| Monitoring |  |
| Appendices |  |

### 1. Anbefalinger – Dansk (Quick guide)

Quick guiden er målrettet den travle læser. Den genereres af Retningslinjesekretariatet ved at anbefalingerne i kapitel 3 kopieres, oversættes til dansk og samles i kapitel 1.

### Recommendations English (Quick guide)

The quick guide is aimed at the busy reader. It is generated by the Clinical Guidelines Secretariat by copying the recommendations from chapter 3 to create a brief overview in chapter 1.

###

### Flow chart for treatment (optional)

You can insert a flow chart here to visually support the guideline recommendations.
This is optional. If superfluous, simply delete the header and this text.

### 2. Introduction

Please give a brief description of the patient population and any specific challenges related to this group (e.g. population size, morbidity, mortality, incidence, prevalence and probable comorbidity etc.).

See guidance on choosing a subject [here](https://www.dmcg.dk/Kliniske-retningslinjer/skabeloner-og-vejledninger/).

##### Objective

The overall objective of this guideline is to support evidence-based cancer care of high and consistent quality across the Danish healthcare system.

If relevant, please insert a brief description of the specific objective of developing a clinical guideline in this specific field and specify the clinical issue (e.g. variations in practice, new risk-based technology, new pharmaceuticals, possible indication change, the severity of the issue and the expected effects of the recommendation).
Make sure the title and objective is reflected in the literature search.

Patient population

Please describe the target population for the guideline by noting relevant diagnoses, stages, other clinical characteristics, age, sex, severity/stage of disease, in-patients vs. out-patients etc.
If relevant, please note the importance of comorbidity for the recommendations.

Target users

This guideline is primarily developed to support clinical decision-making and quality improvement. The target users are healthcare professionals working in Danish cancer care.
If relevant, please define the target users for this specific guideline more in-depth (e.g. hospital physicians, specific specialized areas of treatment, family physicians, nurses, therapists).

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### 3. Scientific basis

### Insert section header – e.g. Screening, diagnosing or treatment

#### **Recommendation 1 (A, B, C or D)**

#### **Recommendation 2 (A, B, C or D)**

Recommendations must be formulated in precise, clear and active language, i.a. by using words such as 'can', 'should', 'must', 'give', 'use, 'do not use', etc. If there are decision aids that can support the recommendation, they can be linked directly to them - Read more about this in the guidance Formulation of Recommendations [here.](https://www.dmcg.dk/Kliniske-retningslinjer/skabeloner-og-vejledninger/)

Literature and evidence review

Please give a brief summary of the evidence underlying the recommendation (e.g. total number of articles distributed by study type). If there is little or no evidence, please describe.

This section can advantageously be divided into subsections; "Regarding recommendation 1", "Regarding recommendation 2", "Regarding recommendation 3" etc., in order to enhance the link between evidence and recommendations.

Please describe the included studies, including population and interventions Please define the quality of the individual study based on the Oxford scale: <https://www.cebm.net/2009/06/oxford-centre-evidence-based-medicine-levels-evidence-march-2009/>

References should be marked with ( ) and levels of evidence should be marked with [ ]. All references must be followed by level of evidence, example; (4) [1a].

Please include the most important beneficial and unfavorable effects of the relevant interventions described in the studies.

Patient values and preferences

Please indicate whether the recommendations are sensitive to patient preferences; are patients' choices of treatment expected to vary greatly when informed of the expected positive and negative effects of the treatment? How does the treatment affect the patient's quality of life? Please describe how this is uncovered (for instance based on clinical experience, literature, patient panels etc.).

If patients have been systematically involved in this guideline, this process can be described in more detail in chapter 5, Methods under the subheading Stakeholder Involvement.

Rationale

Please describe briefly the considerations that form the basis of the wording of the recommendation, including which results and studies that are particularly emphasized, the importance of patient preferences, the balancing of positive effects versus negative side effects etc. Please pay specific attention to how the use of the words 'can', 'ought to' and 'must' reflect the evidence base of the recommendations. For instance, please explain if the recommendation is graded A but the words 'ought to' or 'can' are used, or if a B/C/D grade recommendation uses the word 'must'. For further information read the guidance Formulation of Recommendations, [here.](https://www.dmcg.dk/Kliniske-retningslinjer/skabeloner-og-vejledninger/)

Comments and considerations

If relevant, please specify any particular clinical focal points, such as the need for continuing education, logistic challenges or other challenges related to following the recommendation. If there are no special comments or considerations, please note this.

### 4. References

Insert list of references in Vancouver Style.

1. Author surname Author Initial. Title. Journal Title. Year Published [cited Date Accessed]; Volume number (Issue number): pages used. Available from: URL DOI
2. Author surname Author Initial. Title. Journal Title. Year Published [cited Date Accessed]; Volume number (Issue number): pages used. Available from: URL DOI
3. Author surname Author Initial. Title. Journal Title. Year Published [cited Date Accessed]; Volume number (Issue number): pages used. Available from: URL DOI
4. etc.

###

### 5. Method

Please give a brief description of the guideline development process:

Literature searchPlease include details of the strategy used to search for and select literature (name the electronic databases or evidence sources where the search was performed), include in- and exclusion criteria (e.g. patient population, existing guidelines/systematic reviews/primary studies, time periods, languages),and please also include the search strategy (the search terms used and in which combinations). If ad hoc searches have been used or the use of literature is adapted from an international guideline, please describe this. Please also include the full search strategy or search description in appendix 1 to be used when the guideline is revised. If no relevant literature is located, please describe the expert consensus process (e.g. expert opinion/consensus process, participants, clinical experience etc.).

See the guidance for Literature search [here](https://www.dmcg.dk/Kliniske-retningslinjer/skabeloner-og-vejledninger/).

Literature review

Please describe who has conducted the critical appraisal of the selected literature and how it was done:

* State who has reviewed the literature
* Outline the process for the literature review with specific focus on;
	+ which studies are included in the review (population, study design, outcomes, language, context if relevant)
	+ evidence appraisal (how is the evidence appraised)
	+ data extraction (what types of data are emphasized in the articles)
	+ data synthesis (how the results are synthesized)

See the guidance for Literature review and evidence appraisal [here.](https://www.dmcg.dk/Kliniske-retningslinjer/skabeloner-og-vejledninger/)

Formulation of the recommendationsPlease state who formulated the recommendations including a recount of the process ( e.g. formal/informal consensus among clinical experts in the guideline steering committee, and describe how consensus was achieved in case of disagreements etc.. Briefly describe how the steering committee have decided between the words 'could', 'ought to' and 'must' in the guideline (for instance that the imperative 'must' is to be used in connection with an evidence-base that prompts a grade A-recommendation). See the guidance for Formulation of recommendations [here](https://www.dmcg.dk/Kliniske-retningslinjer/skabeloner-og-vejledninger/).

Stakeholder involvement

State if, and if relevant how, patients and/or others not related to the specific multidisciplinary group have been involved in the guideline development (e.g. participants in the guideline steering committee, ad hoc expert consultation, collaboration with patient reference groups). If patients and/or others not related to the specific multidisciplinary group have not been involved in the guideline development, please describe future plans for this in this section. See guidance for patient perspective [here](https://www.dmcg.dk/Kliniske-retningslinjer/skabeloner-og-vejledninger/).

Hearing

Please describe any peer review activities during the development of the guideline; who has commented on the guideline and how was the peer review process designed (number of reviewers, characteristics, title, affiliation etc.). In addition, please describe whether the [Hearing Statement Template](https://www.dmcg.dk/Kliniske-retningslinjer/skabeloner-og-vejledninger/) has been used - see guidance for the hearing [here](https://www.dmcg.dk/Kliniske-retningslinjer/skabeloner-og-vejledninger/).

If the guideline has not been in hearing, how does the working group envision this process for future updates?

Approval

*Content approval:*
Please state who has professionally approved the guideline. The content of the guideline must reflect consensus in the multidisciplinary cancer group.

*Administrative approval:*

Is completed by the secretariat before approval.

Recommendations that entail significant additional costs
The term 'significant additional costs' is used to describe costs and organizational changes that will require management level assessment. DMCG.dk and Danish Comprehensive Cancer Center (DCCC) have agreed to send all recommendations estimated to entail additional costs in a hearing process to be assessed by the DCCC Governance Board (the five regional chief executives within the area of health).
Should a recommendation be estimated to entail significant additional costs, the number of the recommendation will be recorded along with a brief description of the expected costs such as expensive equipment, additional testing or examinations, out-patient visits or treatments that require additional resources.
Recommendations which are estimated to entail additional costs by the authors, but NOT at a level requiring management level assessment, must be described in chapter 3, Scientific evidence under the subheading Comments and considerations.

If there are NO significant additional costs for the recommendations, this must also be stated

Need for further research

If the literature review identifies areas with little or no research, please give an account of these areas here.

Authors and conflicts of interest
Please state the authors of the guideline (first author first – the ensuing order should be decided when starting the guideline development process).

* Author first name Surname, medical specialty, position, place of employment
* Author first name Surname, medical specialty y, position, place of employment
* Author first name Surname, medical specialty, position, place of employment
* Author first name Surname, medical specialty, position, place of employment

# For detailed cooperative relationships, please refer to the declaration via the Danish Medicines Agency's website: [List of proprietary pharmacists, doctors, nurses, dentists, proprietary pharmacists and prescribing pharmacists who have a relationship with a company](https://laegemiddelstyrelsen.dk/en/licensing/relationships/companylists/proprietary-pharmacists%2C-doctors%2C-nurses-and-dentists/)

If non of the author's have any cooperative relationsships to companies and no potential conflicts of interest, simply state "no conflicts of interest" after the author's name.

After specifying conflicts of interest, a brief overall assessment of the ability to take part in the guideline development is subsequently indicated. See examples below.

Example regarding overall assessment of ability:

The overall ability of the author group: The majority of the authors of this guideline have collaborated with pharmaceutical companies in 2022. The collaboration included trial protocols, teaching, travel activity and participation in meetings with pharmaceutical companies. The opinion of the chairman is that the above cooperative relationships have no influence on the guideline development and recommedation.

Example where a person has had conflicts of interest in parts of the guideline preparation:

XX did not participate in the preparation of the section dealing with medical treatment of XX due to conflict of interest. XX participated in the preparation of the rest of the guideline.

Plan for revision

Outline a plan for revision of the guideline – including who is responsible and the process for this (an updated literature search must be carried out in one or more areas, a review of the evidence etc.)

Version of guideline template

The guideline has been developed in the 2.5 version of the template.

### 6. Monitoring

###### Standards and indicators

Development of quality in this area is supported by knowledge from (insert database name) under the auspices of the Regions' Clinical Quality Development Program (RKKP), as the indicators in the database must illuminate relevant clinical guidelines (insert footnote to BEK).

The clinical quality database's steering group has the mandate to decide on the database's indicator set, including which specific processes and results are monitored in the database.

If the author group has proposals for specific recommendations that can be usefully included in the steering group's discussion in connection with the ongoing revision of the indicator set, they can be listed here:

Recommendation no (insert recommendation no.): State a brief justification for the proposal.

Proposals for new monitoring can be stated or arguments can be made for maintaining already existing monitoring. The examples below can be used for inspiration.

Example regarding new monitoring

Recommendation 2 and 3: In recent years, there has been increasing attention to the fact that a large proportion of patients undergoes operation several times because the desired result is not initially achieved. It is therefore proposed that an indicator be set up that allows comparison of the individual units in this area.

Example regarding retention of already established monitoring

Recommendation 6: It is still recommended to monitor survival, as studies have shown that neoadjuvant chemoradiotherapy + surgery versus surgery alone improves 2-year survival.

### 7. Appendices

Appendix 1 – Search protocol

Insert search protocol and/or search strategy, in order to reuse when updating the guideline.

###

### 8. About this clinical guidline

This clinical practice guideline is developed in collaboration between the Danish Multidisciplinary Cancer Groups (DMCG.dk) and the Danish Clinical Registries (RKKP). The development is part of an intensified guideline effort launched in relation to the National Cancer Plan IV. The aim is to support high quality cancer care across the Danish healthcare system. The guideline content is approved by the disease specific Multidisciplinary Cancer Group, whereas the format is approved by the Center for Clinical Practice Guidelines | Cancer. Further information about clinical practice guidelines concerning cancer treatment in Denmark can be found here: [www.dmcg.dk/kliniske-retningslinjer](http://www.dmcg.dk/kliniske-retningslinjer)

The target users of this guideline are health care professionals working in the Danish Healthcare system. The guideline consists of systematically prepared statements that can be used as a decision-making support tool by healthcare professionals and patients, when deciding on appropriate and correct care in a specific clinical situation.

Clinical practice guidelines concerning Danish cancer care is characterized as professional advice. The guidelines are not legally binding and professional judgement in the specific clinical context will always determine what the appropriate and correct medical care is. Adherence to the guideline recommendations is no guarantee for a successful outcome and sometimes care corresponding to a lower level of evidence will be preferred due to the individual patient's situation.

The clinical practice guideline contains central recommendations (chapter 1) and a description of the scientific evidence (chapters 3+4). Recommendations marked A are the strongest, whereas recommendations marked D are the weakest. For further information on strength of evidence see the ”Oxford Centre for Evidence-Based Medicine Levels of Evidence and Grades of Recommendations**”,** <https://www.cebm.net/2009/06/oxford-centre-evidence-based-medicine-levels-evidence-march-2009/> Information on the target population (chapter 2) and the method of development (chapter 5) is also included in the guideline. See the table of contents for page reference.

Information on the national integrated cancer pathways – descriptions of the patient journey through the healthcare system – can be accessed at the Danish Health Authority website**:** <https://www.sst.dk/en/disease-and-treatment/cancer/cancer-pathways>

Development of this clinical practice guideline has been funded by The Danish Health Authority (National Cancer Plan IV) and the Danish Clinical Registries (RKKP).