

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Dostarlimab with carboplatin and paclitaxel for treating recurrent or advanced endometrial cancer

Draft scope

**Draft remit/evaluation objective**

To appraise the clinical and cost effectiveness of dostarlimab with carboplatin and paclitaxel within its marketing authorisation for treating recurrent or advanced endometrial cancer.

**Background**

Endometrial cancer is a cancer of the lining of the womb (uterus), known as the endometrium. It is the most common type of womb cancer, often diagnosed in the earlier stages. When diagnosed, endometrial cancer is categorised between stage 1 and 4. Advanced endometrial cancer is defined as stage 3 or 4, where the cancer has spread outside the womb. In stage 3, the spread of cancer is contained within the pelvis. Once the cancer has spread into another area of the body, it is classed as stage 4 or metastatic (stages 3 and 4 are known as advanced cancer). Recurrent endometrial cancer is when the cancer returns after primary treatment. The cancer can recur anywhere, commonly in the abdominal cavity, lymph nodes, lung and vagina. The symptoms of recurrence are variable but include abdominal pain, bloating, nausea, shortness of breath, vaginal bleeding and changes in bowel or bladder habits.<sup>1</sup>

In 2019, there were about 8,200 new cases of endometrial cancer in England.<sup>2</sup> In the UK, around 2,500 deaths occurred in 2017-2019 accounting for 3% of all cancer deaths in females. About 15% of women diagnosed with advanced or recurrent endometrial cancer at late stage survive for 5 or more years, compared to 92% of women diagnosed at early stage. About 3% of endometrial cancers occur in women under 45 years of age.<sup>3</sup>

The first treatment for endometrial cancer is usually to remove the womb (hysterectomy) and both the fallopian tubes and ovaries (bilateral salpingo-oophorectomy). In advanced endometrial cancer, debulking surgery may be carried out to remove as much of the cancer as possible.<sup>4</sup> Radiotherapy may be used for people who cannot have surgery, or alongside surgical treatment. Chemotherapy can be used adjunct to surgery for people with stage 2-4 disease. Hormone therapy or chemotherapy may be used for cancer that has metastasised or relapsed. [NICE technology appraisal guidance 779](#) recommends dostarlimab for use within the Cancer Drugs Fund to treat advanced or recurrent endometrial cancer with high microsatellite instability or mismatch repair deficiency in people who have had platinum-based chemotherapy.

**The technology**

Dostarlimab (Jemperli, GlaxoSmithKline) in combination with carboplatin and paclitaxel does not currently have a marketing authorisation in the UK for endometrial

cancer. It has been studied in a clinical trial in which dostarlimab plus carboplatin-paclitaxel followed by dostarlimab or dostarlimab plus carboplatin-paclitaxel followed by dostarlimab plus niraparib were compared with placebo in people with recurrent or primary advanced (Stage 3 or 4) endometrial cancer. It is administered intravenously.

Dostarlimab as monotherapy has a marketing authorisation in the UK for the treatment of people with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) recurrent or advanced endometrial cancer that has progressed on or following prior treatment with a platinum-containing regimen.

<b>Intervention(s)</b>	Dostarlimab with carboplatin and paclitaxel
<b>Population(s)</b>	People with recurrent or advanced endometrial cancer
<b>Comparators</b>	<ul style="list-style-type: none"> <li>• Chemotherapy, including:             <ul style="list-style-type: none"> <li>- Carboplatin and paclitaxel</li> <li>- Paclitaxel monotherapy</li> <li>- Doxorubicin monotherapy</li> <li>- Carboplatin monotherapy</li> </ul> </li> <li>• Pembrolizumab plus lenvatinib (subject to ongoing NICE appraisal)</li> <li>• Hormone therapy (such as medroxyprogesterone acetate and megestrol)</li> <li>• Best supportive care</li> </ul>
<b>Outcomes</b>	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> <li>• progression-free survival</li> <li>• overall survival</li> <li>• response rates</li> <li>• duration of response</li> <li>• adverse effects of treatment</li> <li>• health-related quality of life.</li> </ul>

<b>Economic analysis</b>	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p> <p>The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account.</p>
<b>Other considerations</b>	<p>Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.</p>
<b>Related NICE recommendations</b>	<p><b>Related technology appraisals:</b></p> <p><a href="#">Dostarlimab for previously treated advanced or recurrent endometrial cancer with high microsatellite instability or mismatch repair deficiency</a> (2022) NICE technology appraisal guidance 779.</p> <p><b>Related technology appraisals in development:</b></p> <p><a href="#">Pembrolizumab with lenvatinib for previously treated advanced, metastatic or recurrent endometrial cancer</a>. NICE technology appraisal guidance [ID3811] Publication expected March 2023.</p> <p><b>Related interventional procedures:</b></p> <p><a href="#">Laparoscopic hysterectomy (including laparoscopic total hysterectomy and laparoscopically assisted vaginal hysterectomy) for endometrial cancer</a> (2010) NICE interventional procedures guidance 356.</p> <p><b>Related diagnostics guidance:</b></p> <p><a href="#">Testing strategies for Lynch syndrome in people with endometrial cancer</a> (2020) NICE diagnostics guidance 42.</p>
<b>Related National Policy</b>	<p>The NHS Long Term Plan (2019) <a href="#">NHS Long Term Plan</a>. NHS England (2018) <a href="#">NHS manual for prescribed specialist services (2018/2019)</a>. Chapter 105.</p>

### Questions for consultation

Where do you consider of dostarlimab with carboplatin and paclitaxel will fit into the existing care pathway for recurrent or advanced endometrial cancer?

Draft scope for the evaluation of dostarlimab with carboplatin and paclitaxel for treating recurrent or advanced endometrial cancer

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Would dostarlimab with carboplatin and paclitaxel be a candidate for managed access?

Do you consider that the use of dostarlimab with carboplatin and paclitaxel can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which dostarlimab with carboplatin and paclitaxel will be licensed;
- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.

NICE intends to evaluate this technology through its Single Technology Appraisal process. (Information on NICE's health technology evaluation processes is available at <https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation>).

### References

1. Murali R, Soslow RA, Weigelt B (2014) [Classification of endometrial carcinoma: more than two types](#). The Lancet. Oncology 15(7): 268-278.
2. NHS Digital (2021) [Cancer registration statistics, 2019](#). Accessed January 2023.
3. Cancer Research UK (2021) [Uterine cancer statistics](#). Accessed January 2023.
4. NHS (2021) [Treatment: womb \(uterus\) cancer](#). Accessed January 2023.