# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Health Technology Evaluation

## Sacituzumab govitecan for treating hormone receptor-positive HER2-negative metastatic breast cancer after 2 or more therapies

## Draft scope

### Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of sacituzumab govitecan within its marketing authorisation for treating hormone receptor-positive HER2-negative metastatic breast cancer after 2 or more therapies.

### Background

Breast cancer arises from the tissues of the ducts or lobules of the breast. The cancer is said to be metastatic if it has spread to other parts of the body such as the bones, liver, and lungs.

In 2019 in England, 48,387 people were diagnosed with breast cancer.[1] Approximately 4% of people with breast cancer in England in 2019 had stage IV (metastatic) breast cancer when they were diagnosed.[2] The 1-year survival rate for adults diagnosed at stage IV in England is 66%.[3] Around 35% of people with early or locally advanced disease will progress to metastatic breast cancer in the 10 years following diagnosis.[4]

Current treatments for advanced breast cancer aim to relieve symptoms, prolong survival and maintain a good quality of life with minimal adverse events. Treatment depends on whether the cancer cells have particular receptors, the extent of the disease, and previous treatments. Approximately 56% of women with advanced (metastatic) breast cancer in the UK have hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative disease.[5,6]

Treatments for advanced breast cancer include chemotherapy and endocrine therapy (also known as hormonal treatment). Endocrine therapy is mainly given to people whose cancer is determined to be hormone-responsive, and is recommended as first line treatment for most people with advanced hormone receptor-positive breast cancer. Cyclin-dependent kinase (CDK) 4/6 inhibitors are recommended in NICE technology appraisals 495, 496 and 563, alongside hormonal treatment.

NICE clinical guideline 81 (CG81) recommends systemic sequential therapy for most patients with advanced breast cancer having chemotherapy. Where anthracyclines are not suitable (because they are contraindicated or because of prior anthracycline treatment) the sequencing should follow: single-agent docetaxel as a first-line treatment, single-agent vinorelbine or capecitabine as second line treatment, and single-agent capecitabine or vinorelbine (whichever was not used as second line treatment) as third line treatment. In

addition, NICE technology appraisal 423 recommends eribulin as an option for treating locally advanced or metastatic breast cancer when it has progressed after at least two chemotherapy regimens.

**The technology**

Sacituzumab govitecan (Trodelvy, Gilead) does not currently have a marketing authorisation in the UK for treating hormone receptor-positive HER2-negative metastatic breast cancer after 2 or more therapies. Sacituzumab govitecan is being studied in a phase 3 clinical trial versus treatment of clinicians choice for people with hormonal receptor-positive, HER2-negative metastatic breast cancer who have had at least 2 prior chemotherapy regimens.

Sacituzumab govitecan has a marketing authorisation in the UK for the treatment of unresectable locally advanced or metastatic triple-negative breast cancer after 2 or more prior lines of systemic therapies, at least 1 of them given for unresectable locally advanced or metastatic disease.

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| **Intervention(s)** | Sacituzumab govitecan |
| **Population(s)** | People with hormone receptor-positive HER2-negative metastatic breast cancer after 2 or more therapies including at least one chemotherapy for metastatic disease |
| **Comparators** | Chemotherapy (in accordance with NICE guidance) including eribulin, vinorelbine, and capecitabine. |
| **Outcomes** | The outcome measures to be considered include:<br>• overall survival<br>• progression-free survival<br>• response rate<br>• adverse effects of treatment<br>• health-related quality of life |
| **Economic analysis** | The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.<br>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.<br>Costs will be considered from an NHS and Personal Social Services perspective.<br>The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account. |

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| **Other considerations** | 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. |
| **Related NICE recommendations** | **Related Technology Appraisals:**<br><br>Abemaciclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy (2021) NICE technology appraisal guidance 725. Next review 2024<br><br>Ribociclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy (2021) NICE technology appraisal guidance 687. Next review 2024<br><br>Palbociclib with fulvestrant for treating hormone receptor-positive, HER2-negative, advanced breast cancer (2020) NICE technology appraisal guidance 619. Next review 2022<br><br>Abemaciclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer (2019) NICE technology appraisal guidance 563. Next review 2022<br><br>Ribociclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer (2017) NICE technology appraisal guidance 496. Next review 2020<br><br>Palbociclib with an aromatase inhibitor for previously untreated, hormone receptor-positive, HER2-negative, locally advanced or metastatic breast cancer (2017) NICE technology appraisal guidance 495. Next review 2020<br><br>Eribulin for treating locally advanced or metastatic breast cancer after 2 or more chemotherapy regimens (2016) NICE technology appraisal guidance 423. Next review N/A<br><br>Everolimus with exemestane for treating advanced breast cancer after endocrine therapy (2016). NICE technology appraisal guidance 421. Next review 2019<br><br>**Related appraisals in development:**<br><br>Alpelisib in combination with fulvestrant for treating advanced hormone-receptor positive, HER2-negative, PIK3CA-mutated breast cancer NICE technology appraisal guidance [ID3929] publication expected 29 July 2022<br><br>**Related Guidelines:** |

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| | Advanced breast cancer diagnosis and treatment (2009; updated 2017) NICE guideline [CG81]<br><br>Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer (2013; updated 2019) NICE guidance CG164<br><br>Improving outcomes in breast cancer (2002; checked 2014) NICE guideline CSG1<br><br>MammaTyper in vitro diagnostic test for determining breast cancer subtypes (2018) NICE Medtech Innovation Briefing 135<br><br>**Related Quality Standards:**<br><br>Breast cancer (2011; updated 2016) NICE quality standard 12 |
| **Related National Policy** | The NHS Long Term Plan, 2019. NHS Long Term Plan<br><br>NHS England (2018/2019) NHS manual for prescribed specialist services (2018/2019) Chapter 105: Specialist cancer services (adults) |

**Questions for consultation**

Where do you consider sacituzumab govitecan will fit into the existing care pathway for hormone receptor-positive HER2-negative metastatic breast cancer?

What treatments are established clinical management for hormone receptor-positive HER2-negative metastatic breast cancer, following two prior therapies including hormonal treatment, CDK 4/6 inhibitors and one line of chemotherapy?

Do you consider there to be any relevant subgroups?

Would sacituzumab govitecan be a candidate for managed access?

Do you consider sacituzumab govitecan to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of sacituzumab govitecan 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 the treatment 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. We welcome comments on the appropriateness of appraising this topic through this 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 NHS Digital (2022) Cancer registration statistics, England, 2019. Accessed May 2022.

2 Cancer Research UK (2022) Early diagnosis data hub. Accessed May 2022.

3 Cancer Research UK (2020) Breast cancer survival by stage at diagnosis: adults diagnosed 2013-2017, followed up to 2018. Accessed May 2022.

4 Dewis R and Gribbin J (2009) Breast cancer: diagnosis and treatment, an assessment of need. Cardiff: National Collaborating Centre for Cancer. Accessed May 2022.

5 NICE (2017) Palbociclib with an aromatase inhibitor for previously untreated, hormone receptor positive, HER2-negative, locally advanced or metastatic breast cancer (TA495). Accessed May 2022.

6 NICE (2020) Palbociclib with fulvestrant for treating hormone receptor-positive, HER2-negative, advanced breast cancer (TA619). Accessed May 2022.