

Supplementary Materials

Sacituzumab Govitecan for Second and Subsequent Line Palliative Treatment of Patients with Triple-negative Breast Cancer: A Polish Real-world Multicenter Cohort Study

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Current criteria for qualification for Polish national reimbursement program [1]

1. Age 18 and above;
2. Histologically confirmed advanced breast cancer: a) metastatic breast cancer (stage IV) or b) Locally advanced, if radical local treatment (surgery, radiotherapy) is ineffective or not applicable (stage III);
3. Histologically confirmed triple-negative breast cancer;
4. Documented absence of steroid hormone receptor expression $\geq 1\%$;
5. Documented absence of HER2 receptor overexpression in cancer cells (result /0 or 1+ in IHC examination) or absence of HER2 gene amplification (result +/- in ISH examination);
6. Not applicable
7. Not applicable
8. Feasibility of assessing response to cancer treatment according to current RECIST classification;
9. Performance status 0-1 according to Zubrod-WHO or ECOG criteria;
10. Exclusion of pregnancy and breastfeeding period;
11. Absence of massive metastases to visceral organs posing immediate life threat;
12. Absence of clinically significant and uncontrolled comorbidities, which are contraindications to treatment;
13. Absence of symptomatic metastases in the central nervous system or signs of progression of metastases in the central nervous system in patients after previous local treatment (surgery, radiotherapy); adequate organ function determined based on laboratory blood tests allowing safe initiation of therapy, as assessed by the treating physician;
14. In case of concurrent active tumors, qualification for treatment must consider prognosis associated with the coexisting tumor.

The above qualification criteria must be met collectively.

Exclusion criteria from the program:

1. Disease progression assessed according to currently applicable RECIST criteria;
2. Clinically significant worsening of patient's condition related to cancer without confirmed progression in physical or imaging examination;
3. Occurrence of toxicity requiring treatment discontinuation, as judged by the treating physician according to the current SmPC;
4. Decrease in performance status: a) to grade 2-4 according to Zubrod-WHO or ECOG – for early HER2-positive breast cancer and triple-negative breast cancer, b) to grade 3-4 according to Zubrod-WHO or ECOG – for metastatic HER2-negative or HER2-positive breast cancer;
5. Occurrence of hypersensitivity to the drug, murine protein, or excipient preventing continuation of treatment;
6. Clinically significant decrease in quality of life according to physician's assessment;

7. Pregnancy or breastfeeding period – except in cases where the physician jointly with the National or Provincial Consultant assesses that the risk of applying anticancer therapy outweighs the risk and financing of therapy in the program is justified in such cases;
8. Lack of cooperation or non-compliance with medical recommendations, especially regarding periodic follow-up examinations assessing the efficacy and safety of treatment by the beneficiary or their legal guardians.

Abbreviations: ECOG, Eastern Cooperative Oncology Group; HER2, Human Epidermal Growth Factor Receptor 2; IHC, Immunohistochemistry; ISH, *In Situ* Hybridization; RECIST, Response Evaluation Criteria in Solid Tumors; SmPC, Summary of Product Characteristics; WHO, World Health Organization.

Reference

- [1] Obwieszczenia ministra zdrowia - lista leków refundowanych n.d.
<https://www.gov.pl/web/zdrowie/obwieszczenia-ministra-zdrowia-lista-lekow-refundowanych>
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