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NCCN Guidelines Panel: Ovarian Panel

While reviewing the recent update to the NCCN Ovarian Cancer guidelines, I noticed that bevacizumab-awwb (Mvasi) was not included as an appropriate substitution for bevacizumab (Avastin) in Epithelial Ovarian Cancer (including Fallopian Tube Cancer and Primary Peritoneal Cancer). Could the panel provide rationale for this omission?

FDA Status:

Bevacizumab-awwb (Mvasi) is a biosimilar currently FDA approved for all labeled indications of Avastin with the exception of the indication for the treatment of Epithelial Ovarian Cancer (including Fallopian Tube Cancer and Primary Peritoneal Cancer). Amgen, the manufacturer of Mvasi, has stated that they didn't apply for this indication based on Avastin's orphan drug exclusivity for these indications.

FDA approval of bevacizumab-awwb was "based on comparisons of extensive structural and functional product characterization, animal data, human pharmacokinetic and pharmacodynamic data, clinical immunogenicity between Mvasi and U.S.-licensed Avastin demonstrating that Mvasi is highly similar to US-licensed Avastin and that there are no clinically meaningful differences between the products"(FDA.gov<sup>3</sup>).

Clinically, bevacizumab-awwb's indication should apply to epithelial ovarian cancer (including fallopian tube cancer and primary peritoneal cancer) as it does for metastatic colorectal cancer, non-squamous NSCLC, glioblastoma, metastatic renal cell cancer, and cervical cancer.

The following articles are submitted for your review which indicates that Mvasi could be an appropriate substitution for Avastin in the treatment of epithelial ovarian cancer (including fallopian tube cancer and primary peritoneal cancer):

1. Biosimilar Development, Review, and approval. FDA website.  
<https://www.fda.gov/drugs/biosimilars/biosimilar-development-review-and-approval>  
Published October 2017. Accessed September 25, 2019
2. Guidance document: scientific considerations in demonstrating biosimilarity to a reference

product. FDA website. [www.fda.gov/regulatory-information/search-fda-guidance-documents/scientific-considerations-demonstrating-biosimilarity-reference-product](http://www.fda.gov/regulatory-information/search-fda-guidance-documents/scientific-considerations-demonstrating-biosimilarity-reference-product). Published April 2015. Accessed September 25, 2019

3. FDA approves first biosimilar for the treatment of cancer [news release]. Silver Spring, MD: FDA; September 14, 2017. <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-first-biosimilar-cancer-treatment>. Accessed September 25, 2019.
4. Burger RA, Brady MF, Bookman MA, et al; Gynecologic Oncology Group. Incorporation of bevacizumab in the primary treatment of ovarian cancer. *N Engl J Med*. 2011;365(26):2473-2483. doi: 10.1056/NEJMoa1104390
5. European Medicines Agency: MVASI. EMA Website. <https://www.ema.europa.eu/en/medicines/human/EPAR/mvasi> Published October 2017. Accessed September 25, 2019

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