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NCCN Guidelines Panel: Cervical Cancer

On behalf of Genentech, Inc., I respectfully request the NCCN Cervical Cancer Guideline Panel to review the enclosed recent key publication for:

- **Avastin® (bevacizumab):** Chemotherapy-naïve recurrent cervical cancer

Tewari KS, Sill MW, Long HJ, et al. Improved survival with bevacizumab in advanced cervical cancer. *N Engl J Med* 2014;370:734-43.

Specific Changes:

There are no specific changes being requested. We are providing the full manuscript of previously submitted data on Avastin in chemotherapy-naïve recurrent cervical cancer for your review and consideration.

FDA Clearance: Avastin is not FDA approved for cervical cancer.

Please refer to the enclosed prescribing information for the full FDA-approved indications and safety information.

Rationale:

- Efficacy and safety results of the phase III trial evaluating Avastin in chemotherapy-naïve recurrent cervical cancer were previously submitted. The recently published full manuscript for this study is being submitted for your review.

Respectfully submitted,



Supplemental References

1. Scheffer TE, Winter K, Kwon JS, et al. A Phase II study of bevacizumab in combination with definitive radiotherapy and cisplatin chemotherapy in untreated patients with locally advanced cervical carcinoma: preliminary results of RTOG 0417. *Int J Radiat Oncol Biol Phys* 2012;83:1179-184.
2. Monk BJ, Sill MW, Burger RA, et al. Phase II trial of bevacizumab in the treatment of persistent or recurrent squamous cell carcinoma of the cervix: a gynecologic oncology group study. *J Clin Oncol* 2009;27:1069-1074.
3. Zigelboim I, Wright JD, Gao F, et al. Phase II trial of topotecan, cisplatin, and bevacizumab for recurrent or persistent cervical cancer. Presented at the American Society of Clinical Oncology 2012 Annual Meeting in Chicago, IL; June 1-5, 2012. ASCO Abstract #5101. <http://www.asco.org>.

4. Kikuchi Y, Takano M, Goto T, et al. Effects of weekly bevacizumab and paclitaxel/carboplatin with or without sorafenib on heavily pretreated patients with recurrent or persistent cervical cancer. J Clin Oncol 2011;29.ASCO Abstract #5085.
5. Takano M, Kikuchi Y, Ikeda Y, et al. Effects of weekly bevacizumab and gemcitabine/oxaliplatin with or without dasatinib on heavily pretreated patients with recurrent or persistent cervical cancer. Presented at the American Society of Clinical Oncology 2012 Annual Meeting in Chicago, IL; June 1- 5, 2012. ASCO Abstract #e15579. <http://www.asco.org>.
6. Basu B, Basu C. Targeted therapy in second line treatment of cervical cancer. Int J Gynecol Cancer 2012;22 (suppl 3):E559.
7. Wright JD, Viviano D, Powell MA, et al. Bevacizumab combination therapy in heavily pretreated, recurrent cervical cancer. Gynecol Oncol 2006;103:489-493.