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NCCN Guidelines Panel: Ovarian Cancer
National Comprehensive Cancer Network
500 Old York Road, Suite 250
Jenkintown, PA 19046

RE: Clinical Evidence in Support of Doxorubicin in Ovarian Cancer

Dear Sir/Madam;

On behalf of Oncology Analytics, we respectfully request the NCCN Ovarian Cancer Guidelines Panel to review the enclosed data for the use of doxorubicin in the treatment of patients with ovarian cancer.

Specific Changes: We request consideration of including doxorubicin as a single agent in the management of platinum resistant or refractory ovarian cancer.

FDA Status: Doxorubicin is approved by the FDA in the United States for the treatment of ovarian cancer.

Rationale for recommended changes:

The efficacy of single agent doxorubicin in patients with ovarian cancer has been demonstrated in approximately 100 patients across several published studies. Additionally, doxorubicin has been shown to be an effective component in CAP and AP combinations in virtually thousands of patients with ovarian cancer treated during the last three decades. Furthermore, doxorubicin is the parent drug of Doxil, the liposomal formulation of doxorubicin, which is also FDA approved and part of the NCCN guidelines for the management of ovarian cancer.

Data to support the use of doxorubicin in ovarian cancer:

This request to amend the NCCN Ovarian Cancer guidelines to broaden the list of single agents to include doxorubicin is based on several studies that are enumerated below and briefly described in the accompanying synopsis. The studies are also submitted to NCCN in support of the proposed changes:

1. Barlow JJ et al. Adriamycin and bleomycin, alone and in combination, in gynecologic cancers. Cancer 32:735-743, 1973.
2. O'Bryan RM et al. Phase II evaluation of Adriamycin in human neoplasia. Cancer. 32:1-8, 1973.
3. De Palo GM et al. Melphalan versus Adriamycin in the treatment of ovarian cancer. Surgery, Gynecology and Obstetrics.141; 899-901, 1975.
4. De Palo GM et al. Cancer Treatment Reports. 61:30:355-357, 1977
5. Bolis G et al. Europ Journal of Cancer. 1978;14:1401-1402



6. Hubbard SM et al. Cancer Treatment Reports. 1978;62(9):1375-1377

We appreciate the opportunity to provide this information for consideration by the NCCN ovarian cancer panel. If you have any questions or require additional information, or of any of the referenced articles for CAP or AP, please do not hesitate to contact me at 1-888-916-2616 or via email at marc@oncologyanalytics.com.

Thank you for your time and consideration.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Marc Fishman'.

Marc Fishman, MD
William Hrushesky, MD, FACP
William Shimp, MD
James Krook, MD
Laura Bobolts, PharmD BCOP

A handwritten signature in dark ink, appearing to read 'David E. Cohn'.

David E. Cohn, MD
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Director, Division of Gynecologic Oncology
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Enclosures:

Synopsis

Table of Proposed Changes

References for single agent doxorubicin studies