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:


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@oncoloeanalytcs.com.

Thank you for your time and consideration.

Sincerely,

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

David E. Cohn, MD
Professor, Department of Obstetrics & Gynecology
Director, Division of Gynecologic Oncology
Ohio State University
david.cohn@osumc.edu

Enclosures:
Synopsis
Table of Proposed Changes
References for single agent doxorubicin studies