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May 21, 2003

The Honorable Thomas Scully
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave., S.W.
Room 314G
Washington, D.C. 20201

Dear Mr. Scully:

By law, the Medicare program uses a designated set of medical journals to determine whether new uses of anticancer drugs should be covered. The American Society of Clinical Oncology (ASCO) has reviewed the existing list of journals and would like to recommend that several additional journals be added. ASCO is the national organization representing physicians who specialize in the treatment of cancer.

Under section 1861(t)(2)(ii)(II) of the Social Security Act, Medicare covers a new use of an anticancer chemotherapy drug if a carrier determines that the use is "medically accepted based on supportive clinical evidence in peer reviewed medical literature appearing in publications which have been identified for purposes of this subclause by the Secretary." Section 2049.4,C.4. of the Medicare Carriers Manual (Part 3) lists 15 journals for this purpose. This list has not been revised since it was originally published following enactment of the 1993 legislation it implements.

ASCO recommends that the following journals be added to the list in the Carriers Manual:

- Annals of Oncology
- Biology of Blood and Marrow Transplantation
- Bone Marrow Transplantation
- Cancer Investigation
- International Journal of Cancer
- Lancet Oncology
- Gynecologic Oncology
- Lung Cancer
- The Cancer Journal

2003 Annual Meeting
May 31-June 3, 2003
Chicago, Illinois

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Phone: (703) 631-6200
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All of these journals publish peer-reviewed original research and are important sources of scientific information on new uses of cancer drugs.

If your staff requires any further information on these journals, they should contact Bela Sastry at 703-299-1050. Thank you for your consideration of this request.

Sincerely,

A handwritten signature in black ink that reads "Joseph S. Bailes". The signature is written in a cursive, flowing style.

Joseph S. Bailes, MD
Chair, Clinical Practice Committee

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May 4, 2006

Mark McClellan, MD, PhD
 Administrator
 Centers for Medicare & Medicaid Services
 Department of Health and Human Services
 200 Independence Ave., SW
 Room 314G
 Washington, D.C. 20201

Dear Dr. McClellan:

By law, the Medicare program uses a designated set of medical journals to determine whether new uses of anticancer drugs should be covered. The American Society of Clinical Oncology (ASCO) has reviewed the existing list of journals and would like to recommend that several additional journals be added. ASCO is the national organization representing physicians who specialize in the treatment of cancer.

Under section 1861(t)(2)(ii)(II) of the Social Security Act, Medicare covers a new use of an anticancer chemotherapy drug if a carrier determines that the use is "medically accepted based on supportive clinical evidence in peer reviewed medical literature appearing in publications which have been identified for purposes of this subclause by the Secretary." Section 2049.4.C.4. of the Medicare Carriers Manual (Part 3) lists 15 journals for this purpose. This list has not been revised since it was originally published following enactment of the 1993 legislation it implements.

ASCO recommends that the following journals be added to the list in the Carriers Manual:

- Annals of Oncology
- Biology of Blood and Marrow Transplantation
- Clinical Cancer Research
- Gynecologic Oncology
- Journal of the National Comprehensive Cancer Network
- Journal of Thoracic Oncology
- Breast Cancer Research and Treatment
- International Journal of Radiation Oncology, Biology, Physics

ASCO developed this list through extensive consultation with physician leadership about which publications provide the best clinical evidence on new uses of cancer drugs. Following a careful review of a number of journals commonly referenced by oncologists, we have concluded that these periodicals have significant scientific value and publish original research only after a rigorous peer-review process; it is these original research articles that we recommend be reviewed by Medicare carriers for the purpose of making

2006 Annual Meeting
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 Atlanta, Georgia

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determinations about new off-label uses. Attachment A includes for reference a brief description of the peer-review process used by each of the journals (as described by the journal publisher) as well as general publishing information. A number of the publications we are recommending have been introduced since 1993 and are important new sources of information. Others are well-respected peer-reviewed journals overseen by our partner societies in oncology such as the Society of Gynecologic Oncology and the American Society for Therapeutic Radiology and Oncology.

If your staff requires any further information on these journals, they should contact Bela Sastry at (703) 299-1050. Thank you for your consideration of this request.

Sincerely,

Joseph S. Bailes
Interim Executive Vice President and CEO

Attachment A

<i>Annals of Oncology</i>	The editorial office will rapidly review the manuscripts in order that new findings may appear with minimum delay. The editorial office will return to authors within 3 weeks, whenever possible, all papers that are found to be of insufficient priority for further consideration. Papers of high interest will be sent out for external review.	Oxford University Press	European Society for Medical Oncology	1990	United Kingdom
<i>Biology of Blood and Marrow Transplantation</i>	Manuscripts are reviewed by two or more experts in the field, and detailed comments from the reviewers are generally returned to the authors. Manuscripts requiring extensive revision will be at a disadvantage for publication. Manuscripts are submitted with the understanding that they are original contributions and do not contain data that have been published elsewhere, including symposia volumes, etc. Meeting abstracts do not constitute prior publication.	Elsevier	American Society for Blood and Marrow Transplantation	1995	United States
<i>Clinical Cancer Research</i>	Each submitted manuscript is evaluated for suitability for consideration for publication in Clinical Cancer Research and must meet minimal general requirements to warrant peer review. After submission, a manuscript undergoes Pre-Review. If a manuscript successfully passes Pre-Review, it will then be sent out for peer review.	American Association for Cancer Research	American Association for Cancer Research	1995	United States
<i>Gynecologic Oncology</i>	Manuscripts are accepted for review with the understanding that no substantial portion of the study has been published or is under consideration for publication elsewhere and that	Academic Press	Society of Gynecologic Oncologists	1972	United States

	its submission for publication has been approved by all of the authors and by the institution where the work was carried out.						
<i>Journal of the National Comprehensive Cancer Network</i>	All articles except guest commentaries... undergo full peer review. Reviewers are selected by the editor-in-chief and issue editors from our editorial board, guidelines panels, and the oncology community at large based on their expertise in the topic.	Jones and Bartlett	National Comprehensive Cancer Network		2003		United States
<i>International Journal of Radiation Oncology, Biology, Physics</i>	All manuscripts submitted to the <i>IJROBP</i> are subject to peer review.	Elsevier	American Society for Therapeutic Radiology and Oncology		1975		United States
<i>Journal of Thoracic Oncology</i>	Peer-reviewed	Lippincott Williams and Wilkins	International Association for the Study of Lung Cancer		2006		United States
<i>Breast Cancer Research and Treatment</i>	All manuscripts are peer reviewed by a distinguished group of advisory editors from many countries covering all of the various disciplines of breast cancer.	Springer	N/A		1981		Netherlands