



Related MLN Matters Article #: MM5729

Date Posted: September 25, 2007

Related CR #: 5729

Unlabeled Use for Anti-Cancer Drugs: Medical Literature used to Determine Medically Accepted Indications for Drugs and Biologicals used in Anti-Cancer Treatment

Key Words

MM5729, CR5729, R78BP, Unlabeled, Cancer, Drugs, Biologicals, Anti-Cancer, Treatment

Provider Types Affected

Physicians, providers, and suppliers submitting claims to Medicare carriers and Part A/B Medicare Administrative Contractors (A/B MACs) for services provided to Medicare beneficiaries

Key Points

- The effective date of the instruction is October 22, 2007.
- The implementation date is October 22, 2007.
- The Social Security Act (Section 1861(t)(2)(B)(ii)(II); http://www.ssa.gov/OP_Home/ssact/title18/1861.htm) states that:
"The carrier involved determines, based upon guidance provided by the Secretary to carriers for determining accepted uses of drugs, that such 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."
- Accordingly, Section 50.4.5 of the *Medicare Benefit Policy Manual* (Chapter 15, Section 50.4.5; <http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf>) lists 15 peer-reviewed journals that a Medicare contractor must use to determine, "whether there is supportive clinical evidence for a particular use of a drug."

- These 15 peer-reviewed medical journals include:
 - American Journal of Medicine;
 - Annals of Internal Medicine;
 - The Journal of the American Medical Association;
 - Journal of Clinical Oncology;
 - Blood;
 - Journal of the National Cancer Institute;
 - The New England Journal of Medicine;
 - British Journal of Cancer;
 - British Journal of Hematology;
 - British Medical Journal;
 - Cancer;
 - Drugs;
 - European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology);
 - Lancet; and
 - Leukemia.
- None of these 15 existing peer-reviewed medical journals are being deleted at this time.
- In letters dated May 21, 2003 (2003 letter), and May 4, 2006 (2006 letter), the American Society of Clinical Oncology (ASCO) noted that this list of 15 journals was created in 1993, and it has not been revised since that time.
- ASCO formally submitted requests for the Centers for Medicare & Medicaid Services (CMS) to revise the list of 15 journals by adding 14 more journals.
- CMS staff conducted a review of the journals listed in the ASCO requests.
- In addition, CMS informally consulted oncology experts from the National Cancer Institute at the National Institutes of Health and from the Center for Drug Evaluation and Research at the Food and Drug Administration (FDA) to request their opinions about the ASCO-recommended journals.
- CMS also provided public notice and solicited public comment from October 27, 2006, through December 26, 2006 (http://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=9), through a CMS website posting.

- CMS staff integrated the data from its review and from the above sources into its final decision to add the following 11 journals to the current list of 15 journals at Section 50.4.5 of the *Medicare Benefit Policy Manual*:
 - Annals of Oncology;
 - Biology of Blood and Marrow Transplantation;
 - Bone Marrow Transplantation;
 - Gynecologic Oncology;
 - Clinical Cancer Research;
 - International Journal of Radiation, Oncology, Biology, and Physics;
 - Journal of the National Comprehensive Cancer Network (NCCN);
 - Radiation Oncology;
 - Annals of Surgical Oncology;
 - Journal of Urology; and
 - Lancet Oncology.
- Medicare carriers are not required to maintain copies of these publications.
- If a claim raises a question about the use of a drug for a purpose not included in the FDA-approved labeling or the compendia, the carrier will ask the physician to submit copies of relevant supporting literature.

Important Links

The related MLN Matters article can be found at

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5729.pdf> on the CMS website.

The official instruction (CR5729) regarding this change may be viewed at

<http://www.cms.gov/Transmittals/downloads/R78BP.pdf> on the CMS website.

The CMS decision memorandum on this issue was posted at

http://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=9 on the CMS website.

If providers have questions regarding this issue, they may contact their carrier or A/B MAC at their toll-free number, which may be found at

<http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.