Medicare Learning Network
MLN Matters®
CMS
Information for Medicare Fee-For-Service Health Care Professionals

News Flash - A new preventive services brochure entitled *Diabetes-Related Services,* ICN# 006840, is now available from the Centers for Medicare & Medicaid Services' (CMS), Medicare Learning Network (MLN). This tri-fold brochure provides health care professionals with an overview of Medicare's coverage of diabetes screening tests, diabetes self-management training, medical nutrition therapy, and supplies and other services for Medicare beneficiaries with diabetes. The new brochure is available as a downloadable pdf file on the Medicare Learning Network's (MLN) Publications web page at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/DiabetesSvcs.pdf on the CMS website.

MLN Matters Number: MM5729 Revised

Related Change Request (CR) #: 5729

Related CR Release Date: September 21, 2007

Effective Date: October 22, 2007

Related CR Transmittal #: R78BP

Implementation Date: October 22, 2007

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

Note: Note: This article was updated on September 20, 2012, to reflect current Web addresses. This article was also revised on October 16, 2007, to reflect that the Centers for Medicare & Medicaid Services decision memorandum on this issue has now been posted at http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx on their website. All other information remains the same.

Provider Types Affected

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

Provider Action Needed

This article is informational only and it is based on Change Request (CR) 5729, which revises the "Medicare Benefit Policy Manual", (Chapter 15, Section 50.4.5 (Unlabeled Use for Anti-Cancer Drugs)).CR 5729 adds 11 peer-reviewed medical journals to the existing list of 15 peer-reviewed medical journals used to determine

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medically accepted indications for drugs and biologicals used in Anti-Cancer Treatment. Medicare contractors processing Medicare claims use this list of medical journals to determine whether there is supportive clinical evidence for a particular use of a drug in the treatment of Medicare beneficiaries. None of the 15 existing peer-reviewed medical journals are being deleted at this time.

Background

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.gov/Regulations-and-Guidance/Guidance/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);

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- Lancet; and
- Leukemia.

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 (NCI) at the National Institutes of Health (NIH) 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 through a CMS website posting from October 27, 2006, through December 26, 2006 (http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx). The CMS decision memorandum on this issue has also been posted at this Web site. 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.

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Additional Information

The official instruction, CR5729, issued to your carrier and A/B MAC regarding this change may be viewed at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R78BP.pdf on the CMS website.

If you have any questions, please contact your carrier or A/B MAC at their toll-free number, which may be found at http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html on the CMS website.

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