

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services



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- [“Medicare Enrollment and Claim Submission Guidelines.”](#) Booklet ICN 906764, Downloadable

MLN Matters® Number: MM9386

Related Change Request (CR) #: CR 9386

Related CR Release Date: November 6, 2015

Effective Date: August 12, 2015

Related CR Transmittal #: R212BP

Implementation Date: February 10, 2016

Update to the List of Compendia as Authoritative Sources for Use in the Determination of a “Medically-Accepted Indication” of Drugs and Biologicals Used Off-label in an Anti-Cancer Chemotherapeutic Regimen

Provider Types Affected

This MLN Matters® Article is intended for physicians, other providers, and suppliers who submit claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

What You Need to Know

This article is based on Change Request (CR) 9386 which announces that effective for services on or after August 12, 2015, the Centers for Medicare & Medicaid Services (CMS) is adding Wolters Kluwer Lexi-Drugs® to the list of authoritative compendia for use in the determination of a medically-accepted indication of drugs and biologicals used off-label in an anti-cancer chemotherapeutic regimen.

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Background

The Social Security Act ([Section 1861\(t\)\(2\)\(B\)\(ii\)\(I\)](#)); as amended by the [Deficit Reduction Act of 2005](#) (Pub. Law 109-171; Section 6001(f)(1)), recognized the following three compendia as authoritative sources for use in the determination of a "medically accepted indication" of drugs and biologicals used off-label in an anti-cancer chemotherapeutic regimen:

1. American Medical Association Drug Evaluations (AMA-DE);
2. United States Pharmacopoeia-Drug Information (USP-DI) or its successor publication; and
3. American Hospital Formulary Service-Drug Information (AHFS-DI).

These authoritative sources could be used in the determination of a "medically-accepted indication" of drugs and biologicals used off-label in an anti-cancer chemotherapeutic regimen, unless:

- The Secretary of Health and Human Services (HHS) determined that the use is not medically appropriate; or
- The use is identified as not indicated in one or more such compendia.

This provision was implemented through instructions to the MACs in the "Medicare Benefit Policy Manual" (Chapter 15, Section 50.4.5).

Due to changes in the pharmaceutical reference industry:

- The AHFS-DI was the only remaining statutorily-named compendia available for CMS reference;
- The AMA-DE and USP-DI are no longer published;
- Thomson Micromedex designated Drug Points was the successor to USP-DI; but
- Drug Points has since been deleted from the list of recognized compendia.

In January 2008, CMS established, via the Physician Fee Schedule Final Rule for calendar year 2008:

- A process for revising the list of compendia, as authorized under the Social Security Act (Section 1861(t)(2)), and
- A definition for "compendium."

This sub-regulatory process for revising the list of compendia is described in the "Medicare Benefit Policy Manual" (Chapter 15, Section 50.4.5.1).

Based on this process, CMS updated the list in 2008 to include the following four compendia:

1. Existing - American Hospital Formulary Service-Drug Information (AHFS-DI),
2. Effective June 5, 2008 - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium,

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3. Effective June 10, 2008 - Truven Health Analytics Micromedex DrugDex, and
4. Effective July 2, 2008 - Elsevier/Gold Standard Clinical Pharmacology.

On August 12, 2015, CMS announced the addition of Wolters Kluwer Lexi-Drugs® to the above list of four compendia used by the Medicare program in the determination of a "medically-accepted indication" for off-label drugs and biologics used in an anticancer chemotherapeutic treatment regimen. This is effective for services on or after August 12, 2015.

Further details on this issue are in the revised Chapter 15, Section 50.4.5.1 of the "Medicare Benefit Policy Manual," which is an attachment to CR9386.

Additional Information

The official instruction, CR 9386, issued to your MAC regarding this change is available at <http://www.cms.hhs.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R212BP.pdf> on the CMS website.

If you have questions, please contact your MAC at their toll-free number. The number is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html> under - How Does It Work?

Each Office Visit is an Opportunity to Recommend Influenza Vaccination.
Protect your patients, your staff, and yourself. Medicare Part B covers one influenza vaccination and its administration each influenza season for Medicare beneficiaries. If medically necessary, Medicare may cover additional seasonal influenza vaccinations.
- Preventive Services Educational Tool
- Influenza Vaccine Payment Allowances MLN Matters Article
- Influenza Resources for Health Care Professionals MLN Matters Article
- CDC Influenza website

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