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BY ELECTRONIC DELIVERY

**Re: Wolters Kluwer Clinical Drug Information Lexi-Drugs
Compendium Revision Request - CAG-004430**

Dear Dr. Gilbreath:

The Association of Community Cancer Centers (ACCC) appreciates this opportunity to comment on the recent compendium revision request for the addition of Lexi-Drugs.¹ ACCC is a membership organization whose members include hospitals, physicians, nurses, social workers, and oncology team members who care for millions of patients and families fighting cancer. ACCC represents more than 20,000 cancer care professionals from approximately 1,100 hospitals and more than 1,000 private practices nationwide. These include Cancer Program Members, Individual Members, and members from 32 state oncology societies. It is estimated that 60 percent of cancer patients nationwide are treated by a member of ACCC. ACCC believes that compendia serve as a vital source of information regarding novel and life-saving therapies, and we urge the Centers for Medicare & Medicare Services (CMS) to protect beneficiary access to these therapies by recognizing Lexi-Drugs as a compendium.

ACCC is committed to ensuring that Medicare beneficiaries have access to quality cancer care, including the innovative and cutting-edge therapies our patients require to win their battles against this deadly disease. Many of these treatment regimens involve new uses of drugs already approved for other indications by the Food and Drug Administration (FDA). This "off-label" use of cancer drugs is a common medical practice that is a critical component of many treatment regimens and is integral to the discovery of new cures. Compendia serve as an important resource for physicians when determining the most appropriate treatment regimen for their Medicare beneficiaries. It is imperative, therefore, that both CMS ensure that coverage policies keep up with the pace of innovation and clinical discovery to allow Medicare beneficiaries timely access to

¹ <http://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=31>.

the most appropriate treatment options as described in the peer-reviewed literature and compendia in their battles against deadly diseases.

The Medicare statute protects access to these innovative therapies by requiring contractors to cover off-label uses of cancer drugs that are listed in recognized compendia. As of 2008, CMS has recognized the following compendia for use in the determination of medically-accepted indications of drugs/biologicals used off-label in anti-cancer chemotherapeutic regimens:

- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
- Truven Health Analytics Micromedex DrugDex
- Elsevier/Gold Standard Clinical Pharmacology
- American Hospital Formulary Service-Drug Information

Each of these publications uses a different method of identifying the medically accepted indications for a drug. Recognition of an additional compendium will protect beneficiary access to advanced cancer therapies by providing physicians and policymakers with a wider body of evidence to use in making treatment and coverage decisions. Although all of the compendia are evidence-based, the content of the compendia may vary due to differences in publication schedules, priorities, review processes, local practices and methods of describing the evidence for each listing. To improve the chances of a treatment option being recognized by a compendium in a timely manner, we recommend that CMS recognize Lexi-Drugs as an additional compendium.

CMS adopted a list of desirable compendium characteristics outlined by the Medicare Evidence Development and Coverage Advisory Committee (MedCAC) as criteria for adding additional compendia for use in the determination of medically accepted indications of drugs and biologicals in anti-cancer therapy.² ACCC agrees with the requester, Wolters Kluwer, that Lexi-Drugs is a desirable addition to the list of compendia because it fulfills a number characteristics described adopted by CMS. Of the list of desirable characteristics for additional compendia, ACCC believes that Lexi-Drugs fulfills the following most important characteristics to improve cancer care.

I. Extensive Breadth of Listings

Lexi-Drugs includes an extensive breadth of listings that reflect multiple treatment regimens for each of the hundreds of types of cancer, including more than 2052 drug monographs. ACCC believes that a compendium must provide clearly written entries that describe the evidence for each use. A publication is useful to physicians and contractors only if it presents information on treatment options in clear language and an easily understood format. Lexi-Drugs is user-friendly because its database is searchable by generic drug names, brand names, NDC, keyword, and synonyms. Lexi-Drugs' monographs include information such as

² Benefit Policy Manual, ch. 15, § 50.4.5.1(B).

brand names, pharmacologic category, labeled indications, off-label uses and applicable evidence, dosages, interactions, and adverse reactions. This information assists physicians to make more informed choices.

II. Quick Processing from Application for Inclusion to Listing

Lexi-Drugs demonstrates the flexibility to rapidly integrate literature and issue readily accessible updates because drug monographs can be revised in real-time on its publishing system. Delays of months, and sometimes years, between the announcement of significant clinical research outcomes and their inclusion in the compendia can obstruct Medicare beneficiaries' access to care. ACCC believes that through its Clinical Drug Information's surveillance model, Lexi-Drugs is committed to identifying and incorporating updates to the drug monographs listed in its database in order to improve access to cancer care.

III. Detailed Description of the Evidence Reviewed for Every Individual Listing

Lexi-Drugs uses a clearly described and transparent application and review process for new listings and revisions to listings, and incorporates this evidence into a clear and easily understood format. This allows physicians to easily understand the basis for treatment recommendations, and determine whether the listing incorporates the latest research. This process also protects access to new treatment options by making it easier for researchers, physicians, and patients to request that the regimens be included in the compendium. Lexi-Drugs includes references to published literature for off-label uses, therapy considerations, and level of evidence ratings. ACCC believes that Lexi-Drugs's system is intended to aid physicians in quickly identifying published literature regarding a specific drug use.

IV. Use of Pre-Specified Published Criteria for Weighing Evidence

Lexi-Drugs considers data from various types of trials. Although randomized controlled trials are recognized as the gold standard for clinical research, they cannot be performed for rare cancers. Accordingly, Lexi-Drugs does not limit its review to large randomized-controlled trials. Lexi-Drugs also weighs evidence from a host of other types of studies, including observational studies, unsystematic clinical experience, and potentially flawed randomized, controlled trials. For each off-label use listed, the Lexi-Drugs database identifies and rates the type of evidence cited, using its Level of Evidence Scale for Oncology Off-Label Use scale consisting of:

1. A (consistent evidence from well-performed randomized, controlled trials or overwhelming evidence of some other form)
2. B (evidence from randomized, controlled trials with important limitations);
3. C (evidence from observational studies, unsystematic clinical experience; or potentially flawed randomized, controlled trials); and
4. G (substantiated by inclusion in at least one evidence-based or consensus-based clinical practice guideline).

For these reasons, ACCC urges CMS to add Lexi-Drugs to the list of recognized compendia. We firmly believe that by CMS providing greater access to state-of-the-art care

Lead Analyst Cheryl Gilbreath

May 20, 2015

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listed in the Lexi-Drugs compendia, Medicare beneficiaries have a better chance of surviving a cancer diagnosis. Please feel free to contact Leah Ralph, Manager, Provider Economics and Public Policy, at (301) 984-5071 if you have any questions regarding these comments or need any additional information. Thank you for your attention to this very important matter.

Respectfully submitted,

A handwritten signature in black ink that reads "Steven D'Amato". The signature is written in a cursive style with a large, stylized 'S' and 'D'.

Steven D'Amato, BSPharm, BCOP
President
Association of Community Cancer Centers