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June 22, 2017

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BY ELECTRONIC DELIVERY

Re: Proposed/Draft Local Coverage Determination (LCD): Chemotherapy Drugs and their Adjuncts (DL 37205)

Dear Dr. Ray:

The Association of Community Cancer Centers (ACCC) appreciates this opportunity to comment on the Wisconsin Physicians Service Insurance Corporation's (WPS) Proposed/Draft Local Coverage Determination (LCD): Chemotherapy Drugs and their Adjuncts (DL 37205) issued on May 8, 2017. 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 23,000 cancer care professionals from approximately 2,000 hospitals and private practices nationwide. These include Cancer Program Members, Individual Members, and members from 32 state oncology societies. It is estimated that 65% of cancer patients nationwide are treated by a member of ACCC.

ACCC is concerned that the Proposed/Draft LCD could harm Medicare beneficiaries by denying access to medically necessary treatments prescribed by their doctors when they are used outside of Food and Drug Administration (FDA)-approved labeling. The Proposed/Draft LCD conflicts with the Medicare statute and Benefit Policy Manual provisions that are intended to protect access to medically accepted cancer therapies. If WPS adopts the Proposed/Draft LCD's language, ACCC believes Medicare patients' ability to access the most appropriate cancer care will become significantly more challenging.

We ask WPS to revise the Proposed/Draft LCD to clarify that WPS will cover on-label and off-label uses of drugs supported by any of the CMS-recognized compendia listed in the Medicare Benefit Policy Manual as well as the peer-reviewed medical literature, as provided by the statute.¹ Alternatively, we ask WPS to retain the language from its current LCD that recognizes as “medically accepted” uses of drugs listed in all five compendia, including off-label uses.²

As per the “Coverage Guidance” section of the Proposed/Draft LCD language:

...chemotherapy agents can be covered if reasonable and medical necessity is met **AND** the drug is FDA approved **AND** used on-label for the FDA listed indications per the [National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium] list of diagnoses. The chemotherapy agent must be listed in Category 1 or 2A in NCCN and if step care is listed in the NCCN the agent must be used in the order (or combination) as listed.

OR

Specifically, listed drug in Group 1 under the CPT/HCPCS codes for only the listed diagnoses codes.³

ACCC understands that the intent of this Proposed/Draft LCD is to assist providers in clarifying chemotherapy coverage and guidance by referring to a single publication, the NCCN Drugs & Biologics Compendium, to identify covered uses of these drugs. As drafted, however, the Proposed/Draft LCD creates confusion about which uses of chemotherapy drugs are covered. The Proposed/Draft LCD refers only to on-label uses of drugs, not the off-label uses that are critical components of many cancer therapeutic regimens. The statute clearly recognizes as “medically accepted” not only “any use which has been approved by the FDA for the drug,” but also “another use of the drug” if supported by certain compendia or certain peer-reviewed medical literature.⁴ We assume that WPS did not intend to deny coverage for all off-label uses of anticancer drugs, and we ask you to revise the Proposed/Draft LCD to clarify this point.

We also ask WPS to continue to base its coverage decisions on listings in any of the five compendia recognized by CMS. The Proposed/Draft LCD refers to only the NCCN Compendium, not the other four publications identified in the statute and recognized by CMS for purposes of identifying “medically accepted indications.”⁵ The Proposed/Draft LCD does not provide any justification for not covering uses supported any of the other recognized compendia. There are good reasons for covering a use supported by any one of the five publications, however. Because each publication has a unique schedule for reviewing and revising its listings, new evidence might be recognized in one publication months before it is included in another publication. WPS’s current LCD correctly covers uses supported by any of the five compendia, and WPS should continue to use this approach to coverage.

Similarly, the statute and manual also recognize certain peer-reviewed medical literature as a basis for coverage.⁶ Supportive evidence might be published in one of the peer-reviewed publications long before it is included in any of the compendia. As provided by the statute and the manual, WPS should recognize

¹ Social Security Act (SSA) § 1861(t)(2)(B); Medicare Benefit Policy Manual, ch. 15, § 50.4.5(B). These publications are American Hospital Formulary Service-Drug Information, Micromedex DrugDex, Clinical Pharmacology, and Lexi-Drugs, in addition to the NCCN Drugs & Biologics Compendium.

² WPS, LCD: Chemotherapy Drugs and their Adjuncts (L35053), rev. eff. June 1, 2017, <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35053&ver=75&SearchType=Advanced&CoverageSelection=Local&ArticleType=SAD%7cEd&PolicyType=Both&s=All&AdvSearchName=8&Keyword=chemotherapy&KeywordLookUp=Title&KeywordSearchType=Exact&kq=true&bc=IAAAACAAAAAAA%3d%3d&>

³ WPS, LCD: Chemotherapy Drugs and their Adjuncts (DL37205), [https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=37204&ContrId=268&ver=2&ContrVer=1&CntrctrSelected=268*1&Cntrctr=268&name=Wisconsin+Physicians+Service+Insurance+Corporation+\(05901%2c+MAC+--+Part+A\)&s=56&DocType=All&bc=AggAAAQAAAAAAA%3d%3d&](https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=37204&ContrId=268&ver=2&ContrVer=1&CntrctrSelected=268*1&Cntrctr=268&name=Wisconsin+Physicians+Service+Insurance+Corporation+(05901%2c+MAC+--+Part+A)&s=56&DocType=All&bc=AggAAAQAAAAAAA%3d%3d&)

⁴ SSA § 1861(t)(2)(B).

⁵ SSA § 1861(t)(2)(B); Medicare Benefit Policy Manual, ch. 15, § 50.4.5.

⁶ SSA § 1861(t)(2)(B)(ii)(II); Medicare Benefit Policy Manual, ch. 15, § 50.4.5(C).

all five publications and peer-reviewed medical literature as the basis for coverage policies, rather than limiting itself to a single publication, to ensure that its policies reflect rapidly evolving standards of care.

In addition, the Proposed/Draft LCD's "Coverage Guidance" language requiring drugs to be "used in the order (or combination) as listed" in NCCN if step care is listed⁷ runs contrary to the statute and manual. We do not believe that coverage for a drug should be restricted to the order or combination specified in such listed compendia. From our understanding, a medically accepted indication is not defined according to a specific order or combination under which a drug is used. Both the statute and manual refer only to accepted "uses," not the order in which the drugs must be used.⁸ We ask that the final LCD not include a requirement for drugs to be used in a specific order or combination.

ACCC's concerns over the Proposed/Draft LCD reflect our members' sincere belief that Medicare beneficiaries must not face barriers to appropriate cancer treatment. Not only is some of the proposed language cumbersome—denying coverage for currently covered cancer therapies and requiring beneficiaries and providers to pursue a potentially onerous process to seek coverage for their prescribed treatments—it is also incongruent with CMS guidance. ACCC asks WPS to please revise its Proposed/Draft LCD to address these inconsistencies so as not to ultimately limit patients' access to clinically appropriate care.

ACCC thanks WPS for considering our comments. We appreciate your time in answering our queries and look forward to hearing from you. If you should have any questions, please don't hesitate to contact, Leah Ralph, ACCC Director of Health Policy, at: lralph@acc-cancer.org.

Sincerely,



Mark Soberman, MD, MBA, FACS
President, ACCC

⁷ WPS, LCD: Chemotherapy Drugs and their Adjuncts (DL37205), [https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=37204&ContrlId=268&ver=2&ContrVer=1&CntrctrSelected=268*1&Cntrctr=268&name=Wisconsin+Physicians+Service+Insurance+Corporation+\(05901%2c+MAC+-+Part+A\)&s=56&DocType=All&bc=AggAAAQAAAAAA%3d%3d&](https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=37204&ContrlId=268&ver=2&ContrVer=1&CntrctrSelected=268*1&Cntrctr=268&name=Wisconsin+Physicians+Service+Insurance+Corporation+(05901%2c+MAC+-+Part+A)&s=56&DocType=All&bc=AggAAAQAAAAAA%3d%3d&).

⁸ SSA § 1861(t)(2)(B); Medicare Benefit Program Manual, chapter 15, § 50.4.5(B).