March 19, 2018

Kate Goodrich, MD
Director of CMS Center for Clinical Standards and Quality & CMS Chief Medical Officer
CMS Center for Clinical Standards & Quality (CCSQ)
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. Goodrich:

On behalf of the American Society of Clinical Oncology (ASCO), I am writing to request that you intervene to address concerns with the new Wisconsin Physician Services Insurance Corporation (WPS) Medicare local coverage determination (LCD) involving patient access to anticancer drugs under Medicare Part B. As written, LCD L37205 (Chemotherapy Drugs and their Adjuncts) undermines patient access to appropriate, evidence based off-label uses of anticancer chemotherapy. Further, this policy contradicts the plain meaning of safeguards within both the Social Security Act and the Medicare Benefit Policy Manual. We welcome the opportunity to further discuss the impacts of this policy on cancer care, and we recommend that CMS direct WPS to immediately suspend and withdraw the policy.

ASCO is the national organization representing nearly 45,000 physicians and other healthcare professionals specializing in cancer treatment, diagnosis, and prevention. ASCO members are also dedicated to conducting research that leads to improved patient outcomes. We are committed to ensuring that evidence-based practices for the prevention, diagnosis and treatment of cancer are available to all Americans, including Medicare beneficiaries.

Although we generally support efforts by WPS and other contractors to reduce administrative burdens and streamline processes, in this case the new LCD has the effect of overturning the longstanding patient access protections for cancer patients arising from Section 1861(t) of the Social Security Act and Section 50.4.5 of the Medicare Benefit Policy Manual. The federal protections require Medicare to cover off-label uses of anticancer chemotherapy regimens when supported by compendia identified by the statute or the Secretary, or alternatively when the contractor determines the use is supported in the peer-reviewed clinical literature using criteria developed by the Secretary.
enacted these safeguards in 1993 to address concerns about delays and barriers that prevented cancer patients from accessing the most appropriate cancer drug on a timely basis.

LCD L37205 undermines the clear meaning of the statute’s coverage mandates and limits patient access because WPS will only approve initial claims for an anticancer drug when the off-label use is supported by only one compendium—the National Cancer Care Network Clinical Practice Guidelines for Oncology (NCCN Guidelines). The WPS policy creates a de facto standard for the use of one compendium to support off-label use of anticancer chemotherapy drugs over all other compendia and clinical literature identified by the Secretary as recognized sources to support off label uses of drugs.

In direct contrast to LCD L37205, the Medicare Benefit Policy Manual prohibits the denial of claims without consideration of additional sources of evidence. For example, CMS states: “Do not deny coverage based solely on the absence of FDA-approved labeling for the use, if the use is supported by any of the following compendia...”1 (Emphasis added). Currently, there are five compendia and 26 peer-reviewed journals listed in the Medicare Benefit Policy Manual that Congress and CMS have expressly recognized as potential sources of evidence to support off-label uses of anticancer chemotherapy.

LCD L37205 states that—after a claim is denied—WPS will consider requests for coverage based on evidence from sources other than the NCCN on an individual basis. However, this approach falls short of the coverage protections that Congress enacted and that cancer patients deserve. An appeals process is no substitute for a clear and appropriate coverage policy that is consistent with the federal requirements. Timely access to the right drug for the appropriate patient is critical in cancer care. Delays in commencing or continuing treatment can have significant adverse effects on treatment outcomes. Further, the uncertainty and delays associated with appealing claims for legitimate indications are likely to have chilling effects on patient access to the most appropriate anticancer drugs.

The WPS LCD should be withdrawn and amended to make clear that WPS will embrace the full scope of evidence-based rationales for coverage of anticancer drugs under Medicare Part B with timely determinations based on the initial claims submitted to the contractor. We request the opportunity to meet with you to provide additional information on the impacts of this LCD on cancer care.

1 Medicare Benefit Policy Manual. 50.4.5 Off-Label Use of Drugs and Biologics in an Anti-Cancer Chemotherapeutic Regimen.
Thank you for your time and attention to this matter. We hope to hear from you in the near future. If you have any additional questions or need any additional information, please contact Sybil Green at Sybil.Green@asco.org with any questions.

Sincerely,

Bruce Johnson, MD, FASCO
President, American Society of Clinical Oncology