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October 5, 2007

Kerry N. Weems  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
200 Independence Ave, S.W.  
Washington, D.C. 20201

Dear Acting Administrator Weems:

The American Society of Clinical Oncology (ASCO) requests that CMS issue instructions to its Medicare contractors, state Medicaid programs, and Medicare Part D plans regarding Medicare and Medicaid coverage of indications listed in the compendium *DrugPoints*. As discussed below, this new compendium has official status under the Medicare and Medicaid statutes, but CMS has not yet issued implementing instructions. ASCO is the national organization representing physicians who specialize in the treatment of cancer, and Medicare and Medicaid coverage of new drug uses, which the compendium addresses, is extremely important to our patients.

Section 1861(t)(2) of the Social Security Act (in conjunction with sections 1812(a)(1), 1832(a)(2)(B), 1861(b)(2), and 1861(s)(2)) establishes a special Medicare coverage rule for drugs used in cancer chemotherapy regimens. The provision mandates Medicare coverage of drugs administered in physician offices and hospitals when used for indications approved by the Food and Drug Administration (FDA), and in the case of off-label uses of approved drugs, when the uses are supported by citations in specified compendia.

The compendia also play an important role in Medicaid and Medicare Part D coverage. Subsections (d)(4), (g)(1)(B), and (k)(6) of section 1927 generally require state Medicaid programs to cover all medically accepted indications of drugs, and uses supported by a citation in a specified compendium are considered medically accepted. Similarly, section 1860D(e)(1) requires Medicare Part D plans to cover all medically accepted indications of drugs, using the Medicaid definition of that term.

One of the specified compendia for Medicare and Medicaid coverage purposes is *United States Pharmacopoeia – Drug Information (USP-DI)*. This compendium, which is owned by the Micromedex division of Thomson Healthcare, Inc. is being phased out. As we understand it, the electronic version is no longer being updated, and the annual printed version will no longer be published. This change is the result of Micromedex no longer having the legal right to use the “United States Pharmacopoeia” name. In anticipation of this change, section 6001(f)(1) of the Deficit Reduction Act of 2005 amended sections 1861(t)(2) and 1927(g)(1)(B) of the Social Security Act to grant official status to “successor publications” of the *USP-DI*.

2008 Annual Meeting  
May 30–June 3, 2008  
Chicago, Illinois

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Phone: (703) 631-6200  
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Earlier this year, Micromedex announced its successor publication to *USP-DI*, which is called *DrugPoints*. *DrugPoints* is now available on the market.

As in the case of *USP-DI*, *DrugPoints* separately lists the FDA-approved and the accepted off-label uses. According to an explanation issued by Micromedex, an off-label use is listed in *DrugPoints* only if, in the publisher's rating system, the strength of recommendation for the indication is (1) "recommended," (2) "recommended in most cases," or (3) "recommended in some cases" with the strength of evidence in "Category A" or "Category B." In other words, if the off-label use is "recommended in some cases," the indication will not be listed in *DrugPoints* if the supporting evidence is "Category C" – expert opinion, consensus, case reports, or case series. All off-label uses published in *DrugPoints* should be considered accepted, as those uses with inadequate support are excluded from publication in the compendium. CMS should notify contractors immediately with this guidance in order to avoid delays in coverage.

It is very important for the proper care of Medicare beneficiaries with cancer that CMS recognize *DrugPoints* as the successor publication to *USP-DI*. Consequently, as new uses of cancer drugs become medically accepted, we expect that the *DrugPoints* compendium will promptly recognize those uses. It is essential that Medicare coverage extend to new uses as soon as they are medically accepted.

ASCO therefore requests that CMS immediately issue instructions to its Medicare contractors, state Medicaid agencies, and Medicare Part D plans that (1) recognize *DrugPoints* as the successor publication to *USP-DI* with the same authoritative status as *USP-DI*, and (2) require coverage of all FDA-approved and off-label uses listed in *DrugPoints* under the respective programs involved. We believe that such instruction will be critical in alleviating confusion and ensuring that cancer patients have access to medically appropriate therapies.

Thank you for your consideration of this request. Please have your staff contact me if they have any questions.

Sincerely,

A handwritten signature in black ink that reads "Joseph S. Bailes". The signature is written in a cursive, slightly slanted style.

Joseph S. Bailes, MD  
Chair, ASCO Government Relations Council