

March 4, 2011

Member Organizations

*American Childhood
Cancer Organization*

*American Association
for Cancer Research*

*American Cancer Society
Cancer Action Network*

*American College
of Radiation*

*American Society for
Therapeutic Radiology
and Oncology*

*American Society of
Clinical Oncology*

*American Society
of Hematology*

*Association of American
Cancer Institutes*

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Oncology Nursing Society

*Pancreatic Cancer Action Network
PanCAN*

Prostate Cancer Foundation

Society of Nuclear Medicine

*The Society of
Gynecologic Oncologists*

*The V Foundation for
Cancer Research*

Ms. Deondra Moseley
Centers for Medicare & Medicaid Services
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C-13-07
Baltimore, Maryland 21244

Submitted Electronically to AdvanceNotice2012@cms.hhs.gov

SUBJECT: Advance Notice of Methodological Changes for Calendar Year (CY) 2012 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2012 Call Letter

Dear Ms. Moseley:

The National Coalition for Cancer Research (NCCR) is pleased to provide the following comments regarding the 2012 Advance Notice and Call Letter that the Centers for Medicare and Medicaid Services (CMS) issued on February 18, 2011.

For patients with cancer and others struggling with life-threatening illnesses, standard therapy may not be beneficial; the best therapies are frequently available only through participation in a clinical trial. The landmark 2000 Executive Memorandum directing the Secretary of Health and Human Services to explicitly authorize Medicare payment for routine patient care costs associated with participation in clinical trials has yielded important clinical data on the safety and efficacy of drugs, devices and procedures in older patient populations.

However, cost sharing requirements have limited the ability for some patients, including Medicare Advantage (MA) beneficiaries, from participating in clinical trials.

Beginning in 2011, Medicare Advantage plans were required to reimburse enrollees for the difference in Medicare fee-for-service cost sharing incurred for clinical trials services that exceed the MA plans' in-network cost sharing for the same category of service. We greatly appreciated that the Agency has addressed this inequity in Medicare coverage policy. However, for the reasons stated below, the current policy continues to place undue administrative and financial hardships on MA enrollees.

Section E -Clinical Trials - of the 2012 call letter states, "In 2012, we will continue the policy of paying on a fee-for-service basis for qualified clinical trial items and services provided to MA plan members that are covered under the relevant National Coverage Determinations on clinical trials."

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As we have discussed with CMS staff, the current scenario places an undue administrative and financial burden on MA enrollees participating in clinical trials. Participants must provide necessary documentation of covered out-of-pocket expenses associated with participation in approved clinical trials. Furthermore, MA enrollees must then endure sometimes lengthy waiting periods for reimbursement of excess out-of-pocket expenses. For these enrollees, this places them in a financial hardship to pay the out-of-pocket expenses at the time when services are provided when they may not have the financial resources to do so. This could have the unintended consequence of some patients electing not to participate in clinical trials.

We therefore recommend that CMS rectify this situation in the final 2012 plan document by requiring Medicare Advantage plans to directly cover all routine costs for clinical trial participants.

We note the 2011 plan document that CMS stated, "*MA participation in, and access to, clinical trial services outweighs the plans' concern for heightened administrative burden.*" Requiring MA plans to cover routine patient costs directly associated with participation in approved clinical trials would help alleviate that burden on MA enrollees. The 2011 plan document also states, "*Clinical trial services are covered under FFS Medicare and MAOs must cover all in-network services – see section 1852(a)(1)(A) of the Social Security Act.*" We do not believe the current policy of forcing MA enrollees to revert to fee-for-service coverage when participating in a clinical trial is warranted.

The tremendous advances in the treatment of cancer have been made largely because therapies have been tested in clinical trials and have been found to be significant improvements over standard therapy. The clinical research process is a lifeline for those with life-threatening illnesses, and the failure of public and private insurers to cover the costs of routine patient care, including cost sharing requirements, not only denies patients of the best care available but also threatens the American clinical trial enterprise as a whole. We also note that numerous studies have documented that costs of treating patients in clinical trials are not substantially different than costs for patients receiving standard care. Furthermore, we believe the MA clinical trial benefit will help enhance clinical trial participation by underserved patient populations, including racial and ethnic minorities, the elderly, and lower-income patients.

For these reasons, we respectfully request that CMS change its current policy, and require MA plans to provide coverage for clinical trials in a manner that such coverage is provided for other Medicare-covered benefits.

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Thank you for your careful consideration of our comments. Should you have questions, or if we may provide you with additional information, please feel free to contact us at any time.

Sincerely,

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American Childhood Cancer Organization
American College of Radiology
American Society of Clinical Oncology
American Society of Hematology
American Society for Radiation Oncology
Association of American Cancer Institutes
Gateway for Cancer Research
Coalition of Cancer Cooperative Groups
CureSearch Childhood Cancer Foundation
Friends of Cancer Research
International Cancer Advocacy Network
International Myeloma Foundation
Kidney Cancer Association
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SNM – Society of Nuclear Medicine
V Foundation for Cancer Research