AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 226
(A-22)

Introduced by: Association for Clinical Oncology

Subject: Coverage for Clinical Trial Ancillary Costs

Referred to: Reference Committee B

Whereas, clinical trials are key to advancing new standards of care that can improve survival and quality of life for people with cancer and other conditions;

Whereas, many patient populations continue to be underrepresented in trials, especially certain racial and ethnic groups, older adults, rural residents, and those with limited incomes;

Whereas, private payers, Medicare, and Medicaid are responsible for covering routine care costs associated with clinical trials, but patients are often left responsible for ancillary costs, such as transportation to a trial site, lodging, meals, and additional childcare;

Whereas, ancillary costs can lead to lower rates of participation for lower-income patients as well as rural patients who might not have trial sites nearby[1];

Whereas, some trial sponsors provide financial support for ancillary costs but others cite concerns about running afoul of federal research participant protections that could subject them to civil monetary penalties;

Whereas, pilot financial assistance programs that provide compensation for ancillary costs have demonstrated promise in improving clinical trial accrual and clinical outcomes[2]; therefore be it

RESOLVED, that our AMA amend Policy H-460.965, Viability of Clinical Research Coverages and Reimbursement, as follows "…(11) legislation and regulatory reform should be supported that establish program integrity/fraud and abuse safe harbors that permit sponsors to cover co-pays/coinsurance/ deductibles, ~~and~~ otherwise not covered clinical care, and non-clinical ancillary costs in the context of nationally approved clinical trials (Modify Current HOD Policy); and be it further

RESOLVED, That our AMA actively advocate for federal and state legislation that would allow coverage of non-clinical ancillary costs by sponsors of clinical trials. (Directive to Take Action)

Fiscal Note: Not yet determined

Received: 05/11/22

[1] Journal of Clinical Oncology. Addressing Financial Barriers to Patient Participation in Clinical Trials: ASCO Policy Statement. Journal of Clinical Oncology website. https://ascopubs.org/doi/pdf/10.1200/JCO.18.01132. Published September 13, 2018. Accessed April 28, 2022.
[2] Nipp RD, Powell E, Finkelstein D, et al: 2014. Alleviating financial burden for cancer patients in clinical trials. J Clin Oncol 32, 2014 (suppl; abstr 10).

RELEVANT AMA POLICY

Viability of Clinical Research Coverages and Reimbursement H-460.965
Our AMA believes that:
(1) legislation and regulatory reform should be pursued to mandate third party payer coverage of patient care costs (including co-pays/co-insurance/deductibles) of nationally approved (e.g., NIH, VA, ADAMHA, FDA), scientifically based research protocols or those scientifically based protocols approved by nationally recognized peer review mechanisms;
(2) third party payers should formally integrate the concept of risk/benefit analysis and the criterion of availability of effective alternative therapies into their decision making processes;
(3) third party payers should be particularly sensitive to the difficulty and complexity of treatment decisions regarding the seriously ill and provide flexible, informed and expeditious case management when indicated;
(4) its efforts to identify and evaluate promising new technologies and potentially obsolete technologies should be enhanced;
(5) its current efforts to identify unproven or fraudulent technologies should be enhanced;
(6) sponsors (e.g., NIH, pharmaceutical firms) of clinical research should finance fully the incremental costs added by research activities (e.g., data collection, investigators' salaries, data analysis) associated with the clinical trial. Investigators should help to identify such incremental costs of research;
(7) supports monitoring present studies and demonstration projects, particularly as they relate to the magnitude (if any) of the differential costs of patient care associated with clinical trials and with general practice;
(8) results of all trials should be communicated as soon as possible to the practicing medical community maintaining the peer reviewed process of publication in recognized medical journals as the preferred means of evaluation and communication of research results;
(9) funding of biomedical research by the federal government should reflect the present opportunities and the proven benefits of such research to the health and economic well being of the American people;
(10) the practicing medical community, the clinical research community, patient advocacy groups and third party payers should continue their ongoing dialogue regarding issues in payment for technologies that benefit seriously ill patients and evaluative efforts that will enhance the effectiveness and efficiency of our nation's health care system; and
(11) legislation and regulatory reform should be supported that establish program integrity/fraud and abuse safe harbors that permit sponsors to cover co-pays/coinsurance/ deductibles and otherwise not covered clinical care in the context of nationally approved clinical trials.
Citation: CSA Rep. F, I-89; Reaffirmed: Joint CMS/CSA Rep., I-92; Reaffirmed: BOT Rep.40, I-93; Reaffirmed: CSA Rep. 13, I-99; Reaffirmation A-00; Reaffirmed: CMS Rep. 4, A-02; Reaffirmed: CMS Rep. 4, A-12; BOT Action in response to referred for decision: Res. 813, I-15; BOT Action in response to referred for decision: Res. 823, I-15; Reaffirmation: I-18