

June 24, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Verma:

The undersigned organizations representing cancer patients, health care professionals, and researchers appreciate the opportunity to comment on the hospital inpatient prospective payment system (IPPS) update for FY 2020. We focus below on improvements in the payments for chimeric antigen receptor (CAR) T-cell therapy and its administration. We offer advice that is aimed at improving patient access to CAR T-cell therapy, a therapy that may represent the best or only treatment option for some patients.

Institutions that are currently administering CAR T-cell therapy identify financial shortfalls from the diagnosis related group payment for administration of CAR T-cell therapy and also the inadequacy of the New Technology Add-on Payment (NTAP) for the CAR T-cell product. As a result of the combination effect of those funding issues, institutions question their ability to sustain their commitment to providing CAR T-cell therapy. A different concern relates to the decision of many institutions to forgo offering CAR T-cell therapy to their patients. The decision of institutions to decline to offer CAR T-cell therapy means that there are fewer options for patients overall and often no option for treatment near their residence. The location of treatment is meaningful in the case of CAR T-cell therapy, as the two CAR T-cell therapies which have been approved by the Food and Drug Administration and others in clinical trials affect patients who are in poor health, experience poor outcomes, and have limited treatment options. In addition, patients benefit from a family and friend support network as they manage the side effects of treatment. Of course, a reversal of the commitment of institutions currently providing CAR T-cell therapy would further exacerbate the access challenges that patients face.

We commend the Centers for Medicare & Medicaid Services (CMS) for its proposal to continue the NTAP for CAR T-cell therapies in FY 2020 and to increase the NTAP from 50% of estimated costs to 65%. We appreciate the movement by CMS to increase the maximum allowable NTAP, but institutions indicate that this still leaves them absorbing a significant portion of the cost of the drug. We understand that a number of providers have signaled that raising the allowable NTAP to 80% of costs would better enable them to continue to provide CAR T-cell therapy.

CMS has declined to modify the current MS-DRG assignment for cases reporting CAR T-cell therapies. The agency cites the increased NTAP as an alternative to DRG reassignment. We urge that CMS immediately begin consideration of an alternative payment model for CAR T-cell therapy, with a goal of implementing such a system as soon as FY 2021. Our organizations have in recent years expressed our support for a steady movement toward alternative payment models as a means of encouraging coordination of care, fostering the management of treatment side effects and late and long-term effects, and incentivizing oncology practice transformation that ensures quality care across an episode of care and prepares for quality survivorship care.

We understand that the DRG-based system is fundamentally an episode of care system. The alternative that we seek may be a revision of the DRG to which CAR T-cell therapy is assigned, although we think that the episode for CAR T-cell therapy may go beyond a typical DRG and therefore require a different scope and structure. Fundamental to this new model should be incentives for proper management of side effects during treatment and management of side effects after administration of therapy and after the inpatient stay. CAR T-cell therapy is innovative as a treatment, and it will likely require an innovative payment approach to protect access and ensure quality care for those receiving the therapy.

We urge CMS to seek the input of patients who have received CAR T-cell therapy, in trials and after approval, regarding the administration of the therapy and management of side effects and for advice about how the treatment experience might be structured and financed.

We appreciate the opportunity to comment on the reimbursement for CAR T-cell therapy and its administration, and we look forward to ongoing discussion with CMS regarding innovative ways to pay for this groundbreaking therapy.

Sincerely,

Cancer Leadership Council