July 10, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals

Submitted electronically

Dear Administrator Verma,

Biocom appreciates the opportunity to offer comments on the Centers for Medicare and Medicaid Services (CMS) proposed rule **Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals** ("the Proposed Rule")[1].

Biocom is the largest, most experienced leader and advocate for California's life science sector, which includes biotechnology, pharmaceutical, medical device, genomics and diagnostics companies of all sizes, as well as research universities and institutes, clinical research organizations, investors and service providers. With more than 1,300 members dedicated to improving health and quality of life, Biocom drives public policy initiatives to positively influence the state's life science community in the research, development, and delivery of innovative products. California's life sciences industry generates $372 billion in annual economic output, boosts the state's total gross product by $212 billion, supports over 1.4 million jobs, and increases labor income by more than $115 billion per year[2].

[1] 85 Fed. Reg. 32460 (May 29, 2020).
[2] Biocom 2020 Economic Impact Report Databook. https://www.biocom.org/eir/

Biocom thanks CMS for its continued efforts to identify more appropriate ways to reimburse transformative technologies, including Chimeric Antigen Receptor T-cell (CAR-T) therapies. Our members are at the forefront of this therapy, researching multiple cancer treatments, with therapies currently approved to treat patients with certain types of lymphoma and leukemia. We share CMS's goal of ensuring patients have access to CAR-T and other innovative therapies through modernizing payment models that will adequately reimburse hospitals for the cost of care.

Biocom commends the Agency on its proposal to create a new MS-DRG for cases involving CAR-T therapies. We urge the Agency to finalize the proposal as written and ensure that new CAR-T therapies map to MS-DRG 018 immediately upon the Food and Drug Administration (FDA) approval to ensure appropriate patient access at launch. This CAR-T MS-DRG will reduce barriers caused by the antiquated payment systems that have not kept pace with emerging technologies and give patients access to critical, life-saving new therapies.

We offer our comments below:

Proposal to Create New MS-DRG 018 for Chimeric Antigen Receptor T-cell (CAR-T) Therapies

Biocom strongly supports CMS's proposal to create a new MS-DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy), moving CAR-T cases out of their current MS-DRG 016. This proposal would increase the degree of payment predictability for CAR-T inpatient therapy and improve access for patients.

CAR-T therapies represent a major paradigm shift in the approach to cancer treatment. For decades, the standard cancer treatment encompassed a triad of surgery, chemotherapy, and radiation. Over the past years, CAR-T therapy has emerged as a potentially curative option for cancer patients. There has been significant progress in this space with the landmark approvals of Kymriah® and Yescarta® in 2017, but the inadequate reimbursement of these treatments is proving to be prohibitive for hospitals treating these critically ill patients. CAR-T therapies are not easily compatible with traditional CMS payment models, which causes barriers to patient access.

Currently, CAR-T therapy is designated under MS-DRG 016: Autologous Bone Marrow Transplant with Complications or Major Complications (CC/MCC) or T-Cell Immunotherapy. In addition to the hospital-specific DRG payment, a hospital may also be eligible for a new technology add-on payment (NTAP) for the CAR-T therapy along with an additional outlier case payment based on reported charges. The American Action Forum reports the average CAR-T case payment under the IPPS in FY 2020 is about $353,000, which includes the NTAP, outlier payments, and all hospital-specific adjustments[3]. This is below the total cost of care which includes the average acquisition cost for CAR-T of $373,000 in addition to the cost of the hospitalization and other ancillary treatment. We estimate the average total Medicare payment fails to cover the full price of treatment and administration by about $50,000 and can be significantly higher in some cases. This level of reimbursement is insufficient for hospitals, leading to financial losses for each treatment and importantly, reducing access for patients to this therapy.

[3] Strohman, A. (2020, April 08). A Path Forward for CAR-T Therapy Reimbursement Under the IPPS. https://www.americanactionforum.org/research/a-path-forward-for-car-t-therapy-reimbursement-under-the-ipps/

Biocom has long advocated for the creation of a CAR-T specific MS-DRG as the NTAP for CAR-T expires in September 2020 and cannot be extended because it has been three years since the Food and Drug Administration (FDA) approved the CAR-T therapies. Without the NTAP or a new MS-DRG 18, hospitals would face drastic reductions in reimbursements for these cases.

We also support the Agency's proposed methodology for calculating the relative weight for the new MS-DRG 018. Removing both clinical trial cases identified using the Z00.6 code as well as any standardized drug charges lower than the cost of the current two CAR-T products for diffuse large b-cell lymphoma of $373,000 will ensure that the base payment for the new MS-DRG 018 accurately captures the true cost of treating CAR-T patients.

We believe establishing a new MS-DRG is a step in the right direction toward reducing the burden on hospitals and expanding patient access to life-saving therapies. We applaud and thank the Agency for proposing changes that ensure adequate payment for CAR-T therapies. As more novel CAR-T therapies reach the market in the near future, we hope that newly FDA-approved CAR-T therapies are immediately assigned to the new MS-DRG 018. We also encourage CMS to further consider if the current reimbursement levels are sufficient to promote access and consider taking steps to better align the cost of care to reimbursement in the future, as appropriate.

Biocom is dedicated to improving patient access to innovative therapies and thank you again for the opportunity to provide these comments. We look forward to a continued dialogue with CMS. If you have any questions about these comments, please contact Brittany Blocker, Manager of Regulatory Affairs at bblocker@biocom.org.

Sincerely,

Joe Panetta
President and CEO
Biocom