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BY ELECTRONIC DELIVERY

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS–1694–P
7500 Security Boulevard
P.O. Box 8011, Baltimore, MD 21244–1850
Mail Stop C4–26–05

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 2020

Dear Administrator Verma:

Celgene Corporation (Celgene) appreciates this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) fiscal year (FY) 2020 Hospital Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital (LTCH) Proposed Rule (the "Proposed Rule").[1]

Celgene is a global biopharmaceutical company specializing in the discovery, development, and delivery of therapies designed to treat cancer, and inflammatory and immunological conditions. Celgene strongly believes that medical innovation can lead to better health, longer life, reduced disability, and greater prosperity for patients and our nation.

To this end, Celgene seeks to discover, develop and deliver truly innovative and life-changing drugs and biologics for patients with serious unmet medical needs. Central to achieving this mission is research to develop new medical technologies that benefit those who experience serious and life-threatening diseases. Currently, there are more than 225 Celgene-sponsored clinical trials underway, examining at least 47 unique compounds for more than 60 indications. This deep research and development pipeline drives Celgene's ability to develop cutting-edge and life-changing treatments that are both safe and effective.

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1 84 Fed. Reg. 19,158 (May 3, 2019).

As committed as Celgene is to clinical progress, we are equally committed to our guiding principles of patient access and support. Celgene focuses on putting patients first with programs that provide information, support, and access to our innovative therapies. We believe that all who can benefit from our therapies should have the opportunity to do so and have developed patient support programs that have provided education and support to more than 360,000 patients to date.

Celgene supports Medicare reimbursement policies that promote beneficiary access to new and effective medical treatments and ensure that Medicare patients benefit from the innovation that defines the U.S. healthcare system.

With respect to the Proposed Rule, Celgene greatly appreciates CMS' willingness to engage with stakeholders over the past two years to discuss the unique challenges facing hospitals with regard to the delivery of chimeric antigen receptor (CAR) T cell therapy. As was the case during the FY 2019 rulemaking cycle, we believe that some of the policies discussed in the Proposed Rule have significant merit to address the short-term access challenges facing Medicare beneficiaries who could benefit from CAR T cell therapy.

We believe it is imperative that CMS finalize a short-term solution for FY 2020 that will provide reimbursement stability and ensure that patients can access this transformative therapy across a range of capable and certified institutions. We feel strongly that reimbursement incentives should not drive where patients access CAR T cell therapy, creating a divide between Medicare and commercially insured patients, or between those living near a small number of major medical centers and those who do not.

With this in mind, Celgene urges CMS to consider the following approaches to inpatient reimbursement for CAR T cell therapy:

- Celgene urges CMS to finalize a comprehensive solution to reimbursement for CAR T cell therapies that would utilize drug acquisition costs in the calculation of new technology add-on payment (NTAP) and outlier payments. We believe this is the most straightforward way to effectuate the goal of a cost-to-charge ratio (CCR) of 1.0, which CMS sought comment on in the proposed rule. This policy would achieve CMS' multi-faceted objectives of program transparency, enhanced patient access, and data collection for sustainable long-term payment.

- At a minimum, Celgene urges CMS to finalize a uniform maximum NTAP amount for all CAR T discharges for FY 2020.

- Celgene agrees with CMS' assessment that there do not appear to be enough claims data on which to build a new MS-DRG specific to CAR T cell therapy in FY 2020.[2] We also urge CMS to finalize short-term policy solutions for FY 2020 that will enable more accurate data collection, including the collection of drug acquisition cost

[2] *Id*. at 19,181.

information, for the construction of a new MS-DRG for CAR T cell therapy in the future.

- Our detailed comments on each of the below issues follow.

I. CAR T Cell Therapies Have Transformative Treatment Potential

Throughout its history as a biopharmaceutical company, Celgene has been committed to discovering and developing treatments in disease areas of unmet medical need. Notably, Celgene has played a central role in the significant improvement in patient outcomes for patients with serious and life-threatening hematological malignancies. We believe that genetic modification of T cells with CARs represents a potential new era for the effective treatment of such malignancies.

Celgene is at the vanguard of CAR T cell innovation. We currently are developing two CAR T cell therapies in pivotal clinical trials that we believe have the potential to significantly transform patient outcomes in the treatment of certain blood-based cancers that are under-served by existing treatment modalities:

- **bb2121**. Part of a collaboration between Celgene and bluebird bio, bb2121 is a B-cell maturation antigen (BCMA)-directed CAR T cell therapy currently in clinical trials for multiple myeloma. Multiple myeloma is a rare plasma cell cancer, which is diagnosed in approximately 30,000 new Americans each year. With an average age onset of 69 years, multiple myeloma disproportionately impacts the Medicare population. Despite significant advances in five-year survival rates in the past two decades, this blood cancer has remained a persistent challenge to treat using traditional techniques because of its cyclical and progressive nature, as well as its ability to mutate and adapt over time. Multiple myeloma has remained an incurable disease and heavily pretreated patients traditionally have had limited therapeutic

options. Based on early clinical trial data, bb2121 has been shown to have the potential to induce durable responses in these heavily pre-treated multiple myeloma patient populations and has been granted Breakthrough Therapy designation by the Food and Drug Administration (FDA).

- **JCAR017**. A CD19-directed CAR T cell therapy, JCAR017 is in clinical trials for B-cell Non-Hodgkin Lymphoma (NHL) and Chronic Lymphocytic Leukemia (CLL). NHL is the most commonly diagnosed blood cancer in the United States and claims the lives of approximately 20,000 Americans each year. Well over half a million Americans currently live with NHL, and approximately 66,000 new cases are diagnosed in any given year. The risk of developing NHL increases over time, and more than half of all NHL patients are ages 65 or older. NHL also has traditionally been characterized by a number of difficult-to-treat subsets, including diffuse large B cell lymphoma. JCAR017 will be used in a subset of these B cell lymphoma patients who have relapsed or are refractory to prior treatment.

  CLL is the most common type of leukemia in adults, with approximately 21,000 new cases diagnosed each year. Approximately 90% of CLL patients diagnosed are over the age of 50, and diagnoses of patients younger than 40 are quite rare. CLL represents approximately one quarter of new leukemia diagnoses and results in approximately 4,000 American deaths each year.

  JCAR017 also is an advancement with respect to CAR T cell technology. Using a differentiated manufacturing approach, JCAR017 is composed of separately formulated modified cytotoxic (or "killer") T cells and modified helper T cells in a defined composition. Although the clinical impact of this manufacturing approach is not yet known, the goal of this approach is to develop a differentiated CAR T therapy for patients with relapsed/refractory DLBCL with a unique safety and efficacy profile. JCAR017 has been granted Breakthrough Therapy designation by the FDA for the DLBCL indication.

II. Medicare's Reimbursement Approach Should Recognize the Unique Nature and Transformative Potential of CAR T Cell Therapy

Celgene recognizes that developing an appropriate Medicare reimbursement policy for novel and innovative breakthrough therapies such as CAR T cells can be complex. We offer the following patient-centric, innovation-supporting guiding principles for CAR T cell therapy access and reimbursement. These principles inform our perspective on the appropriate CAR T cell reimbursement mechanisms and our evaluation of the specific alternatives that CMS has presented in its Proposed Rule. We believe these principles will be helpful to CMS' evaluation of possible reimbursement options for CAR T cell therapies.

First, Medicare's policy should continue to support ongoing innovation that leads to transformative new technologies such as CAR T cell therapy. The development of

transformational medical advances, especially new cutting-edge technologies such as CAR T, is resource- and time-intensive. The emergence of CAR T cell therapies is the realization of decades of research, development, and investment and countless hours of work by physicians, scientists, and researchers.

Celgene believes that the Medicare program has an important role to play in ensuring that America's seniors have access to such innovations. Transformational innovation has long been a distinctive and defining feature of the American healthcare system; appropriate reimbursement is critical to sustaining this progress in developing new medical advances. Medicare reimbursement policy should account for the intensive long-term research and development required to create new technological advancements that empower patients and save lives.

Second, Medicare's reimbursement policy should accurately reflect the value-based benefit generated for patients by new CAR T cell therapies. CAR T cell technology is still in an early stage. However, even at this early stage, it is clear that CAR T cells have the potential to dramatically improve patient outcomes with a single administration treatment. The first two marketed CAR T cell products, Yescarta® and Kymriah®, both have shown promising benefits for specific patient populations that have failed prior lines of treatment. What makes CAR T cell therapy so exciting is that in many cases, patients have seen durable remissions as a result of CAR T cell therapy in stages of diseases where a durable remission has historically been very difficult to achieve.

Medicare's reimbursement policy should reflect and account for the unprecedented clinical value that new CAR T cell therapies offer to patients. As CAR T cell science evolves, innovative new CAR T cells will be developed to treat different types of cancers that will target other new and specific patient populations. Medicare's reimbursement policy should acknowledge the benefit generated for distinct patient populations with each new CAR T cell breakthrough. Celgene believes that adopting an approach that acknowledges the unique clinical benefits that CAR T delivers is important to ensuring adequate access to innovative CAR T cell techniques for the full range of Medicare beneficiaries who need such life-saving treatments.

Third, Medicare's policy should appropriately acknowledge clinical and technological differentiation between CAR T cell products. Celgene believes that beneficiaries and their trusted health care providers should determine whether CAR T cell therapy is an appropriate treatment and, if so, which specific therapy is the best choice for the individual beneficiary. Medicare's reimbursement policy, therefore, should be structured in a way that does not function as a barrier to a beneficiary and his or her medical providers' selection of the best CAR T cell treatment modality given the beneficiary's specific medical needs and disease type.

CAR T cell therapies are highly specific and differentiated. They are personalized for an individual patient and the CAR T cell technologies are significantly different from one another. Among other things, the CAR design, vector used for genetic transfer, and manufacturing process can all vary substantially between therapies because each CAR T cell

therapy must be tailored to treat a unique combination of clinical indications, safety profiles, and patient populations in order to provide a therapy that is both effective and personalized for each unique patient.

It is critical that Medicare's reimbursement policy for CAR T cells recognizes the significant differences between CAR T cell products, including the specific disease states in which they are used, to ensure adequate beneficiary access and choice. It would not, for example, be appropriate to assume that two CAR T cell therapies targeting entirely different receptors, cancers, or patient populations (and relying on entirely different manufacturing processes) should be treated identically for reimbursement purposes. If all CAR T cell products were reimbursed in exactly the same way, this would distort reimbursement in a way that would significantly slow the adoption of—and beneficiary access to—certain CAR T cell therapies, even when such CAR Ts are the most appropriate clinically indicated treatments for the beneficiary given his or her individual medical needs and disease state.

Fourth, Medicare's policy should enable access to CAR T cell therapy across all appropriate settings of care. Although these comments are specific to the IPPS Proposed Rule, Celgene believes that patients are likely to receive CAR T cell therapy in a variety of clinical settings. The medically appropriate selection of administration as an inpatient or outpatient, in a transplant or non-transplant center, will depend on the treating provider's informed judgment as to a particular patient's individualized clinical circumstances and the safety-related labeling provisions for the relevant CAR T cell product, which may vary based on the safety profile as established in clinical studies.

Celgene believes that Medicare's reimbursement framework should not limit a provider's ability to deliver CAR T cells in the setting that is safest and most appropriate for each patient. Celgene strongly believes that the informed medical judgment of the provider and the patient's individual medical needs should determine the appropriate site of care and that Medicare reimbursement should support provider decision-making regardless of setting, rather than make that decision for the patient and the provider.

Lastly, Medicare's reimbursement policy should appropriately value the requirements that may be placed on providers by the proposed Coverage with Evidence Development (CED) decision. CMS' proposed decision memo (PDM) regarding coverage for CAR T cell therapy represents an important step forward for national coverage of CAR T cell therapy.[3] However, the CED framework also would represent a burden on healthcare providers with regards to evidence collection, administration of Patient Reported Outcomes (PRO) tools and ongoing patient follow-up and tracking. In order to minimize disruptions in patient access and also appropriately expand treatment sites, CMS' reimbursement policy will need to appropriately recognize the infrastructure and resources required at the provider sites to comply with any CED requirements that are finalized. If

[3] CMS, Proposed Decision Memo for Chimeric Antigen Receptor (CAR) T-cell Therapy for Cancers (CAG-00451N), https://www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=291 (Feb. 5, 2019).

reimbursement continues to be insufficient in FY 2020, it will be very difficult for CMS to collect the robust registry data required by the Coverage with Evidence Development Proposed Decision given the limited number of sites actively treating Medicare beneficiaries.

III. FY 2020 Payment Solutions to Enable Greater Access to CAR T Cell Therapy

Celgene appreciates CMS' interest in moving toward an appropriately paying MS-DRG for CAR T cell therapy cases, which we believe to be an appropriate solution given the uniqueness of delivering CAR T in the inpatient setting.[4] However, we want to emphasize that it is essential for CMS to finalize one or more of the policy proposals considered for the 2020 fiscal year to both enable greater patient access and to create the infrastructure and data collection necessary to build an appropriately paying MS-DRG in the future. Without action to finalize one or more of these proposals, patient access to CAR T cell therapy will continue to be limited to certain institutions and as a result, only those patients with both the physical capability and financial means to reach those specific institutions will be able to access this innovative therapy.

Celgene has reviewed the available inpatient CAR T cell therapy claims for FY 2018 as well as the first quarter of fiscal year 2019, the first quarter that NTAP for CAR T cell therapies were available.[5] We believe these data tell an important story regarding the state of access to the current FDA-approved CAR T cell therapies. For the time period reviewed, only 33 IPPS hospitals had a CAR T cell therapy claim for a non-clinical trial case; that is, a case utilizing one of the already FDA-approved CAR T cell therapies. There are currently approximately 80 institutions in the United States that are certified to deliver CAR T cell therapy. In addition to those 33 institutions, CAR T patients were also treated at 6 PPS-exempt hospitals.

Since CAR T cell therapies came to market in the fourth quarter of 2017, fewer than 40 hospitals in the U.S. treated the entire volume of Medicare beneficiaries who received commercially available CAR T cell therapies, despite the well documented efficacy and safety profiles of these therapies. Nearly half of the total volume of claims during this period have come from 6 PPS-exempt cancer hospitals. While there are many good reasons for the PPS-exempt centers to treat a significant share of cancer patients with a new technology, including their role on the cutting edge of cancer treatment, we believe the holistic picture of these claims shows a broader pattern of limited access at IPPS institutions due in part to Medicare reimbursement inadequacy.

For IPPS institutions, the median payment for hospitals for CAR T cell therapy cases was $350,000, based upon median total charges of $1.7 million. This charging pattern is consistent with what we know to be true for CAR T cell therapy cases – that drug charges must be significantly marked up in order to receive appropriate reimbursement when rates

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4 84 Fed. Reg. at 19,180-82.

5 Analysis by the Moran Company of FY 2018 and Q1 2019 Standard Analytic File data, June 2019.

are calculated using a hospital's operating CCR. This has resulted in an unequal playing field among institutions in which those willing to significantly mark-up charges for CAR T cell therapies are treating Medicare beneficiaries and those not engaged in significant markups are not treating Medicare beneficiaries. In fact, 8 IPPS hospitals treated Medicare beneficiaries in a clinical trial setting but did not treat a single Medicare patient with an FDA-approved CAR T cell therapy during the time period examined in the claims.

The data show only 32 discharges for non-clinical trial cases at IPPS institutions in the fourth quarter of calendar year 2018, the first quarter in which NTAP was available. This makes the urgency for CMS to act greater than ever before to address the current drivers of inadequate reimbursement and the associated limitations in patient access. These numbers highlight that despite the potential for CAR T cell therapy in these unique subsets of very sick patients, many Medicare beneficiaries who could benefit from CAR T cell therapy do not have the opportunity to access this innovation.

A. Celgene Recommendations: Principles for FY 2020 Solutions

Celgene believes that solving the Medicare CAR T access problem in the short term will require CMS to directly address the challenges hospitals face regarding the need to significantly mark up costs in their hospital charges in order to achieve appropriate outlier and NTAP payments. Given the unique nature of CAR T cell therapy and the significant amount of the total case cost comprised by the cost of the therapy, it appears many institutions are reluctant to use their operating CCR according to standard practice, which in many cases would result in marked up costs of more than 300%.

Celgene asks that CMS prioritize the following principles when considering which policy proposals to finalize for FY 2020:

- Policy solutions should eliminate the need for hospitals to significantly mark up the costs associated with acquiring the CAR T cell therapy.
- Policy solutions that CMS pursues for FY 2020 should also create the infrastructure to move toward an appropriately valued CAR T MS-DRG in future fiscal years, including the generation of accurate data required for future rate setting.
- Policy solutions should seek to meaningfully improve patient access to CAR T cell therapy through appropriate expansion of the number of certified sites that actively treat Medicare beneficiaries.

Below, we discuss the policy solutions that CMS sought comment on in the FY 2020 proposed rule and the degree to which they meet the principles outlined above.

B. Utilize Actual Drug Acquisition Costs in Calculating NTAP and Outlier Payment

Based upon our review of the FY 2018 claims data, Celgene believes there are three primary drivers of inadequate payment for IPPS institutions that seek to deliver CAR T cell therapy

to Medicare beneficiaries:

- First, the fundamental insufficiency of the current base payment in MS-DRG 016, which is dominated by transplant cases and does not reflect the costs associated with CAR T cell therapy cases.

- Second, the overreliance on NTAP and outlier payments to recoup treatment-associated costs for CAR T cell therapy discharges, which is a reflection of the insufficiency of the base MS-DRG payment.

- Third, the need to mark up the cost of the therapy between three and five times actual acquisition costs to achieve NTAP and outlier payments that reflect a hospital's true costs, which is an artifact of a reimbursement method that did not envision transformative therapies delivered in an inpatient system that would represent a significant percentage of total case costs.

We believe this third and final issue is driving a large portion of the limitation on access for Medicare beneficiaries seeking CAR T cell therapy. Celgene understands that reducing charges to costs based on an individual hospital's operating CCR is a longstanding component of the structure of Medicare Part A reimbursement. However, as CMS has recognized by seeking comment on a proposal to apply a CCR of 1.0 to the cost of the CAR T cell therapy, applying a hospital's individual operating CCR to all charges, including the pharmacy charges associated with the CAR T cell therapy, will not produce sufficient payment for IPPS institutions if they set charges at or close to the cost of the therapy.[6] In order to address this specific challenge, CMS should consider alterations to the payment formulas that would allow hospitals to utilize actual drug acquisition costs in the Medicare payment formulas. This is in the best interest of patients, because it levels the playing field across IPPS institutions, and it also helps meet the Administration's goal of greater transparency in hospital pricing and billing.

Celgene recommends that CMS apply a comprehensive approach to setting more appropriate payment for cases using CAR T cell therapy, including both the calculation of the NTAP and outlier payments. We recommend that CMS maintain current reimbursement formulas for all of the non-CAR T cell therapy-associated charges, including applying a hospital's operating CCR to the patient care related charges, which will allow CMS to accurately isolate the charges associated with patient care from the costs associated with acquisition of the drug. Celgene supports the goal behind CMS' idea of using a CCR of 1.0 for charges for CAR T cell therapies– to calculate a more accurate estimate of the cost of those therapies – but we also recognize that variations in hospitals' charging practices could frustrate achievement of that goal. We recommend that instead of estimating acquisition cost, CMS should use the actual acquisition cost, as reported using the new value code 86, as the basis for calculating NTAP and outlier payments. CMS also should require hospitals to use this new value code on all claims for CAR T cell therapy. Alternatively, CMS could use a CCR of 1.0 to pull the hospitals' full charge for the drug into the NTAP and outlier calculation, while encouraging hospitals to set their charges at cost.

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6 84 Fed. Reg. at 19,182.

Under these approaches, CMS would calculate outlier payments by subtracting the drug charges in revenue code 0891 from the total charges on the claim to identify the charges associated with items and services other than the CAR T cell therapy itself. CMS would apply the hospital operating CCR to those charges to estimate costs associated only with the *other costs* of delivering the CAR T cell therapy.

CMS would then add the CAR T cell therapy acquisition cost, as identified with the new value code 86, to the rest of the claim cost. CMS would compare the sum of the CAR T cost and other costs to the outlier threshold (fixed loss threshold plus federal payment with Disproportionate Share Hospital (DSH), Indirect Medical Education (IME), and uncompensated care payments plus NTAP) to calculate outlier payments. The outlier payment would be 80 percent of the difference between the two amounts.

Celgene supports utilizing a maximum uniform amount for the NTAP amount that would be used in the calculation of the formula outlined above. The uniform maximum NTAP would provide hospitals with significantly greater predictability than the current NTAP formula and eliminate any need to mark up drug costs as a matter of practice. This predictability will be an essential component of solving the CAR T cell therapy access challenge.

This approach is a logical way to eliminate the need to mark up costs solely for the purposes of achieving adequate NTAP and outlier payments while allowing CMS to isolate the CAR T cell therapy charges from other services provided to CAR T cell patients.

C. The Uniform Maximum NTAP Amount

Celgene appreciates CMS' proposal for a uniform maximum NTAP.[7] This proposal moves meaningfully toward reducing incentives for IPPS hospitals to engage in significant mark ups to recoup their costs by neutralizing the "lesser of" provision in the current NTAP formula.

The use of the uniform maximum could also be an important foundational step for proper rate setting for a new MS-DRG in future years, if structured utilizing the new value code 86. If the uniform maximum amount were to be based on acquisition cost reported in value code 86, this policy would encourage hospitals to report their costs in FY 2020, providing more precise cost data for use in future rate-setting. It also would provide CMS with more accurate data on the costs of CAR T cell therapies over time, rather than estimating costs from charges.

While we do not believe that the uniform maximum NTAP proposal in and of itself can solve the challenges facing providers who want to deliver CAR T cell therapy to Medicare beneficiaries, it is a meaningful improvement in reimbursement methodology.

D. Increase from 50% to 65% NTAP Proposal

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7 *Id*. at 19,279.

Celgene appreciates that CMS acknowledges that 50% may no longer be an appropriate payment percentage to provide for NTAP.[8] However, without additional changes to the payment formulas, an increase from 50% to 65% will have little practical impact for institutions that do not engage in significant markups on the cost of their CAR T cell therapy.

This change in payment rate should be combined with the other changes we recommend above. As noted in our earlier comments, we believe that leveling the playing field amongst institutions through other policies such as use of acquisition cost data and the uniform maximum NTAP amount will enable better access to CAR T cell therapy than exists today.

IV. Creation of Long-Term Sustainable Payment that Supports Patient Access to CAR T Cell Therapy

Celgene continues to believe that a new MS-DRG is the right long-term solution that will create reliable and predictable payment solution for institutions to be able to consistently deliver access to CAR T cell therapy for Medicare beneficiaries. Among other things, a new MS-DRG establishes a *sustainable* reimbursement structure to ensure beneficiary access over the long term. If designed appropriately, a new MS-DRG ensures that the base payment rate for CAR T cell therapy would be appropriate.

As CMS considers the timing and structure of such an MS-DRG, it is likely that a novel approach to rate setting will be necessary in the future to address the uniqueness of CAR T cell therapy delivery in the inpatient setting. Celgene believes that CMS should consider novel policy options when structuring a CAR T cell specific MS-DRG, as innovative solutions will play an important role to ensure that that CMS payment policy does not hinder long-term access to these life-changing new technologies.

We have identified several concerns with CMS' standard rate setting methodology that support the need for an alternative approach for cases using CAR T cell therapies. First, use of overall operating CCR would drastically underestimate the cost of CAR T cell therapy if hospitals do not apply the same markup as for other drugs. As discussed above, this approach creates an unequal playing field between hospitals that are willing to apply those markups and those that are not, with the hospitals that want to set charges at or near acquisition cost severely disadvantaged.

Second, there are a small number of cases using CAR T cell therapies in the claims data, and many of those cases involve clinical trials and do not include the cost of the CAR T cell therapy. This leaves a small number of claims to use for rate setting. CMS is well aware that small sample size and variations in charging practices produce instability in rates.

Third, as a CAR T DRG evolves over time, it will encompass different disease areas and patient populations with unique needs and treatment costs, given the heterogeneity in both disease burden and CAR T cell therapy associated costs.

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8 *Id*. at 19,165.

V. Proactive Suggestions to Consider for Rate Setting a Future CAR T Cell Therapy MS-DRG

We offer the following suggestions to help CMS establish a new MS-DRG for cases using CAR T cell therapy in the future. First, CMS should use acquisition cost data to determine the cost of the drug. To ensure that CMS receives acquisition cost data, we recommend that CMS require hospitals to use the new value code 86 to report acquisition cost, and that CMS use a CCR of 1.0 for revenue code 0891 to encourage hospitals to set charges for CAR T cell therapies at acquisition cost. This combination of measures would reassure hospitals that they do not need to mark up their charges to achieve appropriate reimbursement, while also providing CMS with timely and more accurate data on acquisition cost of these therapies in the short term and in the long term. CMS could use the reported acquisition cost data until it confirms that hospitals' charges are set at or near cost. Second, CMS should take clinical trial cases out of the calculation of relative weight for the new MS-DRG. These cases will not have a charge for the CAR T cell therapy, and as a result, will have significantly lower overall charges and costs.

Lastly, CMS should account for the fact that, as CAR T cell technology develops, and new CAR T cell products are approved by the FDA, a CAR T cell specific MS-DRG approach will need to account for therapies targeting different disease states and patient populations. As the diversity of CAR T cell therapy increases with time, there are likely to be differences in the costs of providing different classes of CAR T cells. We encourage CMS to be proactive in evaluating how these distinctions will affect adequacy of reimbursement for different CAR T cells and to structure any CAR T cell specific MS-DRG (or related adjustments) in a manner that recognizes and accounts for material distinctions in the costs of different CAR T cells based on the disease state and patient population they target.

Conclusion

Celgene appreciates the opportunity to comment on the FY 2020 IPPS Proposed Rule. We are excited about the potential for CAR T cell therapy to dramatically improve outcomes for patients who, in many cases, have exhausted all of their other treatment options. That is why it is so important that the policies finalized during the FY 2020 rulemaking cycle take a meaningful step toward leveling the playing field for hospitals capable of delivering CAR T cell therapy, create greater transparency and predictability for these institutions, and ultimately provide greater access to CAR T cell therapy for patients who need to receive this treatment. With these policy improvements, we will make important strides toward realizing the promise of CAR T cell therapy for patients across the United States.

Sincerely,

Richard H. Bagger
Executive Vice President
Corporate Affairs and Market Access