ASTCT
American Society for
Transplantation and Cellular Therapy

October 5th, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1734-P
P.O. Box 8016
Baltimore, MD 21244–1850

SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV

Re: Medicare Program: CY 2021 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; etc.

Dear Administrator Verma:

The American Society for Transplantation and Cellular Therapy (ASTCT) is pleased to offer the following comment letter on issues related to coding and payment policies under the Medicare Physician Fee Schedule (MPFS).

The ASTCT is a professional membership association of more than 2,200 physicians, scientists and other health care professionals promoting blood and marrow transplantation and cellular therapy through research, education, scholarly publication and clinical standards. The clinical teams in our society have been instrumental in developing and implementing clinical care standards and advancing cellular therapy science, including participation in trials that led to current FDA approvals for Chimeric Antigen Receptor T-cell (CAR-T) therapy.

Evaluation & Management Component

The ASTCT supports CMS' adoption of the American Medical Association's (AMA's) CPT documentation and coding changes for reporting office and outpatient Evaluation and Management (E/M) visits that go into effect on January 1, 2021. This will facilitate simplification of documentation requirements and reduction of the administrative burdens our physicians and other eligible providers face. It will, most importantly, enable them to spend more time with patients and less time on paperwork. Specifically, the ASTCT agrees with CMS' proposal to eliminate the history and physical exam component to select code levels, and instead allow clinicians to select either time or medical-decision-making.

CMS' movement to the new guidelines is a step in the right direction however we encourage the agency to take additional steps as soon as possible to complete the elimination of the 1995/1997 guidelines. This is critical to our clinicians since most of them see patients in both the outpatient and inpatient settings, which means that they will face the unnecessary administrative burden of

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keeping track of both the new guidelines (when treating patients in their office or outpatient setting) and also the 1995/1997 guidelines when treating inpatients, emergency department (ED) patients, and patients receiving observation services. We urge CMS to migrate fully AMA's CPT documentation guidelines for all E/M services, regardless of care setting, as this will fundamentally reduce administrative burden while allowing uniformity in reporting by all providers.

Therefore, the ASTCT recommends CMS eliminate use of the 1995/1997 guidelines as soon as possible, ideally no later than January 1, 2022.

Additionally, the ASTCT supports both the AMA's decision to eliminate the New Patient Visit Level 1 CPT code, 99201. We also support CMS' proposal to adopt the new add-on CPT code associated with the fifth-level office/outpatient E/M visit for use when the time associated with delivering care exceeds the duration described in the code definition. CMS' proposal will appropriately recognize that certain patients, such as our immunocompromised patients, often require more time with their physicians; being able to reflect this and receive additional reimbursement is appropriate.

HCPCS Code GPC1X

The ASTCT agrees with CMS' proposal to allow providers to use add-on code (GPC1X), as applicable, with every level of office and outpatient E/M visit when those services are rendered for ongoing care related to a patient's single, serious, or complex chronic condition. Patients with blood cancers, such as ours, exemplify the type of complex conditions that depend upon team-based care in order to achieve optimal outcomes. Treating chronic conditions as well as other serious and life-threatening complex conditions necessitates significant expertise for appropriate and ongoing patient management including the delivery of team-based care that is coordinated across a number of practitioners and providers. We appreciate CMS' recognition and continued commitment to both care coordination and the delivery of collaborative care to manage complex procedures and treatments especially for patients such as ours receiving stem cell transplants and other innovative cellular therapies. **We fully support and urge CMS to finalize its proposal to provide separate payment for add-on code GPC1X**.

Financial Impact of Changes to the Resource-Based Work, Practice Expense, and Malpractice Relative Value Units

The ASTCT understands that the decrease to the conversion factor as proposed is due to a combination of factors including the freeze or zero percent inflationary update to the conversion factor required by MACRA, together with a budget neutrality adjustment associated with the revaluation of relative value units (RVUs) for the increasing the value of E/M services. The end result is an almost $4.00 decrease in the conversion factor applicable to all services with varying financial impact across specialties.

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While the Proposed Rule describes that hematology and oncology will receive a 14% increase (on average), the ASTCT cautions that this increase will not be the case for all hematology/oncology practices, since it is simply an average reflective of the mix of both E/M and procedural services. We raise this merely to acknowledge that, while payments are expected to rise significantly for many of our members (particular for intense cognitive efforts and team-based care approaches), we are concerned about colleagues in other specialties who also care for cancer patients. These colleagues provide cancer patients with more procedural services (i.e., surgery, radiation oncology etc.) that face a significant and immediate payment reduction. As such, we are concerned with CMS' approach to implement the payment changes simultaneously—particularly during a year in which physicians have seen large volume reductions due to the COVID-19 public health emergency (PHE).

We appreciate CMS' recognition that the work rendered through the delivery of E/M services must be valued in a manner that accounts for the intellectual activities and cognitive work that our clinicians have been providing for years. Additionally, we applaud CMS' efforts to increasingly recognize the value of "caring for patients," as opposed to. just *treating* patients. Our members pride themselves on this value and see the fundamental difference this makes in patients' lives. However, the large negative financial impacts that CMS' revaluation may cause leaves us concerned. As a result, **the ASTCT recommends that CMS mitigate large payment swings that its revaluation of RVUs is causing, as well as phase-in reductions over the course of at least 3-years..** Another option, given the PHE, is for CMS to waive the budget neutrality requirement for one year or until the end of the calendar year in which the pandemic is declared to be over.

Remote Physiologic Monitoring (RPM) Services

The ASTCT appreciates CMS' thoughtful explanation of RPM services. We agree that these services are furnished remotely using communication technologies that enable interactions between a patient and his/her physician, non-physician practitioner, and clinical staff who provide services. Because the CPT code descriptors do not specify that practitioners must perform RPM services, CMS proposes that auxiliary personnel (which includes non-clinical staff who are employees, leased, or contracted employees) may furnish RPM services.

We note that these auxiliary personnel are often employees of hospitals; the patients are often registered hospital outpatients who are being followed longitudinally through the use of RPM and other care management and E/M services. Therefore, it is important that the payment for these services recognize the outpatient hospital expense under the OPPS as well as the professional component under the MPFS.

The ASTCT also believes it is important for CMS to be able to track the incidence and frequency of these codes. For these reasons, **the ASTCT requests that CMS recognize the actual CPT codes for RPM both under MPFS and under the OPPS.** Finally, the ASTCT agrees that post-PHE, RPM services are best deployed for established patients; we also appreciate the policy that consents can be made at the time at which RPM services are initiated.

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Telehealth

The COVID-19 pandemic has tested us all, but especially our healthcare system. CMS has responded appropriately by creating waivers to ensure the continuation of vital patient care and expand access to telehealth services during the PHE. Expanded telehealth services have protected the health of providers and their patients alike. The shift in delivery of patient care from the in-person model has been positive and appreciated. It has proven to be a safe, efficient, and popular way for patients to communicate with their health care providers. This is particularly true for ASTCT members' patients, who are immunocompromised and at high risk for infection in general, and even more so under the COVID-19. In fact, we suspect that many will resist returning to the pre-PHE status quo, after experiencing the significant benefits of expended telehealth services.

Within the bounds of its statutory authority, CMS has an opportunity to expand the use of this popular treatment modality. It may be possible to seek Congressional amendments to the statutory definition of "Telehealth" so physicians can continue to use this method for delivering care; particularly to patients in their homes. Doing so also would advance CMS' goals of improving patient safety and quality of care, reducing unnecessary admissions, and minimizing costs to the system.

We recognize that the expansion of Telehealth services for professionals differs from continuing to allow a hospital to designate a patient's home as a provider-based department where services can be rendered via Telehealth. Nonetheless, the PHE has made clear to our treating clinicians that they must be able to continue providing telehealth services to patients in their homes, not just in originating sites like hospitals and offices that are also not geographically limited to rural areas. As a result, **we urge CMS to work with Congress to make statutory changes that will facilitate this**. We raise this critical issue in our MPFS comment letter because our understanding is that, if a patient's home no longer qualifies as an originating telehealth site when the PHE ends, then patients would not be able to receive any Category 1 or Category 3 services in their homes (per the MPFS).

For this reason, the ASTCT sincerely requests that CMS address these issues in the Final Rule. We encourage the agency to do whatever is necessary to expand current Telehealth services under existing statutory requirements and also work with Congress to expand the statue so that Telehealth does not continue to exclude patient populations that could otherwise benefit from this technological advancement.

Additionally, below we provide a few specific comments to CMS on services that we believe are appropriate to add to the list of telehealth services completely allowed or those allowed in limited circumstances:

- The ASTCT requests that CMS add discharge planning codes 99238 and 99239 to its list of permanent Telehealth services. We believe that a physician can easily and

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appropriately conduct a discharge E/M inpatient visit using telehealth services. This is particularly clear, given that the clinician would have treated the patient during the inpatient admission, would have access to the patient's medical record, and would be able to communicate with the other qualified hospital and healthcare staff.

- The ASTCT also requests CMS add home visit codes for established patients (CPT codes 99349-99350) to the permanent Telehealth services list. We believe patients who are homebound and meet the criteria for home visits should not first have to see a provider in person in order to receive home care.

- The ASTCT believes that consultative care can be provided via audio-visual tools to patients who are in EDs, the ICU, or are receiving observation services. Of course, this depends on the nature of the needed care and requires patients to be located where other qualified healthcare professionals are on-site. For example, transplant patients or cell therapy patients who receive highly specialized care and have a complication resulting in ED or ICU care will benefit immediately from having clinicians present at the hospital. In addition, they would also benefit from access to other care providers who can assist with and inform the patient's future treatment virtually. This is likely to become increasingly important as advances continue in cell and gene therapy. In these cases, a limited number of hospitals are trained to treat patients, such as a specialist in immune effector cell therapy may be needed immediately to engage with other healthcare providers such as nurses at the bedside who can facilitate an exam, communicate vitals and other critical information that enables the clinician to direct care while in their home or at another hospital. This situation can result in significant clinical benefit that might not otherwise be available if the patient had to wait for an in-person consult from a specialist. As a result, we ask CMS to look at these services as ones that can be suitable for Telehealth in limited circumstances.

Audio-Only CPT Codes

The ASTCT is pleased that CMS established separate payment for audio-only telephone E/M services in CMS-1744-IFC. We also appreciate that the agency recognized the need to increase the value of these services in CMS-5531-IFC.

Audio-only services represent an effective, safe, and efficient way to deliver care to patients, particularly patients a clinician does not need to see (including beneficiaries in our survivorship programs, and/or those who must continue to avoid infection exposure). In these and other situations, clinicians should be allowed to conduct audio-only E/M visits even after the PHE ends. Based on feedback from our members, the ASTCT believes that these visits are likely longer in length compared to existing virtual visit check-ins. Our members have indicated that they can spend anywhere from 25 to 60 minutes on the phone with a patient.

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As a result, **the ASTCT urges CMS to make permanent the option for a clinician and beneficiary to have an audio-only E/M choice**. Making this option available is especially important to the elderly population. We agree that audio *and* video is preferable and should be encouraged; but A/V should not be mandatory, given that some patients may find this challenging and others lack robust Internet access or the bandwidth needed to support audio and visual communication.

Supervision Related Issues

The ASTCC agrees with CMS' proposal to enable physicians and non-physician practitioners (NPPs) to render direct supervision of services, and faculty physicians to supervise residents via interactive telecommunications technology. We also agree with CMS that this flexibility should be made permanent beyond the end of the PHE. We also agree with CMS' proposal that NPPs should be able to provide direct supervision for diagnostic services within their scope of practice.

The ASTCT recommends CMS finalize both proposals for CY 2021 and beyond.

National Coverage Decision Removal

CMS proposes to use its rulemaking process to remove National Coverage Decisions (NCDs), stating: "*We are proposing this change of vehicle because removing an NCD changes a substantive legal standard related to Medicare coverage and payment for items and services.*"

CMS proposes to identify and remove NCDs that no longer contain clinically pertinent and current information; items and services that no longer reflect current medical practice; or that involve items and/or services that beneficiaries use infrequently. If CMS implements this change, coverage determinations for those items and services will be made by Medicare Administrative Contractors (MACs.) CMS notes that:

> *The process of removal does not result in an NCD as that term is defined in sections 1869(f) and 1862(l) because there would be no uniform national decision about whether or not the particular item or service would be covered under Title XVIII of the act. Rather, the initial coverage decision which is normally made for a specific beneficiary who has already received an item or service and has submitted a Medicare claim would be made by local contractors.*

CMS' stated goal for this proposal is to ensure that agency policies are effective, efficient, open, and transparent. The agency seeks to ensure that its policies align with evolutions in clinical science and technology, foster innovation, and reduce burdens faced by stakeholders and CMS. We share CMS' goals and applaud the agency for beginning a dialogue around addressing coverage. The ASTCT is, however, concerned that CMS' proposal will not result in achieving these goals, given the numerous burdens we already face with our MACs such as lengthy appeals

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to support medical necessity and varying coverage for the same condition from one MAC to the next.

CMS states that it will base its determination about removal of an "older NCD" (designated as 10 or more years old) on *any* (not all) of the following circumstances:

- Allowing local contractor discretion to make a coverage decision better serves the needs of the Medicare program and its beneficiaries;
- The technology is generally acknowledged to be obsolete and is no longer marketed;
- The item or service in the NCD is no longer considered experimental (for non-coverage NCD based on an item or service's experimental status);
- The NCD has been superseded by subsequent Medicare policy;
- The national policy does not meet the definition of an ''NCD'' as defined in sections 1862(l) or 1869(f) of the Act; or
- The benefit category determination is no longer consistent with a category in the Act.

Based upon these circumstances, CMS proposes to eliminate the following NCDs:

NCD Manual Citation	Name of NCD
20.5	Extracorporeal Immunoadsorption (ECI) using Protein A Columns (01/01/2001)
30.4	Electrosleep Therapy
100.9	Implantation of Gastroesophageal Reflux Device (06/22/1987)
110.14	Apheresis (Therapeutic Pheresis) (7/30/1992)
110.19	Abarelix for the Treatment of Prostate Cancer (3/15/2005)
190.1	Histocompatability Testing
190.3	Cytogenetic Studies (7/16/1998)
220.2.1	Magnetic Resonance Spectroscopy (09/10/2004)
220.6.16	FDG PET for Inflammation and Infection (03/19/2008)

CMS seeks comments that may identify additional reasons for removing an NCD. CMS is also interested in feedback about whether the time-based threshold of "older" is appropriate, or if a shorter period of time—or a non-time-based criterion—is preferable. The agency is also interested in feedback about the removal process as a whole, and the use of its rule-making process to implement this change.

The ASTCT is pleased to present our feedback for CMS' consideration. In general, we are concerned that CMS acknowledges that its process cannot be used to create a new NCD. Hence, any item or service that was covered prior to elimination of an NCD would no longer be automatically covered which could immediately result in beneficiaries facing inconsistent (and arbitrary) differences in access to care. This is deeply concerning to us for many reasons.

First, a beneficiary who receives care in multiple states would face barriers to uniform access to needed services. Individual MACs may deem some services covered, while other MACs do not.

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This has a significant and negative impact on beneficiary care. In addition, many MACs use an automated approach for considering claims and/or reviewing appeals, which makes it challenging, if not impossible, to appeal a denial and it entails significant administrative resources to pursue appeals to levels beyond the MAC.

Second, the ASTCT does not believe that all of these NCDs meet CMS' criteria for retirement. For example, NCD 190.1 (Histocompatability Testing) is needed to match donors and patients for transplant services and should be protected nationally.

Third, this proposal has the potential to impact access to Hematopoietic Stem Cell Transplantation (HSCT), given the procedure's high costs and older NCD status, as well as the rapidly evolving nature of the transplant field as a whole. We believe that high-cost items or services (like HSCT) may require an active NCD regardless of its age, in order to mitigate the need for beneficiaries to sign a Hospital-Issued notice of Non-Coverage (HINN) or provide a deposit for life-saving care.

Fourth, as part of this change, we note that the proposal may impact Coverage with Evidence Determination (CED) NCDs. Guidance for the Public, Industry and CMS Staff: Coverage with Evidence Development states that:

> *…there are ways to avoid or minimize the gap between the end of clinical studies under a CED NCD and a revised coverage decision based on the results of CED studies. Sponsors should build interim analyses into their study design and communicate these results to CMS. If the results support consideration of a change in the coverage status of the item or service, a revised NCD could be expedited.*

If CMS eliminates a CED NCD, it is not clear what the impact would be on beneficiaries who receive care under a CED, or facilities that provide these services. We note that a CED cycle is considered completed when CMS completes a reconsideration of the CED coverage decision, and removes the requirement for study participation as a condition of coverage.

Fifth, MACs lack the up-to-date medical knowledge to adequately consider what items and services should be covered as the field evolves—like HCST does. It is very likely that MACs will be incapable of keeping pace with the rapidly changing medical environment in which discoveries occur on a daily basis. Expertise in medical science should rest with CMS, as a whole, rather than being farmed out to lower-level entities with varying knowledge bases. In addition, the situation is complicated for the many providers that have more than one MAC. How does CMS envision the process when different MACs issue conflicting decisions about life-saving coverage, particularly in the face of clinical evidence (i.e., lymphoma coverage for allogeneic stem cell transplant on which the NCD is silent is granted by some MACs, but not all)?

Sixth, we note that Medicare Advantage (MA) plans are required to comply with NDCs, but not with Local Coverage Decisions (LCDs). Hence, eliminating NCDs would eliminate the

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guaranteed coverage for beneficiaries in MA plans, which is an increasing number of individuals.

In conclusion, the ASCTC respectfully asks CMS to address the following questions and considerations before proceeding with its proposal to remove existing or additional NCDs that are not non-coverage NCDs:

- Is the 10-year timeframe of "older NCDs" tied to the last effective date or to the NCD's original implementation date?
- How will CMS consider NCDs that are greater than the 10-year timeframe, but have been updated to address clinical changes affecting the services?
- If an NCD covers an item or service for multiple indications, would this process be used to remove non-coverage for specific indications?
- How would CMS address situations when a specific non-coverage portion of the NCD could be considered for removal?
- Would CMS use this process to remove and/or wrap up CEDs as well as NCDs, given that CEDs are part of an NCD?
- How does CMS envision introducing new NCAs?
- What is CMS' role in ensuring that MACs appropriately consider LCD requests and/or auditing coverage decisions?

The ASTCT supports CMS' goals to enhance the effectiveness, efficiency, openness, and transparency of its policies. However, we do not believe this proposal meets those laudable goals. Rather than implementing a complicated process to eliminate NCDs (including CED NCDs), **we recommend that CMS start by eliminating *only* completely outdated non-coverage NCDs with regard to evidence-based medicine, and specific NCDs for which current medical practice suggests a different therapeutic or diagnostic service**. This is not expected to create any unintended consequences and can be done while CMS continues to address specific limitations as we've noted them of its existing proposal which, in our view, relies too heavily upon MAC engagement.

Any NCD that addresses currently used therapeutic and/or diagnostic services must be maintained until safeguards are implemented to ensure that MACs can respond to requests for discussion and additional coverage based on clinical evidence and the scientific literature. Until the MACs are able to support the provider community using processes that are timely, consistent, and nimble, the ASTCT is reluctant to relegate additional coverage decisions to them.

The ASTCT wishes to express its appreciation for the opportunity to provide these comments on the CY2021 Physician Fee Schedule and Other Changes to Part B Payment Policies Proposed Rule. The ASTCT welcomes the opportunity to discuss these recommendations in more detail or to answer any questions you may have. Please contact Alycia Maloney, ASTCT Director of Government Relations, at amaloney@astct.org for any follow up issues.

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Sincerely,

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