ASTCT
American Society for
Transplantation and Cellular Therapy

This document contains submitted ASTCT comments and CMS responses from the CMS MPFS Final Rule, dated November 2, 2023.

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

September 11, 2023

SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV

RE: CMS–1784–P Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies

Dear Administrator Brooks-LaSure:

The American Society for Transplantation and Cellular Therapy (ASTCT) is pleased to submit the following comments letter regarding the CY 2024 Medicare Physician Fee Schedule (MPFS) Proposed Rule.

The ASTCT is a professional membership association of more than 3,700 physicians, scientists, and other health care professionals promoting blood and marrow transplantation and cellular therapy through research, education, scholarly publication, and clinical standards. Our Society's clinical teams have been instrumental in developing and implementing clinical care standards and advancing cellular therapy science, including participation in trials that led to current Food and Drug Administration (FDA) approvals for chimeric antigen receptor T-cell (CAR-T) therapy and hematopoietic stem cell-based gene therapies for genetic immune system and blood disorders.

For more than 25 years, ASTCT members have focused on innovation in the treatment of hematologic malignancies, hematologic disorders, and other immune system diseases. ASTCT members very much rely on team care for the complex cancers and other disorders requiring hematopoietic stem cell transplants (HSCTs) and newer cell therapies like CAR-T. If CMS has any questions regarding these comments, please contact Alycia Maloney, the ASTCT's Director of Government Relations, at amaloney@astct.org.

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Evaluation and Management Codes and Shared/Split Services

ASTCT supports CMS' adoption of American Medical Association (AMA) CPT codes, including all Evaluation and Management (E/M) codes. **The ASTCT asks that CMS continue to work with AMA such that HCPCS level II codes are no longer needed for E/M services.** For example, it is preferable if CPT could develop level I codes for the new G2211 add-on code. It is also desirable for the time requirements for prolonged services to be aligned, thereby no longer necessitating those level II HCPCS codes. By reducing HCPCS level II codes, both parties will help uphold the intent of the Administrative Simplification Act (ASA), which is to reduce administrative burden by applying standard code sets and definitions to all providers and payers.

CMS Response: pgs 453

We also acknowledge that in some circumstances, when we must act to address beneficiary access or practitioner payment issues, we can establish HCPCS level II coding, and we do so in the public interest, reflecting our consideration of appropriate coding and provider administrative burden.

Additionally, ASTCT asks that CMS release more guidance regarding its expectations of specialists' use of HCPCS code G2211 for longitudinally treating a patient's single, serious, or complex chronic condition for separate payment. Cell therapy and transplant patients have a serious condition that involves an evolving, complex, team-based plan of care, which relies upon intensive care coordination. **This is currently documented by our clinicians and team members; if additional medical record documentation is expected to support billing G2211, ASTCT asks that CMS provide explicit guidance on this issue.**

CMS Response: p 439 continuing to p 441 with a clinical example

This code should be used when furnishing O/O E/M visit associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition.

We clarify that it is the relationship between the patient and the practitioner that is the determining factor of when the add-on code should be billed. First, the "continuing focal point for all needed health care services" describes a relationship between the patient and the practitioner, when the practitioner is the continuing focal point for all health care services that the patient needs. For example, a patient has a primary care practitioner that is the continuing focal point for all health care services, and the patient sees this practitioner to be evaluated for sinus congestion. The inherent complexity that this code (G2211) captures is not in the clinical condition itself— sinus congestion —but rather the cognitive load of the continued responsibility of being the focal point for all needed services for this patient. There is previously unrecognized but important cognitive effort of utilizing the longitudinal relationship itself in the diagnosis and treatment plan and weighing the factors that affect a longitudinal doctor patient relationship. In this example, the primary care practitioner could recommend conservative treatment or prescription of antibiotics. If the practitioner recommends conservative treatment and no new

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prescriptions, some patients may think that the doctor is not taking the patient's concerns seriously and it could erode the trust placed in that practitioner. In turn, an eroded primary care practitioner/ patient relationship may make it less likely that the patient would follow that practitioner's advice on a needed vaccination at the next visit. The primary care practitioner must decide—what course of action and choice of words in the visit itself, would lead to the best health outcome in this single visit, while simultaneously building up an effective, trusting longitudinal relationship with this patient for all of their primary health care needs. Weighing these various factors, even for a seemingly simple condition like sinus congestion, makes the entire interaction inherently complex, and it is this complexity in the relationship between the doctor and patient that this code captures.

The second part of the add-on code also describes a relationship between the practitioner and patient, but for specific types of conditions.

(p. 441) The most important information used to determine whether or not the add-on code could be billed is missing: the relationship between the practitioner and the patient. If the practitioner is the focal point for all needed services, such as a primary care practitioner, this add-on code could be billed in these examples. Or, if the practitioner is part of ongoing care for sickle cell disease (a single, serious and complex condition) then the add-on code could be billed. Otherwise, this add-on code could not be billed. Again, this add-on code captures the inherent complexity of the visit that is derived from the longitudinal nature of the practitioner and patient relationship.

We also note unequivocally that this code is not restricted to medical professionals based on particular specialties. Instead, it should be used by medical professionals, regardless of specialty, with O/O E/M visits (other than those reported with the -25 modifier) for care that serves as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. We reiterate that when physicians and other practitioners provide care that serves as the continuing focal point for all needed healthcare services, they should report the inherent complexity add-on code along with all reasonable and necessary O/O E/M visits (not reported with the -25 modifier).

In the 2022 MPFS rule, CMS finalized the definition of a shared/split visit in a new section at 42 CFR § 415.140. This definition will enable the clinician who furnished the history, exam, medical decision making (MDM) components—or more than half of the total visit time (e.g., the summation of the distinct time spent by each physician and non-physician provider [NPP])—to bill the E/M service. CMS retained the 2022 policy for CY 2023 and proposes to retain it for CY 2024, as well. This sets up a challenging situation whereby E/M service levels are based on MDM or visit time, rather than on the history and exam components.

As ASTCT has commented over the last two years, we believe that, if MDM is performed by a physician in the shared/split visit, the physician should be considered to be the clinician who furnished the "substantial portion" of the visit. MDM involves work such as modifications to the plan of care for the patient and evaluating risk; hence, physicians contribute a level of work based on their expertise and scope that goes beyond simply counting the time furnished during the visit. Further, specialists such as transplant physicians have, by definition, specialized knowledge and experience;

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thus, they will contribute more to the MDM component overall when they furnish this component in a visit.

ASTCT agrees with CMS' proposal to retain the current policy through CY 2024 because we strongly disagree with using more than half the visit time as the definition of the substantive portion. **ASTCT asks CMS to consider a policy for CY 2025 and beyond that, when MDM is used to select the E/M level for a shared/split visit and the physician documentation supports physician contribution to MDM, then the physician should automatically be considered to be the provider who furnished the substantial portion and the one to bill for the visit.** We believe this will appropriately recognize the physician effort involved in MDM as part of a shared/split visit.

CMS Response: (p. 474)

We note that the CPT Editorial Panel recently issued its revised guidelines for "split or shared visits" for CY 2024. Specifically, the Editorial Panel changed the definition of a " split or shared visit" to refer to the substantive portion of a service as either more than half of the total time spent by the physician and NPP performing the split (or shared) visit or a substantive part of the medical decision making, and to indicate that these guidelines should be applied to determine whether the physician or NPP may bill for the service… However, given these recent changes in the CPT Guidelines for split (or shared) visits and our interest in reducing coding and billing administrative burden on health professionals through continued alignment with revised overarching guidelines for E/M visits, we are reconsidering our policy for defining 'substantive portion' as it applies to split or shared visits…we agree that we should align our definition of substantive portion with the CPT E/M guidelines for this service.

Medicare Coverage of Dental Care

ASTCT very much appreciates CMS' continued proposals to pay for oral health care that is medically necessary according to accepted standards of practice; that is reasonable, necessary, integral, and prudent to the pre- and intra- management and/or treatment of a covered medical condition; and/or for prevention of a medical complication from oral/dental pathologies. ASTCT strongly supports CMS' proposals to expand coverage of dental services that are inextricably linked to chemotherapy, CAR T-cell therapy, and high-dose bone modifying agents (antiresorptive therapy). **We urge the agency to finalize dental coverage as proposed.**

CMS Response: (p. 584)

Under our current policy, we have identified several clinical scenarios where dental services are inextricably linked to other covered services that is covered by Medicare, such that Medicare payment for the dental services is not precluded by section 1862(a)(12) of the Act. After further review of current medical practice, and through internal and external consultations and consideration of the submissions received through the public process established in the CY 2023 PFS final rule (87 FR 69669), we believe there are additional circumstances that are clinically similar to the scenarios we codified in our regulation at § 411.15(i)(3)(i) as examples of clinical

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scenarios under which Medicare payment may be made for certain dental services because they are inextricably linked to other covered medical services.

As described in the CY 2024 PFS proposed rule, in the case of the proposed primarycovered services, we believe that dental services are inextricably linked to, and substantially related and integral to the clinical success of, the proposed covered services because such dental services serve to mitigate the substantial risk to the success of the medical services, due to the occurrence and severity of complications caused by the primary medical services, including infection (88 FR 52374 through 52380). Additionally, section 1862(a)(12) of the Act does not apply only when dental services are inextricably linked to, and substantially related and integral to the clinical success of, certain other covered services, such that the standard of care for that medical service would be compromised or require the dental services to be performed in conjunction with the covered services or if the dental services are considered to be a critical clinical precondition to proceeding with the primary medical procedure and/or treatment. As such, we believed the certain dental services are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, but instead are inextricably linked to, and substantially related and integral to the clinical success of, the following medical services, and we proposed that the statutory dental exclusion would not apply:

(1) Chemotherapy when used in the treatment of cancer;

(2) CAR T-Cell therapy, when used in the treatment of cancer; and

(3) Administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer.

As such, we proposed to revise our regulation at § 411.15(i)(3)(i)(A) by adding to the list of clinical scenarios in which Medicare Part A and B payment is permitted for dental or oral examinations performed as part of a comprehensive workup prior to, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, the following Medicare-covered services: chemotherapy, chimeric antigen receptor (CAR) T-cell therapy, and the administration of high-dose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer.

Revised 42 CFR 411.15

(A) Dental or oral examination performed as part of a comprehensive workup prior to, and medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, the following Medicare-covered services: organ transplant, hematopoietic stem cell transplant, bone marrow transplant, cardiac valve replacement, valvuloplasty procedures, chemotherapy when used in the treatment of cancer, chimeric antigen receptor (CAR) T-cell therapy when used in the treatment of cancer, and administration of highdose bone-modifying agents (antiresorptive therapy) when used in the treatment of cancer.

(E) Dental or oral examination performed as part of a comprehensive workup prior to, medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to or contemporaneously with, and medically necessary diagnostic and treatment services to address dental or oral complications after, treatment of head and neck cancer using radiation,

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chemotherapy, surgery, or any combination of these.

Appropriate Use Criteria for Advanced Diagnostic Imaging

CMS has taken a measured approach to implementing Appropriate Use Criteria (AUC) requirements. As a result of the significant issues with claims processing, CMS proposes to pause implementation of the AUC program and has not suggested a set timeframe to recommence it. CMS also proposes to remove the regulatory references. ASTCT agrees with CMS' assessment of the problems with implementing the AUC's tracking and penalty portions and its decision to pause implementation. **ASTCT asks that CMS partner with Congress to remove the requirements for the AUC from statute.**

CMS Response: (p. 1337)

Summary of the Proposal to Rescind: We believe the removal of these regulations [the AUC regulations] is consistent with our proposal to pause efforts to implement the AUC program for reevaluation and would avoid the potential confusion that could result if we were merely to retain or amend the regulation text at § 414.94.

Telehealth Provisions

ASTCT appreciates the consideration and intention to implement policies that extend coverage and payment for telehealth through December 2024; this is consistent with the intent of the Consolidated Appropriation Acts of 2022 and 2023.

Many of our member transplant centers rely on telehealth, particularly for their immunocompromised patients. Unfortunately, they are well-aware that the COVID-related public health emergency (PHE) flexibilities ended on May 11, 2023. These PDE-related flexibilities enabled hospitals to temporarily expand outpatient locations to patient homes for purposes of the billing and payment of hospital outpatient services. ASTCT believes this loss of the ability to provide telehealth in the same manner will cause a significant gap in coverage and payment to our member transplant centers.

ASTCT cannot stress enough to CMS how important it is that facility-based clinicians, including our members, can bill Medicare accurately when they furnish telehealth services to patients who are in their homes. Further, it is critical that the distant-site hospitals from which the clinicians conduct the telehealth services can be assured that there is no risk of compliance concerns.

Transplant and cell therapy clinicians are often located in hospital departments (i.e., the hospital is the distant site) when they furnish telehealth services to patients in homes and other originating sites. The technology, space, and ancillary staff support are provided by hospital employees and reported as hospital costs. The ability of our facility-based clinicians to furnish care via telehealth is vital to our patient population due to the distances they may have to travel

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to a qualified center and their compromised immunity during transplant and cell therapy treatments.

CMS proposes to pay for telehealth services furnished to patients in their homes at the non-facility physician fee schedule (PFS) rate instead of the facility-based rate until December 31, 2024. This will apply to both facility-based and non-facility-based clinicians billing telehealth services. This proposal means that physicians will be paid a higher non-facility rate even when the clinician is located at a hospital when furnishing telehealth services to patients in their homes. Hospitals are concerned that paying physicians located in a hospital a non-facility fee for a service provided to patients in their home raises compliance risks, since much of the practice expense to support the telehealth services is furnished by the hospital where the clinician is located.

CMS has directed clinicians to use place of service (POS) code 02 for telehealth services to patients not in their homes and POS 10 for patients in their homes as of January 1, 2024 (see CMS' telehealth fact sheet https://www.cms.gov/files/document/mln901705-telehealth-services.pdf). In other instructions, CMS describes the billing requirement for the clinician to use the address of where he or she is located in item 32 of the 1500 claim form. ASTCT believes the use of item 32 is correct for reporting telehealth services and that, when the clinician is in a hospital, the hospital address would be used on the 1500 claim. However, it remains unclear what POS code should be used when clinicians are providing the service from a hospital location vs. a physician office or other location.

The ASTCT asks CMS to confirm the appropriate billing and payment for telehealth services when the clinician is in the hospital and the patient is in the home and that there are no concerns for the hospitals that the clinician will be paid the higher non-facility rate.

CMS Response: (p. 159)

A few commenters requested that CMS clarify the appropriate billing and payment for telehealth services when the clinician is in the hospital and the patient is in the home, and whether we require that facility-based clinicians should report POS 02. Response: We wish to clarify that for telehealth services, when the clinician is in the hospital and the patient is in the home, the billing practitioner should use a hospital POS code along with modifier '95.'

ASTCT is also aware that absent further Congressional action, delivering telehealth to patients in their homes will no longer be covered beginning CY 2025, other than for the treatment of mental health and/or substance use disorders (SUD). The ASTCT wants to support CMS in providing evidence to Congress that telehealth is needed for immunocompromised patients in their homes in the same manner that the agency recognized the need when beneficiaries suffer mental health or SUD conditions. **Additionally, ASTCT asks CMS to evaluate whether it has any discretion to enable telehealth for immunocompromised patients after December 31, 2024, as this is vital to the patients we serve.**

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CMS Response: CMS did not respond to this issue in the Final Rule.

Services Addressing Health-Related Social Needs and Caregiver Behavior Management Training

ASTCT affirms CMS' proposals to recognize the resources required to address complex health-related social needs of patients who are eligible for cell therapy and transplant—as well as the importance of training their caregivers. **ASTCT asks that CMS accept questions for various use cases, then publish and update guidance to enable clinicians to report and receive appropriate separate payment without onerous documentation or other compliance requirements.**

CMS Response: (p. 311 for Principal Illness Navigation, Community Health Integration and SDOH Assessment)

Comment: A few commenters requested that CMS clarify whether these services can be billed at safety-net clinics in academic medical centers. Commenters also raised concerns that academic medical centers and other facility-based providers could not furnish the services, given the reliance on incident to billing. Commenters requested that CMS clarify how such facilities may furnish these services to ensure that patients can benefit from the services regardless of where they receive their care.

Response: We thank the commenters for their feedback and acknowledge that there are aspects of the policy that we must consider further for possible future rulemaking. As proposed, these services can only be furnished and billed by physicians and practitioners who can bill for services performed by auxiliary personnel incident to their professional services.

Principal Illness Navigation

Principal Illness Navigation (PIN) services are well-known for cancer patients. ASTCT supports separate codes and billing for navigator services (placeholder HCPCS codes GXXX3 and GXXX4).

We understand that PIN services are expected to be initiated with an E/M service, and that continuing PIN services would not require an E/M visit be billed. To meet the proposed definition of a principal illness (e.g., one serious, high-risk condition that is expected to last at least three months and that puts the patient at significant risk of hospitalization, nursing home placement, acute exacerbation/decompensation, functional decline, or death), monthly E/M visits with the PIN billing clinician would not be unexpected.

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ASTCT supports separate billing and payment for PIN services but has the following questions for CMS:

- CMS lists several diagnoses, including cancer, that it believes would require PIN services focused on social aspects of health system navigation. CMS did not list conditions such as sickle cell disease or autoimmune diseases, which often require navigation services for complex treatments, including stem cell transplant. Would these conditions qualify for PIN services? Would the PIN services qualify for coverage and payment when the patient plans to undergo cell therapy and transplant treatments for these conditions?
- PIN services may be needed for patients on clinical trials. Would the PIN services be considered standard of care (SOC) and billable under the NCD 310.1 Routine Costs in Clinical Trials?
- If a patient is determined to not have any social determinants of health (SDOH) identified with "Z codes" (Z55-Z65), does this make the PIN services non-billable or non-covered? What if the assessment identifies issues outside of the identified Z code range, such as conditions in the Z71 range concerning counseling needs?
- Can PIN services be initiated without having performed and billed an SDOH assessment?
- When a clinician orders PIN services, does the order need to identify the issue(s) that interfere with, or present a barrier to, diagnosis or treatment of the serious, high-risk condition? Or, can the auxiliary staff who perform the PIN services document the issue(s)?
- Does CMS expect PIN services to be delineated in the plan of care like other diagnostic tests and therapeutic services?
- Can communication via patient portals be counted in the time spent performing PIN services, in the same manner that in-person, telephone, and audio-visual communication time will be counted?

Social Determinants of Health Risk Assessment

ASTCT supports separate billing and payment for administering a standardized SDOH assessment tool. Billing and payment for a SDOH risk assessment (placeholder HCPCS code GXXX1) would be allowed when furnished on the same day as an E/M visit and not more frequently than once every six months.

ASTCT has the following questions and considerations about the proposed guidelines to bill and receive payment for this service:

- Do all E/M codes qualify as an E/M visit (for example, initial and subsequent and discharge E/M visit codes), or is this service expected to be furnished concurrent with an office/outpatient visit only?

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- The code states that the SDOH assessment cannot occur more frequently than every six months—is that limitation for the billing clinician or the patient? When a patient is referred to a specialist, such as from a medical oncologist to a transplant specialist, each clinician may need to perform the SDOH risk assessment and include domains that are important to the episode of care.
- Is the SDOH assessment intended to identify long-standing/systemic needs or does identification of short-term needs of patients meet the intent? For example, patients traveling to qualified centers for transplant may face short-term food and housing insecurity as well as transportation needs. Can the SDOH assessment be focused on needs during a treatment episode like cell therapy and stem cell transplants?
- If a patient is determined to not have any SDOH concerns identified with "Z codes" (Z55-Z65), does this make the administration of the SDOH assessment non-billable or non-covered? What if the assessment identifies issues outside of the proposed Z-code range, such as conditions in the Z91 range concerning compliance with medical regimens?
- Can patients complete the SDOH assessment and then work with auxiliary staff to review, elicit any needed explanations, and then provide the results of the assessment to the clinician? This would be similar to the process used for past medical, family, and social history surveys today? Can patients complete the assessment via a patient portal prior to the visit as long as the responses are reviewed and discussed at the visit?

Caregiver Training Service

ASTCT supports CMS' proposals to acknowledge Caregiver Training Services (CTS) by clinicians and their teams in support of each patient's individualized treatment plan. ASTCT agrees that education and training of caregivers is vital to effectuate patient outcomes; this is particularly true for patients undergoing cell therapy and transplants. CTS are crucially important to patient safety, since caregivers must be able to monitor the patient and recognize signs of decompensation that require immediate medical attention.

Acknowledging clinicians' significant investment in CTS is long overdue. While some caregiver training focuses on skills to assist the patient in completing daily life activities, much of it entails learning how to monitor the patient for signs of neurological or other physiological changes and communicating those changes to the treating clinician. ASTCT emphasizes that caregiver training is necessary to assist the patient's adherence to the treatment plan, and that major components of the plan could not be implemented without caregiver involvement.

ASTCT has the following questions and considerations about the proposed guidelines to bill and receive payment for these services:

- Will CTS be covered when needed to effectuate a treatment plan for cell therapy and stem cell transplants?

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- Does CMS expect specific diagnosis codes to cover and pay CTS services (these could include those indicating issues with problem-solving; environmental adaptation; training in use of equipment or assistive devices; or focusing on motor, process, and communication skills)? Or, will the patient's primary diagnosis be acceptable?
- CTS services may be needed for patients who are participating in clinical trials. Would the CHI services then be considered SOC and billable under the NCD 310.1 Routine Costs in Clinical Trials?

CMS Response: (pp. 301-302)

These specific services are reasonable and necessary when treating practitioners identify a need to involve and train caregivers to assist the patient in carrying out a treatment plan. (p.301)

We proposed to designate 97550, 97551, and 97552 as "sometimes therapy" services. This means that the services described by these codes are always furnished under a therapy plan of care when provided by PTs, OTs, and SLPs; but, in cases where they are appropriately furnished by physicians and NPPs outside a therapy plan of care, that is, where the services are not integral to a therapy plan of care, they can be furnished under a treatment plan by physicians and NPPs.

CMS also does not appear to recognize CTS services for clinician billing in the facility setting as the RVUs have NA under facility RVUs. Please see Addendum B in the CY 2024 PFS Final Rule Addenda for additional detail.

CPT[1]/ HCPCS	Mod	Status	Not Used for Medicare Payment	DESCRIPTION	Work RVUs[2]	Non-Facility PE RVUs[2]	Facility PE RVUs[2]	Mal-Practice RVUs[2]	Total Non-Facility RVUs[2]	Total Facility RVUs[2]	Global
97550		A		Caregiver traing 1st 30 min	1.00	0.56	NA	0.03	1.59	NA	XXX
97551		A		Caregiver traing ea addl 15	0.54	0.24	0.18	0.01	0.79	0.73	ZZZ
97552		A		Group caregiver training	0.23	0.43	NA	0.01	0.67	NA	XXX
G0019		A		Comm hlth intg svs sdoh 60mn	1.00	1.35	0.42	0.07	2.42	1.49	XXX
G0022		A		Comm hlth intg svs add 30 m	0.70	0.76	0.29	0.05	1.51	1.04	ZZZ
G0023		A		Pin service 60m per month	1.00	1.35	0.42	0.07	2.42	1.49	XXX
G0024		A		Pin srv add 30 min pr m	0.70	0.76	0.29	0.05	1.51	1.04	ZZZ
G0136		A		Adm of soc dtr assess 5-15 m	0.18	0.38	0.08	0.01	0.57	0.27	XXX

Community Health Integration Services

ASTCT supports CMS' proposals for codes and payment for Community Health Integration (CHI) services. Patient services provided by our member clinicians and transplant centers rely on significant community support not only where our patients reside, but also in temporary communities that are necessitated by the need to travel to a qualified center for treatment. ASTCT understands that a CHI-initiating E/M visit would be a pre-requisite to billing for CHI services. ASTCT further understands that the patient's SDOH needs would be the indication for CHI services (i.e., food, transportation, housing insecurity, or unreliable access to public utilities)

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when those needs significantly interfere with the treating clinician's ability to diagnose or treat the problem(s).

ASTCT has the following questions and considerations about the proposed guidelines to bill and receive payment for these services:

- Would CHI services to address travel, housing, and food needs during cell therapy and stem cell transplant episodes qualify for coverage and payment?
- CHI services may be needed for patients on clinical trials. Would the CHI services now be considered to be SOC and billable under the NCD 310.1 Routine Costs in Clinical Trials?
- If a patient is determined not to have any SDOH identified with "Z codes" (Z55-Z65), would CHI services be non-billable or non-covered? What if the assessment identifies other issues that do not fall within this Z-code range?
- Can CHI services be initiated without having performed and billed an SDOH assessment?
- When a clinician orders CHI services, does the order need to identify the issue(s) that interfere with, or present a barrier to, diagnosis or treatment of the patient? Or, can the auxiliary staff who perform the CHI services document those issue(s)?
- Does CMS expect CHI services to be delineated in the plan of care as other diagnostic tests and therapeutic services are?
- Since CHI services can be furnished by entities incident to the clinician, would email and other communication about the work the outside entities are furnishing be sufficient documentation in the patient's medical record to meet the incident to rules?

The ASTCT thanks CMS for the opportunity to comment. Please contact Alycia Maloney, ASTCT's Director of Government Relations, at *amaloney@astct.org*, for any further questions or to discuss these issues.

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