

POLICY BRIEF

KEY TERMS

CAR-T (Chimeric Antigen Receptor T-Cell) Therapy - Treatment in which a patient's T cells (a type of immune system cell) are changed in the laboratory so they will attack cancer cells. T cells are taken from a patient's blood. Then the gene for a special receptor that binds to a certain protein on the patient's cancer cells is added in the laboratory, prior to re-administering these cells back into the patient. This administration can be either inpatient or outpatient.

IPPS (Inpatient Prospective Payment System) – System whereby CMS sets base payment rates prospectively for inpatient stays based on the patient's diagnosis and severity of illness. Subject to certain adjustments, a hospital receives a single payment for the case based on the payment classification assigned at discharge.

MS-DRG (Medicare Severity Diagnosis Related Group) – Payment classification defined by a particular set of patient attributes which include principal diagnosis, specific secondary diagnoses, procedures, sex and discharge status, and used to determine reimbursement for hospital services.

NTAP (New Technology Add-on Payment) – Medicare policy providing additional payments for cases with high costs involving eligible new technologies while preserving some of the incentives under the average-based payment system.

Background

In recent years, the US Food and Drug Administration (FDA) approved two new CAR-T treatments – Gilead's Yescarta (axicabtagene ciloleucel) and Novartis' Kymriah (tisagenlecleucel) for advanced lymphomas in adults, and also approved Kymriah for pediatric acute lymphoblastic leukemia (ALL). In September 2020 there were a reported 1100 clinical trials underway for additional new and different CAR-T therapies.

CAR-T is a ground-breaking immunotherapy treatment. It is described by the National Cancer Institute (NCI) as follows, "A type of treatment in which a patient's T cells (a type of immune system cell) are changed in the laboratory so they will attack cancer cells. T cells are taken from a patient's blood. Then the gene for a special receptor that binds to a certain protein on the patient's cancer cells is added in the laboratory. The special receptor is called a chimeric antigen receptor (CAR). Large numbers of the CAR T cells are grown in the laboratory and given to the patient by infusion."

CAR-T therapy is extremely expensive. Treatment for adults with advanced lymphomas is reported to have a list price of \$373,000 for both Kymriah and Yescarta, while Kymriah is listed at \$475,000 for its pediatric indication. These list prices do not include the hospitalization costs for patients or the care involved in managing their often life-threatening side effects and adverse events. Another under-reported expense is the cost to a hospital or clinical setting to gain certification to administer the

therapy from the manufacturer; along with all the training, staff, and coordination required to successfully administer CAR-T. Payment from private payers involves complicated negotiations and is frequently delayed or outright denied.

Concerns for ASCO Members & the Cancer Community

A primary concern is patient access, which is threatened by multiple factors. Similar to clinical trials, these therapies are currently provided at select institutions or practices. This limits availability to traditionally underserved patients, who often reside in more geographically isolated or rural areas. As with all expensive therapeutics, lingering financial toxicity from prior regimens can also negatively affect an individual's ability to obtain CAR-T therapy.

When CAR-T is provided on an outpatient basis under Medicare Part B, there is a required 20% cost-sharing. The beneficiary is financially responsible for cost-sharing for the physician's service which is generally 20% of the Medicare approved amount under the Physician Fee Schedule and the hospital outpatient co-payment under the Outpatient Prospective Payment System. The hospital outpatient co-payment is capped at the inpatient deductible (which is \$1,408 in 2020). This total amount can easily prove too great a financial burden for many patients. When administered in the inpatient setting, there are also a host of reimbursement concerns that may limit the ability of providers to continue to provide CAR-T therapy. Over the long term, these could exert negative pressure on the availability of CAR-T therapy, further exacerbating issues of patient access.

Cancer care stakeholders, including ASCO, are concerned about these interrelated issues of access and reimbursement. Specifically, ASCO is concerned that Medicare beneficiaries will continue to face barriers accessing CAR T-cell therapy unless providers are reimbursed equitably for this treatment. Relevant areas of Medicare coverage and reimbursement policy are described briefly below.

In-Patient Prospective Payment System (IPPS)

The IPPS is a system whereby CMS sets base payment rates prospectively for inpatient stays based on the patient's diagnosis and severity of illness. Subject to certain adjustments, a hospital receives a single payment for the case based on the payment classification assigned at discharge, known as a Medicare Severity Diagnosis Related Group (MS-DRG). In the initial years after FDA approval of the first CAR-T therapies, CMS resisted establishing a new MS-DRG upon which to base reimbursement for CAR-T therapies administered in the inpatient setting. Citing insufficient information, claims data, etc. to support the development of a new MS-DRG, CMS instead determined that the most similar MS-DRG they could use in the interim was the DRG for bone marrow transplants (MS016). The payment rate for this MS-DRG was approximately \$39,000 in Fiscal Year 2019. Additional reimbursement was enabled through a payment system known as the New Technology Add-on Payment (NTAP), through which CMS has the option of providing additional payments for high costs involving eligible new technologies, while preserving some of the incentives under the average-based payment system. These temporary NTAP payments were finalized at 65% of the products costs. In other words, CMS stated that it would pay 65% of the product's cost of the actual therapy to the provider in addition to the MS-DRG that they had identified for CAR-T. This value remained well below the cost of administering CAR-T therapy, as outlined above.

An additional concern was that NTAP payments are only authorized for three years and would expire after 2020. Cancer care stakeholders including ASCO expressed the need for a permanent solution that meets the needs of patients and providers. For this reason, CMS established a new MS-DRG for CAR-T in the 2021 IPPS, resulting in a national, unadjusted payment amount of \$239,929. This amount remains insufficient to cover the costs of administering CAR-T therapy.

There are eleven cancer care hospitals that are exempt from the IPPS, and thus were not eligible for NTAP, and are not paid based upon the new MS-DRG for CAR-T. These centers are treating an estimated half of the patients receiving CAR-T therapy, and future policy must ensure sufficient reimbursement for these hospital systems as well.

Out-Patient Payment for CAR-T

An increasing number of out-patient clinics or centers are expressing interest in administering CAR-T. If administered on an out-patient basis, the treatment cost is covered under Medicare, Part B. This means the full cost of the product itself plus 4.3% (intended to cover handling and storage costs for drugs) is paid to the clinician. The patient, however, is still responsible for the 20% cost sharing for the physician services and the hospital outpatient copayment (capped at the inpatient deductible which is \$1,408 in 2020). One major concern in this situation is that if a patient is admitted as in-patient for a clinically related purpose in less than 72 hours after receiving therapy as an out-patient at a facility that is wholly owned or operated by the hospital; the facility will lose the ability to bill under Part B. This scenario is not unlikely given the potential for neurotoxicity and life-threatening systemic inflammatory reactions during CAR-T administration.

National Coverage Determination

On August 7th, 2019 CMS published a final National Coverage Determination (NCD) regarding CAR-T therapy coverage in the Medicare program. [According to CMS](#),

“Medicare coverage is limited to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury (and within the scope of a Medicare benefit category). National coverage determinations (NCDs) are made through an evidence-based process, with opportunities for public participation. In some cases, CMS' own research is supplemented by an outside technology assessment and/or consultation with the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC). In the absence of a national coverage policy, an item or service may be covered at the discretion of the Medicare contractors based on a local coverage determination (LCD).”

Therefore, the NCD for CAR-T establishes a standard, nation-wide requirement for coverage of the therapy in the Medicare program. It also provides for coverage when CAR-T therapy is administered in inpatient facilities or in outpatient health care facilities that are enrolled in FDA risk evaluation and mitigation strategies (REMS) with expertise in delivering cellular therapies. Finally, the NCD established that Medicare will cover CAR-T therapy for off-label uses that are recommended by [CMS-approved compendia](#), in addition to any FDA-approved indications.

Where ASCO Stands on CAR-T Issues

The Medicare payment system does not adequately reimburse for variable patient care costs or the cost of the product itself. Providers currently bear an unreasonable financial burden for providing this life-saving treatment to patients for whom this is a therapy of last resort as they have relapsed and failed previous treatments. At a time when access is a matter of life and death, there is no time to determine if their centers can withstand the associated financial losses of offering CAR T-cell therapy, either inpatient or outpatient.

ASCO has outlined the following position on CAR-T therapies:

Principles:

- ASCO supports coverage for all FDA-approved indications of CAR-T therapy.
- ASCO supports the delivery of CAR-T therapy in all manufacturer-approved, high-quality health care settings where patients can be safely and effectively treated with this very complex and demanding treatment regimen, including any and all care required for adverse events and follow-up.
- ASCO supports CMS in their proposed NCD approach of Coverage with Evidence Development, but conditions that support on the minimization of any unnecessarily duplicative or additional administrative requirements.
- ASCO believes that Medicare should cover the full cost of CAR-T therapy, with the exception of any applicable patient or provider cost-sharing that would apply to any other covered drug or therapy under the Medicare program.
- ASCO believes that all patients should be supported by the right therapy at the right time. Providers do not set list prices for drugs or treatments and should not bear the financial burden of any unpaid portion of an innovative cancer care therapy simply because a manufacturer has set a high price.

For More Information

[2017 ASCO Position Statement - On Addressing the Affordability of Cancer Drugs](#)