Proposal – PACER: Provisional Accelerated Coverage to Encourage Research

Introduction

This proposal would expand patient access to new technologies by clarifying the authority of the Centers for Medicare & Medicaid Services (CMS) and Medicare Administrative Contractors (MACs) to cover certain innovative medical devices and diagnostics following approval by the Food and Drug Administration (FDA) while the manufacturer collects additional data on the technology. The proposed approach would give CMS and MACs the ability to expand and accelerate access to innovative medical devices and diagnostics while encouraging manufacturers to increase the evidence base for their technologies. After an initial period of provisional coverage, CMS or a MAC could conduct a coverage analysis to determine whether to continue to cover the technology. The proposed approach also could be implemented by CMS or the MACs through administratively simple mechanisms, such as a national coverage determination (NCD) that describes the mechanism and notifications of technologies subject to the policy on their websites.

This proposal is built on the concept CMS has described in guidance documents and implemented through the national coverage determination process known as "coverage with evidence development" (CED). Similar to the existing CED process, this approach would not be used when other forms of coverage are justified and would lead to the production of evidence complementary to existing medical evidence. To minimize burdens on CMS, MACs, and manufacturers, it would be available only at the request of the manufacturer of the item or service. This approach also would address a number of limitations of the current CED program:

- CMS has stated that under its current CED policy based on Social Security Act (SSA) § 1862(a)(1)(E), an item or service may not be covered for beneficiaries within a clinical study and, at the same time, be covered for beneficiaries outside the clinical study. This proposal is based on SSA § 1862(a)(1)(A) and would cover use of the technology in beneficiaries both inside and outside of the clinical study contingent on the manufacturer's commitment to collect data on use of the device in the Medicare population. This would expand beneficiary access to innovative technologies while furthering CMS's goal of promoting beneficiary participation in research.
- Moreover, under CED there is a "coverage gap" during the time period between when a CED study ends enrollment and when CMS completes a reconsideration of the CED coverage decision. The proposal would eliminate this coverage gap because it would allow coverage to continue until CMS or a MAC decides to limit coverage.
- Finally, the CED program only is utilized at the national level and due to limited resources, CMS can process only a handful of CEDs per year. CMS has stated that the definition of local coverage determination (LCD) in the SSA does not support the use of CED under 1862(a)(1)(E) of the Act. As a result, MACs have been reluctant to promote coverage policies based on data collection. This proposal also would communicate clear authority to MACs under section 1862(a)(1)(A).

This voluntary applicative approach to CED could be applied at the local or national level.

Overview

At the manufacturer's request, CMS could consider any newly FDA-approved/cleared device to be reasonable and necessary for a limited period of time while the manufacturer collects additional data on the device in the Medicare population. At the end of the limited provisional coverage period, CMS or its contractors could conduct a national or local coverage analysis on the device to determine whether to continue to cover it for the studied population and indication.

- This approach would be applied only at the request of the manufacturer; CMS cannot impose this requirement on manufacturers.
- If a manufacturer does not request provisional coverage, its device could be subject to a coverage determination by CMS or the MACs or claim-by-claim processing.
- This option would be available only if there is no non-coverage policy in place at the time the device is approved.
- The device would be covered for all patients when used for the FDA-approved/cleared indication; manufacturers would be encouraged to seek the broadest enrollment possible in their data collection activities.
- CMS would grant any codes and set payment as needed to facilitate adequate reimbursement during the provisional coverage period. CMS could work to align provisional coverage with new technology add-on payments under the hospital inpatient PPS and pass-through or new technology Ambulatory Payment Classification (APC) status under the outpatient PPS, for example.

To ensure that this research is conducted, CMS will limit provisional coverage to a period of time, defined at the time the request is approved, that allows for collection and analysis of postmarket data.

- The length of time for provisional coverage might vary by type of technology and the amount of evidence available at the time of FDA approval.
- Coverage would continue until CMS or the MAC completes its coverage analysis at the end of the provisional coverage period.
- The design of the data collection activity should be coordinated with the FDA, as appropriate, to fulfill any post-approval/clearance study requirements.
- CMS would identify the approved studies and related devices on its website, similar to the way the agency identifies covered Investigational Device Exemption (IDE) studies.

CMS would encourage Medicare Advantage and private payers to coordinate and cover the technology, as well.

Policy justification: CMS will give new devices the benefit of a presumption of coverage to support data development by the sponsor on use of those devices in the Medicare population.

- CMS may apply a different evidentiary standard to determine a device is reasonable and necessary when the device is first approved/cleared by the FDA.
- CMS can cover a device based on the data available at the time of FDA clearance or approval with the understanding that additional evidence will be developed as the technology matures, allowing for continued data development concurrent with coverage.
- CMS can re-evaluate the technology at the end of the provisional coverage period, using the additional data collected during that time.
- A device would receive the benefit of provisional coverage if its manufacturer agrees to collect additional data and to publish its results.

Legal justification:

- CMS could base this approach on its authority to interpret 1862(a)(1)(A). CMS would, in effect, be interpreting "reasonable and necessary" as requiring different levels of evidence based on how mature the technology is. CMS could expect less evidence at the time of FDA approval/clearance than it does for more mature technologies.
- MACs also could apply this approach under their authority at SSA § 1869(f)(2)(B) to make determinations under 1862(a)(1)(A). This approach would efficiently expand access to innovative technologies, particularly for laboratory services that are subject to a single MAC's jurisdiction or innovative devices offered by a limited number of hospitals. MACs would be encouraged to coordinate with each other to avoid duplicate studies.

CMS could announce this policy through a guidance document, subject to public comment, or through the NCD process.