AdvaMed
Advanced Medical Technology Association

Ensuring Patient Access to Critical Breakthrough Products Act of 2018: Description and Rationale

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Overview

The breakthrough pathway proposal would establish a program of accelerated transitional coverage and payment for new technologies that offer breakthroughs in the treatment or diagnosis of serious illnesses affecting Medicare beneficiaries. In addition it would make improvements in the existing New Technology Add-on Payment (NTAP) program for valuable new technologies. The ***Ensuring Patient Access to Critical Breakthrough Products Act of 2018*** will be introduced soon and seeks to address these issues..

The Problem

The Food and Drug Administration (FDA) currently has an expedited review program to identify and provide priority review to medical devices and diagnostics that meet an unmet need, or offer more effective treatment of life-threatening or irreversibly debilitating diseases. On average, only about three new technologies a year meet these challenging criteria and are subsequently approved by FDA as satisfying its rigorous standards for safety and effectiveness. However, even if a groundbreaking and innovative technology meets FDA's rigorous standards for expedited review and is ultimately cleared or approved, manufacturers face other significant hurdles in navigating the coverage and reimbursement process established by the Centers for Medicare & Medicaid Services (CMS).

Currently, the process to receive a code alone can take as long as three years. Issuance of a code does not guarantee coverage and payment for the technology. Therefore, once a code is received new therapies may still need to be evaluated by each local contractor to determine coverage eligibility before patients can gain access. Many technology manufacturers do not pursue national coverage decisions because they are time consuming and cumbersome. Furthermore, evidence suggests that Medicare national coverage determinations for medical interventions have become more restrictive over time. More recent coverage determinations (from mid-March 2008 through August 2012) were twenty times less likely to be positive than earlier coverage determinations (from February 1999 through January 2002). [1]

The level of delay and uncertainty related to the local and national coverage processes not only delays patient access to groundbreaking technology but also compromises access to venture capital funding. This is a significant problem since a high proportion of therapies to address unmet needs are developed by small start-up companies that typically rely on venture capital funding. Between 2007 and 2013, overall venture capital investment in medical technology dropped by 43%. More importantly, investment in early stage firms dropped by almost three-quarters during that time period.[2] As a result, promising therapies that could change patients' lives for the better are languishing.

Similarly, the NTAP program, while created to remove disincentives to adoption of treatments that are of significant value to Medicare beneficiaries, has resulted in the opposite. NTAP

provides a temporary increase in payments for use of new technologies, if the new technology meets certain rigorous requirements, thereby encouraging appropriate adoption and use by providers who might otherwise not use the technology due to cost concerns. Unfortunately, CMS implementation of the program has curtailed the potentially beneficial impact of NTAP by inadequately reimbursing the cost of the new technology. As a result, since 2003, only 29 of 72 applications have been approved, and in some cases, coverage of NTAP products has been restricted.

The Solution

The breakthrough pathway proposal establishes a rapid seamless route to approval and coverage of breakthrough diagnostics and treatments. The FDA would designate a new therapy as a breakthrough product if it meets the following conditions:

- provides more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions;
- has no approved alternatives;
- offers significant advantages over existing approved alternatives; or
- availability is in the best interest of patients.

If the product meets the threshold it would qualify for expedited FDA review. If the therapy were ultimately approved by FDA, CMS would provide temporary coverage for three years. During the three-year period, the therapy would receive a guaranteed level of payment, and CMS could specify the additional data needed to continue coverage after the three-year period under its statutory "reasonable and necessary" standard.

The proposal also improves the existing NTAP program. These improvements are designed to reduce coverage and payment disincentives that limit prompt patient access to innovative but more costly technologies.

These changes would both stimulate development of important new diagnostics and treatments, and assure prompt availability of those treatments to patients.

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[1] James D. Chambers, et al., "Medicare is Scrutinizing Evidence More Tightly for National Coverage Determinations," *Health Affairs,* February 2015, vol 34, no. 2.

[2] PWC and National Venture Capital Association, "Venture Capital Investments Q1. 2014—Money Tree Results," April, 18, 2014.