



ISSUE BRIEF

NOVEL Act

BACKGROUND

The **New Opportunity for Value that Extend Lives (NOVEL) Act (S. 2416)** is a bipartisan bill designed to speed up patient access to novel therapies, defined as drugs or devices that receive breakthrough or advanced regenerative therapy designation by the Food & Drug Administration (FDA), while maintaining important patient safety protocols. Currently, novel therapies must wait until approval to apply for a Healthcare Common Procedure Coding System (HCPCS) code and for a national coverage determination by the Centers for Medicare and Medicaid Services (CMS). The NOVEL Act would shift these steps to begin during the approval process by allowing a drug or device manufacturer sponsoring a product to apply for a HCPCS code as soon as that product has received breakthrough designation and requiring CMS to grant or deny a code within 180 calendar days of receipt of the application. A code granted to a breakthrough device under this Act would not take effect until the product has been approved by FDA.

The Act also requires CMS to facilitate a pathway that expedites a national coverage determination for coverage with evidence development, meaning the product is covered for patients receiving it as part of a clinical trial. CMS is required to begin its national coverage determination process for products covered by this Act as soon as the product receives a HCPCS code. A determination of coverage with evidence development may be issued for a period of up to four years, and CMS must submit a report to Congress and the sponsor providing options for alternative payment models no later than four years after issuance of the determination.

AMCP'S POSITION

AMCP supports the NOVEL Act and urges Congress to pass it. By allowing these steps to happen concurrently rather than sequentially, patients will receive more timely access to valuable and potentially lifesaving treatments. The Act ensures responsible administration of new treatments by requiring CMS to make a national coverage determination of coverage with evidence development.

CALL TO ACTION

AMCP asks members of the Senate to co-sponsor this important legislation and encourages the House of Representatives to introduce a companion bill. Passing the NOVEL Act will help modernize the drug approval process and reduce delays in patient access, leading to improved health outcomes and lives saved.

CONTACT | JENNIFER L. MATHIEU

Director, Government Relations

314 306 0444 • jmathieu@amcp.org

www.amcp.org • [@amcporg](https://twitter.com/amcporg)