

A Vision of Medicare Coverage for New and Emerging Technologies *JAMA Internal Medicine Article Summary*

The Centers for Medicare & Medicaid Services (CMS) is committed to making sure Medicare beneficiaries are able to access emerging technologies. CMS plans to do this by initiating notice and comment rulemaking in the coming months to explore policy options that would create an accelerated approval pathway. This pathway would build off of prior initiatives, including coverage with evidence development. The proposed rule will meet the following principles:

- 1) Manufacturers may enter the process on a voluntary basis. This process will be limited to medical devices that fall within the Medicare statute and that are relevant to the Medicare population.
- 2) CMS may conduct early evidence review (before the device secures FDA marking authorization) and discuss with the manufacturer the best Medicare coverage pathway, depending upon the strength of the evidence collected.
- 3) At the manufacturer's request, CMS may initiate the coverage process before FDA market authorization, which could require developing an additional evidence development plan and confirming that there are appropriate safeguards and protections for Medicare beneficiaries.
- 4) If CMS determines that further evidence development is the best coverage pathway, the agency would explore how to reduce the burden on manufactures, clinicians and patients while maintaining rigorous evidence requirements.

As CMS develops this proposed rule, the agency will work closely with stakeholders.

CMS recently shared more information about its plans in JAMA. To read the article, visit:
[https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/10.1001/jamainternmed.2022.5085?guestAccessKey=7d1de373-4ebe-4843-bb2b-0504c4eb0021&utm_source=For The Media&utm_medium=referral&utm_campaign=ftm_links&utm_content=tfl&utm_term=101222](https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/10.1001/jamainternmed.2022.5085?guestAccessKey=7d1de373-4ebe-4843-bb2b-0504c4eb0021&utm_source=For%20The%20Media&utm_medium=referral&utm_campaign=ftm_links&utm_content=tfl&utm_term=101222)