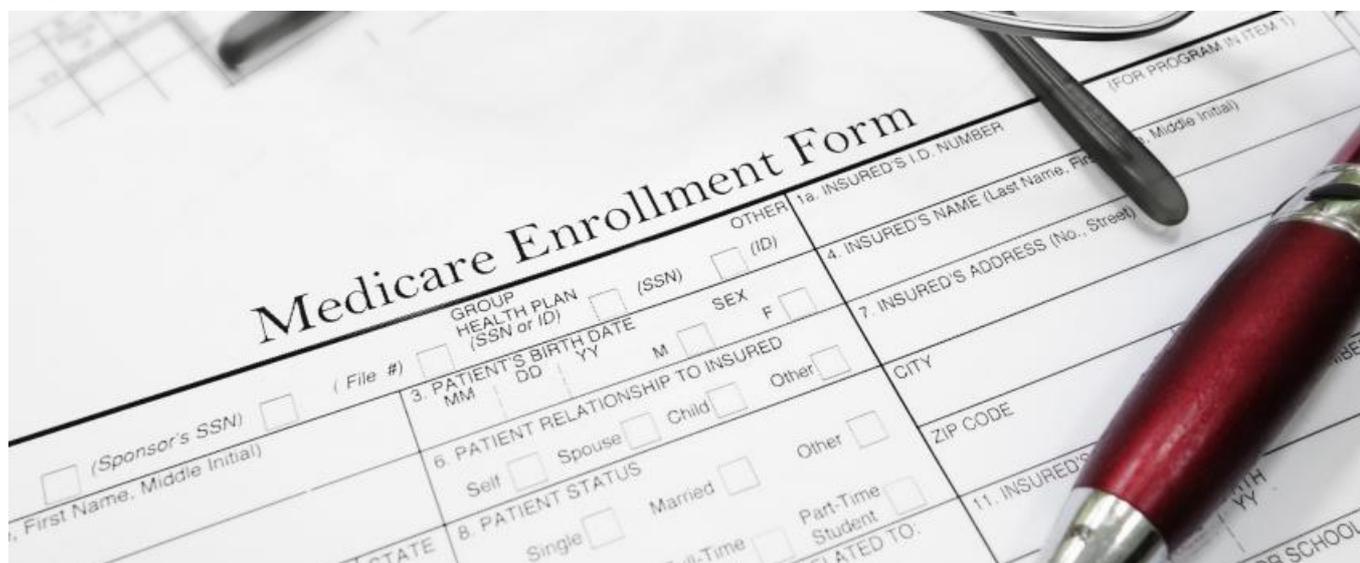


Medicare's new devices



[Elizabeth Cairns](#)



A handful of medtechs will benefit from new reimbursement pathways - but others have been denied the chance.

Last week Pear Therapeutics trumpeted the creation of new reimbursement codes by the Centers for Medicare and Medicaid for its three approved digital therapies, saying this was a step towards more widespread coverage of this category of medical device.

But Pear was not the only company to have its innovative devices recognised by the CMS as worthy of simplified reimbursement. Outset Medical, maker of a portable dialysis system, and the sleep apnoea specialist Signifier Medical Technologies are also beneficiaries, and could see their sales rise as a result.

CMS uses reimbursement codes to facilitate the processing of health insurance claims by Medicare and other insurers. When new devices reach the market, sometimes they are so unlike anything already available that new codes must be created. Similar devices that gain approval subsequently can then use these new codes.

In the latest list of decisions from the CMS, Signifier was awarded two new codes to describe eXciteOSA, which gained de novo FDA clearance in early 2021 for daytime treatment of mild obstructive sleep apnoea and primary snoring.

eXciteOSA is a handheld device that [applies electrical stimulation to the tongue](#). This strengthens the upper airway muscles, Signifier says, improving endurance and preventing airway collapse during sleep. Unlike other sleep apnoea devices such as CPAP machines, which are used while patients sleep, eXciteOSA is the first commercial-stage device that is used when the patient is awake.

According to Dr Marc Benton, a pulmonologist and sleep medicine specialist, once reimbursement is established a broader population of sleep apnoea patients will be able to get hold of eXciteOSA. Like all the new codes, those covering Signifier's device will become effective on April 1.

Rejected

Another device that works by stimulating the tongue was denied reimbursement. Helius Medical's Pons device sends impulses to the tongue to stimulate cranial nerves and then the brain stem, to improve the gait of patients with balance disorders caused by traumatic brain injury. It gained de novo clearance last March [at the second time of asking](#), but the CMS opted not to award it the two new codes Helius requested, saying it needed more information.

Pons is not the only device for which the CMS has declined to create a new code. For example, Smith &

Nephew's Oxinium, an alloy used in many of the company's knee and hip implants, will not receive a new code after the CMS pointed out that the purpose of these codes was to provide a way of conveying information required for accurate payment of claims – "not necessarily to differentiate among similar devices".

But Pear Therapeutics arguably wins the prize for the most important achievement in gaining new codes. The means of reimbursing digital therapeutics has, until now, not been well defined, and the question has dogged not just Pear but companies like Akili, Orexo, Onduo and Mahana Therapeutics.

That said, the revelation of easier reimbursement for Pear's apps has left investors cold. The company's stock has not risen above \$5 since mid-January, meaning it has lost more than half of its value since Pear listed on Nasdaq via the Spac Thimble Point Acquisition Corp last December.

Recipients of new reimbursement codes				
Company	Device	Description	Pathway	US approval date
Coopervision	MiSight 1 day	Contact lens for myopic ametropia	PMA	Nov 2019
Impulse Dynamics	Optimizer patient charger	Implanted muscle stimulator for heart failure	PMA	Mar 2019
Signifier Medical Technologies	eXciteOSA control unit	Tongue stimulator for sleep apnoea	De novo	Feb 2021
Signifier Medical Technologies	eXciteOSA mouthpiece	Tongue stimulator for sleep apnoea	De novo	Feb 2021
Pear Therapeutics	reSET	Digital therapeutic for substance use disorder	De novo	Sep 2017
Koya Medical	Dayspring Lite	Compression garment for lymphoedema and venous disease	510(k)	Sep 2021
Koya Medical	Dayspring*	Compression garment for lymphoedema and venous disease	510(k)	Apr 2021
Triad Life Sciences (Convatec)	InnovaMatrix FS	Bioactive scaffold for wounds and burns	510(k)	Apr 2021
Outset Medical	Tablo	Haemodialysis system for renal disease	510(k)	Mar 2020
Pear Therapeutics	Somryst	Digital therapeutic for insomnia	510(k)	Mar 2020
Pear Therapeutics	reSET-O	Digital therapeutic for substance use disorder	510(k)	Dec 2018
Polymedics	Supra SDRM	Synthetic matrix for difficult to heal wounds	510(k)	Jun 2017
Polymedics	Suprathel	Synthetic dressing for wounds and burns	510(k)	May 2009

*Received two new reimbursement codes. Source: Evaluate Medtech, CMS & FDA.

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