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The Honorable Chiquita Brooks-LaSure
U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services (CMS)

Re: Medicare Program; Transitional Coverage for Emerging Technologies (CMS–3421–NC)

Dear Administrator Brooks-LaSure:

The American Psychiatric Association (APA), the national medical specialty society representing over 38,000 psychiatric physicians and their patients, appreciates the opportunity to comment on the proposed Transitional Coverage for Emerging Technologies (TCET) program. APA shares CMS' commitment to equitable access to innovative medical technologies for Medicare beneficiaries and recognizes the existing challenges to achieving clearance and coverage for potentially effective treatments. **Considering the relatively low threshold of evidence required for FDA's Breakthrough Device designation, APA urges caution in allocating Medicare resources for coverage of this program.** The quality of evidence for approval and coverage for devices should be substantially equivalent to the rigorous threshold of evidence for pharmaceuticals.

The three key elements of the FDA Breakthrough Device program are: (1) the device provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating conditions; (2) the device must satisfy one of the following elements: No approved or cleared alternatives exist; offers significant advantages over existing approved or cleared alternatives; or device availability is in the best interest of patients; and (3) the design of clinical trials is "as efficient and flexible as practicable, when scientifically appropriate."

Thus, while the expectations of these devices are appropriate, the evidence required to demonstrate clinical benefit and effectiveness falls short of the rigorous clinical trial standards applied to other interventions. There are several devices on the Breakthrough Devices list relevant to psychiatric care, including EaseVRx, reSET-O, and the NightWare Kit. We will not provide an opinion on whether or not these devices should or can be used for psychiatric practice; instead, our comments focus on whether the evidence base for inclusion of these (or other future) devices on the Breakthrough Devices list is appropriate to justify Medicare coverage for these experimental approaches.

Safety and effectiveness for mental health devices should not be premised on a device not causing physiological harm or physical danger: rather, **there is significant risk in leading a person with mental illness to believe that they are receiving an effective treatment when they may not be.** The confusing description of these devices as “cleared” by the FDA could lead to clinicians and patients alike believing that the device had been subjected to the same standards and evaluations as medications. Lack of intended outcomes associated with using the device could lead to negative patient beliefs and behaviors including fatalism, or the belief that nothing will help them in recovering from mental illness; lack of trust in clinicians; and avoidance of future care. In patients with serious mental illness, outcomes of ineffective treatment are possible including death due to overdose or suicide.

Accordingly, APA challenges FDA’s assumption that the description of the De Novo premarket review pathway as a regulatory pathway for “low-to moderate-risk devices” is an accurate description for these devices – certainly, a person with opioid use disorder, chronic pain, or chronic nightmares would not view months spent on an ineffective treatment regimen as “low risk.”

APA’s members have also expressed concern that if Breakthrough Device coverage is expanded it could reduce coverage for other evidence-based and effective interventions. The number of participants included in the trials presented to the FDA for Breakthrough Device designation as well as the representativeness of these participants is difficult to endorse. For example, one device was tested on just 188 participants who took part in 56 daily virtual reality sessions. Another FDA Breakthrough Device application was based on results from just 63 patients. Not only do these studies not meet the expectation of randomized, controlled trials required for FDA approval of pharmaceuticals, but for Medicare’s broad patient population with potentially significant health-related social needs, these results seem especially problematic to generalize. **The responsibility for establishing clinical effectiveness should be borne by device developers, not by Medicare beneficiaries.**

Standard FDA approval processes should be sufficient to inform coverage for truly effective devices without CMS subsidizing the cost of clinical trials for medical device companies. While we support innovative approaches to recovery and treatment, we urge CMS, in partnership with FDA and the clinical community, to maintain a rigorous standard of evidence to inform Medicare coverage determinations and ensure access to high-quality mental health and substance use disorder care.

If you have any questions or would like to discuss our comments further, please contact Abby Worthen (aworthen@psych.org), Deputy Director, Digital Health.

Sincerely,

A handwritten signature in blue ink that reads "Saul Levin" with "M.D., M.P.A." written in smaller letters to the right.

Saul M. Levin, M.D., M.P.A., FRCP-E, FRCPsych
CEO and Medical Director
American Psychiatric Association