A new $16,000 postpartum depression drug is here: How will insurers handle it?

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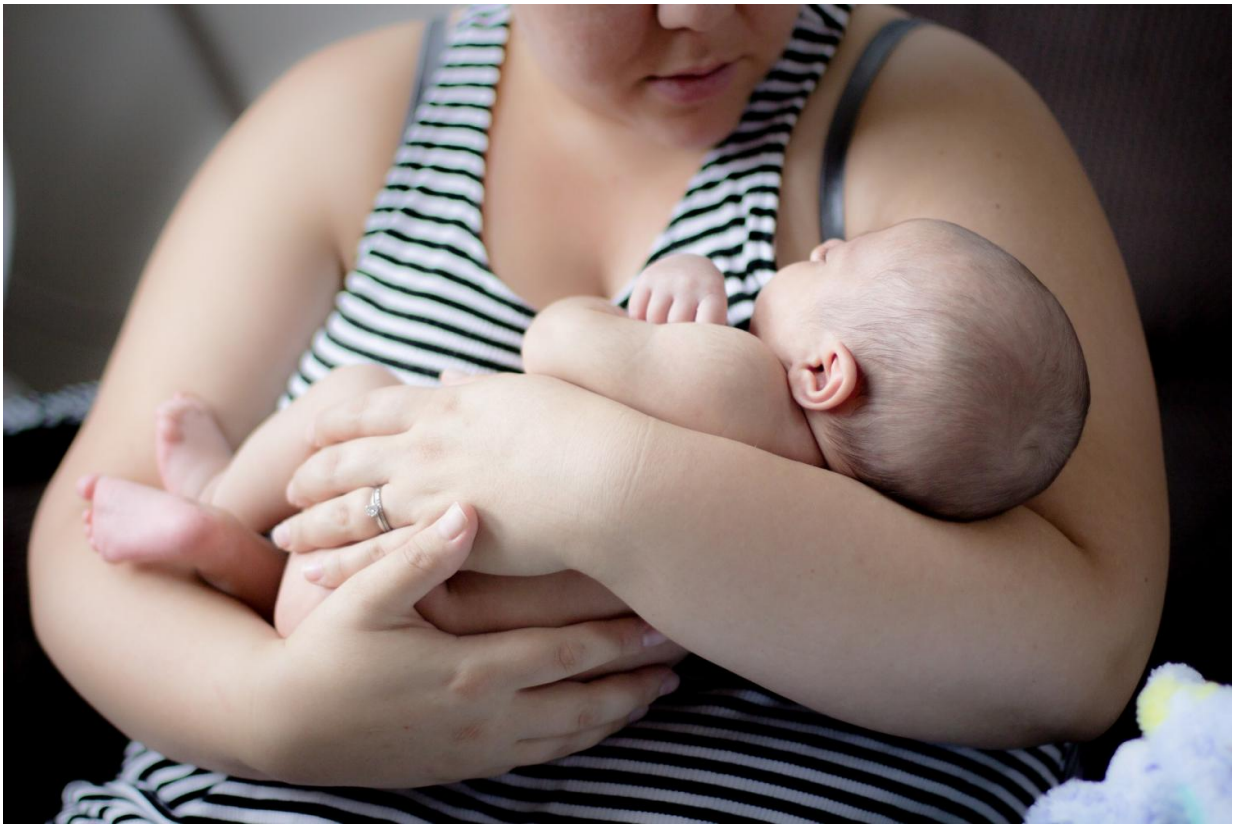

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A much-awaited treatment for postpartum depression, zuranolone, hit the market in December, promising an accessible and fast-acting medication for a debilitating illness. But most private health insurers

have yet to publish criteria for when they will cover it, according to a new analysis of insurance policies.

The lack of guidance could limit use of the drug, which is both novel—it targets hormone function to relieve symptoms instead of the brain's serotonin system, as typical antidepressants do—and expensive, at $15,900 for the 14-day pill regimen.

Lawyers, advocates, and regulators are watching closely to see how insurance companies will shape policies for zuranolone because of how some handled its predecessor, an intravenous form of the same drug called brexanolone, which came on the market in 2019.

Many insurers required patients to try other, cheaper medications first—known as the fail-first approach—before they could be approved for brexanolone, which was shown in early trials reviewed by the FDA to provide relief within days. Typical antidepressants take four to six weeks to take effect.

"We'll have to see if insurers cover this drug and what fail-first requirements they put in" for zuranolone, said Meiram Bendat, a licensed psychotherapist and an attorney who represents patients.

Most health plans have yet to issue any guidelines for zuranolone, and maternal health advocates worry that the few that have are taking a restrictive approach. Some policies require that patients first try and fail a standard antidepressant before the insurer will pay for zuranolone.

In other cases, guidelines require psychiatrists to prescribe it, rather than obstetricians, potentially delaying treatment since OB-GYN practitioners are usually the first medical providers to see signs of postpartum depression.

Advocates are most worried about the lack of coverage guidance.

"If you don't have a published policy, there is going to be more variation in decision-making that isn't fair and is less efficient. Transparency is really important," said Joy Burkhard, executive director of the nonprofit Policy Center for Maternal Mental Health, which commissioned the study.

With brexanolone, which was priced at $34,000 for the three-day infusion, California's largest insurer, Kaiser Permanente, had such rigorous criteria for prescribing it that experts said the policy amounted to a blanket denial for all patients, according to an NPR investigation in 2021.

KP's written guidelines required patients to try and fail four medications and electroconvulsive therapy before they would be eligible for brexanolone. Because the drug was approved only for up to six months postpartum, and trials of typical antidepressants take four to six weeks each, the clock would run out before a patient had time to try brexanolone.

An analysis by NPR of a dozen other health plans at the time showed Kaiser Permanente's policy on brexanolone to be an outlier. Some did require that patients fail one or two other drugs first, but KP was the only one that recommended four.

Miriam McDonald, who developed severe postpartum depression and suicidal ideation after giving birth in late 2019, battled Kaiser Permanente for more than a year to find effective treatment. Her doctors put her on a merry-go-round of medications that didn't work and often carried unbearable side effects, she said. Her doctors refused to prescribe brexanolone, the only FDA-approved medication specifically for postpartum depression at the time.

"No woman should suffer like I did after having a child," McDonald said. "The policy was completely unfair. I was in purgatory."

One month after NPR published its investigation, KP overhauled its criteria to recommend that women try just one medication before becoming eligible for brexanolone.

Then, in March 2023, after the federal Department of Labor launched an investigation into the insurer—citing NPR's reporting—the insurer revised its brexanolone guidelines again, removing all fail-first recommendations, according to internal documents recently obtained by NPR. Patients need only decline a trial of another medication.

"Since brexanolone was first approved for use, more experience and research have added to information about its efficacy and safety," the insurer said in a statement. "Kaiser Permanente is committed to ensuring brexanolone is available when physicians and patients determine it is an appropriate treatment."

"Kaiser basically went from having the most restrictive policy to the most robust," said Burkhard of the Policy Center for Maternal Mental Health. "It's now a gold standard for the rest of the industry."

McDonald is hopeful that her willingness to speak out and the subsequent regulatory actions and policy changes for brexanolone will lead Kaiser Permanente and other health plans to set patient-friendly policies for zuranolone.

"This will prevent other women from having to go through a year of depression to find something that works," she said.

Clinicians were excited when the FDA approved zuranolone last August, believing the pill form, taken once a day at home over two weeks, will be

more accessible to women compared with the three-day hospital stay for the IV infusion.

Many perinatal psychiatrists told NPR it is imperative to treat postpartum depression as quickly as possible to avoid negative effects, including cognitive and social problems in the baby, anxiety or depression in the father or partner, or the death of the mother to suicide, which accounts for up to 20% of maternal deaths.

So far, only one of the country's six largest private insurers, Centene, has set a policy for zuranolone. It is unclear what criteria KP will set for the new pill. California's Medicaid program, known as Medi-Cal, has not yet established coverage criteria.

Insurers' policies for zuranolone will be written at a time when the regulatory environment around mental health treatment is shifting. The U.S. Department of Labor is cracking down on violations of the Mental Health Parity and Addiction Equity Act of 2008, which requires insurers to cover psychiatric treatments the same as physical treatments.

Insurers must now comply with stricter reporting and auditing requirements intended to increase patient access to mental health care, which advocates hope will compel health plans to be more careful about the policies they write in the first place.

In California, insurers must also comply with an even broader state mental health parity law from 2021, which requires them to use clinically based, expert-recognized criteria and guidelines in making medical decisions. The law was designed to limit arbitrary or cost-driven denials for mental health treatments and has been hailed as a model for the rest of the country. Much-anticipated regulations for the law are expected to be released this spring and could offer further guidance for insurers in California setting policies for zuranolone.

In the meantime, Burkhard said, patients suffering from postpartum depression should not hold back from asking their doctors about zuranolone. Insurers can still grant access to the drug on a case-by-case basis before they formalize their coverage criteria.

"Providers shouldn't be deterred from prescribing zuranolone," Burkhard said.