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Accutane Scripts Stalled for Weeks After Safety System Revamp

By Celine Castronuovo

Deep Dive
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- Delayed prescriptions limit treatment's efficacy, providers say
- System updated to remove gender-specific patient categories

Physician assistant Laura Bush called the help center 22 times after she suddenly couldn't access the account she uses regularly to prescribe acne medication to her patients.

But the help line for the iPLEDGE Program—the platform providers and patients must use to get the drug commonly known as Accutane—didn't pick up. She lost access the same day iPLEDGE underwent a system update.

"We were locked out for days and some people weeks," said Bush, who also serves as the secretary and treasurer for the Society of Dermatology Physician Assistants. Yet access to the system is critical for a drug whose efficacy depends on continuous, uninterrupted use over several months.

Bush, who says her access has been restored, is just one of several prescribers frustrated with login issues and longer-than-average wait times on the platform's help line since the system updates rolled out Dec. 13, 2021. The Food and Drug Administration said Jan. 14 that the "majority of iPLEDGE users now have access to their accounts," but there is "a significant amount of work still to be done" to restore full access.

Continuous access to the acne drug is essential because it can take several months for prescribers to work patients up to a dosage level that's best for them, health providers say. The longer patients with severe cystic acne go without treatment, the more likely they will be left with permanent scarring, said Ilona Frieden, chair of the American Academy of Dermatology Association's iPLEDGE work group.

"An urgent solution is needed," Frieden said. "Every day that this problem persists, patients are losing access to necessary treatment."

Over 2 million people have taken the drug to date according to the American Osteopathic College of Dermatology. Medical providers and pharmacy groups say access to iPLEDGE is gradually improving, but that a more permanent solution is needed to ensure the platform works for everyone as intended.

The Isotretinoin Products Manufacturers Group (IPMG), which is responsible for managing the iPLEDGE system, said in an emailed statement Jan. 18 that it is "working—collaboratively with the FDA and stakeholders contributing to solutions—to help resolve the current situation, as quickly as possible."

Platform Changes

The iPLEDGE program, an FDA risk evaluation and mitigation strategy, is made up of companies approved to produce and market isotretinoin—often referred to by its former brand name Accutane—including Teva Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries Ltd. REMS programs are put in place for drugs with potentially severe side effects to ensure the medication's benefits outweigh the risks.

The purpose of the iPLEDGE system is to prevent severe birth defects that can occur when isotretinoin is used among pregnant people. The platform requires that before pharmacies can dispense it, medical providers confirm the results of a patient's pregnancy test and notify a patient of the risks of taking the drug during gestation.

The system's sponsors in December transitioned to a new platform that, among other things, removed gender-specific categories and separates patients solely based on their ability to get pregnant.

But problems merging user data from the previous system into the new one has prevented many users from logging into their iPLEDGE accounts, leading to treatment disruptions for patients across the country.

System Glitches

Bush heard as of mid-January that some patients and pharmacies were still unable to access their accounts, either because they didn't have the necessary login information or because their accounts weren't immediately registered in the new system.

Sara Wilchowski, a dermatology physician assistant in Michigan, said she initially had to get certain prescriptions for isotretinoin filled and shipped by a pharmacy in Florida, because "they were the only pharmacy that was able to access the iPLEDGE system" after the software update.

Pharmacies, like prescribers and patients, have also reported long wait times while trying to get in touch with the iPLEDGE call center. Bush said that on one day, she was left on hold for eight hours straight.

Being "on hold for hours at a time and not getting through to someone to be able to resolve that access issue" can "certainly be a challenge at the pharmacists' side," said Brigid Groves, senior director of practice and professional affairs at the American Pharmacists Association. Pharmacies across the country are already overwhelmed with Covid-19 testing, vaccinations, and other care during the pandemic.

‘Disheartening’ and ‘Frustrating’

Prescribers and pharmacies say patients are suffering the most from the access issues.

Cystic acne has “a lot of negative connotations, psycho-social impact, and it’s severe,” Bush said. “This is a condition that already causes a lot of stress and anxiety to the patient,” so having new obstacles to accessing isotretinoin “was pretty significant.”

Delayed access has been “so disheartening and so frustrating on so many levels,” Wilchowski said. She noted that “being on this medication can take six to nine months of therapy to get” patients “to a specific dose to ensure that the medication was effective.”

The disruptions can also be time consuming for patients, Bush said, especially because patients who are able to get pregnant have to complete a pregnancy test within a certain window of time before starting their isotretinoin treatment.

“When they couldn’t get their medicine, then they had to do another pregnancy test,” Bush said. “They had to miss work or school to do that. We had to do another visit.”

Disrupted access to refills for patients already on isotretinoin can also affect “the efficacy of the drug,” Frieden said.

“Isotretinoin success is based on a full continuous uninterrupted course, so we do not fully know the impact this will have on patients,” she said. “Since there is no equivalent medication for treating severe acne, patients will end up on sub-standard therapies including prolonged oral antibiotics.”

Preparation Is Key

The FDA told Bloomberg Law that it doesn’t run the REMS programs but “is ready to exercise regulatory flexibility on a temporary basis as needed with regard to certain requirements of the iPLEDGE REMS, provided the IPMG proposes a workable solution that also ensures necessary safe use conditions are maintained.”

The IPMG said in a statement that “while the work is ongoing, we have taken multiple immediate actions to alleviate technical issues, handle call volumes and reduce wait times.” The group said it has added staff to the contact center and added features to address login issues, including the option for prescribers to send patients’ links to their accounts if they are still having trouble logging in on their own.

The most recent fix was “a needed update to the system,” but it “is a short-term workaround and further highlights the issues with the call center since the burden is being placed on the prescribers to ensure functionality,” Bruce Brod, chair of the AADA’s council on government affairs and health policy, said Jan. 21.

“In many instances the call center is serving as a triage for problems and still having to escalate issues to a higher level to achieve solutions,” he said.

Groves said manufacturers could have prepared for potential system issues prior to the launch by developing a “workaround” for prescribers to send information to pharmacies without needing to go through the iPLEDGE system.

“Being more proactive and having that foresight and a plan in place ahead of time of what alternative options there can be to get that patient the medication that they need in that time are certainly, I think, something that we need to consider whenever converting any of the technology pieces,” Groves said.

Wilchowski said that while IPMG’s new temporary solution “will be helpful,” dermatology providers and other stakeholders should be included in the development of any future updates so that these access issues and delayed patient access to isotretinoin don’t happen again.

“These frustrations for thousands of patients and prescribers across the nation, truthfully, could have all been avoided had the rollout been done in a better fashion,” she said.

To contact the reporter on this story: Celine Castronuovo at ccastronuovo@bloombergindustry.com

To contact the editor responsible for this story: Alexis Kramer at akramer@bloomberglaw.com

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