Isotretinoin Restrictions Eased for Select Patients

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Women who have no chance of becoming pregnant, as well as men, no longer need to observe a 23-day lockout period before starting a new prescription of isotretinoin for the treatment of acne, according to a statement from the Food and Drug Administration.

To take advantage of this change, however, patients must repeat the qualification process to confirm that they meet the qualifying criteria to skip the 23-day lockout.

The iPLEDGE program was designed as a risk management plan to prevent, because of its severe teratogenic side effects, the use of isotretinoin by females who are or may become pregnant. The program initiated a universal set of strict criteria to be met before any patients could receive isotretinoin, regardless of their childbearing potential.

According to the original criteria, all female patients who wanted to take isotretinoin had to undergo a pregnancy test, and all patients had to be counseled that two types of contraception are essential while taking isotretinoin.

Once these criteria were met, patients had 7 days to fill a prescription. If they didn't fill it within that time, they would have to wait for 23 days, a time frame designed to accommodate another pregnancy test for women who could become pregnant. This process was to be repeated for each refill, which increased the administrative workload for clinicians and put pressure on patients.

Since then, clinicians' frustration with the iPLEDGE criteria has led to efforts by the American Academy of Dermatology and other organizations to convince the FDA and drug manufacturers that iPLEDGE needed revision.

For more information about the changes to the iPLEDGE program, visit the Web site at www.ipledgeprogram.com or call iPLEDGE at 1-866-495-0654. ■