iPLEDGE and Its Implementation in Dermatology Practices

Gary J. Rosenmeier, MD; Helen M. Torok, MD

Isotretinoin is one option in a dermatologist's armamentarium for the treatment of acne; however, it is highly teratogenic, and fetal exposure to isotretinoin can cause severe complications. iPLEDGE is a computer-based risk management program designed to help eliminate fetal exposure to isotretinoin by mandating how all isotretinoin products are prescribed and dispensed. Optimal success of the iPLEDGE program requires physician prescribers along with their office staff and patients to perform specific responsibilities to ensure that patients do not start isotretinoin therapy while pregnant or become pregnant during treatment. We discuss how to successfully implement the iPLEDGE program in dermatology practices.

Background

Isotretinoin (Accutane, Hoffman-La Roche Inc) was first approved by the US Food and Drug Administration in 1982 and was indicated for the treatment of severe recalcitrant nodular acne. (In 2009, Hoffman-La Roche Inc discontinued the manufacture and distribution of Accutane for reasons not related to the product's safety or efficacy.[1]) Over the years, several program initiatives have been introduced with the goal to reduce, if not eliminate, fetal exposure to isotretinoin.[2] iPLEDGE, the latest of these programs, was introduced in 2006.[3] iPLEDGE is a computer-based form of risk management mandating 100% participation; it tracks all isotretinoin transactions in the United States.[4] Prescribers, their office staff, and patients must undertake and successfully perform certain responsibilities to optimize the success of this program (Table). (For more explicit details, visit the iPLEDGE Web site [www.ipledgeprogram.com].)

Prescriber Responsibilities

Before a physician can prescribe isotretinoin, he/she must register and activate his/her enrollment in the iPLEDGE program either online or by telephone.[5] It is a 2-step process. First, prescribers are issued a username and password to activate; annual reactivation is required. Once the initial enrollment is activated, prescribers receive patient educational kits, written instructions, and consent forms by mail within 1 to 2 weeks of registration; it is incumbent on prescribers to become thoroughly familiar with these kits and instructions.[5]

In addition to ensuring that delegates (another physician/prescriber in the practice), designees (staff members in the prescriber's office), and patients are appropriately registered in the iPLEDGE program, prescribers also have specific clinical responsibilities related to the prescription of isotretinoin such as supervising delegates and designees, evaluating patients who are taking isotretinoin at monthly appointments, counseling all patients regarding the proper use of isotretinoin, counseling women of childbearing potential in the appropriate and continued use of at least 2 forms of contraception, ordering appropriate laboratory tests (eg, monthly pregnancy tests in all women of childbearing potential), and prescribing isotretinoin. In the unfortunate circumstance that a female patient becomes pregnant while taking isotretinoin, the prescriber should immediately stop the medication, report the incident to the iPLEDGE program pregnancy registry, and make an appropriate referral to the patient's obstetrician/gynecologist for counseling; pregnancy in a partner of a male patient taking isotretinoin also should be reported.[4]

Both from Trillium Creek Dermatology and Aesthetic Center, Medina, Ohio. Dr. Torok also is from Northeastern Ohio Medical College, Rootstown.

The authors report no conflicts of interest in relation to this article.

Correspondence: Gary J. Rosenmeier, MD, 5783 Wooster Pike, Medina, OH 44256 (grosenmeier@tcohio.com).

Copyright Cosmetic Dermatology 2013. No part of this publication may be reproduced, stored, or transmitted without the prior written permission of the Publisher.

Requirements and Responsibilities Associated With iPLEDGE Implementation in Dermatology Practices[3-5]

Access Level	Requirements/Responsibilities
Prescribers	Initial registration and activation as well as annual reactivation of program enrollment
	Thorough familiarization with program materials
	Initial registration of delegates, designees, and patients in the program
	Management and supervision of delegates, designees, and patients in implementing the program requirements and responsibilities
	Delegation of appropriate responsibilities to delegates and designees as desired
	Clinical management of patients (ie, evaluating and counseling patients taking isotretinoin at monthly appointments, ordering monthly laboratory tests, prescribing isotretinoin, stopping isotretinoin immediately if a patient becomes pregnant, reporting pregnancies to iPLEDGE, making appropriate referrals to the patient's obstetrician/gynecologist for counseling in case of pregnancy)
Delegates[a]	Initial registration and activation as well as annual reactivation of program enrollment
	Clinical management of patients on behalf of the primary prescriber as delegated by the prescriber
Designees[a]	Initial registration and activation as well as annual reactivation of program enrollment (after activation of prescriber enrollment)
	Performance of patient functions on behalf of the prescriber as instructed by the prescriber (ie, registering patients, entering patient pregnancy test results, confirming patient counseling, discontinuing patients, managing delegates, checking patients' program status)
Patients	Registration in the program by a prescriber
	Understand severe potential birth defects that can occur in female patients taking isotretinoin
	Be reliable in understanding and carrying out program instructions
	Sign a patient information/informed consent form containing warnings about the potential risks associated with isotretinoin
	Fill and pick up prescriptions during the designated prescription window
	Get all required laboratory tests (eg, pregnancy test) ordered by the prescriber in a timely manner
	Use 2 forms of contraception during sexual intercourse 1 month before, during, and 1 month after treatment
	Refrain from donating blood during treatment and 1 month posttreatment
	Do not share isotretinoin with anyone

[a]A delegate is another physician/prescriber selected by the primary prescriber. A designee is a staff member in the prescriber's office.

Office Staff Responsibilities

The iPLEDGE program allows prescribers to register another physician (delegate) or member of their office staff (designee) to perform patient functions on their behalf.[5]

Delegates

Prescribers can delegate another registered and activated iPLEDGE prescriber to cover for them during a scheduled absence or in a multiple doctor practice where patients may see any of the doctors in the office.[5] A delegate's

Copyright Cosmetic Dermatology 2013. No part of this publication may be reproduced, stored, or transmitted without the prior written permission of the Publisher.

responsibilities are similar to those of the primary prescriber; however, delegates are under the direct supervision of the primary prescriber who must set an expiration date for delegate status.

Designees

Designees are nonprescriber office staff members, such as nurses and medical assistants, who are authorized by the prescriber to perform various activities on behalf of the prescriber, such as registering patients, entering patient pregnancy test results, confirming patient counseling, discontinuing patients, managing delegates, and checking patients' program status. Once a designee is registered and has received his/her own username and password, he/she must be associated with the prescriber before being authorized to perform these responsibilities.[4]

Patient Responsibilities

When implementing the iPLEDGE program, all is for naught if patients do not adhere to the appropriate and necessary measures for preventing pregnancy while taking isotretinoin. To receive isotretinoin, all patients must be registered with the iPLEDGE program by the prescriber; understand that severe birth defects can occur with the use of isotretinoin by female patients; be reliable in understanding and carrying out instructions; sign a patient information and informed consent form containing warnings about the potential risks associated with isotretinoin; fill and pick up prescriptions during the designated prescription window; get all required laboratory tests (eg, pregnancy test) ordered by the prescriber in a timely manner; use 2 forms of contraception during sexual intercourse 1 month before, during, and 1 month after treatment with isotretinoin; refrain from donating blood while taking isotretinoin and for 1 month after treatment has ended; and not share isotretinoin with anyone.[4,6]

Conclusion

The iPLEDGE program mandates 100% participation by prescribing physicians, their delegates and designees, and patients in the safe prescription of isotretinoin to avoid the serious risks associated with fetal exposure to this teratogenic drug. The success of iPLEDGE depends on the fulfillment of certain requirements and responsibilities by all parties involved.

References

1. Roche discontinues and plans to delist Accutane in the US [press release]. Nutley, NJ: Hoffmann-La Roche Inc; June 29, 2009. http://www.rocheusa.com/portal/synergy/static/file/synergy/alfproxy/download/1414-cd2ddc12b4d211deadd62f6357bc6b3c/. Accessed April 12, 2013.
2. Green J. Babies, blemishes and FDA: a history of Accutane regulation in the United States. Legal Electronic Document Archive at Harvard Law School Web site. http://leda.law.harvard.edu/leda/data/472/Green.html. Published March 2002. Accessed March 21, 2013.
3. FDA and manufacturers of Accutane and its generics to implement iPLEDGE program on March 1, 2006 [press release]. Silver Spring, MD: US Food and Drug Administration; February 23, 2006.
4. The guide to best practices for the iPLEDGE program. iPLEDGE Program Web site. https://www.ipledgeprogram.com/Documents/Guide%20to%20Best%20Practices%20-%20iPLEDGE%20Program.pdf. Published 2010. Updated April 2012. Accessed March 21, 2013.
5. iPLEDGE program frequently asked questions. US Food and Drug Administration Web site. http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM150729.pdf. Published July 21, 2006. Accessed March 21, 2013.
6. iPLEDGE 2007 update. US Food and Drug Administration Web site. http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm094306.htm. Published October 2007. Updated January 15, 2010. Accessed March 21, 2013. ■

Copyright Cosmetic Dermatology 2013. No part of this publication may be reproduced, stored, or transmitted without the prior written permission of the Publisher.