Guide for counselors regarding effective forms of contraception.

This guide contains the Contraception Referral Form and the faxable Reimbursement Form.
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*Located inside back cover pocket.

WARNING
Isotretinoin must not be used by female patients who are or may become pregnant. There is an extremely high risk that life-threatening birth defects will result if pregnancy occurs while taking isotretinoin in any amount, even for a short period of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.

IMPORTANT NOTICE
Use only isotretinoin products approved by the US Food and Drug Administration. Obtain your isotretinoin prescriptions only from pharmacies that are licensed in the United States and are enrolled with and activated in the iPLEDGE REMS.
Contraception Counseling For Isotretinoin Patients

Isotretinoin is used to treat severe recalcitrant nodular acne in non-pregnant patients 12 years of age and older with multiple inflammatory nodules with a diameter of 5 mm or greater. Because of significant adverse reactions associated with its use, isotretinoin is reserved for patients with severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics. Isotretinoin is a known human teratogen; over one-third of all babies exposed to isotretinoin in utero and carried to term have major birth defects.

What Is The iPLEDGE® REMS?

To avoid serious risks to unborn babies, the Food and Drug Administration (FDA) has required a special program called a Risk Evaluation and Mitigation Strategy (REMS) for isotretinoin. The iPLEDGE REMS is a shared (includes multiple manufacturers) system with requirements for prescribers, pharmacies, and patients. The iPLEDGE REMS also includes a pregnancy registry for patients who get pregnant.

The goal of the iPLEDGE REMS is to
- prevent pregnancies in patients taking isotretinoin and to
- prevent pregnant patients from taking isotretinoin

Only registered and activated prescribers can prescribe isotretinoin, and only registered and enrolled pharmacies can dispense isotretinoin. In order to receive isotretinoin, all patients must be enrolled in the iPLEDGE REMS and agree to follow the requirements.
Your Role

This patient is being referred to you because the patient has asked for counseling to help the patient decide which contraceptive forms are best for this patient, and that will enable to comply with the contraception requirements of the iPLEDGE® REMS.

The patient must:

- Select and commit to using 2 forms of effective contraception simultaneously
- One form must be a primary form unless the patient commits to continuous abstinence from having any sexual contact (penis-vaginal) with a partner that could result in pregnancy
- Have undergone a hysterectomy or bilateral oophorectomy
- Have been medically confirmed to be post-menopausal

Isotretinoin is not recommended for patients who can become pregnant, who cannot commit to not having any sexual contact (penis-vaginal) with a partner that could result in pregnancy, whom you believe will not be able to maintain abstinence, or will not use contraception, as the program requires.

Please read this Contraception Counseling Guide completely before you begin your counseling session. This provides an overview of the counseling goals for the patient and the contraception requirements of the iPLEDGE REMS. It does not contain detailed information on the various forms of contraception.

The patient received an iPLEDGE REMS Guide for Patients who can get Pregnant which lists the approved primary and secondary forms of birth control required for the iPLEDGE REMS (www.ipledgeprogram.com).
# iPLEDGE REMS Approved Methods of Contraception

Choose 1 Primary + 1 Secondary Birth Control Form

<table>
<thead>
<tr>
<th>Primary Method of Birth Control (Choose One)*</th>
<th>How to Use it</th>
<th>How Well it Works</th>
<th>Benefits†</th>
<th>Risks†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hormonal Implant</td>
<td>Placed under the skin of the arm by a clinician. Works for 3 years.¹</td>
<td>&gt;99%¹</td>
<td>• Nothing to do or remember</td>
<td>Irregular Periods</td>
</tr>
<tr>
<td>Hormonal IUD</td>
<td>Placed in the uterus by the clinician. Self-check monthly. Works for 5 years.¹</td>
<td>&gt;99%¹</td>
<td>• Light or no periods</td>
<td>Irregular Periods</td>
</tr>
<tr>
<td>Non-Hormonal IUD</td>
<td>Placed in the uterus by a clinician. Self-check monthly. Works for 10 years.³</td>
<td>&gt;99%³</td>
<td>• No hormones</td>
<td>May cause heavier periods and cramping</td>
</tr>
<tr>
<td>Tubal Sterilization</td>
<td>A surgical procedure to close the tubes between the uterus and the ovaries.</td>
<td>&gt;99%²</td>
<td>• It is a virtually permanent method of birth control</td>
<td>If you want to have a child later, it is very difficult to re-open the tubes</td>
</tr>
<tr>
<td>Male Vasectomy</td>
<td>A surgical procedure that closes off the tubes that carry a partner's sperm.</td>
<td>&gt;99%²</td>
<td>• It is a virtually permanent method of birth control</td>
<td>If you want to have a child later, it is very difficult to re-open the tubes</td>
</tr>
<tr>
<td>Hormonal Shot</td>
<td>Given every 3 months by a clinician.</td>
<td>&gt;97%¹</td>
<td>• Light or no periods</td>
<td>Irregular Periods</td>
</tr>
<tr>
<td>Vaginal Ring</td>
<td>You place it in the vagina. Replace monthly.</td>
<td>92%¹</td>
<td>• Lighter periods</td>
<td>Blood clots</td>
</tr>
<tr>
<td>Hormonal Patch</td>
<td>You place it on the skin. Replace weekly.</td>
<td>92%¹</td>
<td>• Lighter periods</td>
<td>Blood clots</td>
</tr>
<tr>
<td>Birth Control Pill (Combination Type)</td>
<td>Swallow at the same time daily.</td>
<td>92%¹</td>
<td>• Lighter periods</td>
<td>Blood clots</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Secondary Method of Birth Control (Choose One)</th>
<th>How to Use it</th>
<th>Benefits</th>
<th>Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Condoms (with or without spermicide)</td>
<td>Partner must be willing to use each and every time you have sex.</td>
<td>• Protects from STIs (Sexually Transmitted Infections) and HIV/AIDS</td>
<td>Allergic Reactions</td>
</tr>
<tr>
<td>Cervical Cap, Diaphragm (must be used with spermicide), Vaginal Sponge</td>
<td>Place in the vagina before you have sex.</td>
<td>• You are in control of its use</td>
<td>Allergic Reactions</td>
</tr>
</tbody>
</table>

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*Consult your doctor if you are considering choosing 2 primary forms of birth control rather than a primary and secondary form.


Reference ID: 4870238
Counseling Goals

Ensure That The Patient:

• Understands and commits fully to not becoming pregnant
• Commits to using 2 forms of contraception together simultaneously, consistently, and correctly. The patient must use 2 forms of effective contraception for at least 1 month prior to initiation of isotretinoin treatment, during isotretinoin treatment, and for 1 month after discontinuing isotretinoin treatment
• Chooses the forms of contraception that will work best for the patient and that the patient and the partner will actually use
• If, after counseling, the patient recognizes they will not be able to commit fully to the iPLEDGE® REMS contraception requirements, encourage the patient to not take isotretinoin and do not prescribe or if counseling, inform the prescriber
• Commits fully to abstinence, not having any sexual contact with a partner that could result in pregnancy. This commitment is required 24 hours a day, 7 days a week for 1 month before, during, and for 1 month after the patient stops taking isotretinoin
• Knows when to contact the prescriber for emergency contraception
• Understands the risk of having a child with significant birth defects from exposure to isotretinoin

Counseling Younger Teens

For younger teens, it is important to stress the following aspects of contraception for the iPLEDGE REMS during counseling:

• Why it is important to use 2 forms of birth control, 1 primary and 1 secondary, at all times. Younger teens may need more emphasis on this point to fully understand it and comply.
• Emergency contraception. Younger teens may need more explanation from you about the need to take immediate action if they have unprotected sexual contact with a partner that could result in pregnancy or if their contraception forms fail.
Contraception Requirements

Using 2 Forms of Contraception Provides More Protection

Use of 2 iPLEDGE REMS approved forms of contraception (at least 1 of which is a primary form) simultaneously substantially reduces the risk that a patient will become pregnant. In addition, it is not known if hormonal contraceptives are less effective when used with isotretinoin. Because of this possibility and the fact that all contraceptive forms are less than 100% effective, the iPLEDGE REMS requires the additional protection of a second form of contraception.

Selecting an Effective Primary Form of Contraception

The single most important decision in contraception for the iPLEDGE REMS is selecting a primary form that the patient can and will use as correctly as possible. Other important factors to consider in counseling the patient on selecting a primary form include side effects, contraindications, and the patient’s ability to use it correctly.

All of these factors influence compliance with the iPLEDGE REMS requirements to prevent pregnancy.

Hormonal Combination Oral Contraceptives as a Primary Form

For a patient who has indicated having difficulty taking oral contraceptives correctly, other contraception not requiring daily dosing may be a better choice. It is critical that such a patient choose a form other than daily oral contraceptive agents.
Selecting an Effective Secondary Form of Contraception

There are 2 forms of secondary contraception: barrier and others. Barrier forms include the diaphragm and cervical cap (both of which must be used with a spermicide) and the male latex condom (which can be used with or without a spermicide). The other form is the vaginal sponge, which contains a spermicide. The most important issue for a secondary form is that it is used correctly each time the patient has sexual contact (penis-vaginal) with a partner that could result in pregnancy and that it be in place should the primary form fail.

Help the patient select a secondary form that the patient can fully commit to using correctly each time they have any sexual contact (penis-vaginal) with a partner that could result in pregnancy.

Unacceptable Forms of Contraception

The following forms of contraception are not acceptable for the iPLEDGE REMS:

- Progesterone-only “mini-pills”
- Female condoms
- Natural family planning (rhythm method or fertility awareness)
- Breastfeeding
- Withdrawal
- Cervical shield, a silicone disc with a one-way air valve that creates suction to adhere to the cervix*

Patients currently using these unacceptable forms of contraception must switch to the iPLEDGE REMS approved forms of contraception.

*A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception.
Emergency Contraception

The patient should also realize that emergency contraception should not be used on a regular basis as a replacement for the other contraceptive forms selected.

Abstinence

For this program, all patients who can become pregnant must fully commit to pregnancy prevention.

Isotretinoin is not recommended for any patient who can become pregnant who cannot or will not follow the contraceptive requirements of the iPLEDGE® REMS. Abstinence (committing to not having any sexual contact with a partner that could result in pregnancy) may be appropriate when it is a lifestyle choice, such as religious practice, and not just a social circumstance, such as not having a current partner. If, after counseling, a patient who has sexual contact chooses abstinence, the patient must understand that the patient has committed to not having any sexual contact with a partner that could result in pregnancy 24 hours a day, 7 days a week for 1 month before, during, and for 1 month after the patient stops taking isotretinoin.

One of the most common reasons that patients become pregnant is that they engage in having sexual activity contact with a partner that could result in pregnancy when they planned to be abstinent.
About The Referral Form

The Contraception Referral form, brought in to you by this patient, has been filled out in part by the prescriber. Please fill out the rest of the form at the conclusion of your counseling session and fax or mail the copy back to the prescriber, keeping a copy for your own records.

Reimbursement Form

Also, in the back pocket is a reimbursement form for contraceptive counseling services. The iPLEDGE® REMS provides reimbursement for 1 contraception counseling session for patients who have been prescribed isotretinoin. Please complete the form and fax it to 1-866-495-0660.

Reporting a Pregnancy

If you become aware of a pregnancy in a patient taking isotretinoin, please report the pregnancy to the iPLEDGE REMS by calling 1-866-495-0654 and choosing the option to “Report a Pregnancy.”

Please remind any patient who is pregnant to contact the doctor/prescriber who prescribed the isotretinoin.

REFERENCES

Isotretinoin Contraception Counseling Referral Form

Prescriber: Please complete the top of this form which should be taken to the contraception counselor by the patient or sent in advance for patients being referred for contraception counseling.

Patient ____________________________, iPLEDGE® REMS ID# ____________________________
is considering treatment with isotretinoin. I am referring the patient for counseling to help choose the 2 forms of contraception before receiving the first prescription.

The patient had a negative (serum/urine) pregnancy test on__________________________________________________________

Isotretinoin Prescriber's Name______________________________________________________________
Address____________________________________________________________________________________
Telephone__________________________________________ Fax______________________________

Isotretinoin Prescriber's Signature_________________________________________________ Date________________

Record of Contraception Counseling

Contraception Counselor:

• Please review the Contraception Counseling Guide (www.ipledgeprogram.com/#/main/resources) for details on the iPLEDGE Program contraception requirements
• Complete this form and fax or mail back to isotretinoin prescriber
• Once form is completed, please copy this completed form and provide to the patient

I have provided the following for your patient:

☐ Comprehensive contraception counseling
☐ Information about emergency contraception

The patient has:

☐ Chosen 2 forms of contraception
☐ Committed to abstain from any sexual contact (penis-vaginal) with a partner who could get the patient pregnant and is not planning to use 2 forms of contraception. I informed the patient that is not recommended for the patients who have had sexual contact (penis-vaginal) with a partner who could get the patient pregnant.
☐ The patient has not yet decided upon the forms of contraception to be used.

Primary Form__________________________________________________________
Secondary or Second Primary Form__________________________________________

I have prescribed the selected contraception.

☐ Yes ☐ No (Please comment below)

I have counseled the patient and patient agrees to complying with the contraceptive requirements of the iPLEDGE REMS.

☐ Yes ☐ No (Please comment below)

__________________________________________________________
Name__________________________________________________________
Address____________________________________________________________________________________
Telephone____________________________________________________________________________________

Specialty (circle one): OB-GYN  Fam Prac  IM Contraception  RN  LPN  Other________________________

Counselor's Signature_________________________________________________ Date________________

Once Form is Completed, Please Copy this Completed Form and Provide to the Patient

Please see accompanying complete product information, including boxed
CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, AND ADVERSE REACTIONS
**FAXABLE REIMBURSEMENT FORM**

The Following Restrictions Apply:

Only consulting clinicians who provide initial pregnancy prevention counseling are eligible for reimbursement for such counseling. Other services provided during this visit are eligible for reimbursement. The physician prescribing isotretinoin, or any other person working under the direct supervision of said physician, is not eligible for this reimbursement provision. The reimbursement fee is up to $150.00, which has been determined to be an average, usual, and customary reimbursement for service of this type. Information will be used only for reimbursement; the isotretinoin manufacturers will not use it for any other purpose.

**Reimbursement For Pregnancy Prevention Counseling**

To receive reimbursement for providing pregnancy prevention counseling to an isotretinoin patients, please answer the following questions, and sign, date, and send the completed form via fax to: **1-866-495-0660**.

Contraception Counselor Name: ________________________________

Payee Name (if different than Contraceptive Counselor): ________________________________

Office Telephone Number: __________ - __________ - ______________  Tax ID Number: ________________________________

Payee Address: ____________________________________________

City: ____________________________  State: _________  ZIP: __________

Name of Referring Physician: ________________________________

Office Telephone Number: __________ - __________ - ______________

City: ____________________________  State: _________  ZIP: __________

Patient’s Name: ________________________________

Patient’s iPLEDGE REMS ID Number: ________________________________

☐ I have provided pregnancy counseling to this patient. I have mailed or faxed the record of pregnancy prevention counseling to the isotretinoin prescriber.

☐ I am not the prescribing physician of isotretinoin to the patient referenced above, nor am I employed by said prescribing physician.

☐ I have not, and will not, bill or submit for reimbursement either directly or indirectly, under Medicaid, Medicare, or similar federal or state healthcare programs, or under any private insurance, HMO, or other healthcare benefit program for the pregnancy prevention counseling services described above.

☐ I attest that all of the above information is accurate and understand that I must check each box above to receive reimbursement.

☐ I have included a signed W-9 Form, or already have a W-9 form on file for payment from iPLEDGE. A blank W-9 form and instructions for completion can be found at www.irs.gov

Signature: ____________________________  Date: ____________________________

Please see accompanying complete product information, including boxed CONTRAINDICATIONS AND WARNINGS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS, AND ADVERSE REACTIONS.

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