

**iPLEDGE PROGRAM  
FREQUENTLY ASKED QUESTIONS  
As of October 6, 2006**

**A. TECHNICAL ASSISTANCE**

**B. PRESCRIBER**

**C. PHARMACY**

**D. ALL USERS**

**E. PATIENT**

## A. TECHNICAL

### **What are the steps for first-time login to iPLEDGE?**

*Once registered, you will receive your username and password in the mail. Upon first login to iPLEDGE you will be asked to select a personal 4-digit numeric password and select a date of personal significance. The selection of a personal password is a security feature that ensures password confidentiality. A date of personal significance is collected by the system as confidential data that will be asked of you for identity authentication purposes should you require assistance from a Call Center operator during your participation in the iPLEDGE program. The date of personal significance can be any memorable date such as an anniversary date.*

*If you are logging into iPLEDGE via phone or web for the first time you will enter your Username and Password from the user form that was mailed to you [Please see “**How can I login using my telephone?**” or “**How can I login using the web?**”]. Immediately after you have successfully logged in the system will ask you to select your personal password. You will be asked to enter the old (original) password from your user form and then you will enter a new 4-digit number of your choice. You will use the new password you have just chosen to login again in the future. To continue, you will be asked for your new password, then you will be asked to enter your date of personal significance twice. If you are using the telephone system you will enter the date in a mmddyyyy format. If you are using the iPLEDGE website you will enter the date in a mm/dd/yyyy format using the forward slash key. Upon successful entry of the date of personal significance the system will proceed to your main menu of options and you may begin performing functions in the iPLEDGE system.*

### **How can I login using the web? How do I handle Internet browser issues?**

*To use the iPLEDGE web functionalities it is required that you use Internet Explorer 6.0 or greater. If you do not have this Internet browser, you can download it at [www.microsoft.com](http://www.microsoft.com). To login to iPLEDGE go to [www.ipledgeprogram.com](http://www.ipledgeprogram.com) and locate the Login section in the middle of the screen. Type your username and password into the appropriate boxes. For example, if your username is ABC123, type exactly ABC123 in the Username box. If your password is 1234, type 1234 in the Password box. Please note that your password will always be a four digit numeric code. Click on the green “Login” button and your homepage with all appropriate functions will appear.*

*If you are experiencing browser issues, your browser (i.e. Mozilla Firefox) may be blocking the iPLEDGE site, or parts of the iPLEDGE site. You can resolve this by 1) Disabling the pop-up blocker completely every time you need to use the site, or 2) adding [www.ipledgeprogram.com](http://www.ipledgeprogram.com) into your browser’s list of allowed sites. If this does not resolve the issue, it is recommended that you use Internet Explorer 6.0.*

### **What should I do if I become locked out of iPLEDGE?**

*If you make three unsuccessful attempts to login to iPLEDGE, a security feature that locks your account is deployed. Your account will automatically unlock after 30 minutes or you can speak with an iPLEDGE customer service representative to have it unlocked. Call the iPLEDGE Program at 1-866-495-0654 (press 1, #0, 1, \*) to speak to a representative for assistance with passwords and lockouts.*

### **How can I login using my telephone?**

*To login using the telephone, dial 1-866-495-0654 and when you hear the main menu press 1 to login. The system first asks for your iPLEDGE user ID followed by the pound sign. Enter each digit of your user ID/username followed by the \* key on your telephone touchpad. Then press the # key at the end of your username. Refer to the table below.*

To Enter	Press	To Enter	Press	To Enter	Press	To Enter	Press
2	2*	A	22*	J	55*	S	7777*
3	3*	B	222*	K	555*	T	88*
4	4*	C	2222*	L	5555*	U	888*
5	5*	D	33*	M	66*	V	8888*
6	6*	E	333*	N	666*	W	99*
7	7*	F	3333*	O	6666*	X	999*
8	8*	G	44*	P	77*	Y	9999*
9	9*	H	444*	Q	777*	Z	99999*
0	0*	I	4444*	R	7777*	1	1*

*For example, if your username is 12345, type 1\*2\*3\*4\*5\*# on your telephone touchpad. If your username is alpha-numeric, for example BK12345, you would enter 222\*555\*1\*2\*3\*4\*5\*#. The system then asks for your iPLEDGE password. Enter your 4-digit numeric password. For example, if your password is 1234, simply enter 1234 (no \* or # this time). The system will confirm your successful login and will read your menu of options in the iPLEDGE system.*

**How are iPLEDGE patient numbers assigned?**

*Once a Prescriber performs the “Activation” step in iPLEDGE, a shipment of patient educational kits is sent to the Prescriber’s address via UPS. The shipment includes two yellow kits (binders) for female patients of childbearing potential and two green kits (binders) for male patients or female patients who cannot get pregnant. Inside each kit is a tab labeled “Patient Identification Card”. In this section you will find a patient ID card attached, which can be peeled off and given to the patient along with the kit. In the upper right corner of the card appears a 10-digit patient number, which is the patient ID number you will enter when registering the patient. For each new patient you must have a new patient educational kit available to assign to the patient.*

**How can I order additional program materials?**

*To order additional program materials prescribers must first login to iPLEDGE via telephone or web. If you are accessing the system by telephone you must login and then choose option 4, “To hear options on requesting program information.” The system will guide you through the ordering options. If you are accessing the system by web you must login and then click on “Order Materials” from the options listed down the left side of the screen. The system will display the options so you can place your order. The materials you order should be delivered to you within 7 to 10 business days from the order date.*

**Why is the “Confirm Counseling” button not available for my patient on the web?**

*There are several reasons why the “Confirm Counseling” button is not available for a patient.*

- 1. The patient is a Female of Childbearing Potential and was registered in the last 30 days. See “Please show the iPLEDGE program requirements with respect to days: 30-days, 23-days, and 7-days”.*
- 2. The patient is a Female of Childbearing Potential who must wait 23 days after the end of her 7-day window to start the qualification process for another prescription.*
- 3. The patient is still in their 7-day window.*
- 4. The patient’s program status is one of the following*
  - a. Lost To Follow Up*
  - b. Confirmed Positive*
  - c. Reported Positive*
  - d. Inactive*

*If your patient is not eligible for the next monthly visit according to the program timelines, the “Confirm Counseling” activity cannot be performed for that patient and the button will be grayed out. Once the appropriate number of days elapses from the previous counseling date, the system will allow you to enter the next counseling date.*

## **B. PRESCRIBERS**

### **Please explain the registration process.**

*Registration and activation is a two-step process.*

*Registration - Prescribers may obtain a registration form on-line from the website's homepage or by calling 1-866-495-0654 (press 1, #0, 1, 4), and requesting to have a pre-filled registration form faxed to the office. They are instructed to complete and fax the signed form to the iPLEDGE program 1-866-495-0660. If a prescriber fills out the application form on-line they will still need to print it and fax or mail the signed form to iPLEDGE. The program requires a signed registration form received by iPLEDGE for each prescriber who requests to enroll in the program.*

*Mailing 1 - Once registered, the prescriber will receive a mailing which includes the prescriber's iPLEDGE Program username (which is your DEA# or a system generated number), the prescriber's iPLEDGE password, instructions for prescriber activation, instructions for office designee registration, the prescriber guide, among other iPLEDGE Program related-materials.*

*Activation - You will need your username and password to activate. You may activate via either the web site, [www.ipledgeprogram.com](http://www.ipledgeprogram.com), or automated phone system, 1-866-495-0654. For ease of use, it is recommended that you activate on the website. The system will present a list of attestation points that you must agree to in order to complete your activation. This is a quick procedure that the prescriber must perform. The activation expires in one year from the date of activation. A prescriber only needs to activate once a year, however, the green activation button is always available. There is no need to register every year.*

*Mailing 2 - Once activated, the prescriber will receive a second mailing, which includes four patient's kits. Two kits are for females who can get pregnant and two kits are for males and females who cannot get pregnant. If the prescriber requires additional patient kits you may order these via the web site at [www.ipledgeprogram.com](http://www.ipledgeprogram.com) or automated phone system, 1-866-495-0654.*

### **Do I need to activate my registration annually?**

*Yes. You must re-activate your registration annually or the system will revert your status back to a "Registered" status once your current activation expires. Prescribers must maintain a status of "Attested" to perform all necessary requirements of the iPLEDGE Program. You can re-activate at any time. Please see your program status page to review your current status and to obtain your expiration date.*

### **What are the steps to re-activate my registration?**

*You can re-activate at any time using one of the following methods:*

*Website - To re-activate through the website, log into your account. Once you have logged in, you may select the green "Activate" button or select the Prescriber/Pharmacy Activation tab located on the top left side of your homepage. You are then required to read the list of statements that appear on the screen. After you have read the statements, you must attest to the statements.*

*IVRS - Automated Phone System - To re-activate through the IVRS automated phone system, log into your account. Once you have logged in, listen to the menu choices and select the prompt to activate. The system will read the attestation/activation statements then request you attest by selecting the correct menu choice on your phone keypad.*

## **What is the difference between a Delegate and a Designee?**

Delegate – another physician/prescriber

*A prescriber can delegate another registered and activated iPLEDGE prescriber to cover for him/her during a scheduled absence (travel, vacation, etc.). This also can be used to delegate to another registered and activated prescriber in a multiple doctor practice where a patient may see any of the doctors in the office. Delegate status has an expiration date that can be set by the delegating prescriber.*

Designee – an office staff designee, a staff member in the prescriber's office

*After the prescriber has registered and activated with iPLEDGE the office staff associated with the prescriber will be able to register as well. Each office staff designee will receive his/her own username and password. A prescriber may have one or more designated office staff. Prescribers must designate office staff separately. A registered designee may perform all patient functions on behalf of the prescriber. An office designee may support all the registered prescribers in a multi-physician practice and will also have rights for any patient delegated to a delegate prescriber. Each office staff designee will only need to register once, even if they support several prescribers. Also, if a prescriber is not activated in the iPLEDGE system, neither the prescriber nor the designated office staff can register a patient. The prescriber is responsible for any actions of all designees under him/her.*

## **How does an Office Staff Designee register and become affiliated to a Prescriber?**

*Registration and affiliation is a two-step process.*

Registration - *To register an Office Staff Designee, the **Prescriber** must login to the iPLEDGE website and click on "Register New Designee" from the options listed down the left side of the screen. The **Prescriber** must then complete the fields on the registration form, click on "Save and Print" at the bottom of the page, and sign the printout. The signed form must then be faxed to the number that appears on the form. (Please note that iPLEDGE will no longer accept hand-written forms created using the blank forms that were provided in the program binders). Upon processing of the signed form, the Designee's Username and Password is sent via US Mail. Each designee should be registered only **ONCE** in the iPLEDGE system no matter how many prescribers he or she supports.*

Affiliation - *Upon receipt of the Username and Password, the Designee must arrange with the Prescriber to affiliate the Designee to the Prescriber. To do this the Prescriber must login to the iPLEDGE website and click on "Manage Designees" from the options listed down the left side of the screen. The Prescriber must then enter the Designee's username into the Designee Username box and click on the "Add" button. The Designee's name will then appear on the "Your Designees" list and the Designee may begin to perform functions on behalf of the Prescriber. If the office does not have access to the iPLEDGE website, the prescriber can call 1-866-495-0654 (press 1, #0, 1, 4), to be assisted with Designee registration.*

## **Please explain the elimination of the 23-day lockout requirement for Males and Females of Non Childbearing Potential (FNCP).**

*Effective immediately, the 23-day lockout period for Males and FNCP has been eliminated. Previously, whether a prescription was filled or not, a patient could not start the qualification process for another prescription until 23 days after the end of their 7-day window. While the prescribing procedures and qualification criteria for isotretinoin will remain the same for **all patients**, the elimination of the 23-day lockout period will allow Males and FNCP the ability to re-qualify and have a new prescription filled immediately after the initial 7-day window has expired. A **new prescription** is required and both the patient and the prescriber must complete the qualification process again to ensure that all qualification criteria, including patient counseling have been met and confirmed in the iPLEDGE system.*

**Does the elimination of the 23-day lockout requirement apply to Females of Childbearing Potential?**

*No. The 23-day lockout period remains in effect for Females of Childbearing Potential. However, a change to this aspect of iPLEDGE is under development and will be rolled out next year. The call center **cannot** authorize exceptions to the lockout period.*

**How do I confirm a Male or Female of Non Childbearing Potential (FNCBP) patient after their 7-day window expires?**

*Prescribers must provide a new prescription and complete the qualification process again to ensure the patient has met all qualification criteria, including confirming patient counseling in the iPLEDGE system. System instructions are detailed below.*

To re-confirm a *Male or Female of Non Childbearing Potential* patient after their 7-day window has expired, please do the following

- Go to the **Manage Patient** screen
- Select the patient in the **Manage Patient** screen
- Then, select the **Confirm Patient Counseling** button
- Follow the prompts.

**The qualification process can start immediately after a patient’s 7-day window has expired.**

**A new prescription must be provided to the patient.**

**Note that if the Confirm Patient Counseling is grayed out – it indicates that the patient (males and FNCBP only) is still within the 7-day window.**

**How does the elimination of the 23-day lockout for Males and Females of Non-Childbearing Potential affect pharmacy requirements to obtain prescription authorizations?**

*This change has no affect on pharmacy requirements. Pharmacists must continue to authorize every isotretinoin prescription using the iPLEDGE system.*

**Please show the iPLEDGE program requirements with respect to days: 30-days, 23-days, and 7-days.**

**Female of Child Bearing Potential (FCBP)**

***Initial 30 Days***

*Day 1 = Patient Registration and entry of screening pregnancy result. Screening pregnancy test can occur up to 30 days prior to patient registration. Screening pregnancy test may be conducted in the prescriber’s office.*

*30 Days – Patient must be on two forms of contraception for 30 days after patient registration.*

***First Month***

*As early as Day 31 = Once the patient has been on contraception for 30 days, the patient is eligible for the office visit and the prescriber has the ability to confirm counseling.*

***Day 1***

- *The Confirmation Counseling Date. (The counseling is done on this office visit.) This date starts the 7-day window. You can backdate this date, however, the system only will take dates after the previous 30-day waiting period has ended.*

***Days 1 to 7***

- *The second pregnancy test must occur within 7 days after counseling and during the first 5 days of the patient's menstrual cycle. This, and all subsequent monthly pregnancy tests, must be conducted at a CLIA certified laboratory.*
- *The patient must answer questions in the system to demonstrate her comprehension of the iPLEDGE requirements.*
- *The prescriber must enter the pregnancy results. The pregnancy results can be entered on the "Enter Pregnancy Test Results" screen.*
- *The patient can fill the prescription if all program requirements are met.*

*Days 8 to 30*

- *The 23- day waiting period (whether a patient filled the prescription or not).*

### ***Each Subsequent Month (Through End of Therapy)***

*As early as Day 31, Resets to Day 1*

*Day 1*

- *The Confirmation Counseling Date. (The counseling is done on this office visit.) This date starts the next 7-day window. You can backdate this date, however, the system only will take dates after the previous 23-day waiting period has ended. If you backdate, please do so within the 7-day window. See "Can I backdate?"*

*Days 1 to 7*

- *The next pregnancy test must occur within 7 days after counseling.*
- *The patient must answer questions in the system to demonstrate her comprehension of the iPLEDGE requirements.*
- *The prescriber must enter the pregnancy results.*
- *The patient can fill the prescription if all program requirements are met.*

*Days 8 to 30*

- *The 23- day waiting period (whether a patient filled the prescription or not).*

### ***After Therapy***

*Continue using two forms of contraception for 30 days after therapy*

*Immediately (Day 1 or 2)*

- *The follow up pregnancy test must occur.*

*Day 30*

- *The final pregnancy test must occur 30 days post therapy.*
- *The patient should not donate blood until she has been off isotretinoin therapy for at least 30 days.*

### ***Females of Non-Childbearing Potential (FNCP) and MALES***

#### ***Initial 30 Days***

*Day 1 = Patient Registration, eligible for the office visit and the prescriber has the ability to confirm counseling. There is no 30-day waiting period requirement.*

*Day 1*

- *The Confirmation Counseling Date. This date starts the 7-day window. You can backdate this date, however, the system only will take dates on or after the date of registration. If you backdate, please do so within the 7-day window. See "Can I backdate?"*

*Days 1 to 7*

- *The patient can fill the prescription.*

*Day 8 to 30*

- *The patient's 7-day window is closed. There is no 23-day waiting period. The patient can re-qualify and have a new prescription filled immediately after the 7-day window has expired. A new*



*prescription is required and both the patient and the prescriber must complete the qualification process again to ensure that all qualification criteria, including patient counseling have been met and confirmed in the iPLEDGE system.*

### **Each Subsequent Month (Through End of Therapy)**

#### **Day 1**

- *The Confirmation Counseling Date. This date starts the next 7-day window.*
- *Days 1 to 7*
- *The patient can fill the prescription.*

#### **Days 8 to 30**

- *The patient's 7-day window is closed. There is no 23-day waiting period. The patient can re-qualify and have a new prescription filled immediately after the 7-day window has expired. A new prescription is required and both the patient and the prescriber must complete the qualification process again to ensure that all qualification criteria, including patient counseling have been met and confirmed in the iPLEDGE system.*

### **After Therapy**

*The patient should not donate blood until he or she has been off isotretinoin therapy for at least 30 days. Please remember to discontinue a patient that has completed therapy. See "Why do I need to discontinue a patient?"*

### **Can I backdate?**

*Yes, you may backdate a counseling date or pregnancy test specimen collection date. For male patients and female patients of non-childbearing potential, the counseling date must be on or after the patient's date of registration. For female patients of childbearing potential, the counseling date must be after the 30-day waiting period (for the first month) or after the 23-day waiting period (for subsequent months). Additionally, the counseling date will be day 1 of the 7-day window. If a counseling date of more than 7 days in the past is entered, the patient will not be able to fill the prescription, as the 7-day window will have already passed. The pregnancy test specimen collection date must be on or after day 1 of the 7-day window to be considered as the mandatory monthly pregnancy test for an FCBP patient.*

*FCBP example (correct backdating):*

*An office visit occurred on March 1. The next office visit occurred on March 31. Data can be entered on April 1 for the visit that occurred on March 31, but not for a visit that occurred on March 30 (because this is inside the 30 day wait period).*

### **How does a patient become Lost to Follow Up?**

*Patients become lost to follow up due to the following conditions:*

- *Patient has been in a "Registered" status for greater than 90 days and the prescriber/designee has not interacted with the patient's record*
- *Patient has been in a "Requires Confirmation" status for greater than 53 days and the prescriber/designee has not interacted with the patient's record*
- *FCBPs who are missing their pregnancy test at date of last dose*
- *FCBPs who are missing their final pregnancy test 30 days post treatment*

### **What should I do with patients with a Lost to Follow Up status?**

*Determine if the patient needs to be **discontinued** or **re-registered**. The patient needs to be discontinued if the patient has completed treatment, has not returned for treatment, has become pregnant, terminated treatment, etc. To discontinue a patient, see "What are the steps to discontinue a patient?" To re-register a patient that needs to resume or continue treatment contact the call center.*

### **Why do I need to discontinue a patient?**

*It is critical to discontinue the patient to accurately reflect the patient's iPLEDGE status. It is also critical to obtain the post-discontinuation pregnancy tests per the program requirements (pregnancy test at date of last dose and pregnancy test 30 days post treatment). Discontinuing the patients (additionally for FCBPs, documenting the necessary post treatment pregnancy tests) will avert phone calls from the iPLEDGE Program to your office inquiring about the patient's status.*

### **When should I discontinue a patient?**

*Patients should be discontinued when the following occurs:*

- *Patient completes treatment and is no longer taking the medication*
- *Patient was never confirmed and did not receive a prescription from your office*
- *Patient rescinded consent to participate*

*Please note that when a FCBP is discontinued, they must have a pregnancy test at date of last dose and a pregnancy test 30 days post treatment.*

*Please see "What are the steps to discontinue a Patient?"*

### **What are the steps to discontinue a Patient?**

*Directions for discontinuing patients that are Lost to Follow Up are as follows:*

1. *Log on to [www.ipledgeprogram.com](http://www.ipledgeprogram.com) and go to the "manage patients" screen.*
2. *Select the appropriate patient from the patient list by highlighting his/her name. (You can search for LTFU patients by "clicking" on the status tab).*
3. *Enter any new pregnancy test results. (If not available, proceed; pregnancy test results may be entered while the patient is in "Inactive" status)*
4. *Select the option to "discontinue patient" towards the bottom of the screen.*
5. *Choose the reason for discontinuation. If you choose "other" you must enter a brief comment explaining the reason for discontinuation.*
6. *Once you have entered the reason for discontinuation, select "discontinue patient". You will then be prompted to enter "Date of Last Dose". Please enter the date of last dose (the day the patient last took medication and NOT the date of last prescription) in MMDDYYYY format.*
7. *Choose "discontinue patient" and you will notice that the patient's status has been changed to inactive.*
8. *It is critical that you enter the patient's pregnancy test results if the results have not been entered and make every attempt to have the patient take the pregnancy test for Date of Last Dose and 30 days post treatment.*

### **I have a patient who is in Lost to Follow Up status. How can I get this patient back on therapy?**

*To resume a patient's active status, you need to speak with an iPLEDGE representative for technical support. Call 866/495-0654 (press 1, #0, 1, 2) to begin this process. You should not make any changes in the system with this patient until instructed to do so by the technical support agent. When calling, please have all pregnancy test results available for Female Patients of Child Bearing Potential (FCBP).*

### **What happens if a patient loses his or her iPLEDGE ID card?**

*A patient should record his or her iPLEDGE User ID number for future reference. If the patient loses his or her iPLEDGE ID card and/or number, he or she should contact the prescriber for the number. Call center agents cannot provide patient ID numbers over the phone to patients, but can provide this information to the prescriber. The patient can take his or her ID number and date of birth to the pharmacy for a prescription fill. Pharmacists do not need to see a patient's actual ID card to fill a prescription.*

**Do males or females of non-child bearing potential have to wait 30 days to start isotretinoin, answer questions each month, and use contraception for the iPLEDGE program?**

*No, once the male or female of non-childbearing potential patient is registered, the prescriber can start the 7-day window by going to the “manage patients” screen and confirming patient counseling. Males and females of non-childbearing potential do not have to answer questions each month in the iPLEDGE system; only females of child bearing potential need to do so. Males and females of non-childbearing potential do not need to use contraception to qualify for the iPLEDGE program.*

**Can pregnancy tests be conducted prior to the prescriber office visit?**

*No, the pregnancy test cannot be done prior to the prescriber office visit. For female patients of childbearing potential, the initial screening pregnancy test (1<sup>st</sup> test) must be conducted on the date of registration or no more than 30 days prior to patient registration. For ongoing monthly pregnancy tests, the specimen must be collected in a CLIA certified laboratory and the results must be entered on or within 7 days after the office visit. (see Package Insert for timing requirements).*

**Does a female of non-child bearing potential need to take pregnancy tests?**

*No, only females of child bearing potential need to take pregnancy tests and answer monthly questions.*

**How long does the patient need to wait between monthly pregnancy tests?**

*The patient can take their next pregnancy test 23 days after the end of her last 7-day window and within 7-days after the next office visit (after the prescriber has confirmed them in the system).*

**Does a female of childbearing potential need to be on birth control or another form of contraception if she chooses abstinence? Or, is abstinence an acceptable option for iPLEDGE?**

*The program requirement for an FCBP is to be on two effective forms of birth control unless you choose to be abstinent. A patient choosing abstinence does not need to choose another form of birth control, however, a secondary choice of “none” must still be entered if abstinence is listed as the primary form. Abstinence means an FCBP will not have sex or sexual contact with any male 24 hours a day, 7 days a week. This could be hard to do especially if the patient is used to having sex. It is easier not to have sex when it is a lifestyle choice, such as a religious practice. One of the most common causes of unplanned pregnancy is not being able to avoid sex (failing to maintain abstinence). Abstinence is not a recommended way to prevent pregnancy for the iPLEDGE Program.*

**What are acceptable primary forms of birth control?**

*FCBP patients must use two forms of effective birth control together correctly all the time (of which one must be a Primary form):*

- *For at least one month before starting isotretinoin*
- *While taking isotretinoin – treatment usually lasts four to five months*
- *For one month after the last dose of isotretinoin – for continued protection against pregnancy*

*Effective forms of contraception include both primary and secondary forms of contraception:*

<b>Primary Forms</b>	<b>Secondary Forms</b>
<ul style="list-style-type: none"> <li>• <i>Tying my tubes (tubal sterilization)</i></li> <li>• <i>Partner’s vasectomy</i></li> <li>• <i>Intrauterine device</i></li> <li>• <i>Hormonal (combination birth control pills, skin patches, shots, under-the-skin implants, or vaginal ring)</i></li> </ul>	<p><i>Barrier forms (always used with spermicide):</i></p> <ul style="list-style-type: none"> <li>• <i>Male latex condom</i></li> <li>• <i>Diaphragm</i></li> <li>• <i>Cervical cap</i></li> </ul> <p><i>Others:</i></p> <ul style="list-style-type: none"> <li>• <i>Vaginal sponge (contains spermicide)</i></li> </ul>

**What forms of birth control are NOT acceptable for the iPLEDGE Program?**

*You cannot use the following forms of birth control while you are taking isotretinoin. They do not give enough protection even when used with a second form of birth control.*

- Birth control pills without estrogen (progesterone-only mini-pills)
- IUD Progesterone T
- Female condoms
- Natural family planning (rhythm method) or breastfeeding
- Fertility awareness
- Withdrawal
- Cervical shield

**What if the primary forms of contraception are contraindicated for the patient?**

*The patient should discuss this issue with her gynecologist.*

**Please explain the data entry requirements for contraception.**

*The primary method of contraception entered into the system by the prescriber and patient must match each month. Advise patients that if they have incorrectly entered their contraceptive method and they receive a message, from the system, “to contact their prescriber,” the patient can go back into the system and re-enter the correct information regarding their contraceptive method.*

**How many attempts do patients have to demonstrate comprehension?**

*If an FCBP answers her questions incorrectly, she will be given an opportunity to answer another question on the same topic. If she gets this wrong, she will be directed to review the appropriate educational materials. She can, at a later time, login again and attempt to answer the questions correctly.*

**The patient just filled their isotretinoin prescription, how much time do we need to wait before the patient fills their next prescription.**

*Patients can fill their next prescription 30 days from the recorded counseling date / office visit date.*

**Does a new FCBP patient starting on isotretinoin need to wait 30 days to start the medication if she is already taking birth control?**

*Yes. The 30-day waiting period is required of all FCBPs taking isotretinoin. There are no exceptions.*

**How do I enter the pregnancy test results using Serum test versus urine tests?**

*Serum test results must be entered using the specific lab value. The iPLEDGE system will not accept a range as the value, nor will it accept a negative value. We recommend contacting the CLIA certified lab to obtain the specific lab value. Urine test results must be entered as positive or negative.*

**I do not understand why when I enter the patient’s pregnancy test results, the system generates a message that says “this patient’s status has not changed?”**

*You can always enter pregnancy test results in the iPLEDGE system. This is to allow reporting of a pregnancy at any time. However, to qualify for a prescription, the patient must have a pregnancy test conducted and the result is entered on or within 7 days after the office visit. The patient’s status will not change if the patient is waiting the initial 30 days to start treatment or the 23 days between 7-day windows.*

**May I fax or phone in prescriptions to the pharmacy?**

*Yes, prescribers may fax or phone in isotretinoin prescriptions to the pharmacy.*

**Where do I find a list of local pharmacies that participate with the iPLEDGE program?**

*Registered patients can obtain a list of pharmacies using the “Find A Participating Pharmacy” feature after they login to the website. At this time it is only accessible under the patient section of the system.*

**How do I manage low-dose maintenance therapy for patients?**

*All patients receiving isotretinoin, regardless of the dose prescribed, are required to have monthly office visits and new prescriptions written. No refills are permitted. For FCBP, monthly pregnancy tests must be conducted throughout treatment regardless of dose or duration. There are no exceptions. All patients receiving isotretinoin therapy must adhere to the requirements of the iPLEDGE program.*

**Who needs to answer patient monthly comprehension questions?**

*Female patients of childbearing potential must answer education questions to demonstrate their comprehension on a monthly basis by logging into the system (either by calling the automated telephone system at 1-866-495-0654 or accessing the website at [www.ipledgeprogram.com](http://www.ipledgeprogram.com)). Males and female patients of non-childbearing potential (FNCP) do not need to answer the monthly comprehension questions.*

**Can I download consent forms from [www.ipledgeprogram.com](http://www.ipledgeprogram.com)?**

*At this time, downloading consent forms from the web is not an option. Consent forms are included in the patient education materials along with their User ID. Because the patient kit is important for the patient to have, consent forms and user IDs are not provided via [www.ipledgeprogram.com](http://www.ipledgeprogram.com).*

**What if my office is excluded from HIPAA requirements?**

*The Health Insurance Portability and Accountability Act (HIPAA) only applies to “covered entities” as defined under the act. Under HIPAA, covered entities are defined as three groups: health plans, health care providers and health care clearinghouses. Pharmaceutical manufacturers are not included in any of these groups, therefore, the manufacturers of isotretinoin are not covered entities under HIPAA and HIPAA does not apply to the iPLEDGE Program. Please note that this is separate and distinct from health care providers needing to be HIPAA compliant as it relates to their individual office practices. Prescribers can refer to a medical specialty society for support on becoming HIPAA compliant.*

## C. PHARMACY

### **Please explain the registration process.**

*Registration and activation is a two-step process.*

Registration – A pharmacy may obtain a registration form on-line from the website's homepage or by calling 1-866-495-0654 (press 1, #0, 1, 5), and requesting to have a blank registration form faxed to the pharmacy. They are instructed to complete and fax the signed form to the iPLEDGE program 1-866-495-0660. If a pharmacy fills out the application form on-line they will still need to print it and fax or mail the signed form to iPLEDGE. The program requires a signed registration form received by iPLEDGE for each pharmacy that requests to enroll in the program.

Mailing – Once registered, your pharmacy will receive a mailing that includes your pharmacy's iPLEDGE Program username (which is your Pharmacy's NCPDP#), your pharmacy's iPLEDGE password, and instructions for pharmacy activation, among other iPLEDGE program related-materials.

Activation – You will need your username and password to activate. You may activate via either the website, [www.ipledgeprogram.com](http://www.ipledgeprogram.com), or automated phone system, 1-866-495-0654. For ease of use, it is recommended that you activate on the web site. The system will present a list of attestation points that you must agree to in order to complete your activation. This is a quick procedure that the Responsible Site Pharmacist can perform. If a store activates today, they will be included in tomorrow's Eligible Pharmacy list provided to the Wholesalers. A pharmacy must activate in order to be able to authorize a prescription in iPLEDGE. The activation expires in one year from the date of activation. A pharmacy only needs to activate once a year, however, the green activation button is always available. There is no need to register every year.

### **Do I need to activate my registration annually?**

*Yes. You must re-activate your registration annually or the system will revert your status back to a "Registered" status once your current activation expires. Pharmacies must maintain a status of "Activated" to perform all necessary requirements of the iPLEDGE Program. You can re-activate at any time. Please see your program status page to review your current status and to obtain your expiration date.*

### **What are the steps to re-activate my registration?**

*You can re-activate at any time using one of the following methods:*

Website - To re-activate through the website, log into your account. Once you have logged in, you may select the green "Activate" button or select the Prescriber/Pharmacy Activation tab located on the top left side of your homepage. You are then required to read the list of statements that appear on the screen. After you have read the statements, you must attest to the statements.

IVRS - Automated Phone System - To re-activate through the IVRS automated phone system, log into your account. Once you have logged in, listen to the menu choices and select the prompt to activate. The system will read the attestation/activation statements then request you attest by selecting the correct menu choice on your phone keypad.

### **How do I access the system if my password failed?**

*If the Responsible Site Pharmacist (RSP) knows his/her iPLEDGE username (NCPDP#) and date of personal significance, he/she can call the iPLEDGE Program at 1-866-495-0654 for assistance. The customer service representative will be able to reset the password and provide the new password via phone. This is a four digit temporary password. Immediately after you successfully login, the system will prompt you to change your password.*

*If the RSP does not know his/her date of personal significance, he or she can call the iPLEDGE Program for assistance at 1-866-495-0654 (press 1, #0, 1, \*). You will need to provide your iPLEDGE username (NCPDP#) and the RSP's name and license number. The customer service representative will be able to reset the password and provide the new password via phone. This is a four digit temporary password. Immediately after you successfully login, the system will prompt you to change your password.*

**How does a pharmacy obtain drug from a wholesaler?**

*Pharmacies must be registered and activated in iPLEDGE in order to receive isotretinoin from a wholesaler. Wholesalers receive a daily list of pharmacies that are registered and activated in iPLEDGE. A pharmacy must be on this list in order to receive isotretinoin. The iPLEDGE Program will not accept faxes of registration forms, username and password forms, screen shots of activation pages, and the like as confirmation of eligibility to receive drug.*

**Can representatives at the iPLEDGE Program confirm a pharmacy's activation status?**

*Yes, iPLEDGE representatives can confirm a pharmacy's activation status if the pharmacy has its NCPDP number and date of personal significance.*

**Do I need to see a patient's iPLEDGE ID card before I can fill an isotretinoin prescription?**

*No, all you need to authorize the prescription is a patient's iPLEDGE ID number and a patient's date of birth. A patient, patient's guardian, or prescriber may provide this information. Call center agents cannot provide this information to pharmacies.*

**Please explain the elimination of the 23-day lockout requirement for Males and Females of Non Childbearing Potential (FNCPB).**

*Effective immediately, the 23-day lockout period for Males and FNCPB has been eliminated. Previously, whether a prescription was filled or not, a patient could not start the qualification process for another prescription until 23 days after the end of their 7-day window. While the prescribing procedures and qualification criteria for isotretinoin will remain the same for **all patients**, the elimination of the 23-day lockout period will allow Males and FNCPB the ability to re-qualify and have a new prescription filled immediately after the initial 7-day window has expired. A **new prescription** is required and both the patient and the prescriber must complete the qualification process again to ensure that all qualification criteria, including patient counseling have been met and confirmed in the iPLEDGE system.*

**Does the elimination of the 23-day lockout requirement apply to Females of Childbearing Potential?**

*No. The 23-day lockout period remains in effect for Females of Childbearing Potential. However, a change to this aspect of iPLEDGE is under development and will be rolled out next year. The call center **cannot** authorize exceptions to the lockout period.*

**How does the elimination of the 23-day lockout for Males and Females of Non-Childbearing Potential affect pharmacy requirements to obtain prescription authorizations?**

*This change has no affect on pharmacy requirements. Pharmacists must continue to authorize every isotretinoin prescription using the iPLEDGE system.*

**I have registered and activated in the iPLEDGE Program, however I am not listed with the wholesaler as an eligible pharmacy to receive drug.**

*One of the following scenarios could be your situation:*

*a) Updating the list of eligible pharmacies occurs once a day. If a pharmacy activates today, they will show up on tomorrow's list of eligible pharmacies. If your pharmacy was activated today (this includes cases where re-activation occurred due to an RSP change), your pharmacy will be able to order product the following day.*

*b) There may be a discrepancy with how your DEA number is listed on the Current Master.xls. Provide your NCPDP number to your wholesalers as the wholesalers can review their lists by both the pharmacy NCPDP number and DEA numbers. Your wholesaler should perform this query and if you still are not listed, your wholesaler can contact the iPLEDGE for further assistance.*

*c) For cases of DEA # discrepancies, you must have your DEA# corrected with NCPDP. You can do so by contacting Jeannine Deese at NCPDP at 480-477-1000 ext. 116. NCPDP updates the iPLEDGE Program weekly.*

### **Have the specific 852 and 867 requirements been determined?**

Contact Dave Flood at ValueCentric: 716-667-0297 Ext. 103, [dave.flood@valuecentric.com](mailto:dave.flood@valuecentric.com)

### **How do I change my responsible site pharmacist (RSP)?**

*The pharmacy can change its designated RSP at any time. The new RSP or the former RSP can make the change on the automated phone line at 1-866-495-0654 by following the appropriate prompts. Please see instructions below:*

## **Process to Change RSP**

Please follow this process to request a change in a pharmacy's Responsible Site Pharmacist (RSP).

**IMPORTANT:** Changing a pharmacy's RSP requires re-activation of the pharmacy to affirm that the new RSP will comply with iPLEDGE requirements.

Before you call iPLEDGE to request the change, please ensure that you have the following information available.

1. **Pharmacy's username** (NCPDP#)
2. **Pharmacy's Date of Personal Significance** (DOPS). If you do not know your pharmacy's DOPS, please reset it before calling iPLEDGE. Please refer to the section below for directions on how to reset a DOPS.
3. **New RSP Name**
4. **New RSP License #**

### **Resetting a Pharmacy's Date of Personal Significance**

#### **On the Web**

1. Go to [www.ipleddgeprogram.com](http://www.ipleddgeprogram.com)
2. Log in using your username (NCPDP#) and password.
3. Select "Update Personal Details" on the left side of the screen
4. Select "Change Date of Personal Significance"
5. Enter requested data and select "Save Changes"
6. Write down the new Date of Personal Significance

#### **On the Phone**

1. Call 1-866-495-0654
2. Press 1 to continue in English
3. Select the option to login, then enter your username (NCPDP#) and password when prompted
4. Select the option to change personal information
5. Select the option to change your Date of Personal Significance



6. Enter requested information when prompted
7. Write down the new Date of Personal Significance

### Changing the RSP

1. Call 1-866-495-0654
2. Press 1 to continue in English
3. Press #0 to transfer to the call center, then press 1 at the prompt
4. Press 5 for pharmacies.
5. A call center agent will answer the call. Tell them that you want to change your pharmacy's RSP and that you need to be transferred to the technical help desk.
6. A technical help desk agent will answer the transferred call. Tell the agent that you would like to change your pharmacy's RSP.
7. The agent will ask for your username (NCPDP#) and DOPS. This is used for authentication. Once authenticated, the agent will ask for the new RSP's name and license #.
8. Once the change is complete, you may ask the agent to transfer you back into the phone system to re-activate the pharmacy or you may perform this on the website. The website is faster and easier.

### To Activate / Re-activate a Pharmacy

#### On the Web

1. Go to [www.ipledgeprogram.com](http://www.ipledgeprogram.com)
2. Log in using your username (NCPDP#) and password.
3. Select "ACTIVATE PHARMACY REGISTRATION" on the left side of the screen or the green "Activate" button in the middle of the screen.
4. Read the attestation points listed on the screen
5. Select "I attest to the statements above"
6. Select "Submit"

#### On the Phone

1. Call 1-866-495-0654 (skip this step if you were transferred back into the phone system)
2. Press 1 to continue in English
3. Select the option to log in, then enter your username (NCPDP#) and password when prompted
4. Select the option to activate your pharmacy
5. Press 1 to continue
6. Follow the prompts

**IMPORTANT:** Failure to reactivate a pharmacy before midnight of the day the RSP was changed will cause the pharmacy to be removed from the Pharmacy Eligibility File that is sent to wholesalers and distribution centers. If this happens, the pharmacy will be added back to the list upon reactivation.

### **How do I process a prescription that is more than 120 capsules per month?**

*A pharmacist may authorize more isotretinoin capsules than available in the provided drop down menu (120 max), by repeating the authorization process for the remainder of capsules necessary. The pharmacist should enter the patient's username and date of birth a second time and then check the box that states, "**Please check this box to confirm that this is an additional fill for the same prescription.**" The pharmacist will then enter the NDC code, number of days dispensed, and the remaining capsules to authorize the remainder of the prescription. The pharmacist also can authorize a prescription requiring capsules with different NDC codes by repeating the authorization process for each unique NDC code. The pharmacist should complete all authorizations necessary for one prescription consecutively and without interruption. However, if interrupted the only requirement is that additional prescriptions must be authorized within one hour of the first prescription. In doing so, the pharmacist must check the box indicating that this is an additional fill for the same prescription. (Within that hour the pharmacist may log out and may authorize prescriptions for other patients.)*

### **I have questions about a letter I received in the mail regarding the iPLEDGE Chain Pharmacy Agreement to Release Data.**

*If you have questions about this letter, please contact ValueCentric at 716-667-0297 x160*

### **I have questions regarding product returns.**

*Please contact the appropriate manufacturers' vendors listed below:*

*Accutane (Roche): **1-800-526-0625***

*Amnesteem (Mylan): Stericycle at **1-800-796-9526***

*Claravis (Barr): MedTurn Inc. at **1-800-967-5952***

*Sotret (Ranbaxy): MedTurn Inc. at **1-817-868-5300***

### **Can I accept isotretinoin prescriptions by phone, fax or email?**

*Yes, you may accept an isotretinoin prescription via any electronic media your pharmacy may use to accept any other prescription.*

## D. ALL USERS

### **Please explain the elimination of the 23-day lockout requirement for Males and Females of Non Childbearing Potential (FNCPB).**

*Effective immediately, the 23-day lockout period for Males and FNCPB has been eliminated. Previously, whether a prescription was filled or not, a patient could not start the qualification process for another prescription until 23 days after the end of their 7-day window. While the prescribing procedures and qualification criteria for isotretinoin will remain the same for all patients, the elimination of the 23-day lockout period will allow Males and FNCPB the ability to re-qualify and have a new prescription filled immediately after the initial 7-day window has expired. A new prescription is required and both the patient and the prescriber must complete the qualification process again to ensure that all qualification criteria, including patient counseling have been met and confirmed in the iPLEDGE system.*

### **Does the elimination of the 23-day lockout requirement apply to Females of Childbearing Potential?**

*No. The 23-day lockout period remains in effect for Females of Childbearing Potential. However, a change to this aspect of iPLEDGE is under development and will be rolled out next year. The call center **cannot** authorize exceptions to the lockout period.*

### **If a Female of Childbearing Potential's (FCBP) 7-day prescription authorization window expires before she arrives at the pharmacy to fill the prescription, will she experience a lapse in treatment of no less than 23 days?**

*Yes. A lapse in treatment would result when a Female of Childbearing Potential does not pick up the isotretinoin prescription within 7 days after the office visit, the office visit being day 1. This will result in the patient missing isotretinoin treatment for no less than 23 days. FCBPs should make every effort possible to complete the iPLEDGE program requirements and pick up the prescription within the 7-day window to avoid a lapse in isotretinoin treatment.*

### **What happens if the pharmacy does not have enough product in stock to fill a prescription within the 7-day window?**

*Prior to filling the prescription, contact the pharmacy to ensure that they have enough product in stock to fill the prescription. The pharmacy must fill AND dispense the prescription within the 7-day window. If the pharmacy cannot meet this deadline, the patient should go to another pharmacy. A potential lapse in treatment would result when a registered patient does not pick up the isotretinoin prescription within 7 days after the office visit, the office visit being day 1.*

### **At what date and time does my 7-day window close?**

*Once all requirements are completed, and the patient has completed the comprehension questions successfully, the system will inform you that you may fill your prescription. Patients will see a message that provides the ending date and time to fill the prescription. For example, the message will read:*

***“You may fill your prescription any time before midnight on 3/31/2006.”***

*In this example you would have until 11:59 pm Eastern Time on 03/30/06 to fill your prescription.*

### **Is there a test database available for prescribers / staff / pharmacist / or patients to use for training purposes to get familiar with the iPLEDGE site?**

*At this time, there is no test database. Please refrain from entering dummy data in the iPLEDGE system as that could negatively impact patient data that is reported to the FDA.*

### **How can I download iPLEDGE materials?**

*Users can download the iPLEDGE materials from the website using version Acrobat 7.0. The link to this free Acrobat download is available on any page that has materials available for download.*

**Can patients who do not reside in the U.S. but receive treatment and fill prescriptions in the U.S. participate in the iPLEDGE Program?**

*Residency is not a requirement of the program as long as patients see a doctor in the U.S. and fill their prescription in the U.S. However, a U.S. mailing address must be provided.*

**Will the manufacturers reinstate veterinary use of isotretinoin?**

*Isotretinoin is for human consumption only. At this time, there are no plans to include animals in the iPLEDGE program.*

**Can inpatient pharmacies obtain isotretinoin in the inpatient hospital setting?**

*Hospital pharmacies must follow all the requirements of the iPLEDGE program and cannot process partial isotretinoin prescriptions (or break blister packs). All pharmacies need to dispense a maximum of a 30-day supply of isotretinoin because the iPLEDGE system will allow one prescription authorization a month. Please note that pharmacies may dispense a smaller supply, however the patient would only be eligible for a refill during the next prescription period no less than 23 days later.*

**I would like to submit something in writing to the iPLEDGE program. Is there a mailing address I should use?**

*All written correspondence should be sent to:  
iPLEDGE-Committed to Pregnancy Prevention  
555 North Lane  
Suite 6000  
Conshohocken, PA 19428*

## E. PATIENTS

### **How do I register with the iPLEDGE program and receive my username and password?**

*Patients' prescribers must first "register" them with the program. The prescriber will provide the patient with an ID card with a username. After a prescriber registers a patient, the patient will be mailed their password.*

### **I either lost or forgot my password. How do I reset my password?**

*If patients lose their password and they know their date of personal significance and their preferred method of communication is email, they can reset their password on the web system and it will be emailed to them. If this does not work, they can call iPLEDGE at 1-866-495-0654 (press 1, #0, 1, \*), for a password reset and this password will be provided over the phone upon authentication.*

### **How do I find an iPLEDGE participating pharmacy?**

*Patients should login to [www.ipledgeprogram.com](http://www.ipledgeprogram.com) and consult with online pharmacy finder to make sure a pharmacy is participating in iPLEDGE.*

### **Why are males included in the iPLEDGE Program?**

*Because iPLEDGE is a restricted distribution program, one of the requirements for iPLEDGE is the reporting and data collection of sales and dispensing of isotretinoin outside of the iPLEDGE program. Therefore, the program is required for all patients in order to effectively manage the distribution of isotretinoin product at all times to all patients.*

### **Please explain the elimination of the 23-day lockout requirement for Males and Females of Non Childbearing Potential (FNCBP).**

*Effective immediately, the 23-day lockout period for Males and FNCBP has been eliminated. Previously, whether a prescription was filled or not, a patient could not start the qualification process for another prescription until 23 days after the end of their 7-day window. While the prescribing procedures and qualification criteria for isotretinoin will remain the same for **all patients**, the elimination of the 23-day lockout period will allow Males and FNCBP the ability to re-qualify and have a new prescription filled immediately after the initial 7-day window has expired. A **new prescription** is required and both the patient and the prescriber must complete the qualification process again to ensure that all qualification criteria, including patient counseling have been met and confirmed in the iPLEDGE system.*

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### **What happens if the pharmacy does not have enough product in stock to fill a prescription within the 7-day window?**

*Prior to filling the prescription, contact the pharmacy to ensure that they have enough product in stock to fill the prescription. The pharmacy must fill AND dispense the prescription within the 7-day window. If the pharmacy cannot meet this deadline, the patient should go to another pharmacy. A potential lapse in treatment would result when a registered patient does not pick up the isotretinoin prescription within 7 days after the office visit, the office visit being day 1.*

*iPLEDGE FAQs – 10.06.06*