

Attachment 1

Mandatory Physician & All Female Patient Isotretinoin Registry

1. All females diagnosed by a registered prescriber to be a candidate for isotretinoin therapy must enroll into this registry.
2. Childbearing potential and Not of Childbearing potential to be decided by the registered prescriber as per guidelines in the PI.
3. Current education and Informed Consent process is followed. This includes consent for patient to be placed into 3rd party database.
4. First pregnancy test is done as a screener in the prescriber's office and under supervision of a staff member. If this test is positive, the patient is not eligible for the product.
5. Education, Consultation and Registration of the female patient occurs. During the consultation the registered prescriber will walk the patient through the need for isotretinoin, the risks associated with treatment and all procedures as outlined in the isotretinoin risk management program. Both subsets of female population, childbearing and non-childbearing potential, will be qualified and registered as per their requirements.
6. Registration information to include specific information to uniquely identify the patient. Transmission of registration information from registered prescriber's office to the registry and back.
7. The Registry will be a single registry for all manufacturers. Registry will assign a patient identification number (PIN) which can uniquely identify the patient in all future transactions.
8. The patient (childbearing potential only) is required to get a laboratory-conducted pregnancy test done. This second test is a confirmatory test and is done on a date derived from the guidelines in the PI for the initial prescription.
9. For all isotretinoin prescriptions after the initial one, the patient will require re-qualification by the prescriber and a laboratory-conducted pregnancy test. The prescriber will enter the re-qualification information into the system.
10. Laboratory pregnancy test results are transmitted to the registry system.
11. For Eligible patients a prescription for 30 days of isotretinoin and a qualification sticker is affixed to the prescription.
12. Patient takes prescription to pharmacy.
13. Pharmacy checks with registry (submitting PIN and other to be identified information) if prescription can be dispensed. Pharmacy enters NABP# into system for identification.
14. Registry issues a YES or NO and invalidates the records in the database so that the prescription cannot be filled by another pharmacy.
15. Pharmacy to dispense isotretinoin if the registry says YES and enters authorization number on prescription. If NO patient is advised to contact physician.
16. Prior to dispensing pharmacist enters product NDC code, LOT #, etc... into system.