

Isotretinoin Onboarding Requirements

Isotretinoin, formerly known as Accutane, is a medication that treats severe cystic scarring acne. Isotretinoin is regulated by a FDA mandated Risk Evaluation and Mitigation Strategy (REMS) program called iPledge that US Dermatologists and patients register with in order to prescribe.

The local facility will print the PDF form for the patient, or parent/guardian if patient is under the age of 18, from the below websites:

- Individual who cannot become pregnant: <https://sals3.patientpop.com/assets/docs/168680.pdf>
- Individual who can become pregnant: <https://sals3.patientpop.com/assets/docs/168679.pdf>

Patient Appointment Process for Potential Isotretinoin:

1. Patient to be seen by Primary Care Provider for referral to Avel Dermatologist as 'Potential Isotretinoin Candidate'.
 - a. Facility scheduler will coordinate Avel Dermatology appointment and include 'Potential Isotretinoin Candidate' in the reason for referral.
2. Avel Dermatologist to meet with patient to determine eligibility utilizing the iPledge booklet as an introduction and discuss risks and benefits of Isotretinoin.
3. Avel Dermatologist will confirm if patient requires behavioral health clearance.
 - i. Clearance Requirements & Process:
 - If patient has history of suicidal ideation or depression, clearance is required to be completed between the first and second visit with the Avel Dermatologist.
 - Patient appointment will be coordinated to see Psychiatry Provider, if applicable.
 - Avel Dermatologist or Primary Care Provider will obtain input from Psychiatry Provider, and document approval of patient moving forward with Isotretinoin.
 - Psychiatry Provider will maintain regular follow up visit with patient.
 - c. Avel Dermatologist will confirm if patient is on birth control:
 - If patient is not on birth control, Avel Dermatologist will refer back to Primary Care Provider for prescribing birth control.
 - Patient of child-bearing age is required to complete (2) pregnancy tests at least 1 month apart with confirmation of no pregnancy before treatment may begin.
 - Patient is required to be on birth control prior to receiving clearance, if applicable.
3. Patient and or parent/guardian, if applicable, will be provided iPledge booklet. Patient to review iPledge booklet, after Dermatology visit. With patient understanding of risks, and plans to move forward with Isotretinoin, patient will schedule a return visit at least 2 weeks later with intent to sign the iPledge consent.

Requirements for Isotretinoin On-Boarding:

4. With the approval to start Isotretinoin, and confirmation patient is on birth control, Avel Dermatologist will order fasting labs, pregnancy test if applicable. Labs to be drawn 1-2 days prior to 2 week follow-up appointment.
5. During patient 2 week follow-up appointment patient and or Parent/guardian, and Avel Dermatologist will sign iPledge consent and scan into facility EHR.
 - a. Avel Dermatologist will confirm fasting labs and pregnancy test results during 2 week follow-up appointment.
6. After iPledge consent signature, a 30 day waiting period will be in place, with exceptions managed between the patient and Avel Dermatologist. The REMS number will be included in the patient's discharge paperwork, documented in the EHR note, and documented in the pharmacy notes.
7. After the waiting period ends, the Avel Dermatologist will prescribe the drug and coordinate the patient appointment.
8. The Avel Dermatologist will educate patient that if more than 40 days elapses between visits, the patient will be deactivated from the iPledge program.
9. The Avel Dermatologist will complete discharge summary with future lab dates, and instructions to patient.
10. Patient is required to attend regular monthly appointments, complete labs and review with the Avel Dermatologist prior to receiving Isotretinoin. Avel Dermatologist will note the acceptance in iPledge on a monthly basis.
 - a. If patient has left the Facility, the Facility will contact the patient to confirm labs are acceptable and prescription is available for pick up.
 - b. eCare Specialty Clinic will monitor the 40 day period, and collaborate with the Facility to reach out to patient for scheduling if close to 40 day period.