



**Clarification from the MHRA:  
Isotretinoin, abstinence, and pregnancy tests  
March 2021**

1. If a patient is not sexually active or not considered to be at risk of becoming pregnant, abstinence could be an acceptable method of avoiding pregnancy during isotretinoin treatment for some women of childbearing potential if the prescriber is satisfied, after a thorough discussion, that the patient will be able to adhere to this. However, unless the prescriber can be confident that this will apply for the duration of treatment, then it would be important that this decision is reviewed regularly with the patient (e.g. at monthly follow-up appointments) as a change in circumstances could mean that this approach is no longer appropriate.

**N.B.** Regular follow-up of patients on isotretinoin is not just about pregnancy prevention – isotretinoin can cause a wide range of side-effects, some of which are rare but very serious. Monitoring for psychiatric adverse effects including mood disorders, and testing for blood lipids and liver function, are part of prescribing isotretinoin in accordance with its licence ([www.medicines.org.uk/emc/product/1114/smpc](http://www.medicines.org.uk/emc/product/1114/smpc)).

2. If the patient is not sexually active (abstinent), there may not be a need for monthly pregnancy tests. However, as above, it would be important that this decision is reviewed regularly, including consideration of any sexual activity and recent menstrual history (abnormal menses, missed periods or amenorrhoea).
3. In terms of medical supervision of pregnancy tests, the MHRA would regard the supervision of an appropriately trained specialist nurse, with access to a dermatologist when required, as 'medical supervision'. The key principle is that the prescriber has confidence that the member of staff is competent to carry out the role to which they are assigned, rather than their job title *per se*.
4. Regarding the question of remote prescribing and pregnancy testing in the COVID pandemic, the MHRA is currently in the final stages of drafting some guidance specific to oral retinoids, and they hope to be able to share a draft with the BAD and other stakeholders for comments soon.