January 2026: PLEASE USE THIS VERSION FOR ALL PRESCRIBING FROM THIS DATE ONWARDS

Information for the Lead Prescriber (the prescriber initiating isotretinoin treatment)

The Lead Prescriber must complete the Acknowledgement of Risk Form for **all patients** treated with isotretinoin.

WARNING: Use of isotretinoin for indications not listed in the Summary of Product Characteristics is outside the licence and patients should be made aware of this[1,2]

Completing the form. The patient must be given:

- A copy of the completed Acknowledgement of Risk Form
- The Patient Information sheet with contact details of the Dermatology team
- The Patient Reminder Card.

Store a copy of the Acknowledgement of Risk Form in the medical notes and share with all healthcare professionals if needed.

The Lead Prescriber and patient (and usually a parent or guardian if the patient is under 18 years old) should go through the form together. Be aware of safeguarding concerns when talking to patients under 18.

A parent or guardian should also be asked to sign the form if the patient is under 18 years old, unless, in the opinion of the prescriber, this is not in the best interests of the patient. The reason should be documented in the patient record.

Mental health assessment

The baseline mental health assessment should include details of mental health history (including previous self-harm and contact with mental health services), discussion about current mental wellbeing (including impact of acne), and the completion of validated mental health Patient Reported Outcome Measures.
For example, PHQ-9/PHQ-A and GAD-2.

Pregnancy Prevention Programme

For patients with childbearing potential (anyone who may be able to get pregnant), the patient must be entered into the pregnancy prevention programme (PPP). People who are medically unable to become pregnant are excluded from the PPP. This means people with no uterus and/or no ovaries (congenital or surgical removal), or who are post-sterilisation or postmenopausal.

The PPP form must be completed by the isotretinoin prescriber at the time the first prescription is written. This will generally be the Lead Prescriber, but it may also be delegated to a Follow-up Prescriber (who monitors the patients and continues to prescribe isotretinoin). Suitable Follow-up Prescribers include any healthcare professional eligible to be a Lead Prescriber, and also non-medical prescribers (such as a Band 6 or above Dermatology Nurse Specialist or a Pharmacist with appropriate dermatology expertise, skills and training) experienced in prescribing isotretinoin, working within a Consultant Dermatologist or GPwER[3] agreed pathway.

Reasons for not requiring contraception (expectation of no risk of pregnancy) include any one of the following:

1. **Only having sex/sexual intercourse with a person who has no potential to make them pregnant.** This must be for the duration of isotretinoin treatment and for 1 month after stopping isotretinoin treatment. This should be confirmed at each clinic visit. Examples include sex with a:

- Person of the same sex
- Person who has had a vasectomy with two confirmed tests of being sperm-free
- Transgender man

2. **Long-term sexual abstinence** (no sexual activity) for the duration of isotretinoin treatment and for 1 month after stopping isotretinoin treatment. This should be confirmed at each clinic visit.

Adverse events

Isotretinoin is a black triangle medicine, and all suspected adverse reactions should be reported via the Yellow Card scheme and to the company listed in the patient's package information leaflet. Reports can be made of suspected reactions experienced at any time, including historic adverse experiences with medicines.

To order further hard copies of the Oral Isotretinoin PPP material please email: oralisotretinoinppp@linney.com or call: 0370 703 0602.

Electronic copies are available at: www.medicines.org.uk/emc

[1] https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices
[2] https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-and-consent
[3] Nationally accredited General Practitioner with an Extended Role in Dermatology (GPwER)

▼Isotretinoin Acknowledgement of Risk Form (for prescribers and patients)

1. Isotretinoin risks

This form is to make sure you know about the side effects and possible risks which have been associated with isotretinoin.

Patient Details

Name of patient:	Date of birth:
NHS/CHI number:	Hospital number:
GP name and address:	

	Patient Acknowledges
I have discussed my treatment options for acne with my prescriber. I am aware that isotretinoin is indicated for use with severe acne after other treatment options have failed.	☐
I have read the relevant information on isotretinoin[1] and will read the patient information leaflet (package insert). I am aware there is a patient video provided by the British Association of Dermatologists (BAD) that I am recommended to watch.	☐
I have been offered a second opinion with another Lead Prescriber.	☐
I understand I am advised to tell a family member or friend I am taking isotretinoin. I should tell them about potential side effects to look out for so I can inform my dermatology team. I understand there are a range of possible side effects associated with taking isotretinoin, and that some side effects have been reported to continue after treatment. Common side effects of isotretinoin include dry skin, lips and eyes, nose bleeds, fragile skin, sun sensitivity, and muscle aches. Potential side effects, of unknown frequency (there is insufficient evidence to estimate the frequency), include mental health side effects, and issues relating to sexual function. Mental health side effects may include low mood, depression, anxiety, agitation, aggression, self-harm, suicidal thoughts/attempts, loss of touch with reality. The Lead prescriber has checked my mental health and I have been directed to appropriate mental health support, if needed. The Lead Prescriber and I have discussed the possible side effects. We agree there are no concerns at this time which would prevent me from starting isotretinoin. If I have concerns about side effects while on isotretinoin, I will inform my Dermatology team. If I notice significant changes in my mental health, I will stop isotretinoin immediately and seek help.	☐
I will have regular clinic appointments during my treatment for monitoring.	☐
I understand I **must not** donate blood during treatment with isotretinoin and for 1 month afterwards.	☐
I will not share my isotretinoin capsules with anyone else.	☐
I have been given a Patient Reminder Card and the contact details for my dermatology team.	☐

Tick the one that applies and sign below:

☐ I **am** of child-bearing potential and am aware I must enter the Pregnancy Prevention Programme – **sign below and then go to section 2: Pregnancy Prevention Programme.**

☐ I **am <u>not</u>** of child-bearing potential and am excluded from the Pregnancy Prevention Programme – **sign below.**

I confirm I understand the possible risks of isotretinoin.	Yes ☐ No ☐	
Name of patient:	Signature of patient:	Date of signature:
Name of parent or guardian (if applicable):	Signature of parent or guardian (if applicable):	Date of signature:

Prescriber: I confirm that the possible risks of isotretinoin have been explained to the patient and that their acne is severe (including acne at risk of permanent scarring) and resistant to adequate courses of standard therapy. I consider that there is no other appropriate effective treatment:

Name of Lead Prescriber:	Role and unique identifier:
Signature of Lead Prescriber:	Date of signature:

[1] British Association of Dermatologists 'Isotretinoin Patient Guide' and/or Medicines for Children 'Oral isotretinoin Guide for young people'.

Patient Details

Name of patient:	Date of birth:
NHS/CHI number:	Hospital number:
GP name and address:	

2. Pregnancy Prevention Programme

For all patients with childbearing potential (anyone who may be able to get pregnant).

This section must be reviewed and signed by the Lead Prescriber or Follow-up Prescriber, and patient together.

	Patient Acknowledges
I understand that isotretinoin can seriously harm an unborn baby or cause miscarriage when taken during pregnancy. I must not get pregnant whilst taking isotretinoin and for 1 month after stopping treatment.	☐
I understand that no contraception is 100% effective.	☐
Hormonal contraception can be less effective in some situations, which I am aware of. I understand I may need to use extra contraception if: I am starting new medications, including antibiotics or herbal preparations such as St John's Wort I have diarrhoea and vomiting I have missed taking my contraception.	☐
If I have unprotected sex or think I am pregnant I will stop isotretinoin immediately and seek medical advice.	☐

Select the category which applies to you below (initial or tick appropriate box):

☐ **A –** I confirm I do not need to use contraception because there is expected to be **no risk** of pregnancy during treatment and for 1 month after treatment. I do not require pregnancy testing. **If my situation changes, I will start appropriate contraception (from GP/family planning clinic) and let my prescriber know.**

Reason: .....

.....

☐ **B –** I confirm I have had a **contraceptive implant** or an **intrauterine coil/system** (IUD/S) for at least 4 weeks at the time of my first prescription. I understand the first prescription for isotretinoin can only be given after I have had one negative pregnancy test checked by the prescriber. I agree to do pregnancy testing at follow up appointments and 1 month after stopping treatment because the risks to an unborn baby last for 1 month after the last dose.

☐ **C –** I confirm have been using a hormonal **contraceptive pill** or injection, **plus** I agree to use a **barrier** method (condom or vaginal cap) at the time of my first prescription. I understand the first prescription for isotretinoin can only be given after I have had one negative pregnancy test checked by the prescriber. I agree to do pregnancy testing at follow up appointments and 1 month after stopping treatment because the risks to an unborn baby last for 1 month after the last dose. My prescription will be for 30 days.

For groups A and B, once stable on isotretinoin the prescription may be for longer than 30 days (up to 12 weeks).

Signed		
Name of patient:	Signature of patient:	Date of signature:
Name of prescriber:	Signature of prescriber:	Date of signature: