A Guide to Completing the Prescription Authorisation Form (PAF)

This guide will help you to complete the Revlimid®▼ (lenalidomide) Prescription Authorisation Form (PAF).

For prescribers and pharmacists not utilising the electronic Risk Management Programme (eRMP) system, this form is available. A PAF must be completed each time you prescribe Revlimid for all patients.

Instructions for prescribers

1. Print your name clearly.

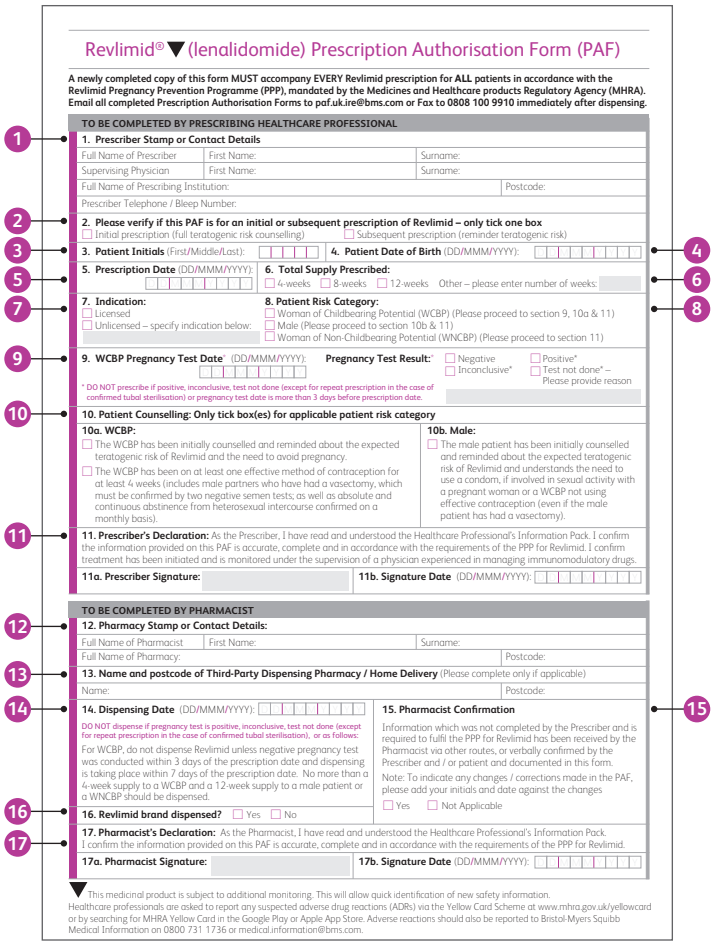
   Print the name of the Supervising Physician (if you are a non-physician prescriber), i.e. the physician experienced in managing immunomodulatory drugs and supervising treatment.

   Print the full name of the Prescribing Institution where the patient is being treated.

   Print your telephone number/bleep number.
2. Tick the appropriate box specifying whether this is an initial or subsequent prescription.
3. Enter the patient's initials.
4. Enter the patient's date of birth.
5. Enter the date of the patient's prescription.
6. Please specify the total supply prescribed for this prescription.
7. Please specify whether Revlimid is being used to treat a licensed or an unlicensed indication. If unlicensed, please specify the indication in the form.
8. Please specify whether the patient is a woman of childbearing potential, male or woman of non-childbearing potential.
9. For women of childbearing potential you must provide a valid negative pregnancy test date (within 3 days prior to prescription date). If this is not the case Revlimid must not be dispensed.
10. Complete this section appropriately to indicate that counselling and appropriate use of contraception has occurred. This is a requirement of the Pregnancy Prevention Programme.
11. You must sign, date and print your name to declare that the information provided on the form is accurate, complete and in accordance with the requirements of the Pregnancy Prevention Programme.

Instructions for pharmacists

12. Enter your full name and the full name and postcode of the pharmacy.
13. If applicable, complete the Third-Party Dispensing Pharmacy / Home Delivery information.
14. Please specify the date Revlimid was dispensed. Prior to dispensing, please check that all relevant sections of the form have been fully completed by the prescriber.
    a. Counselling and contraception measures must be in place
    b. Prescription must be accompanied by an accurately completed PAF
    c. For women of childbearing potential Revlimid can only be dispensed within 7 days of the prescription date
    d. Only a maximum of 4 weeks supply for women of childbearing potential, or a maximum of 12 weeks supply for all other patients, of Revlimid can be dispensed at any one time.
15. Please specify whether there were any changes made to the PAF. To indicate any changes / corrections made in the PAF, please add your initials and date against the changes.
16. Please confirm if Revlimid brand is being dispensed
17. You must sign, date and print your name to declare that the information provided on this form is accurate, complete and in accordance with the Pregnancy Prevention Programme. Email all completed Prescription Authorisation Forms to paf.uk.ire@bms.com or Fax to 0808 100 9910 immediately after dispensing.



Revlimid® ▼ (lenalidomide) Prescription Authorisation Form (PAF)

A newly completed copy of this form MUST accompany EVERY Revlimid prescription for ALL patients in accordance with the Revlimid Pregnancy Prevention Programme (PPP), mandated by the Medicines and Healthcare products Regulatory Agency (MHRA). Email all completed Prescription Authorisation Forms to paf.uk.ire@bms.com or Fax to 0808 100 9910 immediately after dispensing.

TO BE COMPLETED BY PRESCRIBING HEALTHCARE PROFESSIONAL

1. **Prescriber Stamp or Contact Details**
Full Name of Prescriber | First Name: | Surname:
Supervising Physician | First Name: | Surname:
Full Name of Prescribing Institution: | Postcode:
Prescriber Telephone / Bleep Number:

2. **Please verify if this PAF is for an initial or subsequent prescription of Revlimid – only tick one box**
☐ Initial prescription (full teratogenic risk counselling) ☐ Subsequent prescription (reminder teratogenic risk)

3. **Patient Initials** (First/Middle/Last):

4. **Patient Date of Birth** (DD/MMM/YYYY):

5. **Prescription Date** (DD/MMM/YYYY):

6. **Total Supply Prescribed:**
☐ 4-weeks ☐ 8-weeks ☐ 12-weeks Other – please enter number of weeks:

7. **Indication:**
☐ Licensed
☐ Unlicensed – specify indication below:

8. **Patient Risk Category:**
☐ Woman of Childbearing Potential (WCBP) (Please proceed to section 9, 10a & 11)
☐ Male (Please proceed to section 10b & 11)
☐ Woman of Non-Childbearing Potential (WNCBP) (Please proceed to section 11)

9. **WCBP Pregnancy Test Date*** (DD/MMM/YYYY): **Pregnancy Test Result:*** ☐ Negative ☐ Positive* ☐ Inconclusive* ☐ Test not done* – Please provide reason
* DO NOT prescribe if positive, inconclusive, test not done (except for repeat prescription in the case of confirmed tubal sterilisation) or pregnancy test date is more than 3 days before prescription date.

10. **Patient Counselling: Only tick box(es) for applicable patient risk category**

10a. WCBP:
☐ The WCBP has been initially counselled and reminded about the expected teratogenic risk of Revlimid and the need to avoid pregnancy.
☐ The WCBP has been on at least one effective method of contraception for at least 4 weeks (includes male partners who have had a vasectomy, which must be confirmed by two negative semen tests; as well as absolute and continuous abstinence from heterosexual intercourse confirmed on a monthly basis).

10b. Male:
☐ The male patient has been initially counselled and reminded about the expected teratogenic risk of Revlimid and understands the need to use a condom, if involved in sexual activity with a pregnant woman or a WCBP not using effective contraception (even if the male patient has had a vasectomy).

11. **Prescriber's Declaration:** As the Prescriber, I have read and understood the Healthcare Professional's Information Pack. I confirm the information provided on this PAF is accurate, complete and in accordance with the requirements of the PPP for Revlimid. I confirm treatment has been initiated and is monitored under the supervision of a physician experienced in managing immunomodulatory drugs.

11a. Prescriber Signature: **11b. Signature Date** (DD/MMM/YYYY):

TO BE COMPLETED BY PHARMACIST

12. **Pharmacy Stamp or Contact Details:**
Full Name of Pharmacist | First Name: | Surname:
Full Name of Pharmacy: | Postcode:

13. **Name and postcode of Third-Party Dispensing Pharmacy / Home Delivery** (Please complete only if applicable)
Name: | Postcode:

14. **Dispensing Date** (DD/MMM/YYYY):
DO NOT dispense if pregnancy test is positive, inconclusive, test not done (except for repeat prescription in the case of confirmed tubal sterilisation), or as follows:
For WCBP, do not dispense Revlimid unless negative pregnancy test was conducted within 3 days of the prescription date and dispensing is taking place within 7 days of the prescription date. No more than a 4-week supply to a WCBP and a 12-week supply to a male patient or a WNCBP should be dispensed.

15. **Pharmacist Confirmation**
Information which was not completed by the Prescriber and is required to fulfil the PPP for Revlimid has been received by the Pharmacist via other routes, or verbally confirmed by the Prescriber and / or patient and documented in this form.
Note: To indicate any changes / corrections made in the PAF, please add your initials and date against the changes
☐ Yes ☐ Not Applicable

16. **Revlimid brand dispensed?** ☐ Yes ☐ No

17. **Pharmacist's Declaration:** As the Pharmacist, I have read and understood the Healthcare Professional's Information Pack. I confirm the information provided on this PAF is accurate, complete and in accordance with the requirements of the PPP for Revlimid.

17a. Pharmacist Signature: **17b. Signature Date** (DD/MMM/YYYY):

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse drug reactions (ADRs) via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or by searching for MHRA Yellow Card in the Google Play or Apple App Store. Adverse reactions should also be reported to Bristol-Myers Squibb Medical Information on 0800 731 1736 or medical.information@bms.com.

Further information and materials are available from BMS.

Pregnancy Prevention Programme: 0808 156 3059

Email: rmpukire@bms.com

Electronic copies are also available on the Great Britain (GB) and Northern Ireland (NI) electronic medicines compendium websites: www.medicines.org.uk/emc (for Great Britain) or www.emcmedicines.com/en-GB/northernireland (for Northern Ireland).

Alternatively, PAFs can be completed via the eRMP. For further information, please contact:

Tel: 0808 156 3057

Email: paf.uk.ire@bms.com

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Version 10

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TO BE COMPLETED BY PRESCRIBING HEALTHCARE PROFESSIONAL

1. Prescriber Stamp or Contact Details

Full Name of Prescriber	First Name:	Surname:
Supervising Physician	First Name:	Surname:
Full Name of Prescribing Institution:		Postcode:
Prescriber Telephone / Bleep Number:		

2. Please verify if this PAF is for an initial or subsequent prescription of Revlimid – only tick one box

☐ Initial prescription (full teratogenic risk counselling) ☐ Subsequent prescription (reminder teratogenic risk)

3. Patient Initials (First/Middle/Last): | | | | | **4. Patient Date of Birth** (DD/MMM/YYYY): D D M M M Y Y Y Y

5. Prescription Date (DD/MMM/YYYY): D D M M M Y Y Y Y

6. Total Supply Prescribed:

☐ 4-weeks ☐ 8-weeks ☐ 12-weeks Other – please enter number of weeks:

7. Indication:

☐ Licensed

☐ Unlicensed – specify indication below:

8. Patient Risk Category:

☐ Woman of Childbearing Potential (WCBP) (Please proceed to section 9, 10a & 11)

☐ Male (Please proceed to section 10b & 11)

☐ Woman of Non-Childbearing Potential (WNCBP) (Please proceed to section 11)

9. WCBP Pregnancy Test Date* (DD/MMM/YYYY): D D M M M Y Y Y Y

Pregnancy Test Result:* ☐ Negative ☐ Positive* ☐ Inconclusive* ☐ Test not done* – Please provide reason

* DO NOT prescribe if positive, inconclusive, test not done (except for repeat prescription in the case of confirmed tubal sterilisation) or pregnancy test date is more than 3 days before prescription date.

10. Patient Counselling: Only tick box(es) for applicable patient risk category

10a. WCBP:

☐ The WCBP has been initially counselled and reminded about the expected teratogenic risk of Revlimid and the need to avoid pregnancy.

☐ The WCBP has been on at least one effective method of contraception for at least 4 weeks (includes male partners who have had a vasectomy, which must be confirmed by two negative semen tests; as well as absolute and continuous abstinence from heterosexual intercourse confirmed on a monthly basis).

10b. Male:

☐ The male patient has been initially counselled and reminded about the expected teratogenic risk of Revlimid and understands the need to use a condom, if involved in sexual activity with a pregnant woman or a WCBP not using effective contraception (even if the male patient has had a vasectomy).

11. Prescriber's Declaration: As the Prescriber, I have read and understood the Healthcare Professional's Information Pack. I confirm the information provided on this PAF is accurate, complete and in accordance with the requirements of the PPP for Revlimid. I confirm treatment has been initiated and is monitored under the supervision of a physician experienced in managing immunomodulatory drugs.

11a. Prescriber Signature: | **11b. Signature Date** (DD/MMM/YYYY): D D M M M Y Y Y Y

TO BE COMPLETED BY PHARMACIST

12. Pharmacy Stamp or Contact Details:

Full Name of Pharmacist	First Name:	Surname:
Full Name of Pharmacy:		Postcode:

13. Name and postcode of Third-Party Dispensing Pharmacy / Home Delivery (Please complete only if applicable)

Name:	Postcode:

14. Dispensing Date (DD/MMM/YYYY): D D M M M Y Y Y Y

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Note: To indicate any changes / corrections made in the PAF, please add your initials and date against the changes

☐ Yes ☐ Not Applicable

16. Revlimid brand dispensed? ☐ Yes ☐ No

17. Pharmacist's Declaration: As the Pharmacist, I have read and understood the Healthcare Professional's Information Pack. I confirm the information provided on this PAF is accurate, complete and in accordance with the requirements of the PPP for Revlimid.

17a. Pharmacist Signature: | **17b. Signature Date** (DD/MMM/YYYY): D D M M M Y Y Y Y

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