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TEMPORARY modifications to the Pregnancy Prevention Programmes for thalidomide (Thalidomide Celgene®), lenalidomide (Revlimid®▼) and pomalidomide (Imnovid®▼)

22 April 2020

Dear Healthcare professional,

Celgene Limited, following consultation with the Medicines & Healthcare products Regulatory Agency (MHRA), would like to inform you of the following **temporary** modifications to the Pregnancy Prevention Programmes for Celgene's Immunomodulatory drugs to facilitate remote consultations during the COVID-19 (coronavirus) pandemic, where clinically appropriate.

Summary

- **Home pregnancy testing for women of childbearing potential is acceptable, at the discretion of the clinician, provided minimum criteria are met (see modifications to pregnancy testing below)**
- **Editable versions of the paper Prescription Authorisation Forms (PAFs) and Treatment Initiation Forms (TIFs) will be available**
- **These temporary modifications will continue until the recommended shielding measures for extremely vulnerable people during the coronavirus pandemic have been lifted**

Background on the modifications to the Pregnancy Prevention Programmes

Due to the coronavirus pandemic, Public Health England (PHE) [1] has identified people with cancers of the blood or bone marrow such as lymphoma or myeloma, who are at any stage of treatment, as being extremely vulnerable and therefore at very high risk of severe illness from coronavirus. PHE has recommended that extremely vulnerable patients should rigorously follow shielding measures (strongly advised to stay at home and avoid face-to-face contact; to access medical assistance remotely wherever possible; those with a scheduled hospital or other medical appointment during this period should talk to their GP or specialist to ensure continuity of care needed and to determine which appointments are absolutely essential).

Modifications to pregnancy testing

As part of the pregnancy prevention programmes for thalidomide, lenalidomide and pomalidomide, a medically supervised pregnancy test (minimum sensitivity of 25 mIU/mL) must be performed before starting treatment, at least every 4 weeks during treatment and at least 4 weeks after finishing treatment for women of childbearing potential (WCBP) [2,3,4]. To facilitate shielding of WCBP who are receiving thalidomide, lenalidomide or pomalidomide, it has been agreed with the MHRA that home pregnancy testing could be performed, at the discretion of the clinician, if the following minimum criteria are met:

1) ***Adequate instruction and support are provided***. Where possible, the pregnancy tests should be sent to the patient by their clinic and this should include at least one spare test in case there needs to be confirmation of the result or one is damaged or misused. If this is not possible, the healthcare professional should provide the patient with a list of acceptable test kits that the patient can procure, either directly from a pharmacy (by a relative or friend) or over the internet.
2) ***The pregnancy tests meet the minimum required sensitivity (25 mIU/mL).***
3) ***The result of each pregnancy test is verified by the prescriber.*** Ideally, the patient would take a photograph of the test and send this to the healthcare professional by email/video conferencing. If no email or video conferencing is available, then a telephone description of the test result, kit make and how it was used would be a minimum requirement.

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Editable versions of the paper Prescription Authorisation Forms (PAFs)
Where the clinician determines that a remote follow-up consultation is clinically appropriate for a patient established on treatment with thalidomide, lenalidomide or pomalidomide, an electronic editable version of the paper PAF is being made available to allow the prescriber to send the PAF electronically to the pharmacist, who can then dispense the prescription. Note, this option can be utilised for those prescribers and pharmacies who are currently completing paper PAFs.

Editable versions of the paper Treatment Initiation Forms (TIFs)
TIFs are completed by the clinician and patient prior to a patient initiating treatment on thalidomide, lenalidomide or pomalidomide. Although Celgene understands an editable version could help facilitate a remote consultation, the following factors should be considered:

- The clinician should determine on a case-by-case basis, whether a remote consultation is an appropriate environment for initiating treatment with thalidomide, lenalidomide or pomalidomide, in particular whether it can adequately meet the requirements to educate patients and undertake the required clinical review and baseline assessment (NHS Clinical Guide [5]).
- The Summary of Product Characteristics (SmPCs) of these medicines should be consulted to help ensure safe and effective use [2,3,4,]. For example, section 4.4 of the SmPCs for Revlimid®▼ and Imnovid®▼ recommend that a complete blood cell count should be performed at baseline, every week for the first 8 weeks of treatment (and monthly thereafter) to monitor for cytopenias [3,4].
- If the clinician determines that treatment should be started and that this can be done through a remote consultation, the patient **must** still receive a hard copy of the TIF to read, complete and sign before they start treatment, as would be the case in a face-to-face consultation. This will help ensure that patients are fully informed about the risks of treatment (especially teratogenicity) and the required risk minimisation measures. The patient will be required to send the completed TIF back to the prescriber. The method used to send the form back to the prescriber should be at the discretion of the prescriber, depending on the patient's circumstance (e.g. by post if it can't be done electronically).
- The requirement to provide educational materials (patient booklet and card) to new patients who are starting treatment with thalidomide, lenalidomide or pomalidomide must still be met and therefore clinicians will have to consider how best to meet this requirement.

Electronic editable versions of the paper PAFs and TIFs will be made available via the registered Chief Pharmacist (and/or their Deputy). Prescribers should contact their pharmacists to obtain access to these editable forms should they be required.

Call for reporting
Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle▼

It is easiest and quickest to report ADRs online or electronically via:

- the Yellow Card website - www.mhra.gov.uk/yellowcard
- the Yellow Card app available from the Apple App Store or Google Play Store

- through some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

Lenalidomide (Revlimid®▼) and pomalidomide (Imnovid®▼) are subject to additional monitoring. This will allow quick identification of new safety information. Note: Pregnancies (in a female patient or a female partner of a male patient) should be reported **immediately**.

Adverse reactions and reports of pregnancies associated with the use of thalidomide (Thalidomide Celgene®), lenalidomide (Revlimid®▼) and pomalidomide (Imnovid®▼) may also be reported to Celgene: Celgene Drug Safety, Celgene Ltd, 1 Longwalk Road, Stockley Park, Uxbridge, UB11 1DB.
Telephone: 0808 238 9908
Fax: 0844 801 0468
email: drugsafetyuk@celgene.com

Communication information
If you have any further questions or require further information, please contact Celgene's Risk Management team at:
Telephone: 0808 156 3059
Fax: 0808 156 3058
email: rmp.uk.ire@celgene.com

Yours faithfully,

Dr Faisal Mehmud
Executive Medical Director BMS
Celgene Limited

References:

1. Public Health England Guidance on shielding and protecting people defined on medical grounds as extremely vulnerable from COVID-19: https://www.gov.uk/government/publications/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19 Updated March 30th, 2020.
2. Summary of Product Characteristics for Thalidomide: https://www.medicines.org.uk/emc/product/6317
3. Summary of Product Characteristics for Lenalidomide: https://www.medicines.org.uk/emc/search?q=revlimid
4. Summary of Product Characteristics for Pomalidomide: https://www.medicines.org.uk/emc/search?q=imnovid
5. NHS Clinical guide for the management of non-coronavirus patients requiring acute treatment: Cancer 23 March 2020 Version 2: https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/03/specialty-guide-acute-treatment-cancer-23-march-2020.pdf