

This checklist is to assist you with counselling a patient before they start lenalidomide treatment to ensure it is used safely and correctly.

## Checklist for the Initiation of Lenalidomide Treatment in Woman of Childbearing Potential (WOCBP)

### COUNSELLING

	Tick ✓ or NA
Counselled the patient about the expected teratogenic risk to an unborn child	
Outlined the need to use effective contraception** for at least 4 weeks before starting treatment, throughout the treatment (including during treatment interruptions), and for at least 4 weeks after the end of treatment <i>The need for contraception does not apply to patients who confirm monthly absolute and continuous abstinence from heterosexual intercourse.</i>	
Informed the patient that even if a woman has amenorrhea, they must comply with advice on effective contraception.	
Confirmed that the patient can comply with effective contraceptive measures	
Outlined the expected consequences of pregnancy and the need to inform a healthcare professional immediately if the patient becomes pregnant or thinks for any reason that they may be pregnant	
Counselled of the need to stop treatment immediately if the patient is suspected to be pregnant	
Confirmed that the patient agrees to perform pregnancy testing at 4 weekly intervals unless tubal sterilization is confirmed	
Informed of the hazards and the necessary precautions associated with lenalidomide	
Instructed the patient not to share medications	
Counselled that unused capsules must be returned to a pharmacy	
Counselled not to donate blood# whilst taking Lenalidomide (including during treatment interruptions) and for at least 7 days following discontinuation.	
Educated about thromboembolism risk and requirement to take thromboprophylaxis during treatment with lenalidomide	
*Refer to Healthcare Professional booklet for criteria to determine if patient is a woman of non-childbearing potential. **Refer to Healthcare Professional booklet for information on contraception. #In Australia patients with multiple myeloma are permanently excluded from donating blood.	

### Referral for Contraception

	Yes/No
Is a contraceptive referral required?	
Date the contraceptive referral was made	
Contraceptive consultation completed	

### Contraception (Patient is currently established on one of the following for at least 4 weeks)

Contraceptive implant	
Levonorgestrel-releasing intrauterine system (IUS)	
Medroxyprogesterone acetate depot	
Sterilisation	
Sexual intercourse with a vasectomized male partner only: Vasectomy must be confirmed by two negative semen analyses	
Ovulation inhibitory progesterone-only pill (desogestrel)	

**TREATMENT FOR A WOMAN OF CHILDBEARING POTENTIAL CANNOT START UNTIL THE PATIENT HAS BEEN ESTABLISHED ON ONE EFFECTIVE METHOD OF CONTRACEPTION FOR AT LEAST 4 WEEKS PRIOR TO INITIATION OF THERAPY, OR COMMITS TO ABSOLUTE AND CONTINUOUS ABSTENENCE. A NEGATIVE PREGNACNY TEST IS ALSO REQUIRED.**

## Checklist for the Initiation of Lenalidomide Treatment in a Woman of Non-Childbearing Potential (WNCBP)

### COUNSELLING

	Tick ✓ or Not Applicable
Counselled the patient of the expected teratogenic risk to an unborn child	
Informed of the hazards and the necessary precautions associated with lenalidomide	
Instructed the patient not to share medications	
Counselled that unused capsules must be returned to a pharmacy	
Counselled not to donate blood <sup>#</sup> whilst taking Lenalidomide (including during treatment interruptions) and for at least 7 days following discontinuation.	
Educated about thromboembolism risk and requirement to take thromboprophylaxis during treatment with lenalidomide	

### To be classed as a Woman of Non-Child Bearing Potential (WNCBP), at least one of the following criteria must be met:

Age ≥ 50 years of age and naturally amenorrhoeic** for ≥ 1 year (amenorrhoea following cancer therapy does not rule out childbearing potential)	
Premature ovarian failure confirmed by a specialist gynecologist	
Bilateral salpingo-oophorectomy or hysterectomy	
XY genotype, Turner syndrome, uterine agenesis	

<sup>#</sup>In Australia patients with multiple myeloma are permanently excluded from donating blood.

**\*\*Amenorrhoea following cancer therapy or during breastfeeding does not rule out childbearing potential**

## Checklist for Initiation of Lenalidomide Treatment in a Male Patient

### Counselling

	Tick ✓ or Not Applicable
Counselled the patient of the expected teratogenic risk to an unborn child	
Confirmed the patient can comply with effective contraceptive measures	
Outlined the expected consequences of pregnancy and the need to inform a healthcare professional immediately if his partner becomes pregnant or thinks for any reason that she may be pregnant, whilst the patient is receiving lenalidomide or within 7 days after cessation. Advised that the patient's partner should also immediately consult a healthcare professional specialized or experienced in teratology for evaluation and advice.	
Informed of the hazards and the necessary precautions associated with lenalidomide	
Educated in the need to use condoms, including those who have had a vasectomy as seminal fluid may still contain lenalidomide in the absence of spermatozoa, throughout treatment duration, during dose interruption, and for at least 7 days after cessation of treatment if his partner is pregnant or of childbearing potential and not using effective contraception	
Instructed the patient not to share medications	
Counselled that unused capsules must be returned to a pharmacy	
Counselled not to donate blood* whilst taking Lenalidomide (including during treatment interruptions) and for at least 7 days following discontinuation.	
Instructed not to donate semen or sperm during treatment, during dose interruptions and for at least 7 days following discontinuation	
Educated about thromboembolism risk and requirement to take thromboprophylaxis during treatment with lenalidomide	
Outlined the need to use effective contraception** for at least 4 weeks before starting treatment, throughout the treatment (including during treatment interruptions), and for at least 4 weeks after the end of treatment <i>The need for contraception does not apply to patients who confirm monthly absolute and continuous abstinence from heterosexual intercourse.</i>	

\* In Australia patients with multiple myeloma are permanently excluded from donating blood.

\*\*Refer to Healthcare Professional booklet for information on contraception.