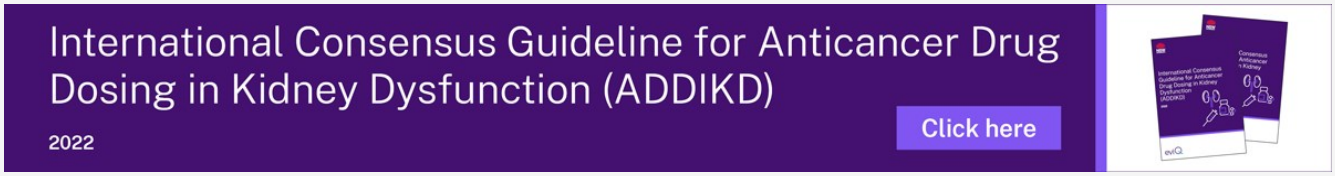
Multiple myeloma lenalidomide maintenance post autologous transplant

ID: 3797 v.2 **Endorsed** Essential Medicine List

Patients with myeloma should be considered for inclusion into clinical trials. Link to ALLG website and ANZCTR website.

Link to Medical Scientific Advisory Group (MSAG) Clinical Practice Guideline Multiple Myeloma

The anticancer drug(s) in this protocol may have been included in the ADDIKD guideline. Dose recommendations in kidney dysfunction have yet to be updated to align with the ADDIKD guideline. Recommendations will be updated once the individual protocol has been evaluated by the reference committee. For further information refer to the ADDIKD guideline. To assist with calculations, use the eviQ Estimated Glomerular Filtration Rate (eGFR) calculator.



Treatment schedule - Overview

Drug	Dose	Route
Lenalidomide	10 mg ONCE a day *	PO

* Dose may be increased to 15 mg daily after 3 months if tolerated

Continuous until disease progression or unacceptable toxicity

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Notes:

- This monotherapy protocol is intended for lenalidomide maintenance and should start at **day 90 - 100** following autologous transplant.
- In the MM09 and MM010 studies, the main dose limiting toxicities of lenalidomide were neutropenia and thrombocytopenia, manageable with dose adjustment and/or addition of growth factor support; and venous thromboembolic events managed with anticoagulants.[1, 2]
- The treatment schedule in this protocol includes continuous 10 mg/day dosing[3, 4, 5], however there are alternative treatment schedules that may be considered and institutional practice may differ.

Drug status: **Lenalidomide** (PBS authority)

NB: Patient registration into a pregnancy prevention risk management program is required.

Lenalidomide is available as **5 mg**, **10 mg, 15 mg** and **25 mg** capsules

Cost: ~ $2,030 per cycle

Treatment schedule - Detail

The supportive therapies (e.g. antiemetics, premedications, etc.), infusion times, diluents, volumes and routes of administration, if included, are listed as defaults. They may vary between institutions and can be substituted to reflect individual institutional policy.

*Antiemetics if included in the treatment schedule are based upon recommendations from national and international guidelines. These are **defaults only** and may be substituted to reflect individual institutional policy. Select here for recommended doses of alternative antiemetics.*

Continuous treatment		
Lenalidomide	10 mg (PO)	ONCE a day. Take at same time each day, either with or without food.

- This monotherapy protocol is intended for lenalidomide maintenance and should start at **day 90 - 100** following autologous transplant.
- Dose may be increased to 15 mg daily after 3 months if tolerated

Continuous until disease progression or unacceptable toxicity

Indications and patient population

- Multiple myeloma patients post autologous stem cell transplant starting on days 90 - 100

Clinical information

Caution with oral anti-cancer drugs	Select links for information on the safe prescribing, dispensing and administration of orally administered anti-cancer drugs. Read more about the COSA guidelines and oral anti-cancer therapy
Emetogenicity minimal or low	No routine prophylaxis required. If patients experience nausea and/or vomiting, consider using the low emetogenic risk regimen. Read more about preventing anti-cancer therapy induced nausea and vomiting
Teratogenic effects	Immunomodulatory drugs (IMiDs) include thalidomide, lenalidomide and pomalidomide. They can cause severe congenital disabilities or death to an unborn baby when taken during pregnancy. All patients and partners of patients that can conceive a child must use at least one reliable contraceptive method for at least 4 weeks before starting treatment, during treatment (including dose interruptions), and for 4 weeks after stopping treatment. Male patients should also use a condom when having sexual intercourse with a woman of childbearing potential during treatment (including dose interruptions), and for 4 weeks after stopping treatment. In female patients and female partners of male patients, a pregnancy test should be carried out prior to initiating treatment (after 4 weeks of contraception use), weekly during the first month of treatment and monthly thereafter. Effective contraception methods and adequate contraception timeframes should be discussed with all patients of reproductive potential. Prescription of an IMiD requires patient registration with a pregnancy prevention program. Full prescribing information and Authority Application forms available from the Department of Human Services website
Thromboembolism	Patients are at an increased risk of venous thrombosis with this treatment. Risk assessment for VTE should be performed prior to and during treatment. It is the consensus opinion of the Haematology Reference Committee that concomitant thromboprophylaxis is recommended in this patient population group: consider using low dose aspirin for patients without pre-existing risk factors, while patients with pre-existing risk factors should receive enoxaparin 40 mg subcut daily for the duration of treatment (unless contraindicated; reduce dose in kidney dysfunction).

Bone modifying agents	Use of a bone modifying agent (BMA) should be considered in all patients with symptomatic myeloma requiring treatment. For patients with newly diagnosed symptomatic myeloma, zoledronic acid, pamidronate or denosumab should be considered for monthly administration (adjust for kidney dysfunction where appropriate) for up to 2 years. A longer duration of therapy may be appropriate (MRC M IX trial).[6] For more information, please see the following protocols: ID 137 Multiple myeloma zoledronic acid ID 147 Multiple myeloma pamidronate ID 3964 Multiple myeloma denosumab - note denosumab is TGA approved but not PBS reimbursed for this indication.
Bisphosphonates and dental review	Caution should be taken with prolonged use of bisphosphonates due to the risk of osteonecrosis of the jaw (ONJ). A dental review prior to treatment is recommended, and all dental issues treated before the initiation of bisphosphonates. Dental review 6 to 12 monthly during treatment is advisable to minimise risk of ONJ. Concurrent daily oral supplements of calcium 500 mg and vitamin D 400 International Units are recommended. Read more about medication-related osteonecrosis of the jaw (MRONJ)
Tumour lysis risk	Assess patient for risk of developing tumour lysis syndrome. Read more about prevention and management of tumour lysis syndrome.
PJP prophylaxis	PJP prophylaxis at the discretion of the treating clinician. Read more about prophylaxis of pneumocystis jiroveci (carinii) in cancer patients
Antiviral prophylaxis	It is the consensus opinion of the Haematology Reference committee that consideration be given to continuing antiviral prophylaxis with valaciclovir while on this treatment due to the ongoing high risk of varicella zoster virus reactivation. Read more about antiviral prophylaxis drugs and doses
Growth factor support	G-CSF (short or long-acting) is available on the PBS for chemotherapy induced neutropenia depending on clinical indication and/or febrile neutropenia risk. Access the PBS website
Blood tests	FBC, EUC, LFTs, calcium, magnesium, phosphate and BSL at baseline then monthly thereafter. Patients with normal pre-treatment FBC: repeat FBC fortnightly for the first four weeks then monthly thereafter. Patients with pre-treatment cytopenias: repeat FBC 1 to 2 weekly for the first four weeks then monthly thereafter. Consider monitoring thyroid function tests (reported cases of hypothyroidism).
Hepatitis B screening and prophylaxis	Routine screening for HBsAg and anti-HBc is recommended prior to initiation of treatment. Prophylaxis should be determined according to individual institutional policy. Read more about hepatitis B screening and prophylaxis in cancer patients requiring cytotoxic and/or immunosuppressive therapy
Vaccinations	Live vaccines are contraindicated in cancer patients receiving immunosuppressive therapy and/or who have poorly controlled malignant disease. Refer to the recommended schedule of vaccination for immunocompromised patients, as outlined in the Australian Immunisation Handbook. Read more about COVID-19 vaccines and cancer.
Fertility and lactation	Cancer treatment can have harmful effects on fertility and this should be discussed with all patients of reproductive potential prior to commencing treatment. Possibility of infant risk should be discussed with breastfeeding patients. Read more about the effect of cancer treatment on fertility

Dose modifications

Evidence for dose modifications is limited, and the recommendations made on eviQ are intended as a guide only. They are generally conservative with an emphasis on safety. Any dose modification should be based on clinical judgement, and the

individual patient's situation including but not limited to treatment intent (curative vs palliative), the anti-cancer regimen (single versus combination therapy versus chemotherapy versus immunotherapy), biology of the cancer (site, size, mutations, metastases), other treatment related side effects, additional co-morbidities, performance status and patient preferences.Suggested dose modifications are based on clinical trial findings, product information, published guidelines and reference committee consensus . The dose reduction applies to each individual dose and not to the total number of days or duration of treatment cycle unless stated otherwise. Non-haematological gradings are based on Common Terminology Criteria for Adverse Events (CTCAE) unless otherwise specified. Renal and hepatic dose modifications have been standardised where possible. For more information see dosing considerations & disclaimer .

The dose recommendations in kidney dysfunction (i.e.renal impairment) displayed may not reflect those in the ADDIKD guideline and have been included for historical reference only. Recommendations will be updated once the individual protocol has been evaluated by the reference committee, with this version of the protocol then being archived. Clinicians are expected to refer to the ADDIKD guideline prior to prescribing in kidney dysfunction.
International Consensus Guideline for Anticancer Drug Dosing in Kidney Dysfunction (ADDIKD).

Initial treatment with lenalidomide should not be started if ANC less than 1.0 x 10^9/L and/or platelets less than 75 x 10^9/L (or platelets less than 30 x 10^9/L if heavy bone marrow involvement), however, may be commenced at the discretion of the treating haematologist.

Dose reduction steps for lenalidomide to manage haematological toxicities	
Starting dose	10 mg
Dose level 1	5 mg
Dose level 2	5 mg on alternate days
Dose level 3	Discontinue lenalidomide
If lenalidomide dose was increased to 15 mg:	
Starting dose	15 mg
Dose level 1	10 mg
Dose level 2	5 mg
Dose level 3	5 mg for 21 days, no lenalidomide for 7 days (Day 1 - 21 of a 28-day cycle)
Dose level 4	Discontinue lenalidomide

Haematological toxicity	
ANC x 10^9/L (pre-treatment blood test)	
Do not initiate if neutrophils are <1	
First fall to less than 0.5	Interrupt lenalidomide treatment
Return to greater than or equal to 0.5	Resume lenalidomide at dose level 1
For each subsequent drop less than 0.5	Interrupt lenalidomide treatment
Return to greater than or equal to 0.5	Resume at next lower dose level (dose level 2 or 3) Do not dose below 5 mg
Consider using G-CSF if neutropenia is the only toxicity at any dose level and maintaining the current lenalidomide dose	
Platelets x 10^9/L (pre-treatment blood test)	
First fall to less than 30	Interrupt lenalidomide treatment
Return to greater than or equal to 30	Resume lenalidomide at dose level 1
For each subsequent drop less than 30	Interrupt lenalidomide treatment
Return to greater than or equal to 30	Resume lenalidomide at next lower dose level (dose level 2 or 3) Do not dose below 5 mg

Renal impairment	
Lenalidomide is substantially excreted by the kidneys. Monitoring of renal function is advised in all patients with renal impairment. The following dose adjustments are recommended at the ***start of therapy*** for patients with moderate or severe impaired renal function or end stage renal disease. Subsequent lenalidomide dose modifications should be based on individual patient treatment tolerance. Patients with impaired renal function should be monitored for signs and symptoms of neutropenia or thrombocytopenia as per the recommendations above.	
Creatinine clearance (mL/min)	
30 to 60	5 mg once daily
less than 30	5 mg on alternate days
On dialysis	5 mg 3 times a week post dialysis

Hepatic impairment
No formal studies of lenalidomide in patients with hepatic impairment, therefore no specific dose recommendations. If abnormal liver function tests are reported, interrupt lenalidomide treatment. Once parameters have returned to baseline, treatment at a lower dose may be considered.

Dermatological reactions[7, 8]	
Rare cases of Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported. These may be potentially fatal.	
Rash	
Grade 1	Continue lenalidomide. Treat with topical corticosteroids and oral antihistamines.
Grade 2	Consider interruption of lenalidomide. Treat with topical corticosteroids and oral antihistamines until toxicity resolves.
Grade 3	Consider interruption of lenalidomide. Treat with oral antihistamines or oral corticosteroids until toxicity resolves.
Stevens-Johnson syndrome or **Toxic epidermal necrolysis**	Permanent discontinuation of lenalidomide treatment.

Thromboembolism
Interrupt lenalidomide and start anticoagulation therapy. Once stabilised on anticoagulation and any complications of thromboembolism have been managed, lenalidomide may be restarted at the original dose depending on the risk-benefit assessment and continue anticoagulation if restarting lenalidomide.

Interactions

Drug interactions in eviQ protocols are under review and being updated to align with current literature. Further site-wide updates and changes will occur in due course. References & Disclaimer

The drug interactions shown below are not an exhaustive list. For a more comprehensive list and for detailed information on specific drug interactions and clinical management, please refer to the specific drug product information and the following key resources:

- *MIMS - interactions tab (includes link to a CYP-450 table) (login required)*
- *Australian Medicines Handbook (AMH) – interactions tab (login required)*
- *Micromedex Drug Interactions (login required)*
- *Cancer Drug Interactions*
- *Cytochrome P450 Drug Interactions*

Lenalidomide		
	Interaction	**Clinical management**
Digoxin	Potentially increased digoxin plasma levels when combined with lenalidomide; mechanism unknown	Monitor digoxin levels and for signs of drug toxicity during treatment with lenalidomide
HMG-CoA reductase inhibitors (Statins)	Potentially additive toxicity	Monitor for signs and symptoms of myotoxicity and rhabdomyolysis (e.g.: unexplained muscle pain, muscle stiffness or tenderness, dark urine) during concomitant use
Erythropoietic agents, combined oral contraceptives or hormone replacement therapy	Additive risk of thromboembolic events due to an increased risk of VTE	Consider the benefit/risk of concomitant therapy

General		
	Interaction	**Clinical management**
Warfarin	Anti-cancer drugs may alter the anticoagulant effect of warfarin.	Monitor INR regularly and adjust warfarin dosage as appropriate; consider alternative anticoagulant.
Direct oral anticoagulants (DOACs) e.g. apixaban, rivaroxaban, dabigatran	Interaction with both CYP3A4 and P-gp inhibitors /inducers. DOAC and anti-cancer drug levels may both be altered, possibly leading to loss of efficacy or toxicity (i.e. increased bleeding).	Apixaban: avoid concurrent use with strong CYP3A4 and P-gp inhibitors. If treating VTE, avoid use with strong CYP3A4 and P-gp inducers. Rivaroxaban: avoid concurrent use with strong CYP3A4 and P-gp inhibitors. Dabigatran: avoid combination with strong P-gp inducers and inhibitors. If concurrent use is unavoidable, monitor closely for efficacy/toxicity of both drugs.
Digoxin	Anti-cancer drugs can damage the lining of the intestine; affecting the absorption of digoxin.	Monitor digoxin serum levels; adjust digoxin dosage as appropriate.
Antiepileptics	Both altered antiepileptic and anti-cancer drug levels may occur, possibly leading to loss of efficacy or toxicity.	Where concurrent use of an enzyme-inducing antiepileptic cannot be avoided, monitor antiepileptic serum levels for toxicity, as well as seizure frequency for efficacy; adjust dosage as appropriate. Also monitor closely for efficacy of the anti-cancer therapy.
Antiplatelet agents and NSAIDs	Increased risk of bleeding due to treatment related thrombocytopenia.	Avoid or minimise combination. If combination deemed essential, (e.g. low dose aspirin for ischaemic heart disease) monitor for signs of bleeding.
Serotonergic drugs, including selective serotonin reuptake inhibitors (SSRIs e.g. paroxetine) and serotonin noradrenaline reuptake inhibitors (SNRIs e.g. venlafaxine)	Increased risk of serotonin syndrome with concurrent use of 5-HT3 receptor antagonists (e.g. palonosetron, ondansetron, granisetron, tropisetron, dolasetron, etc.)	Avoid combination. If combination is clinically warranted, monitor for signs and symptoms of serotonin syndrome (e.g. confusion, agitation, tachycardia, hyperreflexia). For more information link to TGA Medicines Safety Update
Vaccines	Diminished response to vaccines and increased risk of infection with live vaccines.	Live vaccines (e.g. BCG, MMR, zoster and varicella) are contraindicated in patients on immunosuppressive therapy. Use with caution in patients on non-immunosuppressive therapy. For more information; refer to the recommended schedule of vaccination for cancer patients, as outlined in the Australian Immunisation Handbook

Administration

eviQ provides safe and effective instructions on how to administer cancer treatments. However, eviQ does not provide every treatment delivery option, and is unable to provide a comprehensive list of cancer treatment agents and their required IV line giving set/filter. There may be alternative methods of treatment administration, and alternative supportive treatments that are also appropriate. Please refer to the individual

product information monographs via the TGA website for further information.

Administration

This is a continuous oral treatment

Safe handling and waste management (reproductive risk only)

Safe administration

General patient assessment prior to each day of treatment.

Any toxicity grade 2 or greater may require delay of treatment and review by medical officer before commencing treatment.

Peripheral neuropathy assessment tool.

Treatment - Time out

Lenalidomide

- administer orally ONCE a day, at the same time each day
- to be swallowed whole with a glass of water; do not break, crush or chew
- can be taken either with or without food

Note: missed doses should not be taken if it is less than 12 hours until the next dose.

Continue safe handling precautions (reproductive risk only) for 7 days after completion of drug(s).

Discharge information

Lenalidomide capsules

- Lenalidomide capsules with written instructions on how to take them.

Antiemetics

- Antiemetics as prescribed.

Thromboprophylaxis

- Low dose aspirin OR enoxaparin 40 mg subcut daily for the duration of treatment if prescribed.

Growth factor support

- Arrangements for administration if prescribed.

Prophylaxis medications

- Prophylaxis medications (if prescribed) i.e. antivirals, tumour lysis prophylaxis, PJP prophylaxis and medication for constipation.

Patient information

- Ensure patient receives patient information sheet.

Side effects

The side effects listed below are not a complete list of all possible side effects for this treatment. Side effects are categorised into the approximate onset of presentation and should only be used as a guide.

Immediate (onset hours to days)	
Flu-like symptoms	
Taste and smell alteration	Read more about taste and smell changes

Early (onset days to weeks)	
Neutropenia	Abnormally low levels of neutrophils in the blood. This increases the risk of infection. Any fever or suspicion of infection should be investigated immediately and managed aggressively. Read more about immediate management of neutropenic fever
Thrombocytopenia	A reduction in the normal levels of functional platelets, increasing the risk of abnormal bleeding. Read more about thrombocytopenia
Arthralgia and myalgia	Generalised joint pain or and/or stiffness and muscle aches, often worse upon waking or after long periods of inactivity. Can improve with movement. May be mild or severe, intermittent or constant and accompanied by inflammation. Read more about arthralgia and myalgia
Constipation	
Cough	
Diarrhoea	Read more about treatment induced diarrhoea
Fatigue	Read more about fatigue
Respiratory tract infection	
Skin rash	Anti-cancer drugs can cause a number of changes in the skin with maculo-papular rash the most common type of drug-induced skin reaction. Read more about skin rash
Thromboembolism	Venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE) is increased in multiple myeloma patients treated with lenalidomide monotherapy post autologous transplant.

Late (onset weeks to months)	
Anaemia	Abnormally low levels of red blood cells (RBCs) or haemoglobin in the blood. Read more about anaemia
Diarrhoea (late onset)	Chronic loose stools due to bile acid malabsorption has been observed in patients receiving lenalidomide. Referral to Gastroenterology should be considered. An empiric trial of cholestyramine (a bile-acid binding resin) is reasonable for these patients. Read more about treatment induced diarrhoea
Hypothyroidism	
Muscle cramps	Cramping in the hands, calves and/or thighs associated with hypomagnesaemia (low magnesium) and/or hypocalcaemia (low calcium).

Delayed (onset months to years)	
Stevens-Johnson syndrome (SJS)	Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN) is characterised by fever, malaise, a painful rash, erythematous macules, targetoid lesions, or diffuse erythema progressing to vesicles and bullae, and oral, ocular and/or genital mucositis with painful mucosal erosion. Patients who develop SJS/TEN should never be re-exposed to the causative agent.

Evidence

Patient-level data of three Phase III randomised controlled trials evaluating the efficacy of this regimen (CALGB 100104,[3] GIMEMA RV-MM-PI-209[9] and IFM-2005-02[4]) were pooled in a systematic review with meta-analysis.[10] 1208 adults with newly diagnosed multiple myeloma (MM) who received induction therapy and high dose melphalan followed by autologous stem cell transplantation (ASCT) and consolidation therapy were included. Lenalidomide maintenance therapy was shown to have longer progression free survival (PFS) and overall survival (OS) compared with placebo or observation. However, lenalidomide maintenance was also associated with higher cumulative incidence rates of second primary malignancy before disease progression. Longer term follow-

up of CALGB 100104 confirmed these findings of increased time to progression and second primary malignancies with lenalidomide maintenance compared with placebo.[5]

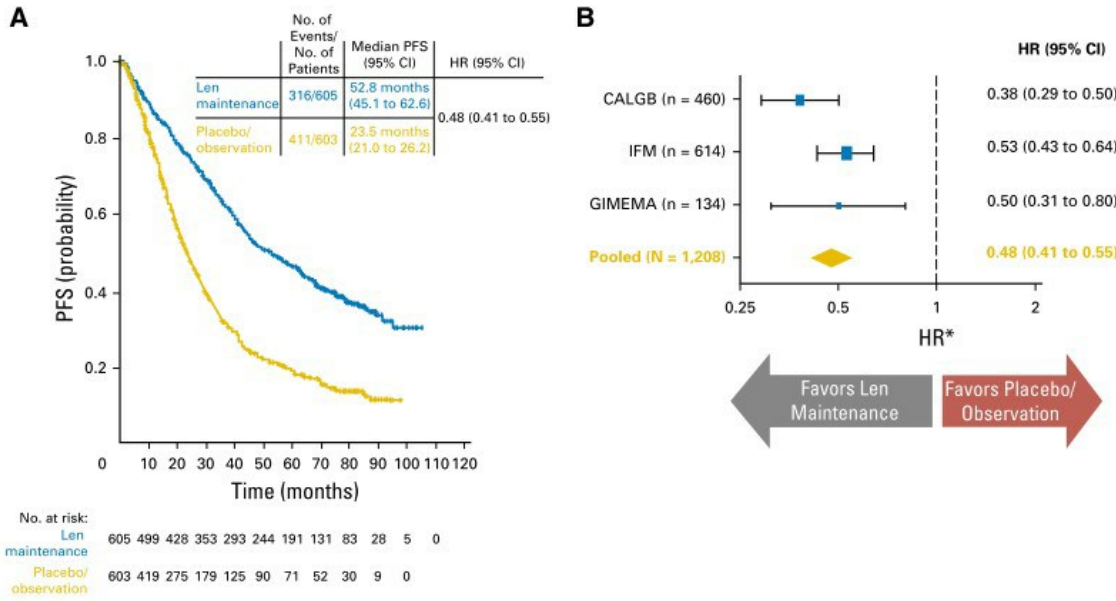
Myeloma XI, the final Phase III randomised control trial (RCT), was not included as it was undergoing data collection at the time of the meta-analysis' publication.[11] Myeloma XI's maintenance arm included 1971 adults with symptomatic or non-secretory MM who had completed their assigned induction and consolidation therapy. In the overall intention-to-treat analysis, Myeloma XI showed lenalidomide maintenance improved PFS, but not OS compared with observation. In transplant-eligible patients, maintenance occurred after high-dose melphalan and ASCT alongside induction and consolidation, but Myeloma XI also included transplant-ineligible patients who only received induction and consolidation therapy with at least minimal response. Importantly, a subgroup analysis of Myeloma XI, although not sufficiently powered, suggested lenalidomide maintenance improved OS in transplant-eligible patients but not transplant-ineligible patients. This may explain why OS was not improved in the overall analysis.

All above RCTs started with a dose of lenalidomide of 10mg daily, either in a full 28-day cycle[3, 4, 5] or days 1-21 of a 28-day cycle.[9, 11] 2 studies allowed increase in dose to 15mg daily after 3 months if the 10mg dosing was tolerated.[4, 5]

Efficacy

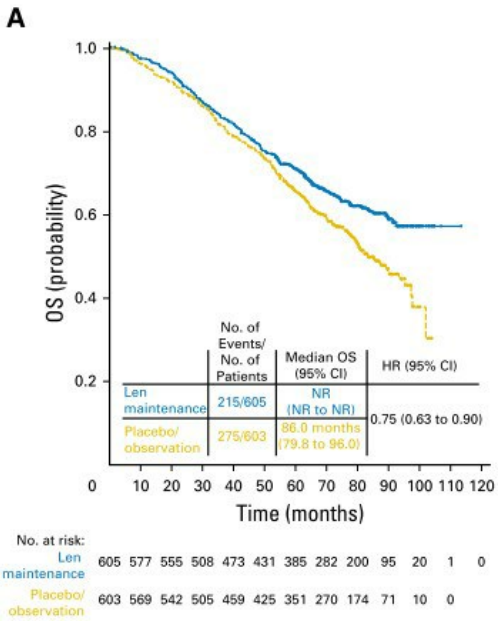
The 1208 patients within the meta-analysis (605 in the lenalidomide maintenance group and 603 in placebo/observation group) had a median follow-up of 79.5 months and mean treatment duration of 28 months with lenalidomide maintenance and 22 months with placebo or observation. Pooled median PFS was 52.8 months in the lenalidomide group and 23.5 months in the placebo/observation group (HR 0.48, 95% CI 0.41-0.55). This improvement was confirmed in all included studies.

Figure 1: Kaplan-Meier estimates of PFS (A). Hazard ratios (HRs) for PFS by individual study (B).[10]



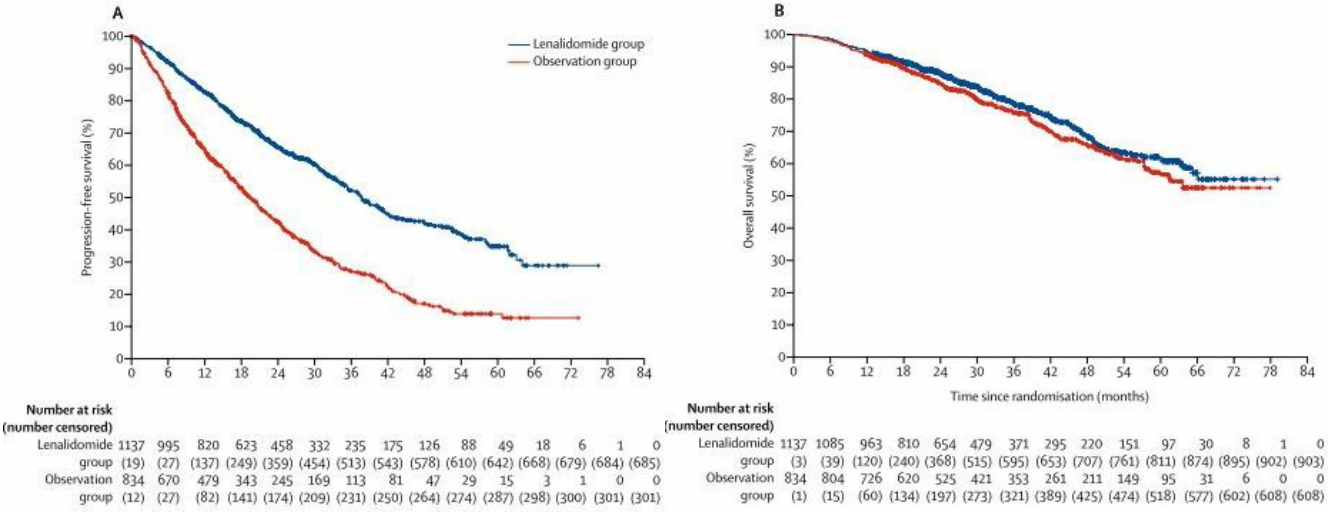
OS was also improved, with median OS not being reached in the lenalidomide maintenance group but 86 months in the placebo/observation group (HR 0.75, 95% CI 0.63-0.90), representing a 25% risk reduction in risk of death. The 7-year survival rate was 62% with lenalidomide maintenance and 50% with placebo/observation.

Figure 2: Kaplan-Meier estimates of OS[10]



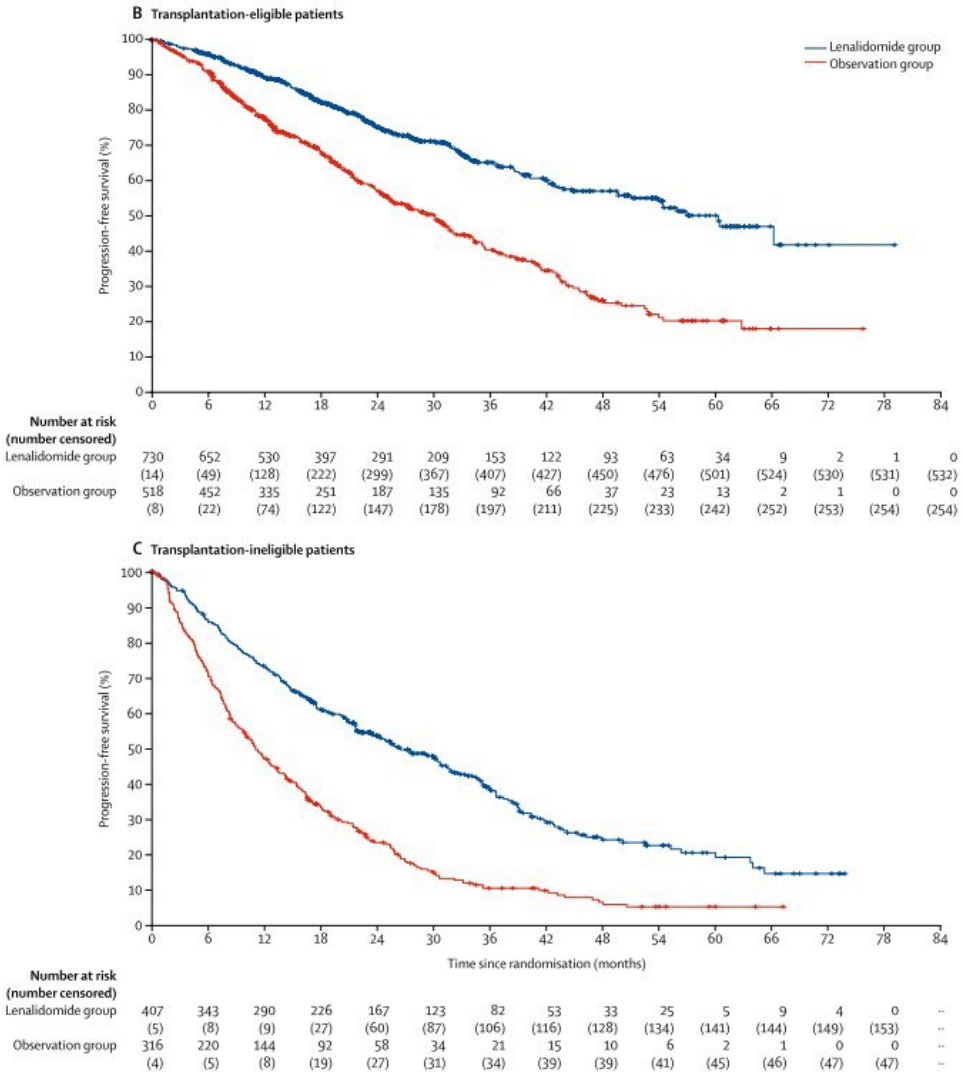
1971 patients were randomised to Myeloma XI's maintenance arm, with 1137 in the lenalidomide maintenance group and 834 in the observation group. With median follow-up after randomisation of 31 months, median PFS was 39 months with lenalidomide maintenance and 20 months with observation (HR 0.46, 95% CI 0.41-0.53). Median OS was not reached in either group and there was no difference between groups in OS (HR 0.87 95% CI 0.73-1.05). 40% of the lenalidomide group and 64% of the observation group had disease progression or died. Median duration of lenalidomide maintenance was 18 cycles.

Figure 3: Kaplan-Meier plots of progression-free survival (A) and overall survival (B) in the intention-to-treat population[11]



Notably, in a pre-specified analysis by transplant eligibility in Myeloma XI, transplant eligible patients received the most benefit from lenalidomide maintenance. Within the transplant eligible group, PFS was 57 months with lenalidomide and 30 months with observation (HR 0.48, 95% CI 0.40-0.58) but in transplant ineligible patients, PFS was 26 months with lenalidomide and 11 months with observation (HR 0.44, 95% CI 0.37-0.53).[11] Similarly, within the transplantation eligible group 3-year OS was 87.5% with lenalidomide and 80.2% with observation (HR 0.69, 95% CI 0.52-0.93) but there was no effect in the transplant ineligible group with 3-year OS of 66.8% with lenalidomide and 69.8% with observation (HR 1.02, 95% CI 0.80-1.29).

Figure 4: Kaplan-Meier plot of progression-free survival 2 in transplantation-eligible patients (A) and transplantation-ineligible patients (B)[11]



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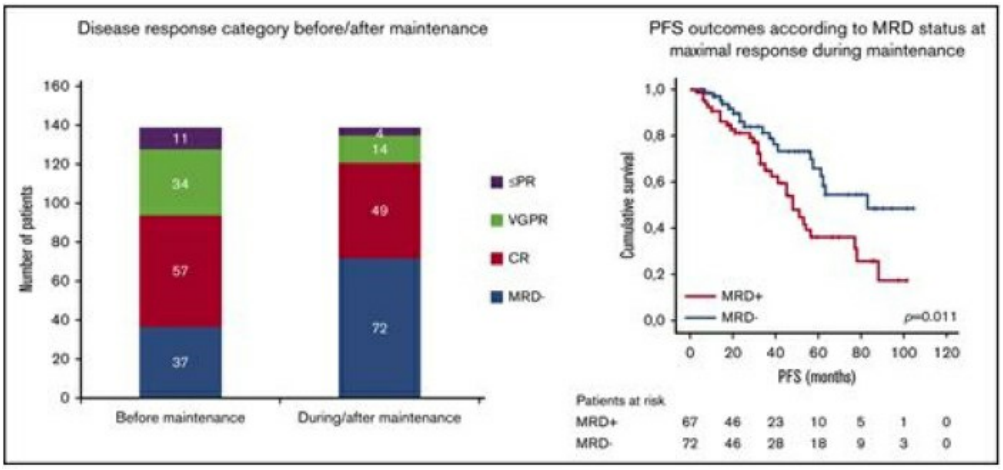
Myeloma XI[11] also included a pooled analysis of all available data for lenalidomide maintenance post SCT for newly diagnosed MM, including other papers (5), (7) and (8). With the addition of the Myeloma XI data, meta-analysis of all published lenalidomide maintenance after autologous stem-cell transplantation data (N = 3179 patients overall) was undertaken and showed OS benefit for post-AutoSCT lenalidomide (compared to observation) with HR 0.72 (0.56 – 0.91).

More contemporary, 'real-world' data[12] exists demonstrating deepening of responses over time in patients receiving lenalidomide maintenance post transplantation. This retrospective 'real-world' analysis included N = 139 patients treated in whom minimal residual disease (MRD) data (sensitivity at least 10-4) were known (Flow cytometry or Next-generation sequencing). Lenalidomide maintenance correlated with an increased depth of the disease response, with 38.1% of patients achieving maximal response during maintenance, and 34.3% of patients who were MRD positive after induction treatment achieved MRD-negative status during maintenance and ultimately had improved PFS. These results support the role of maintenance therapy, to increase depth of response to front-line treatment, which has been shown previously to correlate with improved survival.

Figure 5: Deepening responses with duration lenalidomide exposure post SCT[12]



Toxicity

Figure 5: Adverse events[10]

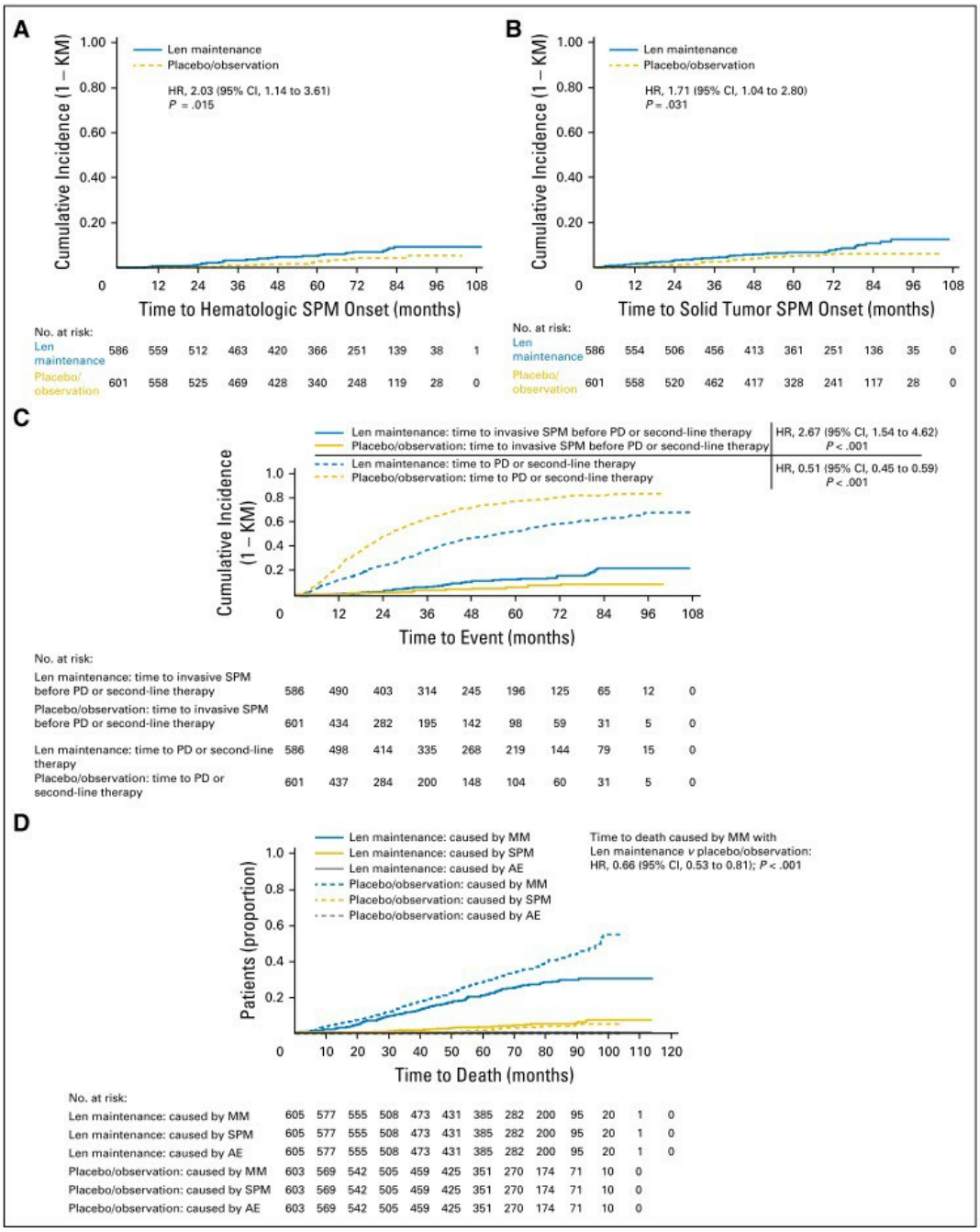
Table 3. Discontinuations as a Result of TEAEs (safety population)

TEAE	No. of Patients (%)					
	CALGB		IFM*		Pooled	
	Len Maintenance (n = 224)	Placebo (n = 221)	Len Maintenance (n = 306)	Placebo (n = 302)	Len Maintenance (n = 530)†	Placebo (n = 523)†
≥ 1 TEAE leading to discontinuation	63 (28.1)	19 (8.6)	91 (29.7)	45 (14.9)	154 (29.1)	64 (12.2)
TEAEs leading to discontinuation (≥ 1% of all patients)‡						
Blood and lymphatic system disorder	11 (4.9)	4 (1.8)	12 (3.9)	7 (2.3)	23 (4.3)	11 (2.1)
Neutropenia	5 (2.2)	0	7 (2.3)	1 (0.3)	12 (2.3)	1 (0.2)
Thrombocytopenia	6 (2.7)	1 (0.5)	3 (1.0)	5 (1.7)	9 (1.7)	6 (1.1)
General disorders and administration site conditions	12 (5.4)	5 (2.3)	13 (4.2)	3 (1.0)	25 (4.7)	8 (1.5)
Adverse event not specified	10 (4.5)	4 (1.8)	0	0	10 (1.9)	4 (0.8)
Neoplasms: benign, malignant, and unspecified§	16 (7.1)	3 (1.4)	7 (2.3)	2 (0.7)	23 (4.3)	5 (1.0)
Skin and subcutaneous tissue disorders	6 (2.7)	1 (0.5)	12 (3.9)	9 (3.0)	18 (3.4)	10 (1.9)
Nervous system disorders	5 (2.2)	3 (1.4)	13 (4.2)	6 (2.0)	18 (3.4)	9 (1.7)
GI disorders	5 (2.2)	0	13 (4.2)	1 (0.3)	18 (3.4)	1 (0.2)
Diarrhea	5 (2.2)	0	6 (2.0)	0	11 (2.1)	0
Infections and infestations	4 (1.8)	0	5 (1.6)	4 (1.3)	9 (1.7)	4 (0.8)
Musculoskeletal and connective tissue disorders	1 (0.4)	1 (0.5)	5 (1.6)	6 (2.0)	6 (1.1)	7 (1.3)

NOTE. Safety population includes patients who received at least one dose of study drug.
Abbreviations: CALGB, Cancer and Leukemia Group B; GIMEMA, Gruppo Italiano Malattie Ematologiche dell'Adulto; IFM, Intergroupe Francophone du Myélome; Len; lenalidomide; TEAE, treatment-emergent adverse event.
*In the IFM study, data from two cycles of lenalidomide consolidation are included.
†Data from the IFM and CALGB studies only.
‡System organ class presented with preferred terms nested below.
§Includes cysts and polyps.

The meta-analysis reported a higher frequency of secondary primary malignancy in the lenalidomide maintenance group compared with placebo/observation.[10] These were either haematologic (6.1% in lenalidomide vs 2.8% in placebo/observation before or after progression of myeloma) or solid organ malignancies (7.3% in lenalidomide vs 4.2% in placebo/observation before or after progression of myeloma). However, the risk of developing progression of myeloma was higher than the risk of second primary malignancy in both groups.

Figure 6: Second primary malignancy and mortality analyses[10]



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History

Version 2

Date	Summary of changes
13/04/2023	This protocol has been updated with the following changes: • Bone modifying agents block added to clinical information, related note removed from treatment schedule and linked pages removed • Link to Medical Scientific Advisory Group (MSAG) guidelines updated • Changed all references of 'i-Access™ program' to 'pregnancy prevention risk management program' • Lenalidomide administration details updated in treatment schedule, administration and patient information • Dose modifications for rash updated to align with product information Other changes include: • Cataract, cough and respiratory tract infection added to side effects Changed to v.2. Review in 2 years.

Version 1

Date	Summary of changes
27/03/2020	New protocol presented at the March 2020 Haematology Reference Committee meeting. Discussion continued over email and protocol approved for publication. For review in 1 year.
30/04/2021	Reviewed and discussed at the April 2021 Haematology Reference Committee meeting. Evidence updated to include study by Alonso et al. For review in 2 years.
15/09/2021	Dose modifications updated.
29/11/2021	Interactions updated.
21/12/2021	Changed antiemetic clinical information block to minimal or low, to align with new categories. See ID 7 Prevention of anti-cancer therapy induced nausea and vomiting (AINV) v5.

First approved: 25 June 2020
Last reviewed: 30 April 2021
Review due: 30 June 2023

The currency of this information is guaranteed only up until the date of printing, for any updates please check:
https://www.eviq.org.au/p/3797
13 Jun 2023

Patient information - Multiple myeloma - Lenalidomide maintenance

Patient's name:

Your treatment

The treatment schedule below explains how the drugs for this treatment are given.

Lenalidomide maintenance		
This treatment is taken continuously. Your doctor will advise you how long to take the capsules.		
Day	**Treatment**	**How it is given**
Continuous	**Lenalidomide** *(len-a-lid-o-mide)*	Take orally ONCE a day at the same time every day. Take either with or without food. Swallow whole, do not break, open, chew or crush capsules.

Missed doses:

- **Lenalidomide:** if you forget to take a capsule and it is less than 12 hours before your next dose, skip the missed dose and take your normal dose at the next time it is due. Do not take an extra dose.

When to get help

Anticancer drugs (drugs used to treat cancer) can sometimes cause serious problems. It is important to get medical help immediately if you become unwell.

IMMEDIATELY go to your nearest hospital Emergency Department, or contact your doctor or nurse if you have any of the following at any time:	**Emergency contact details** Ask your doctor or nurse from your treating team who to contact if you have a problem
• a temperature of 38°C or higher • chills, sweats, shivers or shakes • shortness of breath • uncontrolled vomiting or diarrhoea • pain, tingling or discomfort in your chest or arms • you become unwell.	Daytime:..... Night/weekend:..... Other instructions:..... ....

Important information about taking lenalidomide

Lenalidomide is only available under a restricted distribution pregnancy prevention risk management program. You, your doctor and your pharmacist must be registered and comply with conditions of the pregnancy prevention risk management program.

Lenalidomide can cause major birth defects to an unborn baby. Lenalidomide must not be taken if you are pregnant. Contraception **must** be used while you are being treated with lenalidomide.

- **If you are a male patient and your female partner is of child-bearing potential** you **must** use a barrier method of contraception (e.g. condoms) while taking lenalidomide and for one week after finishing lenalidomide treatment.
- **If you are a woman of child-bearing potential (a patient or a partner of a patient)** you **must** use at least one effective method of contraception during treatment with lenalidomide. You should start using contraception four weeks before taking lenalidomide and continue for four weeks after finishing lenalidomide treatment. It is important that you discuss appropriate contraception with your doctor.

If you become pregnant while taking lenalidomide you must stop the treatment and tell your doctor immediately. If you are a male patient and your female partner becomes pregnant during your treatment you must inform your doctor immediately.

Other information about your treatment

Changes to your dose or treatment delays

Sometimes a treatment may be started at a lower dose or the dose needs to be changed during treatment. There may also be times when your treatment is delayed. This can happen if your doctor thinks you are likely to have severe side effects, if you get severe side effects, if your blood counts are affected and causing delays in treatment, or if you are finding it hard to cope with the treatment. This is called a dose reduction, dose change or treatment delay. Your doctor will explain if you need any changes or delays to your treatment and the reason why.

Blood tests and monitoring

You will need to have a blood test before you start treatment and regularly throughout your treatment. Your doctor or nurse will tell you when to have these blood tests.

Other medications given during this treatment

- **Blood clot prevention medication:** you may be given low dose aspirin or daily injections of a drug called enoxaparin to prevent blood clots. Your doctor will decide if you need this medication.
- **Prophylaxis medication:** you may need to take some medications to prevent infection and to help prevent or reduce some of the side effects of the chemotherapy. Your doctor or nurse will tell you how and when to take these medications.
- **G-CSF:** you may be given injection(s) of a drug called G-CSF (also called filgrastim, lipegfilgrastim or pegfilgrastim) under your skin. This helps to boost your white blood cell count. Your white blood cells help to fight infection. Lipegfilgrastim and pegfilgrastim are given once. Filgrastim is given for several days until your white blood cells recover. Your doctor will decide if you need this medication.

Side effects

Cancer treatments can cause damage to normal cells in your body, which can cause side effects. Everyone gets different side effects, and some people will have more problems than others.

The table below shows some of the side effects you may get with this treatment. You are unlikely to get all of those listed and you may also get some side effects that have not been listed.

Tell your doctor or nurse about any side effects that worry you. Follow the instructions below and those given to you by your doctor or nurse.

Immediate (onset hours to days)	

Flu-like symptoms	• You may get:
	  ◦ a fever
	  ◦ chills or sweats
	  ◦ muscle and joint pain
	  ◦ a cough
	  ◦ headaches.
	• Tell your doctor or nurse if you get any of the symptoms listed above.
	• **Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you have a temperature of 38°C or higher.**

Taste and smell changes	• You may find that food loses its taste or tastes different. • These changes are likely to go away with time. • Do your mouth care regularly. • Chew on sugar-free gum or eat sugar-free mints. • Add flavour to your food with sauces and herbs. • Ask your doctor or nurse for eviQ patient information - Taste and smell changes during cancer treatment.

Early (onset days to weeks)	

Infection risk (neutropenia)	• This treatment lowers the amount of white blood cells in your body. The type of white blood cells that help to fight infection are called neutrophils. Having low level of neutrophils is called neutropenia. If you have neutropenia, you are at greater risk of getting an infection. It also means that your body can't fight infections as well as usual. This is a serious side effect, and can be life threatening.
	• Wash your hands often.
	• Keep a thermometer at home and take your temperature regularly, and if you feel unwell.
	• Do your mouth care regularly.
	• Inspect your central line site (if you have one) daily for any redness, pus or swelling.
	• Limit contact with people who are sick.
	• Learn how to recognise the signs of infection.
	• Ask your doctor or nurse for eviQ patient information - Infection during cancer treatment.
	• **Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you get any of the following signs or symptoms:**
	  ◦ **a temperature of 38°C or higher**
	  ◦ **chills, shivers, sweats or shakes**
	  ◦ **a sore throat or cough**
	  ◦ **uncontrolled diarrhoea**
	  ◦ **shortness of breath**
	  ◦ **a fast heartbeat**
	  ◦ **become unwell even without a temperature.**

Low platelets (thrombocytopenia)	• This treatment lowers the amount of platelets in your blood. Platelets help your blood to clot. When they are low, you are at an increased risk of bleeding and bruising. • Try not to bruise or cut yourself. • Avoid contact sport or vigorous exercise. • Clear your nose by blowing gently. • Avoid constipation. • Brush your teeth with a soft toothbrush. • Don't take aspirin, ibuprofen or other similar anti-inflammatory medications unless your doctor tells you to. • Tell your doctor or nurse if you have any bruising or bleeding. • **Tell your doctor or nurse immediately, or go to your nearest hospital Emergency Department if you have any uncontrolled bleeding.**

Joint and muscle pain and stiffness	• You may get muscle, joint or general body pain and stiffness. • Applying a heat pack to affected areas may help. • Talk to your doctor or nurse about other ways to manage these symptoms. You may need medication to help with any pain.

Constipation	• You may have bowel motions (stools, poo) that are less frequent, harder, smaller, painful or difficult to pass.
	• You may also get:
	  ◦ bloating, cramping or pain
	  ◦ a loss of appetite
	  ◦ nausea or vomiting.
	• Drink plenty of fluids (unless you are fluid restricted).
	• Eat plenty of fibre-containing foods such as fruit, vegetables and bran.
	• Take laxatives as directed by your doctor.
	• Try some gentle exercise daily.
	• **Tell your doctor or nurse if you have not opened your bowels for more than 3 days.**

Cough	• Some people who receive this treatment develop a cough • Tell your doctor or nurse if you develop a cough
Diarrhoea	• You may get bowel motions (stools, poo) that are more frequent or more liquid. • You may also get bloating, cramping or pain. • Take your antidiarrhoeal medication as directed by your doctor. • Drink plenty of fluids (unless you are fluid restricted). • Eat and drink small amounts more often. • Avoid spicy foods, dairy products, high fibre foods, and coffee. • Ask your doctor or nurse for eviQ patient information - Diarrhoea during cancer treatment. • **Tell your doctor or nurse immediately, or go to your nearest hospital Emergency Department if your diarrhoea is not controlled, you have 4 or more loose bowel motions per day, and if you feel dizzy or light-headed.**
Tiredness and lack of energy (fatigue)	• You may feel very tired, have no energy, sleep a lot, and not be able to do normal activities or things you enjoy. • Do not drive or operate machinery if you are feeling tired. • Nap for short periods (only 1 hour at a time) • Prioritise your tasks to ensure the best use of your energy. • Eat a well balanced diet and drink plenty of fluids (unless you are fluid restricted). • Try some gentle exercise daily. • Allow your friends and family to help. • **Tell your doctor or nurse if you get any of the symptoms listed above.**

Chest infection	• You can develop a chest infection whilst receiving this treatment.
	• **Tell your doctor or nurse as soon as possible if you get any of the following symptoms:**
	  ◦ **shortness of breath**
	  ◦ **difficulty breathing**
	  ◦ **wheezing**
	  ◦ **coughing up mucus**

Skin rash	• You may get a red, bumpy rash and dry, itchy skin. • Moisturise your skin with a gentle non-perfumed moisturising cream like sorbolene or aqueous cream. • Do not scratch your skin. • Protect your skin from the sun by wearing sun-protective clothing, a wide-brimmed hat, sunglasses and sunscreen of SPF 50 or higher. • **Talk to your doctor or nurse about other ways to manage your skin rash.**

Blood clots (thromboembolism)	• Blood clots can occur with this treatment. • **Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you get any of the following signs or symptoms:** ◦ **redness, heat or pain in your leg(s)** ◦ **numbness or weakness in your face, arm or leg** ◦ **chest pain** ◦ **sudden shortness of breath** ◦ **dizziness** ◦ **trouble speaking** ◦ **blurred vision** ◦ **severe headache** ◦ **unexplained falls or loss of balance.**

Late (onset weeks to months)	
Low red blood cells (anaemia)	• You may feel dizzy, light-headed, tired and appear more pale than usual. • Tell your doctor or nurse if you have any of these signs or symptoms. You might need a blood transfusion. • **Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you have any chest pain, trouble breathing, or feel like your heart is racing.**
Diarrhoea (late onset)	• Whilst usually mild and easily manageable, bowel motions (stools, poo) that are more frequent or more liquid may persist during treatment with lenalidomide. • Bile acid malabsorption (BAM), a condition in which patients do not absorb bile acids properly from their intestines, can be a cause of persistent diarrhoea in patients taking lenalidomide. • It can be treated by making some dietary changes such as making sure that fat does not make up more than 20% of the diet. • Your doctor will recommend if treatment is necessary for your diarrhoea • Drink plenty of fluids (unless you are fluid restricted). • Ask your doctor or nurse for eviQ patient information - Diarrhoea during cancer treatment. • **Tell your doctor or nurse immediately, or go to your nearest hospital Emergency Department if your diarrhoea is not controlled, you have 4 or more loose bowel motions per day, and if you feel dizzy or light-headed.**
Slow thyroid gland (hypothyroidism)	• You may: ◦ fatigue and low energy levels ◦ depression ◦ slow heart rate ◦ unexplained weight gain ◦ intolerance to cold temperatures ◦ fatigued and aching muscles ◦ dry, coarse skin ◦ puffy face ◦ hair loss ◦ constipation ◦ problems with concentration • You will have regular blood tests to check how well your thyroid is working • **Tell your doctor or nurse if you get any of the symptoms listed above.**
Muscle cramps	• You may get muscle cramps, usually in the hands, calves and thighs. • Tell your doctor or nurse if you get any of these symptoms. Your doctor may prescribe you medication for this.

Delayed (onset months to years)	
Stevens-Johnson syndrome (SJS)	• This side effect is rare, but can be very serious. • **Tell your doctor or nurse immediately, or go to the nearest hospital Emergency Department if you get any of the following symptoms:** ◦ **flu-like symptoms, then a painful red or purple rash that spreads** ◦ **swelling of the face or tongue** ◦ **painful or peeling skin** ◦ **blisters on the skin, mouth, nose, eyes and genitals.**

General advice for people having cancer treatment

Chemotherapy safety

- Learn how to keep you and your family safe while you are having anticancer drugs.
- See our patient information sheet - Chemotherapy safety at home.

Blood clot risk

- Cancer and anticancer drugs can increase the risk of a blood clot (thrombosis).
- Tell your doctor if you have a family history of blood clots.
- A blood clot can cause pain, redness, swelling in your arms or legs, shortness of breath or chest pain.
- If you have any of these symptoms go to your nearest hospital Emergency Department.

Medications and vaccinations

- Before you start treatment, tell your doctor about any medications you are taking, including vitamins or herbal supplements.
- Don't stop or start any medications during treatment without talking to your doctor and pharmacist first.
- Paracetamol is safe to take if you have a headache or other mild aches and pains. It is recommended that you avoid taking aspirin, ibuprofen and other anti-inflammatory type medications for pain while you are having treatment. However, if these medications have been prescribed by your doctor, do not stop taking them without speaking with your doctor.
- Vaccinations such as flu and tetanus vaccines are safe to receive while having treatment. Do not have any live vaccines during your treatment or for 6 months after it finishes. If you are unsure, check with your doctor before you have any vaccinations.
- People you live with should be fully vaccinated, including having live vaccines according to the current vaccination schedule. Extra care needs to be taken with hand washing and careful disposal of soiled nappies for infants who have recently received the rotavirus vaccine.

Other medical and dental treatment

- If you go to hospital or any other medical appointment (including dental appointments), always tell the person treating you that you are receiving anticancer drugs.
- Before you have any dental treatment, talk to your doctor.

Diet and food safety

- While you are receiving this treatment it is important that you try to maintain a healthy diet.
- Speak to your doctor or nurse about whether drinking alcohol is safe with your treatment.
- If you have any concerns about recent weight loss or weight gain or questions about your diet, ask to speak to a dietitian.
- There are some foods that may cause infection in high risk individuals and should be avoided. For more information on foods to avoid and food hygiene please ask for a copy of the Listeria and food brochure.

Fertility

- Some cancer treatments can reduce your fertility. This can make it difficult or impossible to get pregnant or father a child.
- Talk to your doctor or nurse before you start any treatment. Depending on your situation there may be fertility sparing options available to you and/or your partner, discuss these with your doctor or nurse.

Pregnancy and breastfeeding

- This treatment can cause major congenital disabilities or death to unborn babies. Talk to your doctor or nurse if you think there is any chance that you could be pregnant.
- Do not try to get pregnant or father a child during this treatment. You must use contraception while having this treatment and after stopping treatment, see the "Important information" section above for more information. Ask your doctor or nurse about what type of contraception you should use.

- If you are planning pregnancy/fatherhood after completing this treatment, talk to your doctor. Some doctors advise waiting between 6 months and 2 years after treatment.
- Do not breastfeed if you are on this treatment, as anti-cancer medications can also pass into breast milk.

Sex life and sexuality

- The desire to have sex may decrease as a result of this treatment or its side effects.
- Your emotions and the way you feel about yourself may also be affected by this treatment.
- It may help to discuss your concerns with your partner and doctor or nurse.

Quitting smoking

- It is never too late to quit smoking. Quitting smoking is one of the best things you can do to help your treatment work better.
- There are many effective tools to improve your chances of quitting.
- Talk to your treating team for more information and referral to a smoking cessation support service.

Staying active

- Research shows that exercise, no matter how small, has many benefits for people during and after cancer treatment.
- Talk to your doctor before starting an exercise program. Your doctor can advise whether you need a modified exercise program.

For more information about cancer treatment, side effects and side effect management see our Patient and carers section.

Where to get more information

Telephone support

- Call Cancer Council on 13 11 20 for cancer information and support
- Call the Leukaemia Foundation on 1800 620 420 (Mon to Fri 9am – 5pm)
- Call the Lymphoma Nurse Support Line on 1800 953 081 (Mon to Fri 9am - 5pm)

Haematology, transplant and cellular therapy information

- Arrow bone marrow transplant foundation – arrow.org.au
- Australasian Menopause Society – menopause.org.au
- Chris O'Brien Lifehouse - Total Body Irradiation - mylifehouse.org.au/departments/radiation-oncology/total-body-irradiation/
- Healthy Male Andrology Australia – healthymale.org.au/
- International Myeloma Foundation – myeloma.org
- Leukaemia Foundation – leukaemia.org.au
- Lymphoma Australia – lymphoma.org.au
- Myeloma Australia – myeloma.org.au
- NSW Agency for Clinical Innovation, Blood & Marrow Transplant Network – aci.health.nsw.gov.au/resources/blood-and-marrow-transplant
- NSW Agency for Clinical Innovation - aci.health.nsw.gov.au/projects/immune-effector-cell-service
- NCCN Guidelines for Patients Immunotherapy Side Effects: CAR T-Cell Therapy - nccn.org/patientresources/patient-resources/guidelines-for-patients
- Talk Blood Cancer – cmlsupport.org.uk/organisation-type/social-media-groups

General cancer information and support

- Australian Rare Cancer (ARC) Portal – arcportal.org.au/
- Beyondblue – beyondblue.org.au
- Cancer Australia – canceraustralia.gov.au
- Cancer Council Australia – cancer.org.au
- Cancer Voices Australia – cancervoicesaustralia.org
- CanTeen – canteen.org.au
- Carers Australia – carersaustralia.com.au
- eviQ Cancer Treatments Online – eviQ.org.au
- Food Standards Australia New Zealand: Listeria & Food Safety – foodstandards.gov.au/publications/pages/listeriabrochuretext.aspx
- LGBTQI+ People and Cancer - cancercouncil.com.au/cancer-information/lgbtqi

- Look Good Feel Better – lgfb.org.au
- Patient Information - patients.cancer.nsw.gov.au
- Radiation Oncology Targeting Cancer - targetingcancer.com.au
- Redkite – redkite.org.au
- Return Unwanted Medicines – returnmed.com.au
- Staying active during cancer treatment – patients.cancer.nsw.gov.au/coping-with-cancer/physical-wellbeing/staying-active

Quit smoking information and support

Quitting smoking is helpful even after you have been diagnosed with cancer. The following resources provide useful information and support to help you quit smoking. Talk to your treating team about any other questions you may have.

- Call Quitline on 13 QUIT (13 78 48)
- iCanQuit – iCanQuit.com.au
- Patient Information - patients.cancer.nsw.gov.au/coping-with-cancer/physical-wellbeing/quitting-smoking
- Quitnow – quitnow.gov.au

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