POMALIDOMIDE

For relapsed/refractory multiple myeloma post bortezomib, lenalidomide and alkylating agents
Blueteq registration is required before treatment may start

Drugs/Doses:	**Pomalidomide**	4mg po once daily on Days 1 – 21, followed by 7 days rest
	Dexamethasone	Age ≤ 75 years: 40mg po once weekly on Days 1, 8, 15 and 22
		Age > 75 years: 20mg po once weekly on Days 1, 8, 15 and 22

Other drugs: Consider allopurinol - dose according to renal function - for the first four weeks (may be omitted in the context of treatment change in patients with good haematological disease control)
Laxative as required for pomalidomide-induced constipation.
Consider PCP prophylaxis – prescribe according to unit practice/protocol
Use of proton pump inhibitor or H_2 receptor antagonist (e.g. ranitidine) is recommended whilst treating with steroids.
Fluconazole for antifungal prophylaxis
Thromboprophylaxis, according to unit practice, is recommended in the absence of specific contraindication.

Administration: Pomalidomide is available as 1mg, 2mg, 3mg and 4mg capsules
The daily dose should be swallowed whole with water, with or without food, at the same time of day each day.
Dexamethasone to be taken in the morning with or after food.

Frequency: 28 day cycle with pomalidomide taken on Days 1 – 21, followed by a 7-day rest.
Treatment may continue if tolerated and responding.

Main Toxicities: teratogenicity (see Comments); myelosuppression; constipation or diarrhoea; peripheral neuropathy; increased risk of thromboembolic events

Regular Investigations:		
	FBC	every week for the 1st 8 weeks, then Day 1 of every cycle
	LFTs	Day 1
	U&Es	Day 1
	Paraprotein	every month
	Pregnancy test	every month for women of child bearing potential
	Blood glucose	see Comments
	Blood pressure	see Comments

Comments: Pomalidomide is structurally related to thalidomide, so is expected to be teratogenic.
Women of child bearing potential must have a negative pregnancy test within 3 days prior to starting treatment, and within 3 days of each prescription. Pregnancy testing should be repeated monthly thereafter until one month after stopping pomalidomide. If a woman taking pomalidomide thinks she may be pregnant she must stop the drug immediately.

Women of child-bearing potential must use one agreed effective method of contraception for at least 4 weeks before starting pomalidomide, while on pomalidomide and for one month after. (The combined oral contraceptive pill is not recommended due to the increased risk of

thromboembolism.) Men taking pomalidomide must use condoms throughout treatment and for one week after stopping, if their partner is capable of bearing children.

Pomalidomide is supplied through a Pregnancy Prevention Programme. All aspects of the programme should be followed, including completion of an authorisation form by both doctor and pharmacist with every cycle.
All patients should be provided with a Patient Booklet "Treatment with Imnovid for Multiple Myeloma" and Wallet Card before starting treatment.

While on dexamethasone, blood glucose and blood pressure monitoring to be tailored according to individual patient needs.

Dose Modifications

Haematological Toxicity:

	Day 1 of each cycle	**Mid-cycle FBC**
Neutrophils ≥1 x 10^9/l and Platelets ≥ 50 x 10^9/l	Initiate next cycle	Continue treatment
Neutrophils 0.5 – 0.9 x 10^9/l or Platelets 25 – 49 x 10^9/l	Delay next cycle until counts have recovered	Continue with pomalidomide
Neutrophils < 0.5 x 10^9/l or Platelets < 25 x 109/l or Febrile neutropenia	Delay next cycle, and check FBC weekly. Once neutrophils ≥ 1 x 10^9/l and platelets ≥ 50 x 10^9/l, resume pomalidomide at 1mg less than the previous dose (from 4mg to 3mg daily on 1st occasion; from 3mg to 2mg daily on 2nd occasion; from 2mg to 1mg daily on 3rd occasion)	Interrupt pomalidomide treatment, and check FBC weekly. Once neutrophils ≥ 1 x 10^9/l and platelets ≥ 50 x 10^9/l, resume pomalidomide at 1mg less than the previous dose (from 4mg to 3mg daily on 1st occasion; from 3mg to 2mg daily on 2nd occasion; from 2mg to 1mg daily on 3rd occasion)

Non-haem Toxicities: For any Grade 3 or 4 adverse reactions related to pomalidomide, interrupt treatment.
Once resolved to ≤ Grade 2, consider re-starting at 1 mg less than the previous dose.
If adverse reactions occur at 1mg daily, pomalidomide should be discontinued.

Steroid Side Effects: If severe steroid-related side effects develop, step-wise dose reduction of dexamethasone should be considered.

≤ 75 years of age: starting dose 40 mg; reduce to 20mg once weekly; then 10mg once weekly.
> 75 years of age: Starting dose 20 mg; reduce to 12mg once weekly; then 8mg once weekly.

Renal Impairment: No adjustment of start dose is required in patients with renal impairment. On haemodialysis days, patients should take their pomalidomide dose following haemodialysis.

Hepatic Impairment: No adjustment of start dose is required in patients with hepatic impairment.
Patients with hepatic impairment should be carefully monitored for adverse reactions.

Patient Information: No Macmillan leaflet currently available for Pomalidomide