Pomalidomide (Imnovid®)

INDICATION: Relapsed multiple myeloma (CDF approval required)

Prior to a course of treatment

- Patient must be counselled about the risk of birth defects with foetal exposure. See Celgene Pregnancy Prevention Programme. Prescription must be accompanied by a completed prescription authorization form.
- Note that pomalidomide is contraindicated if there is a history of hypersensitivity or desquamating rash with thalidomide or lenalidomide.
- Pomalidomide may cause infertility – offer semen cryopreservation to males.
- All patients must receive thromboprophylaxis for at least 3 months. Low risk patients should receive aspirin 75mg daily and high risk patients prophylactic dose LMW heparin. (High risk = use of EPO, diabetes, cardiovascular disease, previous thrombotic events, HRT, renal failure). In patients with platelets<50 discuss with Consultant.
- Check FBC – neutrophils should be > 1.0 and platelets > 50 unless due to marrow infiltration
- Check renal and liver function – *if abnormal discuss with consultant & see dose modification*.

Prior to each cycle

- Check FBC - *see dose modification*
- Check U&E - *see dose modification*

Days 1-21	Pomalidomide	4mg daily	orally
Day 1, 8, 15, 22	Dexamethasone	40mg weekly	orally

PRESCRIPTION OF POMALIDOMIDE & COUNSELLING MUST BE IN ACCORDANCE WITH THE POMALIDOMIDE CELGENE RISK MANAGEMENT PROGRAMME

Repeat cycle every 28 days

Prophylaxis for acute emesis	Not required
Other medications	Anti infective measures as per local policy DVT prophylaxis see above

Pomalidomide dose modification for haematological toxicity, unless due to disease. (see dose reduction steps below)

Neutropenia

• First fall to < 0.5 (or <1.0 if febrile)	Stop pomalidomide
• Return to > 1.0	Resume pomalidomide at dose level 1
• For each subsequent drop to < 0.5	Stop pomalidomide
• Return to > 1.0	Resume pomalidomide at next lower dose. Do not dose below 1mg od.

Pomalidomide dose modification for thrombocytopenia, unless due to marrow infiltration

• First fall to < 25	Stop pomalidomide
• Return to > 50	Resume pomalidomide at dose level 1
• For each subsequent drop below 25	Stop pomalidomide
• Return to > 50	Resume pomalidomide at next lower dose. Do not dose below 1mg od

Pomalidomide dosing in renal or hepatic dysfunction, unless due to disease

- Pomalidomide is safe and well tolerated in myeloma patients with moderate renal failure but no data are available for patients with more severe renal failure (i.e. CrCl < 45 ml/min).
- No data are available regarding dosing in hepatic failure.

Dexamethasone dose modification

- If age over 75 or dexamethasone poorly tolerated (insomnia, agitation, depression, proximal myopathy, fluid retention) reduce dose to 20mg weekly.
- No dose modification needed in renal failure

Pomalidomide Toxicities

Febrile neutropenia and thrombocytopenia	Rash
Venous thromboembolism	Dyspnoea, cough
Teratogenicity	Fatigue
Dizziness and confusional state	
Decreased appetite	
Peripheral sensory neuropathy	

Pomalidomide dose reduction steps

Starting dose	4mg od every 21 days
Dose level 1	3mg od every 21 days
Dose level 2	2mg od every 21 days
Dose level 3	1mg od every 21 days