PBS CRITERIA CHANGE FOR REVLIMID®:[1]

(lenalidomide), plus dexamethasone

NO NEED FOR PRIOR THALIDOMIDE IN rrMM[1]

FROM 1 FEB 2018

For patients currently progressing on 1st line therapy:[1]

NEW[1]
PBS CRITERIA FOR REVLIMID IN rrMM

THALOMID® (thalidomide) Capsules

Use of thalidomide no longer required prior to REVLIMID in rrMM*

Revlimid® (lenalidomide) capsules

Revlimid in combination with dexamethasone is indicated for the treatment of multiple myeloma patients whose disease has progressed after one therapy.[2]

If you would like to be removed from this distribution list, then please contact Celgene on 1800 235 436.
*Further restrictions apply. Refer to PBS schedule for full information. rrMM: relapsed and/or refractory multiple myeloma.

PBS CRITERIA CHANGE FOR REVLIMID:[1]

MEANS POMALYST AVAILABLE AT 3rd LINE

(pomalidomide), plus dexamethasone

FROM 1 FEB 2018

Pomalyst® (pomalidomide) capsules

✓ Available as early as 3rd line:[1,2]

- Removal of PBS requirement for thalidomide prior to REVLIMID in rrMM, means more patients can receive POMALYST in 3rd line[4]
- In patients that have progressed on both REVLIMID and bortezomib, POMALYST + Lo-Dex significantly prolonged median OS vs Hi-Dex (13.1 months vs 8.1 months, HR 0.72, p=0.009)[3,4]

Pomalyst, in combination with dexamethasone, is indicated for the treatment of patients with relapsed and refractory multiple myeloma who have received at least two prior treatment regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy.[4]

rrMM: relapsed and/or refractory multiple myeloma; Lo-Dex: low-dose dexamethasone (40 mg/day orally on days 1, 8, 15, and 22); OS: overall survival; Hi-Dex: high-dose dexamethasone (40 mg/day orally on days 1-4, 9-12, and 17-20); HR: hazard ratio.

Revlimid® (lenalidomide) capsules

Pomalyst® (pomalidomide) capsules

PBS Information: Authority required for the treatment of transplant-ineligible newly diagnosed or relapsed or refractory multiple myeloma. Refer to PBS Schedule for full authority information.

Before prescribing Revlimid® (lenalidomide) please refer to the full Product Information which is available at http://www.guildlink.com.au/gc/ws/celgene/pi.cfm?product=cjprevli

Teratogenic Effects: Revlimid (lenalidomide) is structurally related to thalidomide. Thalidomide is a known human teratogen that causes severe life-threatening human birth defects. If lenalidomide is taken during pregnancy, it may cause birth defects or death to an unborn baby. Women should be advised to avoid pregnancy whilst taking Revlimid (lenalidomide), during dose interruptions,and for 4 weeks after stopping the drug.

Revlimid (lenalidomide) Capsules Minimum Product Information (Multiple Myeloma) Indications: Revlimid is indicated for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplantation. Revlimid in combination with dexamethasone is indicated for the treatment of multiple myeloma patients whose disease has progressed after one therapy. **Contraindications:** pregnant women; women of childbearing potential unless all conditions of the i-access® program are met; hypersensitivity to lenalidomide or excipients. **Precautions: (Pregnancy Risk Category X) – Pregnancy;** To avoid the risk of foetal exposure, Revlimid is only available under a restricted distribution program (i-access); breastfeeding; paediatric use; elderly; venous and arterial thromboembolism; myocardial infarction; neutropenia and thrombocytopenia – regular blood count monitoring recommended (see full PI); Second Primary Malignancies; peripheral neuropathy; tumour lysis syndrome (TLS) and tumour flare reaction (TFR); allergic reactions and serious skin reactions (including Stevens-Johnson syndrome(SJS), toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and system symptoms (DRESS)); atrial fibrillation; impaired thyroid function; lactose intolerance; hepatic disorders; renal impairment. **Interactions with other medicines:** erythropoietic agents and other agents that increase risk of thrombosis; myelosuppressive agents; digoxin. (Potential Interactions: oral contraceptives; warfarin). **Adverse effects (very common/common/Post-market):** nasopharyngitis; pharyngitis; pneumonia; bronchitis; upper respiratory tract infection; viral, bacterial and fungal infections (including opportunistic infections); viral reactivation (such as hepatitis B virus or herpes zoster); sinusitis; sepsis, TFR; TLS; squamous cell carcinoma of skin; basal cell carcinoma; neutropenias; thrombocytopenia; anaemia; leukopenias; febrile neutropenia; pancytopenia; hypothyroidism; hyperthyroidism; decreased appetite; hyperglycaemia; electrolyte disturbances (see full PI); dehydration; iron overload; diabetes mellitus; gout; insomnia; depression; peripheral neuropathies (excluding motor neuropathy); dizziness; tremor; dysgeusia; headache; lethargy; syncope; cerebrovascular accident; cataracts; blurred vision; vertigo; atrial fibrillation; myocardial infarction; cardiac failure; tachycardia; venous thromboembolic events; hypertension; hypotension; haematoma; dyspnoea; epistaxis; respiratory distress; pneumonitis; gastrointestinal disturbances; abdominal pain; dry mouth; toothache; abnormal liver function tests (including transient); hepatic failure (including acute); hepatitis toxic; cytolytic hepatitis; cholestatic hepatitis; mixed cytolytic/cholestatic hepatitis; cholestasis; pruritus; rash; allergic conditions (SJS, TEN, DRESS); acute graft-vs-host disease (following allogeneic transplant); dry skin; hyperhidrosis; night sweats; erythema; musculoskeletal and connective tissue pain and discomfort; muscle spasms; arthralgia; bone pain; myalgia; muscular weakness; renal failure; pyrexia; influenza-like illness syndrome; fatigue; asthenia; oedema (including peripheral); chest pain; weight decreased; fall; contusion. **Dosage and administration:** (recommended starting dose) 25mg orally daily on days 1-21 of repeated 28-day cycles (see full PI for further information). Dosing is continued or modified based upon clinical and laboratory findings, and to manage grade 3 or 4 toxicities (see full PI).(Min PI MM V4.4.1).

PBS Information: Authority Required. Please refer to PBS Schedule for full authority information

Before prescribing Pomalyst® (pomalidomide) please refer to the full Product Information which is available at http://www.celgene.com.au/product-information/

Teratogenic Effects: Pomalidomide (Pomalyst) is a thalidomide analogue. Thalidomide is a known human teratogen that causes severe life threatening human birth defects. If pomalidomide is taken during pregnancy, it may cause birth defects or death to an unborn baby. Women should be advised to avoid pregnancy whilst taking Pomalyst (pomalidomide), during dose interruptions, and for 4 weeks after stopping the medicine.

Pomalyst® (pomalidomide) Capsules Minimum Product Information. Indication: Pomalidomide, in combination with dexamethasone, is indicated for the treatment of patients with relapsed and refractory multiple myeloma who have received at least two prior treatment regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy. **Contraindications:** Pregnancy (Pregnancy Risk Category X); females of childbearing potential and male patients unless all of the conditions of the i-access® program are met; hypersensitivity to pomalidomide or excipients. **Precautions:** To avoid the risk of foetal exposure, Pomalyst is only available under a restricted distribution program (i-access). Lactation. Paediatric use. Elderly use. Thromboembolic events. Haematological events such as neutropenia, anaemia, thrombocytopenia. Allergic reactions (angioedema and severe dermatologic reactions have been reported). Dizziness, confusion, fatigue, depressed level of consciousness. Second Primary Malignancies. Peripheral Neuropathy. Cardiac dysfunction. Tumour lysis syndrome. Hepatic disorders. Infection. **Interactions:** Pomalidomide is partly metabolized by CYP1A2 and CYP3A4/5, and is a substrate for P-glycoprotein but not organic anion transporting polypeptides OATP1B1 or OATP1B3. If coadministering with strong CYP1A2 inhibitor, reduce the dose of pomalidomide by 50%. Effect of pomalidomide on other medicinal products has not been evaluated clinically. Monitor warfarin concentration. Smoking may reduce efficacy of pomalidomide. **Adverse effects:** anaemia, neutropenia, thrombocytopenia, leukopenia, febrile neutropenia, vertigo, constipation, diarrhoea, nausea, vomiting, fatigue, pyrexia, asthenia, peripheral oedema, hyperbilirubinaemia, pneumonia, upper respiratory tract infection, bronchitis, nasopharyngitis, respiratory tract infection, bronchopneumonia, neutropenic sepsis, neutrophil count decreased, white blood cell count decreased, platelet count decreased, alanine aminotransferase increased, decreased appetite, hyperkalaemia, hyponatraemia, hypercalcaemia, bone pain, muscle spasms, back pain, dizziness, tremor, peripheral sensory neuropathy, depressed level of consciousness, confusional state, insomnia, renal failure, urinary retention, pelvic pain, dyspnoea, cough, pulmonary embolism, pruritus, rash, deep vein thrombosis. **Post-marketing adverse reactions:** pancytopenia, interstitial lung disease, hepatitis, hepatitis B virus reactivation, herpes zoster, gastrointestinal haemorrhage, basal cell carcinoma, squamous cell carcinoma. **Dosage and administration:** Recommended starting dose is 4mg orally daily on days 1-21 of repeated 28-day cycles until disease progression. Dosing is continued or modified based upon clinical and laboratory findings, and to manage grade 3 or 4 toxicities. Monitor patients with renal/hepatic impairment. See full PI for further dosing information. (Min PI V1.6.1).

1. Department of Health. Pharmaceutical Benefits Scheme. Available at www.pbs.gov.au. 2. Revlimid Product Information. 3. Dimopoulos MA *et al. Haematologica* 2015;100:1327-33. 4. Pomalyst Product Information. Celgene Pty Ltd ABN 42 118 998 771. Level 15, 60 City Road, Southbank, VIC 3006, Australia. Tel 1800 CELGENE (1800 235 4363) www.celgene.com.au ®Registered Trademark EMVREV0163 AU-REV0124. BB-CEL2266. Date prepared: 01/2018

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