<table>
<tr><td>Prescribing Protocol Title</td><td>Carfilzomib with dexamethasone (Kd)</td></tr>
<tr><td>Areas where Protocol applicable</td><td>SESLHD Haematology Wards/Units</td></tr>
<tr><td>Areas where Protocol not applicable</td><td>Paediatrics</td></tr>
<tr><td>Authorised Prescribers</td><td>Haematologists</td></tr>
<tr><td>Indication for use</td><td>Multiple myeloma (MM)</td></tr>
<tr><td>Clinical condition</td><td>Relapsed and refractory MM with failure of at least one prior therapy</td></tr>
<tr><td>Contraindications</td><td>Hypersensitivity to carfilzomib</td></tr>
<tr><td>Precautions</td><td>Cardiac disorders, pulmonary hypertension, hypertension, acute renal failure, thrombotic microgangiopathy, venous thromboembolism, tumour lysis syndrome, infusion reactions.
Pregnancy – category C</td></tr>
<tr><td>Proposed Place in Therapy</td><td>Not first line.
Only to be used after at least one prior therapy</td></tr>
<tr><td>If part of combination therapy, list other drugs</td><td>In combination with dexamethasone as per dosing schedule (appendix A)
May also be used in combination with imid agent.
Consider antiviral prophylaxis for patients being treated with carfilzomib to decrease the risk of herpes zoster reactivation.</td></tr>
<tr><td>Dosage</td><td>
Table 6: Recommended dosage regimen for Kyprolis when used in combination with dexamethasone
<table>
<tr><td></td><td colspan="10">Cycle 1</td></tr>
<tr><td></td><td colspan="3">Week 1</td><td colspan="3">Week 2</td><td colspan="3">Week 3</td><td>Week 4</td></tr>
<tr><td>Kyprolis[a]
(20-56 mg/m^2)</td><td>Day 1</td><td>Day 2</td><td>Days 3-7</td><td>Day 8</td><td>Day 9</td><td>Days 10-14</td><td>Day 15</td><td>Day 16</td><td>Days 17-21</td><td>Days 22-28</td></tr>
<tr><td></td><td>20</td><td>20</td><td>-</td><td>56</td><td>56</td><td>-</td><td>56</td><td>56</td><td>-</td><td>-</td></tr>
<tr><td>dexamethasone[b]
(20 mg)</td><td colspan="10">Days 1, 2, 8, 9, 15, 16, 22, 23</td></tr>
</table>
<table>
<tr><td></td><td colspan="10">Cycle 2 and Beyond</td></tr>
<tr><td></td><td colspan="3">Week 1</td><td colspan="3">Week 2</td><td colspan="3">Week 3</td><td>Week 4</td></tr>
<tr><td>Kyprolis[a]
(56 mg/m^2)</td><td>Day 1</td><td>Day 2</td><td>Days 3-7</td><td>Day 8</td><td>Day 9</td><td>Days 10-14</td><td>Day 15</td><td>Day 16</td><td>Days 17-21</td><td>Days 22-28</td></tr>
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<tr><td>dexamethasone[b]
(20 mg)</td><td colspan="10">Days 1, 2, 8, 9, 15, 16, 22, 23</td></tr>
</table>
[a] The dose is calculated using the patient's baseline body surface area (BSA). Patients with a body surface area > 2.2 m^2 should receive a dose based upon a body surface area of 2.2 m^2.
Dose adjustments do not need to be made for weight changes of ≤ 20%. Infusion time is 30 minutes.
[b] Dexamethasone should be administered 30 minutes to 4 hours before Kyprolis.

See Appendix A for further detail and dosing modifications below</td></tr>
</table>

Table 7: Dose modifications during Kyprolis treatment

Haematological toxicity	Recommended action
• Absolute neutrophil count (ANC) < 0.5 x10^9/L (see PRECAUTIONS)	• Stop dose o If recovered to ≥ 0.5 x10^9/L, continue at same dose level • For subsequent drops to < 0.5 x10^9/L, follow the same recommendations as above and consider 1 dose level reduction when restarting Kyprolis[a]
• Febrile neutropenia ANC < 0.5 x10^9/L and an oral temperature > 38.5°C or two consecutive readings of > 38.0°C for 2 hours	• Stop dose • If ANC returns to baseline grade and fever resolves, resume at the same dose level
• Platelet count < 10 x10^9/L or evidence of bleeding with thrombocytopenia (see PRECAUTIONS)	• Stop dose o If recovered to ≥ 10 x10^9/L and/or bleeding is controlled, continue at the same dose level • For subsequent drops to < 10 x10^9/L, follow the same recommendations as above and consider 1 dose level reduction when restarting Kyprolis[a]

[a] see Table 8 for dose level reductions

Table 7: Dose modifications during Kyprolis treatment cont.

Non-haematological toxicity (renal)	Recommended action
• Serum creatinine ≥ 2x baseline; or • Creatinine clearance < 15 mL/min (or creatinine clearance decreases to ≤ 50% of baseline) or need for dialysis) (see PRECAUTIONS)	• Stop dose and continue monitoring renal function (serum creatinine or creatinine clearance) o If attributable to Kyprolis, resume when renal function has recovered to within 25% of baseline; start at 1 dose level reduction[a] o If not attributable to Kyprolis, dosing may be resumed at the discretion of the physician • If tolerated, the reduced dose may be increased to the previous dose at the discretion of the physician • For patients on dialysis receiving Kyprolis, the dose is to be administered after the dialysis procedure
Other non-haematological toxicity	**Recommended action**
• All other grade 3 or 4 non-haematological toxicities (see PRECAUTIONS)	• Stop until resolved or returned to baseline • Consider restarting the next scheduled treatment at 1 dose level reduction[a] • If tolerated, the reduced dose may be increased to the previous dose at the discretion of the physician

[a] see Table 8 for dose level reductions

Table 8: Dose level reductions for Kyprolis

Regimen	Kyprolis Dose	1st Kyprolis dose reduction	2nd Kyprolis dose reduction	3rd Kyprolis dose reduction
Kyprolis, lenalidomide, and dexamethasone	27 mg/m^2	20 mg/m^2	15 mg/m^2[a]	-
Kyprolis and dexamethasone	56 mg/m^2	45 mg/m^2	36 mg/m^2	27 mg/m^2[a]

Note: Kyprolis infusion times remain unchanged during dose reduction(s).
[a] If symptoms do not resolve, discontinue Kyprolis treatment.

Duration of therapy	Until disease progression or intolerance
Important Drug Interactions	Nil specific

Administration instructions	Carfilzomib is a cytotoxic agent. Cytotoxic precautions should be followed when handling this drug. Administer as an intravenous infusion. The 20/27mg/m^2 dose is administered over 10 minutes (see table). The 20/56mg/m^2 dose must be administered over 30 minutes (see table). Carfilzomib should not be administered as a bolus. Reconstituted carfilzomib for injection should NOT be diluted into a sodium chloride 0.9% infusion bag for IV administration. The intravenous administration line should be flushed with sodium chloride 0.9% or glucose 5% injection immediately before and after carfilzomib administration. Do not mix carfilzomib with or administer as an infusion with other medicinal products. Adequate hydration is required prior to dosing in Cycle 1, especially in patients at high risk of tumour lysis syndrome (TLS) or renal toxicity. Recommended hydration includes both oral fluids (30mL/kg/day for 48 hours before Cycle 1, Day 1) and IV fluids (250mL to 500mL of appropriate IV fluid prior to each dose in Cycle 1) If needed, give an additional 250mL to 500mL of IV fluid following carfilzomib administration and continue oral and/or IV hydration as needed in subsequent cycles.
Monitoring requirements	Monitor for haematological and renal toxicity throughout treatment. Serum potassium levels should be monitored monthly or more frequetnly during carfilzomib treatment. Monitor for fluid overload in patients receiving pre-hydration, especially in those with cardiac or renal insufficiency Hypertensive crises (hypertensive urgency or hypertensive emergency) have occurred folowing administration of carfilzomib, with hypertension adverse events occurring in approximately 20% of subjects. In case of hypertensive crises, carfilzomib should be stopped until resolved or returned to baseline and consideration given regarding whether to restart based on benefit/risk assessment. Dyspnoea was reported in approxiamtely 30% of subjects in clinical studies with majority being non-serious and rarely resulting in discontinatuion of treatment. Following administration of 200mg carfilzomib in error, acute onset of chills, hypotension, renal insufficiency, thrombocytopenia and lymphopenia were reported. There is no known specific antidote for carfilzomib overdose.
Management of complications	Reduce dose or discontinue as appropriate
Basis of Protocol: (including sources of evidence, references)	Endeavor study, ASPIRE investigators.
Groups/individuals consulted in development of this protocol	Amy Bloomfield, Haematology CNC, SGH

AUTHORISATION	
Author (Name)	Dr Shir-Jing Ho
Position	Haematologist
Department	Haematology Department, St George Hospital
Department Contact (for ongoing maintenance of Protocol/Guideline)	Shirjing.ho@health.nsw.gov.au
GOVERNANCE	
Enactment date	July 2017
Expiry date: (maximum 36 months from date of original approval)	July 2019
Ratification date by Drug Committee	6 July 2017
Chairperson, QUM Committee	Professor George Rubin
Version Number	1.0

KYPROLIS® (carfilzomib) FACT SHEET[1]

INDICATION

KYPROLIS®, as part of combination therapy with dexamethasone or lenalidomide and dexamethasone, is indicated for the treatment of patients with relapsed or refractory multiple myeloma who have received at least one prior therapy.

ADMINISTRATION – KYPROLIS® IN COMBINATION WITH DEXAMETHASONE

Administer KYPROLIS® (20/56 mg/m²) as a 30-minute IV infusion on two consecutive days each week for three weeks followed by a 12-day rest period as part of a 28-day treatment cycle. Treatment may be continued until disease progression or until unacceptable toxicity occurs.

Administer the starting dose of 20 mg/m² in Cycle 1, on Days 1 and 2. If tolerated, increase the dose to 56 mg/m² on Day 8 of Cycle 1. **Subsequent doses at 56 mg/m²** should be continued.

RATIONALE FOR CONSECUTIVE-DAY DOSING

Rationale for the dosing regimen was based on preclinical studies that demonstrated that consecutive-day dosing of KYPROLIS® suppressed recovery of proteasome activity between doses. Proteasome inhibition was maintained for ≥ 48 hours following the first dose of KYPROLIS® for each week of dosing. The clinical significance of preclinical studies is unknown.

KYPROLIS® & DEXAMETHASONE COMBINATION THERAPY

Administration

- For the combination regimen with dexamethasone, administer KYPROLIS® as a 30-minute IV infusion on two consecutive days each week for three weeks followed by a 12-day rest period as part of a 28-day treatment cycle
- Dexamethasone 20 mg is taken by mouth or intravenously on Days 1, 2, 8, 9, 15, 16, 22, and 23 of each 28-day cycle. Administer dexamethasone 30 minutes to 4 hours before KYPROLIS®

Premedications and concomitant medications

- Consider antiviral prophylaxis for patients being treated with KYPROLIS® to decrease the risk of herpes zoster reactivation

Other practical considerations

- Adequate hydration is required prior to dosing in Cycle 1, especially in patients at high risk of tumour lysis syndrome (TLS) or renal toxicity
- All patients should be monitored for evidence of volume overload and fluid requirements should be tailored to individual patient needs. The total volume of fluids may be monitored as clinically indicated, especially in patients with baseline cardiac failure or who are at risk for cardiac failure
- Cases of TLS, including fatal outcomes, have been reported with KYPROLIS® use. Patients with multiple myeloma and a high tumour burden should be considered to be at greater risk for TLS
- Recommended hydration includes both oral fluids (30 mL/kg/day for 48 hours before Cycle 1, Day 1) and IV fluids (250 mL to 500 mL of appropriate IV fluid prior to each dose in Cycle 1)
- If needed, give an additional 250 mL to 500 mL of IV fluids following KYPROLIS® administration. Continue oral and/or IV hydration, as needed, in subsequent cycles
- Serum potassium levels should be monitored monthly, or more frequently, during treatment with KYPROLIS®

RECONSTITUTION AND PREPARATION FOR INTRAVENOUS ADMINISTRATION

KYPROLIS® vials contain no antimicrobial preservatives and are for single use in one patient only. Discard any residue. Proper aseptic technique must be observed.

The reconstituted solution contains carfilzomib at a concentration of 2 mg/mL.

1. Remove vial from refrigerator just prior to use.
2. Calculate the dose (mg/m²) and number of vials of KYPROLIS® required using the patient's body surface area (BSA) at baseline. Patients with a BSA greater than 2.2 m² should receive a dose based upon a BSA of 2.2 m². Dose adjustments do not need to be made for weight changes of ≤ 20%.
3. Use a 21G, or larger gauge, needle only to aseptically reconstitute each vial by slowly injecting Sterile Water for Injections through the stopper and directing the solution onto the **inside wall of the vial** to minimise foaming.
   - 30 mL vial: reconstitute with 15 mL Sterile Water for Injections
   - 50 mL vial: reconstitute with 29 mL Sterile Water for Injections
4. Gently swirl and/or invert the vial slowly for approximately 1 minute, or until complete dissolution. **Do not shake**. If foaming occurs, allow the solution to settle in the vial until foaming subsides (approximately 5 minutes) and the solution is clear.
5. Parenteral drug products should be inspected visually for particulate matter and discolouration prior to administration; if particulates or discolouration are observed, the contents of the container should not be used. The reconstituted product should be a clear, colourless to slightly yellow solution.
6. Discard any unused portion left in the vial.
7. Optionally, KYPROLIS® can be administered in an IV bag.
8. When administering KYPROLIS® using an IV bag, use a 21G, or larger gauge, needle only to withdraw the calculated dose from the vial and dilute into a 50 or 100 mL IV bag containing 5% w/v glucose injection.

It is not necessary to protect the reconstituted or diluted product from light.

PRESENTATION AND STORAGE CONDITIONS

KYPROLIS® is supplied in a 30 mL or 50 mL Type I clear glass vial, fluoropolymer laminated elastomeric stopper and aluminium seal with plastic flip off cap. Each pack of KYPROLIS® contains a single vial.

Presentations available in Australia:

- 30 mL single-use vial containing 30 mg of carfilzomib
- 50 mL single-use vial containing 60 mg of carfilzomib

After reconstitution, 1 mL of solution contains 2 mg of carfilzomib. Unopened vials should be stored at 2°C to 8°C (Refrigerate. Do not freeze).

Reconstituted solution

To reduce microbiological hazard, use as soon as practicable after reconstitution. If storage of the reconstituted solution is necessary, hold at 2°C to 8°C for not more than 24 hours, or below 25°C for not more than 4 hours. Store in the original carton in order to protect from light.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

RECOMMENDED DOSE MODIFICATIONS

Dosing should be modified based on toxicity. For haematology and non-haematology dose modifications, please refer to the approved Product Information. If dose reductions are recommended the dose level reductions are presented in Table 1.

Table 1: Dose level reductions for KYPROLIS®

Regimen	KYPROLIS® dose	1st KYPROLIS® dose reduction	2nd KYPROLIS® dose reduction	3rd KYPROLIS® dose reduction
KYPROLIS® and dexamethasone	56 mg/m²	45 mg/m²	36 mg/m²	27 mg/m²*

Note: KYPROLIS® infusion times remain unchanged during dose reduction(s).
* If symptoms do not resolve, discontinue KYPROLIS® treatment.

The information on this fact sheet relates to KYPROLIS®. It also contains information on the KYPROLIS® + dexamethasone regimen. For information on the KYPROLIS® + lenalidomide + dexamethasone regimen, please refer to the full approved Product Information.

PBS Information: This product is not listed on the PBS.

Before prescribing, please review the Product Information available at www.amgen.com.au/kyprolis.PI
For more information on KYPROLIS® or to report an adverse event involving KYPROLIS®, please contact Amgen Medical Information on 1800 803 638.

KYPROLIS® (carfilzomib) Minimum PI

Indication: Use in combination with dexamethasone or lenalidomide and dexamethasone for treatment of patients with relapsed or refractory multiple myeloma who have received at least one prior therapy. **Contraindications:** Hypersensitivity to carfilzomib or any excipient. **Precautions:** Cardiac disorders including cardiac failure, myocardial infarction, myocardial ischaemia – closely monitor elderly; safety and efficacy not evaluated in NY Heart Assoc Class III & IV heart failure. Pulmonary toxicity. Pulmonary hypertension. Dyspnoea. Hypertension including hypertensive crisis, hypertensive emergency – routinely evaluate & treat hypertension. Acute renal failure. Tumour lysis syndrome. Infusion reactions up to 24h post treatment – premedicate with dexamethasone. Haemorrhage. Thrombocytopenia on d8 or d15 each cycle. Venous thrombosis – closely monitor patients with risk factors, minimise risk factors. Hepatic toxicity – monitor liver enzymes. Thrombotic microangiopathy including thrombotic thrombocytopenic purpura and haemolytic uraemic syndrome (TTP & HUS) – monitor for TTP & HUS. Posterior reversible encephalopathy syndrome. Pregnancy Category: C. Use effective contraception during & after treatment (females: 1 mo; males 3 mo); consider alternate to oral or hormonal contraceptives. Do not administer to breastfeeding women. Safety & efficacy not established in paediatrics. Increased adverse events in elderly. **Adverse Effects:** V common: thrombocytopenia, neutropenia, anaemia, vomiting, diarrhoea, constipation, nausea, infusion reaction, pyrexia, peripheral oedema, asthenia, fatigue, dyspnoea, cough, hypertension, insomnia, pneumonia, respiratory tract infection, nasopharyngitis, back pain, arthralgia, pain in extremity, muscle spasms, hypokalaemia, hyperglycaemia, decreased appetite, blood creatinine increased. Common: bronchitis, hypocalcaemia, rash. **Dosage & Administration:** Dose based on BSA to max 2.2m²; dose adjust for weight changes >20%. *Kyprolis combined with dexamethasone:* Kyprolis - 30 min IV infusion; Cycle 1: 20mg/m² d1 & 2, 56mg/m² d8, 9, 15 & 16. Cycle 2+: 56mg/m² d1, 2, 8, 9, 15 & 16. Dexamethasone – 20mg oral or iv d1, 2, 8, 9, 15, 16, 22, 23 all cycles. *Kyprolis combined with lenalidomide and dexamethasone:* 10 min IV infusion; Cycle 1: 20mg/m² d1 & 2; 27mg/m² d8, 9, 15 & 16. Cycle 2-12: 27mg/m² d1, 2, 8, 9, 15 & 16. Cycle 13+: 27mg/m² d1, 2, 15 & 16. Lenalidomide – 25mg oral d1-21 all cycles. Dexamethasone – 40mg oral or iv d1, 8, 15, 22 all cycles. Adequate hydration before cycle 1 dose. If toxicity, modify dose – see full PI. Incompatible with 0.9% sodium chloride IV bag. Prepared based on Approved PI: 19 December 2016.

Date of first inclusion in the Australian Register of Therapeutic Goods (ARTG) 19 December 2016

References: 1. KYPROLIS® (carfilzomib) Product Information. www.amgen.com.au/Kyprolis.PI.

AMGEN®

Kyprolis® (carfilzomib)

NSW GOVERNMENT Health
South Eastern Sydney Local Health District

KYPROLIS® (carfilzomib) + dexamethasone
Kd regimen guide[1]

DAYS	-2	-1	1	2	3 4 5 6 7	8	9	10 11 12 13 14	15	16	17 18 19 20 21	22	23	24 25 26 27 28
CYCLE 1														
Hydration* Oral (30 mL/kg/day) Intravenous (250–500 mL)	💧	💧	💧	💧		💧	💧		💧	💧				
Dexamethasone (mg)			20	20		20	20		20	20		20	20	
KYPROLIS® (mg/m²)			20	20		56	56		56	56				
CYCLE 2 ONWARDS														
Hydration	Continue oral and/or intravenous hydration (if assessed by a doctor to be necessary*)													
Dexamethasone (mg)			20	20		20	20		20	20		20	20	
KYPROLIS® (mg/m²)			56	56		56	56		56	56				

- KYPROLIS® is administered at a starting dose of 20 mg/m² in Cycle 1, on Days 1 and 2. If tolerated, the ongoing dose should be increased to the therapeutic dose of 56 mg/m²[1]
- Administer KYPROLIS® (56 mg/m²) as a 30-minute IV infusion on two consecutive days each week for 3 weeks, followed by a 12-day rest period as part of a 28-day treatment cycle[1]
- Dexamethasone should be administered 30 minutes to 4 hours before KYPROLIS®[1]
- To decrease the risk of herpes zoster reactivation, consideration should be given to antiviral prophylaxis in patients being treated with KYPROLIS®[1]

*Recommended hydration includes both oral fluids (30 mL/kg/day for 48 hours before Day 1 of Cycle 1) and intravenous fluids (250 mL to 500 mL of appropriate intravenous fluid before each dose in Cycle 1). Give an additional 250 mL to 500 mL of intravenous fluids as needed following KYPROLIS® administration.[1]

Kyprolis® (carfilzomib)

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Tips for managing Kd patients

- Encourage patients to talk openly to their healthcare team about any concerns they may have, reminding them it is normal to feel many of the emotions they did when first diagnosed with multiple myeloma[2]
- Ask patients to read the KYPROLIS® Consumer Medicine Information and/or Patient Information Booklet and report any new or worsening symptoms while being treated with KYPROLIS®, to their healthcare team immediately[1–3]
- Remind patients not to stop any medication without first discussing with their healthcare team[4]
- Educate patients on their treatment plan – it may help them feel more in control and help with care choices[5]
- Encourage patients to use the KYPROLIS® treatment card, a diary, or program their phone to help remind them of key dates relating to their treatment regimen[6]
- Advise patients to seek emotional and practical support from partners, friends or family, or get advice from multiple myeloma support groups[2]

PBS Information: This product is not listed on the PBS.

Before prescribing, please review the Product Information available at www.amgen.com.au/kyprolis.PI
For more information on KYPROLIS® or to report an adverse event involving KYPROLIS®, please contact Amgen Medical Information on 1800 803 638.

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References: 1. KYPROLIS® (carfilzomib) Product Information. www.amgen.com.au/Kyprolis.PI. **2.** American Cancer Society. Multiple myeloma. Available at: www.cancer.org/acs/groups/cid/documents/webcontent /003121-pdf.pdf accessed October 2016. **3.** KYPROLIS® (carfilzomib) Consumer Medicine Information. www.amgen.com.au/Kyprolis.CMI. **4.** US FDA. Be an active member of your health care team. Available at: www.fda.gov/downloads/Drugs/ResourcesForYou/UCM163211.pdf accessed October 2016. **5.** Myeloma Patients Europe. Report on myeloma patient perspectives. Available at: www.mpeurope.org/publications/reports-and-position-statements/ accessed October 2016. **6.** American College of Preventive Medicine. Medication adherence – Improving health outcomes. Available at: www.acpm.org/?MedAdhereTTProviders accessed October 2016.