Regimen Monograph

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A - Regimen Name

MELPPRED Regimen

Melphalan (oral)-Prednisone

Disease Site Hematologic - Multiple Myeloma

Intent Palliative

Regimen Category

Evidence-Informed:

Regimen is considered appropriate as part of the standard care of patients; meaningfully improves outcomes (survival, quality of life), tolerability or costs compared to alternatives (recommended by the Disease Site Team and national consensus body e.g. pan-Canadian Oncology Drug Review, pCODR). Recommendation is based on an appropriately conducted phase III

pCODR). Recommendation is based on an appropriately conducted phase III clinical trial relevant to the Canadian context OR (where phase III trials are not feasible) an appropriately sized phase II trial. Regimens where one or more drugs are not approved by Health Canada for any indication will be identified

under Rationale and Use.

Rationale and Uses

First line treatment of patients with multiple myeloma who are not candidates

for transplant.

Supplementary

<u>melphalan</u>

Public Funding ODB - General Benefit (melphalan - oral tablets)

prednisone

ODB - General Benefit (prednisone)

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B - Drug Regimen

melphalan 8-9 mg/m² PO Days 1 to 4

(Outpatient prescription in multiples of 2mg tablets; taken on an empty stomach, for maximal absorption)

prednisone 100 mg PO Days 1 to 4

(Outpatient prescription in multiples of 50mg tablets)

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C - Cycle Frequency

REPEAT EVERY 28 DAYS

Until disease progression or unacceptable toxicity

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D - Premedication and Supportive Measures

Antiemetic Regimen: Minimal – No routine prophylaxis; PRN recommended

Other Supportive Care:

Also refer to CCO Antiemetic Recommendations.

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E - Dose Modifications

Doses should be modified according to the protocol by which the patient is being treated. The following recommendations are in use at some centres.

Dosage with toxicity

See Appendix 6 for general recommendations.

Renal Impairment

Creatinine Clearance	(mL/sec)	% usual dose

0.2 - 0.8	REDUCE Melphalan to 75% dose
<0.2	REDUCE Melphalan to 50% dose

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F - Adverse Effects

Refer to melphalan, prednisone drug monograph(s) for additional details of adverse effects

Most frequently occurring adverse effects

- Myelosuppression
- Stomatitis
- Pulmonary toxicity
- Hyperglycemia
- Insomnia
- Mood changes
- Cushingoid syndrome
- Muscle weakness
- Gastric irritation peptic ulcer
- Fluid retention
- Cataracts

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G - Interactions

Refer to melphalan, prednisone drug monograph(s) for additional details

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H - Drug Administration and Special Precautions

Refer to melphalan, prednisone drug monograph(s) for additional details

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I - Recommended Clinical Monitoring

Recommended Clinical Monitoring

- Clinical toxicity assessment (including stomatitis, gastrointestinal)
- · Routine blood glucose test.
- Routine CBC (since absorption of melphalan is erratic, mild myelosuppression should be detected three weeks after drug administration, in order to confirm drug absorption).
- Baseline and regular hepatic and renal function tests and urinalysis.
- Routine pulmonary function test and clinical pulmonary exam.
- Clinical exam for proximal muscle myopathy.
- Baseline ophthalmologic exam for evidence of cataracts.
- Full assessment by ophthalmologist if cataracts suspected.
- Grade toxicity using the current <u>NCI-CTCAE</u> (Common Terminology Criteria for <u>Adverse Events</u>) <u>version</u>

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J - Administrative Information

Outpatient prescription for home administration

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K - References

Bataille R, Harousseau JL. Multiple myeloma. N Engl J Med 1997;336:1657-64.

Bergsagel DE, Sprague CC, Austin C et al. Evaluation of new chemotherapeutic agents in the treatment of myeloma IV: phenylalaine mustard. Cancer Chemothera Rep 1962; 21:87.

Gregory WM, Richards MA, Malpas JS. Combination chemotherapy versus melphalan & prednisolone in the treatment of multiple myeloma: An overview of published trials. J Clin Oncol 1992;10:334-42.

Myeloma Trialists' Collaborative Group. Combination chemotherapy versus melphalan plus prednisone as treatment for multiple myeloma: an overview of 6633 patients from 27 randomized trials. J Clin Oncol 1998;16:3832-42.

PEBC Advice Documents or Guidelines

Treatment of Multiple Myeloma: ASCO and CCO Joint Clinical Practice Guideline

June 2019 Updated emetic risk category; added PEBC guideline link

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M - Disclaimer

Regimen Abstracts

A Regimen Abstract is an abbreviated version of a Regimen Monograph and contains only top level information on usage, dosing, schedule, cycle length and special notes (if available). It is intended for healthcare providers and is to be used for informational purposes only. It is not intended to constitute or be a substitute for medical advice, and all uses of the Regimen Abstract are subject to clinical judgment. Such information is provided on an "as-is" basis, without any representation, warranty, or condition, whether express, or implied, statutory or otherwise, as to the information's quality, accuracy, currency, completeness, or reliability, and Cancer Care Ontario disclaims all liability for the use of this information, and for any claims, actions, demands or suits that arise from such use.

Information in regimen abstracts is accurate to the extent of the ST-QBP regimen master listings, and has not undergone the full review process of a regimen monograph. Full regimen monographs will be published for each ST-QBP regimen as they are developed.

Regimen Monographs

Refer to the <u>New Drug Funding Program</u> or <u>Ontario Public Drug Programs</u> websites for the most up-to-date public funding information.

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