

BC Cancer Protocol Summary for the Treatment of Multiple Myeloma using Melphalan and Prednisone

Protocol Code

MYMP

Tumour Group

Myeloma

Contact Physicians

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ELIGIBILITY:

Patients must have:

- Multiple myeloma or Amyloid light (AL) chain amyloidosis

EXCLUSIONS:

- None

CAUTIONS:

- Platelet count less than $100 \times 10^9/L$
- ANC less than $1.0 \times 10^9/L$ may require filgrastim

TESTS:

- Baseline (required before first treatment): CBC & Diff, platelets, creatinine, urea, sodium, potassium, total bilirubin, ALT, alkaline phosphatase, calcium, albumin, LDH, random glucose.
- Baseline (required, but results do not have to be available to proceed with first treatment; results must be checked before proceeding with cycle 2): serum protein electrophoresis **and** serum free light chain levels, immunoglobulin panel (IgA, IgG, IgM), HCAb, HBsAg, HBcoreAb, **beta-2 microglobulin**
- Every 4 weeks (required, but results do not have to be available to proceed with treatment): serum protein electrophoresis and serum free light chain levels
- Every 4 weeks (optional, results not mandatory but encouraged prior to each cycle): urine protein electrophoresis, immunoglobulin panel (IgA, IgG, IgM), **beta-2 microglobulin**
- Every 4 weeks: CBC & Diff, platelets, creatinine, urea, sodium, potassium, total bilirubin, ALT, alkaline phosphatase, calcium, albumin, LDH, random glucose
- Days 8, 15, 22 (optional if pre-cycle cytopenias, hypercalcemia, hepatic or renal dysfunction, or steroid-induced diabetes a concern. Results do not have to be available to proceed with treatment. Provider to review results, no dose modifications indicated for mid-cycle bloodwork): CBC & Diff, platelets, creatinine, sodium, potassium, total bilirubin, ALT, alkaline phosphatase, calcium, albumin, random glucose

PREMEDICATIONS:

- None

SUPPORTIVE MEDICATIONS:

- If HBsAg or HBcoreAb positive, start hepatitis B prophylaxis as per current guidelines
- Antiviral prophylaxis against reactivation of varicella-zoster virus (VZV) is recommended prior to initiating melphalan. Patients should take valACYclovir 500 mg PO daily

TREATMENT:

Drug	Dose	BC Cancer Administration Guideline
melphalan	9 mg/m ² /day on Days 1 to 4	PO
predniSONE	100 mg/day on Days 1 to 4	PO

Repeat every 28 days.

Treatment can be given for up to one year or up to 6 months after a plateau phase has been achieved (which ever is shorter)

Discontinue when no further response detectable for at least two cycles (usually established by plateau of monoclonal paraprotein level).

DOSE MODIFICATIONS:

1. Hematological: (based on pre-cycle labwork)

ANC (x10 ⁹ /L) On Day 1	Platelets (x10 ⁹ /L) On Day 1	Melphalan Dose
Greater than or equal to 3.0	Greater than or equal to 200	Increase by 2 mg/day
1.0 to less than 3.0	Greater than or equal to 100	100% of previous dose
Less than 1.0 [†]	Less than 100	Check CBC & Diff weekly, resume treatment when ANC is greater than 1 and platelets greater than 100 and use new interval of 6 weeks. If after 6 weeks ANC is still less than 1 or platelets less than 100, reduce dose of melphalan to 75 %

[†] Consider weekly filgrastim if clinically indicated and filgrastim is available. Filgrastim is not covered as a benefit drug by BC Cancer.

2. Renal dysfunction: Dose modification required for melphalan:

Creatinine clearance (mL/min)	Melphalan Dose
Greater than 50	100 %
10 to 50	75 %
Less than 10	50 %

PRECAUTIONS:

1. **Neutropenia:** Fever or other evidence of infection must be assessed promptly and treated aggressively.
2. **Hepatitis B Reactivation:** All myeloma patients should be tested for both HBsAg and HBcAb. If either test is positive, such patients should be treated with hepatitis B prophylaxis according to current guidelines. Such patients should also be monitored with frequent liver function tests and hepatitis B virus DNA at least every three months. If the hepatitis B virus DNA level rises during this monitoring, management should be reviewed with an appropriate specialist with experience managing hepatitis and consideration given to halting chemotherapy.
3. **Need for irradiated blood products:** Patients receiving an autotransplant require irradiated blood products from 7 days prior to collection to 3 months post transplant (6 months if total body irradiation conditioning) to eliminate the risk of potentially life-threatening transfusion-related graft-versus-host-disease. All other myeloma patients do not require irradiated blood products

Call Dr. Christopher Venner or tumour group delegate at 604-877-6000 or 1-800-663-3333 with any problems or questions regarding this treatment program.

References:

1. Standard treatment, see current hematology textbooks
2. Rajkumar SV, Gertz MA, Kyle RA, Greipp PR. Current Therapy for Multiple Myeloma. Mayo Clin Proc. 2002;77:813-822
3. Kyle RA, Gerz MA, Greipp PR. A Trial of Three Regimens for Primary Amyloidosis: Colchicine Alone, Melphalan and Prednisone, and Melphalan, Prednisone, and Colchicine. N Engl J Med 1997; 336:1202-1207.