lenalidomide-dexamethasone Therapy

Multiple Myeloma

Cycle 1-4

**lenalidomide**
25 mg PO Day 1-21 5 mg capsule
- Dose is 25 mg daily Days 1-21 every 28 days with water, swallow whole and preferable on an empty stomach.
- Indicated for the treatment of multiple myeloma patients who have received at least one prior therapy.
- Trade name is Revlimid™ (Celgene)
- Exceptional Access Program (Section 16) with specific criteria
- Continue or modify treatment until disease progression or unacceptable toxicities.
- Available as 5, 10, 15 and 25 mg capsules.
- Physicians, pharmacists and patients must be registered with the Revaid™ program.

**dexamethasone**
40 mg PO Days 1,8,15,22 0.5 mg tablet

Alternate dosing:
- High dose dexamethasone (40 mg PO Days 1-4, 9-12, 17-20) may still be appropriate for some patients with acute myeloma complications (e.g. acute renal impairment, hypercalcemia or hyperviscosity syndrome).
- Outpatient prescription available in 0.5 mg and 4 mg tablets.
- Trade name is Decadron™

REPEAT EVERY 28 DAYS x 4 cycles

Cycle 5 and subsequent cycles

**lenalidomide**
25 mg PO Day 1-21 5 mg capsule
- Dose is 25 mg daily Days 1-21 every 28 days with water, swallow whole and preferable on an empty stomach.
- Indicated for the treatment of multiple myeloma patients who have received at least one prior therapy.
- Trade name is Revlimid™ (Celgene)
- Exceptional Access Program (Section 16) with specific criteria
- Continue or modify treatment until disease progression or unacceptable toxicities.
- Available as 5, 10, 15 and 25 mg capsules.
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**dexamethasone**
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- Trade name is Decadron™

REPEAT EVERY 28 DAYS until disease progression or unacceptable toxicities

TESTS:

Baseline Tests
- WBC HB PLT ANC Ca K Na Chloride Mg Cr Urea
- T.Bili Albumin AST ALT AlkPhosphatase

Monthly
- WBC HB PLT ANC Ca K Na Chloride Cr Urea
- T.Bili Albumin AST ALT

Test Notes:
- Thyroid function tests TSH and T4 levels.
- CBC q2weeks X 12 weeks then monthly.
- Women of child bearing potential require serum regnancy test 10-14 days and 24 hours before first dose; weekly tests during first month of treatment, then monthly and 4 weeks after discontinuing treatment.

**CLINICAL MONITORING**

**Fatigue**
1. Mild fatigue over baseline 2. Moderate or causing difficulty performing some ADL 3. Severe fatigue interfering with ADL 4. Disabling

**Diarrhea**
1. Increase of less than 4 stools per day over baseline; mild increase in ostomy output compared to baseline
2. Increase of 4 - 6 stools per day over baseline; IV fluids indicated less than 24hrs; moderate increase in ostomy output compared to baseline; not interfering with ADL
3. Increase of greater than or equal to 7 stools per day over baseline; incontinence; IV fluids greater than or equal to 24 hrs; hospitalization; severe increase in ostomy output compared to baseline; interfering with ADL
4. Life-threatening consequences (e.g. hemodynamic collapse) 5. Death

**Constipation**
1. Occasional or intermittent symptoms; occasional use of stool softeners, laxatives, dietary modification, or enema 2. Persistent symptoms with regular use of laxatives or enemas indicated 3. Symptoms interfering with ADL; constipation with manual evacuation indicated 4. Life-threatening consequences (e.g., obstruction, toxic megacolon) 5. Death

RATED AT EACH CLINIC VISIT

**TOXICITIES:**

Hematologic

Thrombocytopenia
1. If PLT less than 30x10^9/L HOLD treatment until PLT greater than or equal to 30x10^9/L, then resume lenalidomide at 15 mg/day.
2. If PLT less than 30x10^9/L with subsequent doses HOLD treatment until PLT greater than 30x10^9/L then resume treatment at 5 mg less than the previous dose.

RATED AT EACH CLINIC VISIT

Hematologic

Neutropenia
1. If ANC less than 1.0x10^9/L HOLD treatment until ANC greater than or equal to 1.0x10^9/L, then add G-CSF and resume at 25 mg/day if no other toxicities. If other toxicities present, resume lenalidomide therapy at 15 mg/day.
2. For each subsequent drop, if ANC less than 1.0x10^9/L HOLD treatment until ANC greater than or equal to 1.0x10^9/L and resume lenalidomide at 5 mg less than the previous dose. Do not dose below 5 mg daily.

Renal Failure
1. If CrCl less than 0.8 mL/sec REDUCE dose to 10 mg daily (may increase to 15 mg daily if not responding and tolerating drug).
2. If CrCl less than 0.5 mL/sec (not requiring dialysis) REDUCE dose to 15 mg every other day.
3. If CrCl less than 0.5 mL/sec (requiring dialysis) REDUCE dose to 15 mg three times a week following each dialysis.

**SUGGESTED ACTION**

**FORMULAE:**

CrCl - Cockcroft & Gault ( mL/sec)
- Male: [140-age(yrs)] x TBW(kg) / [50 x SCr( micromol/L)]
- Female: [140-age(yrs)] x TBW(kg) / [50 x SCr( micromol/L)] x 0.85