

**NEWYORK-PRESBYTERIAN HOSPITAL
DIVISION OF NURSING**

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PROTOCOL: HIGH DOSE ALDESLEUKIN AT CUMC

PURPOSE: To direct the nursing management of patients receiving High Dose Aldesleukin

APPLIES TO: 6HN in Milstein Hospital Building.

POLICY STATEMENT:

1. Dr. H. Kaufman and the Surgery Service (Red Team) are responsible for directing and managing all aspects of high dose Aldesleukin (HD Aldesleukin) and are notified/consulted in the event of problems/questions.
2. Because HD Aldesleukin therapy is strenuous, patients are carefully screened and selected for HD Aldesleukin therapy based on the following criteria: Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; normal cardiac, pulmonary, hepatic and central nervous system function; the patient's commitment to receive intense therapy; and no requirement for corticosteroid therapy for concomitant medical conditions.
3. The goal of each course of treatment is to administer the maximum tolerated number of doses within the limits of acceptable toxicity. Planned dosing is based on the condition of the patient. Doses may be delayed or therapy discontinued based on the number and severity of existing toxicities.
4. All patients will be maintained on telemetry.
5. All patients will have a central venous catheter placed upon admission.
6. Nursing priorities for patients receiving HD Aldesleukin are directed at identifying and managing predictable toxicities, specifically, Capillary Leak Syndrome (CLS). **CLS** is a leakage or movement of the intravascular fluid to the extravascular space or subcutaneous tissue space or alveoli. CLS can cause hypotension, pulmonary edema, altered mental status, peripheral edema, tachycardia, and oliguria. These side effects are expected to resolve within 24-48 hours after discontinuation of therapy. Each dose of HD Aldesleukin therapy is based on the ongoing medical and nursing assessment of the patient's condition. Other side effects include flu-like syndrome, and a generalized erythematous, pruritic rash.
7. Corticosteroid therapy is contraindicated for patients receiving HD Aldesleukin.
8. Implement the [Falls and Injury Prevention Protocol](#) and the [Telemetry protocol](#).

SUPPORTIVE DATA:

1. Aldesleukin is a biologic agent involved in immunomodulation, specifically by affecting the proliferation of lymphocytes, the production of cytokines, and by enhancing cell cytotoxicity. It is structurally indistinguishable from endogenous ALDESLEUKIN.

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1. HD Aldesleukin is indicated for the treatment of metastatic renal cell carcinoma and metastatic melanoma. HD Aldesleukin is dosed at 600,000 International Units/kilogram/dose, and each dose is administered at a minimal interval of 8 hours by 15 minute infusions up to a maximum of 14 doses. Following 14 days of rest, this cycle is repeated. Two cycles equal one course of therapy.
2. The 6th floor Satellite Pharmacy will prepare each dose of HD Aldesleukin after notification by the MD/NP/PA or RN that the therapy will proceed. Aldesleukin is compatible with **D5W ONLY**.
3. Because of an increased risk for infection during HD Aldesleukin therapy, all patients will be placed on prophylactic intravenous antibiotics. Oxacillin will be ordered, unless the patient is penicillin-allergic.

NURSING ASSESSMENT AND CARE:

Before administering each dose of HD ALDESLEUKIN, assess the patient focusing on the following parameters. Discuss with MD/NP/PA to determine if therapy will continue, a dose will be delayed, or therapy discontinued. Frequency of additional assessment is performed as the patient's condition warrants.

- I. Cardiovascular
 - A. Dysrhythmia
 1. Possible causes include electrolyte imbalances, anemia, and hypoxia. Medical management includes ordering labs and reviewing telemetry.
 2. Nursing Management:
 - a. Review daily labs, including complete blood count (CBC) and chemistries. Notify MD/NP/PA for any chemistry results not within normal limits, or for a hematocrit <28%.
 - b. Assess patient for signs and symptoms of anemia.
 - c. Assess patient for signs and symptoms of hypoxia, and notify MD if present.
 - d. Assess patient for dysrhythmias as per telemetry protocol.
 - B. Hypotension
 1. Hypotension is a common side effect of HD Aldesleukin therapy. Hypotension commonly occurs about 2 hours after each dose, and lasts for approximately 6 hours. Medical management includes ordering fluid boluses for a SBP<80, delaying doses of HD Aldesleukin, and initiating Phenylephrine (Neosynephrine) infusions for persistent hypotension.
 2. Nursing Management
 - a. Routinely monitor BP every 4 hours, increase monitoring to every 1 hour if SBP <90, and every 15 minutes if SBP <80.
 - b. Notify MD/NP/PA for SBP<80. Administer 250cc NS fluid bolus as per MD/NP/PA order.

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C. Peripheral Edema

1. Peripheral edema is caused by CLS. Common sites include the lower extremities, sacrum, face, and neck. Medical management includes ordering diuretics.
2. Nursing Management
 - a. Assess for edema every shift.
 - b. Monitor strict intake and output.
 - c. Monitor daily weights; notify MD/NP/PA for weight gain >15% over baseline.
 - d. Elevate affected extremities.
 - e. Administer diuretics as per MD/NP/PA order.

II. Pulmonary

- A. Pulmonary edema is caused by CLS. Medical management includes ordering diuretics, ordering oxygen therapy, and ordering a chest x-ray.
- B. Nursing Management
 1. Assess for cough or increased sputum production.
 2. Monitor breath sounds before and after each dose of Aldesleukin, and before and after fluid bolus.
 3. Notify MD/NP/PA for presence of pulmonary edema.

III. Hematologic

A. Anemia and Thrombocytopenia

1. Anemia and thrombocytopenia are related to CLS, and usually occur on or about day four of therapy. Medical management includes ordering a daily CBC, ordering PRBC transfusions to maintain a hematocrit of 28%, ordering platelet transfusions for platelet count <20,000; and stopping HD Aldesleukin therapy for platelet count <50,000.
2. Nursing Management:
 - a. Review CBC daily.
 - b. Notify MD/NP/PA for a hematocrit <28%, or a platelet count below normal limits.
 - c. Assess patient for signs and symptoms of anemia and thrombocytopenia; notify MD/NP/PA if present.

B. Leukopenia

1. Leukopenia is a direct result of HD Aldesleukin therapy. There may be an initial decrease in white blood cell counts during therapy, which is followed by a rebound leukocytosis. Patients may have an increased risk for infection. Medical management includes ordering a daily CBC with differential, and administration of prophylactic antibiotics.
2. Nursing Management
 - a. Review daily CBC with differential.
 - b. Administer antibiotics as ordered.

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- c. Take patient's temperature every 4 hours, notify MD/NP/PA for temperature >101.
- d. Observe patient for signs and symptoms of infection, especially at site of central line, and notify MD/NP/PA if present.

IV. Renal

A. Most patients will experience some form of renal dysfunction during HD Aldesleukin therapy. Normal renal function usually returns within 24-48 hours after discontinuation of therapy. Patients will have decreased urine output and increased serum creatinine levels. Medical management includes ordering daily blood chemistries, ordering fluid boluses, ordering diuretics, delaying doses of HD Aldesleukin or discontinuing HD Aldesleukin therapy, and the initiation of low-dose dopamine.

B. Nursing Management

1. Review daily labs, especially serum creatinine levels.
2. Monitor strict intake and output.
3. Monitor daily weights, and notify MD/NP/PA for weight gain >15% over baseline.

V. Gastrointestinal

A. Many patients receiving HD Aldesleukin will experience gastrointestinal disturbances, such as nausea and vomiting, severe diarrhea, epigastric pain, and stomatitis. Medical management includes ordering antidiarrheals and antiemetics.

B. Nursing Management

1. Assess abdomen every shift for bowel sounds and distension.
2. Administer antidiarrheals prn, notify MD/NP/PA if antidiarrheals are ineffective.
3. Assess patient for nausea and vomiting, and administer antiemetics as ordered.
4. Notify MD/NP/PA if antiemetics are ineffective.
5. Assess patient for epigastric pain, notify MD/NP/PA if present.
6. Assess oral cavity every shift.
7. Notify MD/NP/PA for alterations in oral mucosa.

VI. Flu-Like Syndrome

A. Flu-like syndrome (fatigue, malaise, fever, chills, myalgias and bone pain) is the most common side effect of HD Aldesleukin. The syndrome can occur with the first dose of HD Aldesleukin. Medical management includes ordering medications such as acetaminophen and Indomethicine to ameliorate the symptoms. Meperidine (Demerol) is sometimes ordered to stop shaking chills.

B. Nursing Management

1. Monitor temperature every 4 hours and more frequently as indicated; notify MD/NP/PA for temperature >101.

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2. May provide warm blankets for patients with chills.
3. Notify MD/NP/PA if the patient experiences persistent chills; patients with persistent chills may require IVSS meperidine.

VII. Neurologic

A. The neurologic changes that can occur in patients receiving HD Aldesleukin range from confusion and emotional lability to agitation and hallucinations. Neurologic changes usually occur toward the end of therapy, as a result of cumulative doses. Medical management includes ordering medications, delaying a dose of Aldesleukin, or discontinuing Aldesleukin therapy.

B. Nursing Management

1. Assess neurological status every 8 hours, or more frequently if indicated.
2. Notify MD for alterations in mental status, e.g., vivid dreams, hallucinations, or disorientation.

VIII. Dermatologic

A. Most patients experience skin changes during HD Aldesleukin therapy, which consist of a generalized erythematous rash. Pruritus may be seen. Medical management includes evaluation of all rashes and ordering medications as appropriate.

B. Nursing Management

1. Assess patient every shift for rash, notify MDNP/PA if present.
2. Administer antipruritic prn, notify MD/NP/PA if ineffective.
3. Instruct patient to use only water-based skin lotions, which contain no alcohol, such as Eucerin.

PATIENT TEACHING:

1. Review the potential side effects of HD Aldesleukin with the patient/family.
2. Review telemetry monitoring and bedside monitoring with the patient/family.
3. Review safety with the patient/family and emphasis on increased fall risk.
4. Review written discharge instructions with the patient/family.

DOCUMENTATION:

1. Document the administration of each dose of HD Aldesleukin on the continuation sheet, the medication administration record, and the parenteral fluid record.
2. Document patient and family education on the Interdisciplinary Patient/Family Education Sheet.

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DOCUMENT MANAGEMENT: Medical Surgical Nursing

KEY WORDS: aldesleukin

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