# BC Cancer Protocol Summary for Consolidation Therapy Post-Autologous Stem Cell Transplant (ASCT) for Hodgkin Lymphoma Using Brentuximab Vedotin

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| ***Protocol Code*** | *LYBV* |
| ***Tumour Group*** | *Lymphoma* |
| ***Contact Physician*** | *Dr. Laurie H. Sehn* |

**ELIGIBILITY**:

- Hodgkin lymphoma (HL) after primary treatment with ABVD chemotherapy and secondary treatment with ASCT

**TESTS**:

- Baseline: CBC & diff, platelets, creatinine, total bilirubin, ALT
- Baseline (required, but results do not have to be available to proceed with first treatment; results must be checked before proceeding with cycle 2): HBsAg, HBcoreAb, HBsAb
- Before day 1 of each treatment cycle: CBC & diff, platelets
- If clinically indicated: creatinine, ALT, total bilirubin
- If clinically indicated: HBV viral load, HBsAg (see protocol SCHBV)

**PREMEDICATIONS**:

If past brentuximab vedotin drug reactions:

- diphenhydramine 50 mg PO 30 minutes prior to brentuximab vedotin
- acetaminophen 650 mg to 975 mg PO 30 minutes prior to brentuximab vedotin

**SUPPORTIVE MEDICATIONS:**

Moderate risk of hepatitis B reactivation. If HBsAg or HBcoreAb positive, follow hepatitis B prophylaxis as per SCHBV.

**TREATMENT:**

Treatment with brentuximab vedotin should be started approximately 6 weeks after ASCT.

| Drug | Dose | BC Cancer Administration Guideline |
|---|---|---|
| brentuximab vedotin | 1.8 mg/kg on Day 1* | IV in 100 mL NS over 30 minutes |

Repeat every 21 day for 16 cycles.

*The dose for patients weighing greater than 100 kg should be calculated based on a weight of 100 kg.

**DOSE MODIFICATIONS**:

1. **Hematological:**

| ANC (x$10^9$/L) | | Platelets (x$10^9$/L) | Brentuximab vedotin |
|---|---|---|---|
| greater than or equal to 0.6 | and | greater than or equal to 50 | 100% |
| less than 0.6 | or | less than 50 | Delay until recovery |

2. **Peripheral Neuropathy:**

| Toxicity | Dose Modification |
|---|---|
| Grade 1 | 100% |
| Grade 2 or 3 | Hold until neuropathy improves to grade 1 or baseline, then decrease dose to 1.2 mg/kg |
| Grade 4 | Discontinue brentuximab vedotin |

**PRECAUTIONS**:

1. **Neutropenia**: Fever or other evidence of infection must be assessed promptly and treated aggressively.
2. **Extravasation**: Brentuximab vedotin causes pain and may, rarely, cause tissue necrosis if extravasated. Refer to BC Cancer Extravasation Guidelines.
3. **Thrombocytopenia**: Support with platelet transfusion may be required.
4. **Hepatitis B Reactivation**: See SCHBV protocol for more details.
5. **Peripheral neuropathy:** Brentuximab treatment causes peripheral sensory neuropathy. Cases of peripheral motor neuropathy have also been reported. Brentuximab-induced peripheral neuropathy is cumulative. Monitor patients for symptoms of neuropathy, such as hypoesthesia, hyperesthesia, paresthesia, discomfort, a burning sensation, neuropathic pain or weakness and institute dose modifications accordingly.
6. **Infusion reactions:** Infusion-related reactions, including anaphylaxis, have occurred with brentuximab vedotin. Monitor patients during infusion. If an infusion reaction occurs, stop the infusion. See BC Cancer Hypersensitivity Guidelines.
7. **Tumor lysis syndrome:** Patients with rapidly proliferating tumor and high tumor burden are at risk of tumor lysis syndrome and these patients should be monitored closely.
8. **Progressive multifocal leukoencephalopathy (PML):** JC virus infection resulting in PML and death has been reported in brentuximab-treated patients. Consider the diagnosis of PML in any patient presenting with new-onset signs and symptoms of central nervous system abnormalities. Hold brentuximab vedotin if PML is suspected.
9. **Stevens-Johnson syndrome:** Stevens-Johnson syndrome has been reported with brentuximab vedotin. If Stevens-Johnson syndrome occurs, discontinue brentuximab vedotin.

10. **Acute pancreatitis** including fatal outcomes, has been reported in patients who have received brentuximab vedotin. Consider the diagnosis of acute pancreatitis for patients who present with new or worsening abdominal pain. Hold brentuximab vedotin if suspected pancreatitis and discontinue if confirmed.

**Call Dr. Laurie H. Sehn or tumor group delegate at (604) 877-6000 or 1-800-663-3333 with any problems or questions regarding this treatment program.**

**REFERENCES:**


1. Pro B, et al. Brentuximab vedotin (SGN-35) in patients with relapsed or refractory systemic anaplastic large-cell lymphoma: results of a phase II study. J Clin Oncol 2012;30(18):2190-6.
2. Younes A, et al. Results of a pivotal phase II study of brentuximab vedotin for patients with relapsed or refractory Hodgkin's lymphoma. J Clin Oncol 2012;30(18):2183-9.
3. Chen R, Gopal AK, Smith SE, et a. Five-year survival data demonstrating durable responses from a pivotal phase 2 study of brentuximab vedotin in patients with relapsed or refractory Hodgkin lymphoma. Blood 2015;126:2736 (ASH abstract).
4. Chen R, et a. Five-year survival data demonstrating durable responses from a pivotal phase 2 study of brentuximab vedotin in patients with relapsed or refractory Hodgkin lymphoma.
5. Moskowitz CH, et al. Brentuximab vedotin as consolidation therapy after autologous stem-cell transplantation in patients with Hodgkin's lymphoma at risk of relapse or progression (AETHERA): a randomised, double-blind, placebo-controlled, phase 3 trial. Lancet 2015;385(9980):1853-1862.