

Submitted by:
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NCCN Guidelines Panel: Hodgkin Lymphoma

On behalf of *Seattle Genetics*, I respectfully request the *NCCN Hodgkin Lymphoma Panel* to review the enclosed package insert for inclusion of brentuximab vedotin in the guidelines for Hodgkin lymphoma.

Specific Changes: Recommend brentuximab vedotin for patients with progressive disease or relapse.

FDA Clearance: Brentuximab vedotin is approved for:

- The treatment of patients with Hodgkin lymphoma after failure of autologous stem cell transplant (ASCT) or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not ASCT candidates.
- The treatment of patients with systemic anaplastic large cell lymphoma after failure of at least one prior multi-agent chemotherapy regimen.

Rationale: The FDA has recently approved brentuximab vedotin for this specific indication.

The following references are submitted in support of this proposed change. We would like to acknowledge the contributions of NCCN panel members who are also co-authors or co-contributors of some of these publications.

1. ADCETRIS™ [package insert] Bothell, WA: Seattle Genetics, Inc.; August 2011.
2. Chen R, Gopal AK, Smith SE, et al. Results from a pivotal phase 2 study of brentuximab vedotin (SGN-35) in patients with relapsed or refractory Hodgkin lymphoma. Poster session presented at: 2011 ASCO Annual Meeting; 2011 June 3-7; Chicago, IL.

Sincerely,

Dana Hurley, Pharm.D., M.S.