Submitted by: Dana Hurley, Pharm.D., M.S. Seattle Genetics, Inc. Medical Information 21823 – 30th Drive Southeast Bothell, WA 98021 425-527-2680 dhurley@seagen.com

Date of request: August 19, 2011

NCCN Guidelines Panel: Non-Hodgkin's Lymphoma

On behalf of Seattle Genetics, I respectfully request the NCCN Non-Hodgkin's Lymphoma Panel to review the enclosed package insert for inclusion of brentuximab vedotin in the guidelines for peripheral T-cell lymphomas, noncutaneous.

Specific Changes: Recommend brentuximab vedotin as second-line therapy for patients with systemic anaplastic large cell lymphoma.

FDA Clearance: Brentuximab vedotin is approved for:

- The treatment of patients with systemic anaplastic large cell lymphoma after failure of at least one prior multi-agent chemotherapy regimen.
- 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.

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 cocontributors of some of these publications.

- 1. ADCETRISTM [package insert] Bothell, WA: Seattle Genetics, Inc.; August 2011.
- 2. Pro B, Advani R, Brice P, et al. Durable remissions with brentuximab vedotin (SGN-35): updated results of a phase 2 study in patients with relapsed or refractory systemic anaplastic large cell lymphoma (sALCL). Poster session presented at: 2011 ASCO Annual Meeting; 2011 June 3-7; Chicago, IL.

Sincerely,

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