May 26, 2016

Joan McClure, MS
National Comprehensive Cancer Network
500 Old York Road, Suite 250
Jenkintown, PA 19046

Dear Ms. McClure,

On behalf of Sanofi U.S., I respectfully request the NCCN Non-Hodgkin's Lymphomas panel review the enclosed data regarding the use of rasburicase for hyperuricemia in patients with non-Hodgkins lymphoma (NHL).

The Elitek prescribing information is enclosed for your review.

I appreciate the opportunity to provide this information for consideration by the NCCN. If you have any questions or require additional information, please do not hesitate to contact us at (800) 633-1610, option 1 or via e-mail at MED.INFO@sanofi.com. Thank you for your time and consideration.

Sincerely,

Wynter Balcerski, PharmD
Senior Manager, Oncology Medical Information Services
Sanofi U.S.

Enclosures: Elitek prescribing information

RAS-14177

**Name: Wynter Balcerski**
**Company/Organization: Sanofi U.S.**
**Address: 55 Corporate Drive, Bridgewater, NJ 08807**
**Phone: (800) 633-1610, option 1**
**Email: MED.INFO@sanofi.com**
**Date of request: May 26, 2016**
**NCCN Guidelines Panel: Non-Hodgkin's Lymphomas**

Specific Changes: For section NHODG-B, "Supportive Care for NHL"

- Under the "First-line and at retreatment for hyperuricemia" bullet:
  - Change wording to "**For inpatient treatment,** one dose of rasburicase is frequently adequate. Doses of 3-6 mg are usually effective. Redosing should be individualized."
  - Add additional bullet: "**Currently the available data evaluating the use of fixed dose rasburicase are limited to use in the inpatient setting only along with careful and frequent monitoring. For outpatient use, where monitoring is limited or insufficient, the labeled weight-based dose of 0.2 mg/kg of rasburicase may be more appropriate, as well as the use of multiple rasburicase doses.**"

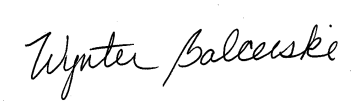
FDA Status: Rasburicase is not FDA-approved for fixed (flat) dosing. The FDA-approved dosing of rasburicase is 0.2 mg/kg, daily for up to 5 days.

Rationale: Currently available data evaluating the use of fixed dose rasburicase are limited to inpatient use only, with careful and frequent monitoring. Patients being treated on an outpatient basis may not receive the same level of monitoring, and may be at risk for tumor lysis syndrome if rapid increases in electrolytes and plasma uric acid are left undetected.

References:

1. Elitek [package insert]. Bridgewater, NJ: sanofi-aventis U.S.; 2015.

Sincerely,



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