Submitted by:
Name:
Company/Organization:
Address:
Phone:
Email:
Date of request:
NCCN Guidelines Panel:

On behalf of *Your Company Name*, I respectfully request the *NCCN (name of Guideline Panel)* to review the enclosed data for inclusion of the serum free light chain assays (Freelite®) in the initial diagnostic evaluation of multiple myeloma.

Specific Changes: Recommend the serum free light chain assays as a routine component of the initial diagnostic evaluation of multiple myeloma (changed from "useful under some circumstances").

FDA Clearance: The serum free light chain assays are FDA-cleared for the diagnosis and monitoring of multiple myeloma, AL amyloidosis, Waldenström's macroglobulinemia, and light chain deposition disease.

Rationale: In support of the proposed change, the 2009 International Myeloma Working Group guidelines for serum free light chain analysis recommended serum free light chain testing as a component of the initial screening algorithm for multiple myeloma, thereby establishing baseline free light chain results to be used to monitor patients with oligosecretory myeloma and AL amyloidosis, to assess for stringent complete response, to gain prognostic insight, and to enable detection of free light chain escape at relapse.

The following articles 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. Dispenzieri A et al. International Myeloma Working Group guidelines for serum-free light chain analysis in multiple myeloma and related disorders. *Leukemia*. 2009;23:215-224. This paper supported the need for a baseline serum free light chain analysis for all patients with multiple myeloma and related disorders.

2. Durie BGM et al. International uniform response criteria for multiple myeloma. *Leukemia*. 2006;20:1467-1473. Baseline serum free light chain measurements are required to enable assessment for stringent complete response.

3. Snozek CLH et al. Prognostic value of the serum free light chain ration in newly diagnosed myeloma: proposed incorporation in the international staging system. *Leukemia*. 2008;22:1933-1937. A baseline serum free light chain ratio was an important predictor of prognosis in newly diagnosed patients with multiple myeloma.

4. Katzmann JA et al. Screening panels for detection of monoclonal gammopathies. *Clin Chem*. 2009;55:1517-1522. In this study of 467 patients with newly diagnosed multiple myeloma, serum free light chain analysis was the single most sensitive serum test for multiple myeloma (97% sensitivity), and was recommended as a component of the initial screening algorithm for identifying a monoclonal gammopathy.

Sincerely,