Serum Free Light Chain Analysis for the Diagnosis, Management, and Prognosis of Plasma Cell Dyscrasias: Comparative Effectiveness Review Number 73

U. S. Department of Health and Human Services, Agency for Healthcare Research and Quality

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Plasma-cell dyscrasias (PCDs) are a group of neoplastic disorders characterized by the uninhibited expansion of a monoclonal population of malignant plasma cells. Multiple myeloma (MM) is the most common malignant plasma-cell tumor, accounting for about 1 percent of all cancer types,1 and the second most common hematologic malignancy in the United States. With an age-adjusted incidence rate of 5.5 cases per 100,000 population, an estimated 19,900 new diagnoses and 10,790 deaths due to myeloma occurred in 2007, according to the American Cancer Society. Although the median survival has improved to 5 years with current standards of treatment, the annual costs of modern therapies can range from $50,000 to $125,000 per patient. In PCDs, each abnormally expanded clone of malignant plasma cells produces an excess of either intact immunoglobulin or free light chains (FLCs) of a single type; either type of excess molecule is called a monoclonal protein (M protein) or paraprotein. Measurement of M proteins (either complete immunoglobulins or FLCs) is integral to diagnosing PCDs, monitoring disease response to therapy and adjusting treatment, and determining disease progression or relapse. The serum FLC (SFLC) assay (i.e., the Freelite® assay, The Binding Site Ltd., Birmingham, United Kingdom) was introduced in 2001 to measure the FLC component in serum. The assay works by recognizing an epitope that is detectable only on light chains that are not bound to the heavy chain of the immunoglobulin molecule—the FLCs—in the serum. This is the sole SFLC assay the U.S. Food and Drug Administration (FDA) has approved for use in the United States. The aim of this CER is to evaluate the present body of evidence addressing the relative effectiveness of the SFLC assay as compared with traditional tests for the diagnosis, management, and prognosis of PCDs. We sought to answer a set of questions focusing on the SFLC assay versus traditional testing in very specific clinical settings to focus on comparative effectiveness. Our goals were to evaluate the SFLC assay as an add-on test in diagnostic settings and to compare it with existing tests in other settings such as for disease monitoring and prognosis. Panels of Key Informants and Technical Experts, who helped identify the important areas for evidence review (as discussed in the Methods section), vetted these questions. To address these areas in an unbiased way that would permit summary of the relevant data, studies had to meet a specific, predefined set of criteria related to population, intervention (diagnostic test/disease monitoring), comparator, and outcome. This CER evaluates the SFLC assay as a diagnostic and prognostic tool adjunctive to the standard diagnostic tests for various PCDs. It addresses five Key Questions (KQs) that pertain to the (1) diagnosis of PCDs, (2) prognosis (i.e., progression from MGUS to MM and overall and disease-free survival in patients with a malignant PCD), (3) change in treatment decisions, (4) assessment of response to treatment, and (5) reduction of the need for other diagnostic tests (e.g., bone marrow biopsy).

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