MAYO CLINIC

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Revenue Compliance Office

1/3/2024

National Government Services, Inc.
Attention: Medical Policy Unit
NGS.lcd.reconsideration@anthem.com

RE: Formal Request for Reconsideration of Local Coverage Decision #L39189 and Article #A58921

To Whom it May Concern:

The Mayo Clinic respectfully requests a reconsideration to LCD #L39189 and Article # A58921 for PLA code 0077U regarding urine testing. We have included evidence that urine IFE and Urine Mass-Fix are equivalent sensitivity. Mayo Clinic Laboratory has published a comparison of the two in clinical chemistry. We are requesting coverage of urine M-protein testing by mass spectroscopy (PLA=0077U aka Mass-Fix) for patients with plasma cell disorders. In addition, we would like to request additional ICD-10 codes to be covered for all plasma cell disorders.

Following successful replacement of serum immunofixation (IFE) with Mass-Fix in 2018, our lab decided to replace urine IFE with urine Mass-Fix. Prior to replacing urine IFE, our lab performed both analytical and clinical validation of the method. The analytical validation compared 1,008 urine IFE to urine Mass-Fix results (1). We concluded that urine Mass-Fix was an acceptable replacement for urine IFE in terms of diagnostic results because urine IFE and urine Mass-Fix were statistically equivalent. In cases in which the two methods disagreed, urine Mass-Fix correlated better with serum testing and had increased specificity given that the M-protein masses could be compared. In addition, the urine mass fix was able to identify cases with light chain glycosylation, a risk factor for disease progression (2).

In a different study to determine the clinical utility of Mass-Fix, we compared serum and urine Mass-Fix to serum and urine protein electrophoresis (PEL), serum/urine IFE, and quantitative serum free-light chain (FLC) for the identification of M-proteins in different clinical diagnoses (3). Paired serum and urine samples from 257 patients were tested. There were six patients for whom s-IFE and FLC ratio were positive and serum MASS-FIX was negative, but when serum and urine MASS-FIX results were combined, only one patient with light chain-MGUS was missed. Serum/urine-MASS-FIX detected M-proteins in 18 patients with negative serum/urine-PEL/IFE and serum-FLC, 10 of whom had multiple myeloma or AL amyloidosis, who were

mistakenly thought to have complete hematologic response by serum/urine-PEL/IFE and serum-FLC.

Urine M-protein testing is important for proper clinical care of patients with plasma cell disorders. In cases where there is a high clinical suspicion for amyloidosis, urine M-protein testing is recommended by both the IMWG (4) and CAP (5). Urine M-protein testing-vital in avoiding an endomyocardial biopsy in patients with suspected ATTR cardiac amyloidosis (6). Assessment of treatment response for multiple myeloma, AL amyloidosis, and Waldenstrom macroglobulinemia patients also requires urine M-protein measurements (7). Given the importance of urine M-protein testing in the care of patients with plasma cell disorders, we are also requesting expansion of the ICD-10 codes to cover all patients with plasma cell disorders and the ability to perform both serum and urine testing 0077U on the same day.

Additional requested ICD-10 codes

- C90.1 Plasma cell leukemia
- C90.2 Extramedullary leukemia
- C90.3 Solitary Plasma~~e~~ytoma
- C88.2 Heavy Chain Disease
- E85.0 Non-neuropathic heredofamilial amyloidosis
- E85.2 Heredofamilial amyloidosis, unspecified
- E85.4 Organ-limited amyloidosis
- E85.81 Light chain (AL) amyloidosis
- E85.82 Wild-type transthyretin related (ATTR) amyloidosis
- E85.89 Other amyloidosis
- E85.9 Amyloidosis, unspecified

In addition, the statutorily-defined Medicare benefit for the requested coverage is under Medicare Benefit Policy Manual, Chapter 15-Covered Medical and Other Health Services, Section 80 – Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests and 80.1-Clinical Laboratory Services. This test involves the diagnosis, prevention, or treatment of a disease or assessment of a medical condition as defined in section 80.1.

We have enclosed supplemental materials which supports our request that addresses the relevance, usefulness, and clinical outcomes. We have followed the CMS Publication 100-08, *Medicare Program Integrity Manual*, Chapter 13, Section 13.3.1, 13.3.2 and 13.3.3 for this request. The new test also meets all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), as set forth at 42 CFR part 493. Should you have any questions regarding this request, please contact me at (904)-953-0422. Thank you in advance for your consideration of this request.

Respectfully,

David L. Murray, M.D., Ph.D.

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Division of Clinical Biochemistry and Immunology
Department of Laboratory Medicine and Pathology
Mayo Clinic Rochester

Attachments

cc Teresa Beard

References

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