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Revenue Compliance Office

October 13, 2022

National Government Services, Inc.
NGS.lcd.reconsideration@anthem.com

RE: Reconsideration Request For Coverage LCD 35000 Molecular Pathology Procedures

To Whom it May Concern:

Mayo Clinic requests a reconsideration coverage to LCD 35000 and Article 56199 to allow coverage for CPT codes 81352 (Tumor Protein 53-TP53), 81263 (IGH) and 88271, 88275 (FISH) for **Chronic Lymphocytic Leukemia (CLL) as a covered diagnosis (see attached list)**.

- 81352-TP53 (Tumor Protein 52) (EG, LI-Fraumeni Syndrome) Gene Analysis; Targeted Sequence Analysis (EG, 4 Oncology)
- 81263-IGH@(Immunoglobulin Kappa Light Chain Locus) (EG, Leukemia and Lymphoma, B-Cell), Gene Rearrangement Analysis, Evaluation to Detect Abnormal Clonal Population(s)
- 88271-Molecular Cytogenetics; DNA probe, Each (eg, FISH)
- 88275-Molecular Cytogenetics; Interphase in Situ Hybridization, analyze 100-300 cells

CPT Code 88271 and 88275 are listed under NCD 190.3-Cytogenetic Studies as discretionary by MAC for coverage for CLL diagnosis and we are requesting that NGS add these diagnosis to LCD 35000 and A56199.

We believe that Medicare's policies are not aligned with standard clinical practice as per the National Comprehensive Cancer Network (NCCN). Evidence proves that CLL diagnoses are medically necessary for TP53, IGH and FISH based on the accumulated evidences that are referenced and listed below.

1. *Tests for TP53, FISH and IGH are critical for hematologist to make decision to choose the correct therapy for CLL patients needing treatment.*

In CLL patients needing treatment, established chemotherapy (e.g FCR) associated with long term remission in CLL patients with IGH mutated status, but not for IGH unmutated patients. (See Thompson et al, Blood 2016). In addition, the results of CLL FISH are highly predictive for eventual survival of CLL patients (Dohner et al, NEJM 2000). The presence of TP53 mutation or FISH abnormality of del (17p) in CLL patients predicts absence of response to chemotherapy, also indicates less durable response when patients treated with venetoclax (see Tausch et al blood 2020).

2. *Tests for TP53, FISH and IGH provide highly prognostic information to guide for patient care and counselling (see CLL IPI group, lancet 2016).*

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. Our recommendation 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. In addition, we have also attached a list of diagnosis that meet the requirements for the diagnostic CLL. The request 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 yours,

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cc: Teresa Beard