



ASSOCIATION FOR MOLECULAR PATHOLOGY

Providing global expertise in molecular testing that drives patient care
6120 Executive Boulevard, Suite 700, Rockville, Maryland, 20852
Tel: 301-634-7987 | Fax: 301-634-7995 | amp@amp.org | www.amp.org

March 18th, 2023

National Government Services Medical Policy Unit
P.O. Box 7108
Indianapolis, IN 46207-7108
NGSDraftLCDComments@anthem.com

RE: Molecular Pathology Procedures (DL35000)

Dear Medical Director,

On behalf of the Association for Molecular Pathology (AMP) and the College of American Pathology thank you for the opportunity to provide comments on National Government Services' (NGS) proposed coverage policy for Molecular Pathology Procedures (DL35000).

AMP is an international medical and professional association representing approximately 2,900 physicians, doctoral scientists, and medical laboratory scientists (technologists) who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from academic medicine, hospital-based and private clinical laboratories, the government, and the in vitro diagnostics industry.

AMP is pleased that based on a reconsideration request received in October 2022, the policy has been expanded to provide coverage for IGH and TP53 genes to facilitate decision-making in the medical management of Chronic Lymphocytic Leukemia (CLL) patients. After reviewing the proposed updates to the LCD, AMP have a few recommendations to ensure that the coverage policy reflects the current state of care for patients with CLL.

CPT Codes for TP53 Gene Analysis

AMP recommends that CPT codes 81351 (TP53 (TUMOR PROTEIN 53) (EG, LI-FRAUMENI SYNDROME) GENE ANALYSIS; FULL GENE SEQUENCE) and 81352 (TP53 (TUMOR PROTEIN 53) (EG, LI-FRAUMENI SYNDROME) GENE ANALYSIS; TARGETED SEQUENCE ANALYSIS (EG, 4 ONCOLOGY)), are moved from Group 2 to Group 1. Tests described by these CPT codes are covered under the policy and used as standard of care and should not need additional documentation for coverage. There is evidence seen in the NCCN guidelines that both Ig rearrangement by PCR and TP53 sequencing is needed in multiple lymphoma types, to aid diagnosis, and make therapy decisions. In addition, minimal residual disease monitoring with baseline testing by Ig rearrangement in CLL, ALL and multiple myeloma is recommended or required.

ICD-10 Codes for TP53

AMP believes that the ICD-10 codes for TP53 gene testing currently included in the policy are not comprehensive of the diagnostics codes used for a CLL diagnosis.

AMP suggests that the ICD-10 codes below be included in the attached document Billing and Coding: Molecular Pathology Procedures (DA56199) for TP53 gene testing:

<u>CODES</u>	<u>DESCRIPTION</u>
C88.8	Other malignant immunoproliferative diseases
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
C91.11	Chronic lymphocytic leukemia of B-cell type in remission
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse
C92.00	Acute myeloblastic leukemia, not having achieved remission
C92.02	Acute myeloblastic leukemia, in relapse
C92.20	Atypical chronic myeloid leukemia, BCR/ABL-negative, not having achieved remission
C92.22	Atypical chronic myeloid leukemia, BCR/ABL-negative, in relapse
C92.30	Myeloid sarcoma, not having achieved remission
C92.32	Myeloid sarcoma, in relapse
C92.40	Acute promyelocytic leukemia, not having achieved remission
C92.42	Acute promyelocytic leukemia, in relapse
C92.50	Acute myelomonocytic leukemia, not having achieved remission
C92.52	Acute myelomonocytic leukemia, in relapse
C92.60	Acute myeloid leukemia with 11q23-abnormality not having achieved remission
C92.62	Acute myeloid leukemia with 11q23-abnormality in relapse
C92.A0	Acute myeloid leukemia with multilineage dysplasia, not having achieved remission
C92.A2	Acute myeloid leukemia with multilineage dysplasia, in relapse
C92.Z0	Other myeloid leukemia not having achieved remission
C92.Z2	Other myeloid leukemia, in relapse
C92.90	Myeloid leukemia, unspecified, not having achieved remission
C92.92	Myeloid leukemia, unspecified in relapse
C93.00	Acute monoblastic/monocytic leukemia, not having achieved remission
C93.02	Acute monoblastic/monocytic leukemia, in relapse
C93.10	Chronic myelomonocytic leukemia not having achieved remission
C93.12	Chronic myelomonocytic leukemia, in relapse
C93.Z0	Other monocytic leukemia, not having achieved remission
C93.Z2	Other monocytic leukemia, in relapse
C93.90	Monocytic leukemia, unspecified, not having achieved remission
C93.92	Monocytic leukemia, unspecified in relapse
C94.00	Acute erythroid leukemia, not having achieved remission
C94.02	Acute erythroid leukemia, in relapse
C94.40	Acute panmyelosis with myelofibrosis not having achieved remission
C94.41	Acute panmyelosis with myelofibrosis, in remission
C94.42	Acute panmyelosis with myelofibrosis, in relapse
C94.6	Myelodysplastic disease, not elsewhere classified
C94.80	Other specified leukemias not having achieved remission

C94.82	Other specified leukemias, in relapse
C95.00	Acute leukemia of unspecified cell type not having achieved remission
C95.02	Acute leukemia of unspecified cell type, in relapse
C95.10	Chronic leukemia of unspecified cell type not having achieved remission
C95.12	Chronic leukemia of unspecified cell type, in relapse
C95.90	Leukemia, unspecified not having achieved remission
C95.92	Leukemia, unspecified, in relapse
C96.Z	Other specified malignant neoplasms of lymphoid, hematopoietic and related tissue
C96.9	Malignant neoplasm of lymphoid, hematopoietic and related tissue, unspecified
D45	Polycythemia vera
D46.0	Refractory anemia without ring sideroblasts, so stated
D46.1	Refractory anemia with ring sideroblasts
D46.20	Refractory anemia with excess of blasts, unspecified
D46.21	Refractory anemia with excess of blasts 1
D46.22	Refractory anemia with excess of blasts 2
D46.A	Refractory cytopenia with multilineage dysplasia
D46.B	Refractory cytopenia with multilineage dysplasia and ring sideroblasts
D46.C	Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality
D46.4	Refractory anemia, unspecified
D46.Z	Other myelodysplastic syndromes
D46.9	Myelodysplastic syndrome, unspecified
D47.1	Chronic myeloproliferative disease
D47.3	Essential (hemorrhagic) thrombocythemia
D47.4	Osteomyelofibrosis
D47.Z9	Other specified neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue
D47.9	Neoplasm of uncertain behavior of lymphoid, hematopoietic and related tissue, unspecified
D61.818	Other pancytopenia
D69.49	Other primary thrombocytopenia
D69.6	Thrombocytopenia, unspecified
D69.8	Other specified hemorrhagic conditions
D69.9	Hemorrhagic condition, unspecified
D70.8	Other neutropenia
D70.9	Neutropenia, unspecified
D72.810	Lymphocytopenia
D72.818	Other decreased white blood cell count
D72.819	Decreased white blood cell count, unspecified
D72.821	Monocytosis (symptomatic)
D72.828	Other elevated white blood cell count
D72.829	Elevated white blood cell count, unspecified
D72.89	Other specified disorders of white blood cells
D72.9	Disorder of white blood cells, unspecified
D75.81	Myelofibrosis
D75.89	Other specified diseases of blood and blood-forming organs

D75.9	Disease of blood and blood-forming organs, unspecified
D77	Other disorders of blood and blood-forming organs in diseases classified elsewhere
R16.1	Splenomegaly, not elsewhere classified
R16.2	Hepatomegaly with splenomegaly, not elsewhere classified

ICD-10 Codes for IGH

Similarly, AMP believes that the ICD-10 codes currently included in the policy are not comprehensive of the diagnostics codes used for a CLL diagnosis in regards to IGH gene testing. AMP suggests that the ICD-10 codes below be included in the attached document Billing and Coding: Molecular Pathology Procedures (DA56199) for IGH gene testing:

CODE	
C82.00 - C83.99	Follicular lymphoma grade I, unspecified site - Non-follicular (diffuse)
C85.10 - C85.99	Unspecified B-cell lymphoma, unspecified site - Non-Hodgkin lymphoma,
C91.00 - C91.02	Acute lymphoblastic leukemia not having achieved remission - Acute
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
C91.11	Chronic lymphocytic leukemia of B-cell type in remission
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse
C95.10	Chronic leukemia of unspecified cell type not having achieved remission
C95.11	Chronic leukemia of unspecified cell type, in remission
C95.12	Chronic leukemia of unspecified cell type, in relapse
D72.828	Other elevated white blood cell count
D72.89	Other specified disorders of white blood cells

Thank you again for the opportunity to review and comment on this proposed policy. We invite the opportunity to have a conversation regarding our procedural concerns about this draft policy and to determine how this draft policy can be changed to reflect the current standard of care for Chronic Lymphocytic Leukemia. Should you have additional questions or require our expertise, please direct your correspondence to Samantha Pettersen, AMP Policy Analyst, Public Policy & Advocacy at spettersen@amp.org.

Sincerely,

Samuel K. Caughron, MD
 Chair, Economic Affairs Committee
 Association for Molecular Pathology