

UnitedHealthcare® Medicare Advantage *Policy Guideline*

Blood Product Molecular Antigen Typing

Guideline Number: MPG388.10 **Approval Date**: April 10, 2024

Terms and Conditions

| Table of Contents | Page |
|--|------|
| Policy Summary | 1 |
| Applicable Codes | 2 |
| References | 7 |
| Guideline History/Revision Information | 8 |
| Purpose | 8 |
| Terms and Conditions | 8 |

Related Medicare Advantage Policy Guidelines

- Molecular Pathology/Molecular Diagnostics/Genetic Testing
- Pharmacogenomics Testing
- Tier 2 Molecular Pathology Procedures

Related Medicare Advantage Reimbursement Policies

- Clinical Laboratory Improvement Amendments (CLIA)
 ID Requirement Policy, Professional
- Laboratory Services Policy, Professional
- Molecular Pathology Policy, Professional and Facility

Related Medicare Advantage Coverage Summary

 Molecular Pathology/Molecular Diagnostics/Genetic Testing

Policy Summary

See Purpose

Overview

Based on the Centers for Medicare & Medicaid Services (CMS) Program Integrity Manual (100-08), this policy addresses the circumstances under which the item or service is reasonable and necessary under the Social Security Act, §1862(a)(1)(A). For laboratory services, a service can be reasonable and necessary if the service is safe and effective; and appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is furnished in accordance with accepted standards of medical practice for the diagnosis of the patient's condition; furnished in a setting appropriate to the patient's medical needs and condition; ordered and furnished by qualified personnel; one that meets, but does not exceed, the patient's medical need; and is at least as beneficial as an existing and available medically appropriate alternative.

Guidelines

Limited coverage is provided for molecular phenotyping of blood product antigens as part of the pre-transfusion evaluation for patients who may require or are expected to require a blood product transfusion(s) (Red Blood Cells, Platelets or Leukocytes) when at least one of the following criteria is met:

- Long term, frequent transfusions anticipated to prevent the development of alloantibodies (e.g., sickle cell anemia, thalassemia, chronic transfusion dependent hematologic disorders or other reasons); **or**
- Autoantibodies or other serologic reactivity that impedes the exclusion of clinically significant alloantibodies (e.g., autoimmune hemolytic anemia, warm autoantibodies, patient recently transfused with a positive DAT, high-titer low avidity antibodies, patients about to receive or on daratumumab therapy, other reactivity of no apparent cause); or
- Suspected antibody against an antigen for which typing sera is not available; or
- Laboratory discrepancies on serologic typing (e.g., rare Rh D antigen variants)

Laboratory developed tests (LDTs) that perform molecular phenotyping of blood product antigens may be considered covered for the same indications if the test demonstrates validity and clinical utility equivalent to or better than covered tests as demonstrated in a technical assessment.

Medicare does not expect molecular testing to be performed on patients undergoing surgical procedures such as bypass or other cardiac procedures, hip or knee replacements or revisions, or patients with alloantibodies identifiable by serologic testing that are not expected to require long term, frequent transfusions. The medical necessity for molecular blood product phenotyping must be documented in the patient's medical record.

Blood product molecular antigen typing tests are considered germline tests and thus must comply with relevant Medicare or Contractor policies regarding germline testing.

As molecular genotyping includes a review of many genes that code for cellular antigens that must be evaluated for proper patient care, single gene tests are not reasonable and necessary.

Nationally Non-Covered Indications

Compliance with the provisions in this policy is subject to monitoring by post payment data analysis and subsequent medical review. Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states "...no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis and treatment of illness or injury...". Furthermore, it has been longstanding CMS policy that "tests that are performed in the absence of signs, symptoms, complaints, or personal history of disease or injury are not covered unless explicitly authorized by statute".

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

| CPT Code | Description |
|-------------------------|---|
| Provisional Cove | erage |
| 0001U | Red blood cell antigen typing, DNA, human erythrocyte antigen gene analysis of 35 antigens from 11 blood groups, utilizing whole blood, common RBC alleles reported |
| 0084U | Red blood cell antigen typing, DNA, genotyping of 10 blood groups with phenotype prediction of 37 red blood cell antigens |
| 0193U | Red cell antigen (JR blood group) genotyping (JR), gene analysis, ABCG2 (ATP binding cassette subfamily G member 2 [Junior blood group]) exons 2-26 [Refer to the Medicare Advantage Medical Policy titled Pharmacogenomics Testing] |
| Non-Covered | |
| 81105 | Human Platelet Antigen 1 genotyping (HPA-1), ITGB3 (integrin, beta 3 [platelet glycoprotein IIIa], antigen CD61 [GPIIIa]) (e.g., neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant, HPA-1a/b (L33P) |
| 81106 | Human Platelet Antigen 2 genotyping (HPA-2), GP1BA (glycoprotein lb [platelet], alpha polypeptide [GPlba]) (e.g., neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant, HPA-2a/b (T145M) |
| 81107 | Human Platelet Antigen 3 genotyping (HPA-3), ITGA2B (integrin, alpha 2b [platelet glycoprotein IIb of IIb/IIIa complex], antigen CD41 [GPIIb]) (e.g., neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant, HPA-3a/b (I843S) |
| 81108 | Human Platelet Antigen 4 genotyping (HPA-4), ITGB3 (integrin, beta 3 [platelet glycoprotein IIIa], antigen CD61 [GPIIIa]) (e.g., neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant, HPA-4a/b (R143Q) |
| 81109 | Human Platelet Antigen 5 genotyping (HPA-5), ITGA2 (integrin, alpha 2 [CD49B, alpha 2 subunit of VLA-2 receptor] [GPIa]) (e.g., neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant (e.g., HPA-5a/b (K505E)) |
| 81110 | Human Platelet Antigen 6 genotyping (HPA-6w), ITGB3 (integrin, beta 3 [platelet glycoprotein IIIa, antigen CD61] [GPIIIa]) (e.g., neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant, HPA-6a/b (R489Q) |

| CPT Code | Description |
|-------------|--|
| Non-Covered | |
| 81111 | Human Platelet Antigen 9 genotyping (HPA-9w), ITGA2B (integrin, alpha 2b [platelet glycoprotein IIb of IIb/IIIa complex, antigen CD41] [GPIIb]) (e.g., neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant, HPA-9a/b (V837M) |
| 81112 | Human Platelet Antigen 15 genotyping (HPA-15), CD109 (CD109 molecule) (e.g., neonatal alloimmune thrombocytopenia [NAIT], post-transfusion purpura), gene analysis, common variant, HPA-15a/b (S682Y) |
| 0180U | Red cell antigen (ABO blood group) genotyping (ABO), gene analysis Sanger/chain termination/conventional sequencing, ABO (ABO, alpha 1-3-N-acetylgalactosaminyltransferase and alpha 1-3-galactosyltransferase) gene, including subtyping, 7 exons |
| 0181U | Red cell antigen (Colton blood group) genotyping (CO), gene analysis, AQP1 (aquaporin 1 [Colton blood group]) exon 1 |
| 0182U | Red cell antigen (Cromer blood group) genotyping (CROM), gene analysis, CD55 (CD55 molecule [Cromer blood group]) exons 1-10 |
| 0183U | Red cell antigen (Diego blood group) genotyping (DI), gene analysis, SLC4A1 (solute carrier family 4 member 1 [Diego blood group]) exon 19 |
| 0184U | Red cell antigen (Dombrock blood group) genotyping (DO), gene analysis, ART4 (ADP-ribosyltransferase 4 [Dombrock blood group]) exon 2 |
| 0185U | Red cell antigen (H blood group) genotyping (FUT1), gene analysis, FUT1 (fucosyltransferase 1 [H blood group]) exon 4 |
| 0186U | Red cell antigen (H blood group) genotyping (FUT2), gene analysis, FUT2 (fucosyltransferase 2) exon 2 |
| 0187U | Red cell antigen (Duffy blood group) genotyping (FY), gene analysis, ACKR1 (atypical chemokine receptor 1 [Duffy blood group]) exons 1-2 |
| 0188U | Red cell antigen (Gerbich blood group) genotyping (GE), gene analysis, GYPC (glycophorin C [Gerbich blood group]) exons 1-4 |
| 0189U | Red cell antigen (MNS blood group) genotyping (GYPA), gene analysis, GYPA (glycophorin A [MNS blood group]) introns 1, 5, exon 2 |
| 0190U | Red cell antigen (MNS blood group) genotyping (GYPB), gene analysis, GYPB (glycophorin B [MNS blood group]) introns 1, 5, pseudoexon 3 |
| 0191U | Red cell antigen (Indian blood group) genotyping (IN), gene analysis, CD44 (CD44 molecule [Indian blood group]) exons 2, 3, 6 |
| 0192U | Red cell antigen (Kidd blood group) genotyping (JK), gene analysis, SLC14A1 (solute carrier family 14 member 1 [Kidd blood group]) gene promoter, exon 9 |
| 0194U | Red cell antigen (Kell blood group) genotyping (KEL), gene analysis, KEL (Kell metalloendopeptidase [Kell blood group]) exon 8 |
| 0195U | KLF1 (Kruppel-like factor 1), targeted sequencing (i.e., exon 13) |
| 0196U | Red cell antigen (Lutheran blood group) genotyping (LU), gene analysis, BCAM (basal cell adhesion molecule [Lutheran blood group]) exon 3 |
| 0197U | Red cell antigen (Landsteiner-Wiener blood group) genotyping (LW), gene analysis, ICAM4 (intercellular adhesion molecule 4 [Landsteiner-Wiener blood group]) exon 1 |
| 0198U | Red cell antigen (RH blood group) genotyping (RHD and RHCE), gene analysis Sanger/chain termination/conventional sequencing, RHD (Rh blood group D antigen) exons 1-10 and RHCE (Rh blood group CcEe antigens) exon 5 |
| 0199U | Red cell antigen (Scianna blood group) genotyping (SC), gene analysis, ERMAP (erythroblast membrane associated protein [Scianna blood group]) exons 4, 12 |
| 0200U | Red cell antigen (Kx blood group) genotyping (XK), gene analysis, XK (X-linked Kx blood group) exons 1-3 |
| 0201U | Red cell antigen (Yt blood group) genotyping (YT), gene analysis, ACHE (acetylcholinesterase [Cartwright blood group]) exon 2 |

| CPT Code | Description | |
|-------------|---|--|
| Non-Covered | | |
| 0221U | Red cell antigen (ABO blood group) genotyping (ABO), gene analysis, next-generation sequencing, ABO (ABO, alpha 1-3-N-acetylgalactosaminyltransferase and alpha 1-3-galactosyltransferase) gene | |
| 0222U | Red cell antigen (RH blood group) genotyping (RHD and RHCE), gene analysis, next-generation sequencing, RH proximal promoter, exons 1-10, portions of introns 2-3 | |

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| Diagnosis Code | Description |
|----------------|---|
| or CPT Codes 0 | 001U and 0084U |
| C85.80 | Other specified types of non-Hodgkin lymphoma, unspecified site |
| C85.89 | Other specified types of non-Hodgkin lymphoma, extranodal and solid organ sites |
| C85.90 | Non-Hodgkin lymphoma, unspecified, unspecified site |
| C85.91 | Non-Hodgkin lymphoma, unspecified, lymph nodes of head, face, and neck |
| C85.92 | Non-Hodgkin lymphoma, unspecified, intrathoracic lymph nodes |
| C85.93 | Non-Hodgkin lymphoma, unspecified, intra-abdominal lymph nodes |
| C85.94 | Non-Hodgkin lymphoma, unspecified, lymph nodes of axilla and upper limb |
| C85.95 | Non-Hodgkin lymphoma, unspecified, lymph nodes of inguinal region and lower limb |
| C85.96 | Non-Hodgkin lymphoma, unspecified, intrapelvic lymph nodes |
| C85.97 | Non-Hodgkin lymphoma, unspecified, spleen |
| C85.98 | Non-Hodgkin lymphoma, unspecified, lymph nodes of multiple sites |
| C85.99 | Non-Hodgkin lymphoma, unspecified, extranodal and solid organ sites |
| C90.00 | Multiple myeloma not having achieved remission |
| C90.01 | Multiple myeloma in remission |
| C90.02 | Multiple myeloma in relapse |
| C91.00 | Acute lymphoblastic leukemia not having achieved remission |
| C91.01 | Acute lymphoblastic leukemia, in remission |
| C91.02 | Acute lymphoblastic leukemia, in relapse |
| C92.60 | Acute myeloid leukemia with 11q23-abnormality not having achieved remission |
| C92.61 | Acute myeloid leukemia with 11q23-abnormality in remission |
| C92.62 | Acute myeloid leukemia with 11q23-abnormality in relapse |
| C92.A0 | Acute myeloid leukemia with multilineage dysplasia, not having achieved remission |
| C92.A1 | Acute myeloid leukemia with multilineage dysplasia, in remission |
| C92.A2 | Acute myeloid leukemia with multilineage dysplasia, in relapse |
| D46.C | Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality |
| D46.Z | Other myelodysplastic syndromes |
| D51.0 | Vitamin B12 deficiency anemia due to intrinsic factor deficiency |
| D53.9 | Nutritional anemia, unspecified |
| D55.0 | Anemia due to glucose-6-phosphate dehydrogenase [G6PD] deficiency |
| D55.1 | Anemia due to other disorders of glutathione metabolism |
| D55.29 | Anemia due to other disorders of glycolytic enzymes |
| D55.3 | Anemia due to disorders of nucleotide metabolism |
| D55.8 | Other anemias due to enzyme disorders |
| D55.9 | Anemia due to enzyme disorder, unspecified |
| D56.0 | Alpha thalassemia |
| D56.1 | Beta thalassemia |
| D56.2 | Delta-beta thalassemia |

| Diagnosis Code | Description | | |
|-----------------|---|--|--|
| For CPT Codes 0 | 001U and 0084U | | |
| D56.3 | Thalassemia minor | | |
| D56.5 | Hemoglobin E-beta thalassemia | | |
| D56.8 | Other thalassemias | | |
| D56.9 | Thalassemia, unspecified | | |
| D57.00 | Hb-SS disease with crisis, unspecified | | |
| D57.01 | Hb-SS disease with acute chest syndrome | | |
| D57.02 | Hb-SS disease with splenic sequestration | | |
| D57.03 | Hb-SS disease with cerebral vascular involvement | | |
| D57.04 | Hb-SS disease with dactylitis (Effective 10/01/2023) | | |
| D57.09 | Hb-SS disease with crisis with other specified complication | | |
| D57.1 | Sickle-cell disease without crisis | | |
| D57.20 | Sickle-cell/Hb-C disease without crisis | | |
| D57.211 | Sickle-cell/Hb-C disease with acute chest syndrome | | |
| D57.212 | Sickle-cell/Hb-C disease with splenic sequestration | | |
| D57.213 | Sickle-cell/Hb-C disease with cerebral vascular involvement | | |
| D57.214 | Sickle-cell/Hb-C disease with dactylitis (Effective 10/01/2023) | | |
| D57.218 | Sickle-cell/Hb-C disease with crisis with other specified complication | | |
| D57.219 | Sickle-cell/Hb-C disease with crisis, unspecified | | |
| D57.3 | Sickle-cell trait | | |
| D57.40 | Sickle-cell thalassemia without crisis | | |
| D57.411 | Sickle-cell thalassemia, unspecified, with acute chest syndrome | | |
| D57.412 | Sickle-cell thalassemia, unspecified, with splenic sequestration | | |
| D57.413 | Sickle-cell thalassemia, unspecified, with cerebral vascular involvement | | |
| D57.414 | Sickle-cell thalassemia, unspecified, with dactylitis (Effective 10/01/2023) | | |
| D57.418 | Sickle-cell thalassemia, unspecified, with crisis with other specified complication | | |
| D57.419 | Sickle-cell thalassemia, unspecified, with crisis | | |
| D57.42 | Sickle-cell thalassemia beta zero without crisis | | |
| D57.431 | Sickle-cell thalassemia beta zero with acute chest syndrome | | |
| D57.432 | Sickle-cell thalassemia beta zero with splenic sequestration | | |
| D57.433 | Sickle-cell thalassemia beta zero with cerebral vascular involvement | | |
| D54.434 | Sickle-cell thalassemia beta zero with dactylitis (Effective 10/01/2023) | | |
| D57.438 | Sickle-cell thalassemia beta zero with crisis with other specified complication | | |
| D57.439 | Sickle-cell thalassemia beta zero with crisis, unspecified | | |
| D57.44 | Sickle-cell thalassemia beta plus without crisis | | |
| D57.451 | Sickle-cell thalassemia beta plus with acute chest syndrome | | |
| D57.452 | Sickle-cell thalassemia beta plus with splenic sequestration | | |
| D57.453 | Sickle-cell thalassemia beta plus with cerebral vascular involvement | | |
| D57.454 | Sickle-cell thalassemia beta plus with dactylitis (Effective 10/01/2023) | | |
| D57.458 | Sickle-cell thalassemia beta plus with crisis with other specified complication | | |
| D57.459 | Sickle-cell thalassemia beta plus with crisis, unspecified | | |
| D57.80 | Other sickle-cell disorders without crisis | | |
| D57.811 | Other sickle-cell disorders with acute chest syndrome | | |
| D57.812 | Other sickle-cell disorders with splenic sequestration | | |
| D57.813 | Other sickle-cell disorders with cerebral vascular involvement | | |

| Diagnosis Code | Description | | |
|-----------------|---|--|--|
| For CPT Codes 0 | For CPT Codes 0001U and 0084U | | |
| D57.814 | Other sickle-cell disorders with dactylitis (Effective 10/01/2023) | | |
| D57.818 | Other sickle-cell disorders with crisis with other specified complication | | |
| D57.819 | Other sickle-cell disorders with crisis, unspecified | | |
| D58.0 | Hereditary spherocytosis | | |
| D58.1 | Hereditary elliptocytosis | | |
| D58.9 | Hereditary hemolytic anemia, unspecified | | |
| D59.0 | Drug-induced autoimmune hemolytic anemia | | |
| D59.10 | Autoimmune hemolytic anemia, unspecified | | |
| D59.11 | Warm autoimmune hemolytic anemia | | |
| D59.12 | Cold autoimmune hemolytic anemia | | |
| D59.13 | Mixed type autoimmune hemolytic anemia | | |
| D59.19 | Other autoimmune hemolytic anemia | | |
| D59.9 | Acquired hemolytic anemia, unspecified | | |
| D60.0 | Chronic acquired pure red cell aplasia | | |
| D60.1 | Transient acquired pure red cell aplasia | | |
| D60.8 | Other acquired pure red cell aplasias | | |
| D60.9 | Acquired pure red cell aplasia, unspecified | | |
| D61.01 | Constitutional (pure) red blood cell aplasia | | |
| D61.02 | Shwachman-Diamond syndrome (Effective 10/01/2023) | | |
| D61.09 | Other constitutional aplastic anemia | | |
| D61.1 | Drug-induced aplastic anemia | | |
| D61.2 | Aplastic anemia due to other external agents | | |
| D61.3 | Idiopathic aplastic anemia | | |
| D61.89 | Other specified aplastic anemias and other bone marrow failure syndromes | | |
| D63.0 | Anemia in neoplastic disease | | |
| D63.1 | Anemia in chronic kidney disease | | |
| D63.8 | Anemia in other chronic diseases classified elsewhere | | |
| D64.0 | Hereditary sideroblastic anemia | | |
| D64.1 | Secondary sideroblastic anemia due to disease | | |
| D64.2 | Secondary sideroblastic anemia due to drugs and toxins | | |
| D64.3 | Other sideroblastic anemias | | |
| D64.4 | Congenital dyserythropoietic anemia | | |
| D64.89 | Other specified anemias | | |
| Z85.72 | Personal history of non-Hodgkin lymphomas | | |

Non-Covered Diagnosis Code

Non-Covered Diagnosis Codes List

This list contains diagnosis codes that are **never covered when given as the primary reason for the test.** If a code from this section is given as the reason for the test and you know or have reason to believe the service may not be covered, call UnitedHealthcare to issue an Integrated Denial Notice (IDN) to the member and you. The IDN informs the member of their liability for the non-covered service or item and appeal rights. You must make sure the member has received the IDN prior to rendering or referring for non-covered services or items in order to collect payment.

References

CMS Local Coverage Determinations (LCDs) and Articles

| LCD LCD | Article | Contractor | Medicare Part | Medicare Part |
|--|--|-------------|---|---|
| Discal Duschust Malassilas Auti | non Trusinon | | Α | В |
| Blood Product Molecular Antig | 1 | 000 | 107.011 | 107 011 |
| L38249 MolDX: Blood Product Molecular Antigen Typing | A57155 Billing and Coding: MolDX: Blood Product Molecular Antigen Typing | CGS | KY, OH | KY, OH |
| L38331 MolDX: Blood Product Molecular Antigen Typing | A57124 Billing and Coding: MolDX: Blood Product Molecular Antigen Typing | Noridian | AS, CA, GU, HI, MP, NV | AS, CA, GU, HI, MP, NV |
| L38333 MolDX: Blood Product Molecular Antigen Typing | A57376 Billing and Coding: MolDX: Blood Product Molecular Antigen Typing | Noridian | AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY | AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY |
| L38240 MolDX: Blood Product Molecular Antigen Typing | A58308 Billing and Coding: MolDX: Blood Product Molecular Antigen Typing | Palmetto | AL, GA, NC, SC, TN, VA, WV | AL, GA, NC, SC, TN, VA, WV |
| L38441 MolDX: Blood Product Molecular Antigen Typing | A57110 Billing and Coding: MolDX: Blood Product Molecular Antigen Typing | WPS | IA, IN, KS, MI, MO, NE | IA, IN, KS, MI, MO, NE |
| General Molecular Diagnostic | Tests | | | |
| L36021 Molecular Diagnostic Tests (MDT) | A56973 Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT) | CGS | KY, OH | KY, OH |
| L35160 MolDX: Molecular Diagnostic Tests (MDT) | A57526 Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT) | Noridian | AS, CA, GU, HI, MP, NV | AS, CA, GU, HI, MP, NV |
| L36256 MolDX: Molecular Diagnostic Tests (MDT) | A57527 Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT) | Noridian | AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY | AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY |
| L35025 MolDX: Molecular Diagnostic Tests (MDT) | A56853 Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT) | Palmetto | AL, GA, NC, SC, TN, VA, WV | AL, GA, NC, SC, TN, VA, WV |
| L36807 MolDX: Molecular Diagnostic Tests (MDT) | A57772 Billing and Coding: MolDX: Molecular Diagnostic Tests (MDT) | WPS | IA, IN, KS, MI, MO, NE | IA, IN, KS, MI, MO, NE |
| L35062 Biomarkers Overview | A56541 Billing and Coding: Biomarkers Overview | Novitas | AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX | AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX |
| | A58917 Billing and Coding: Molecular Pathology and Genetic Testing | Novitas | AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX | AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX |
| L34519 Molecular Pathology Procedures | A57451 Billing and Coding: Molecular Pathology Procedures | First Coast | FL, PR, VI | FL, PR, VI |
| | A58918 Billing and Coding: Molecular Pathology and Genetic Testing | | | |
| L35000 Molecular Pathology Procedures | A56199 Billing and Coding: Molecular Pathology Procedures | NGS | CT, IL, MA, ME, MN, NH, NY, RI, VT, WI | CT, IL, MA, ME, MN, NH, NY, RI, VT, WI |

CMS Benefit Policy Manual

Chapter 15; § 80.1 – 80.1.3 Clinical Laboratory Services

CMS Claims Processing Manual

Chapter 12; § 60 Payment for Pathology Services

Chapter 16, § 10.2 General Explanation of Payment; § 20 Calculation of Payment Rates - Clinical Laboratory Test Fee Schedules; § 40 Billing for Clinical Laboratory Tests

Other(s)

Palmetto GBA MolDx Website

Palmetto GBA MolDx Manual, Palmetto GBA MolDx Website

Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

| Date | Summary of Changes |
|------------|---|
| 08/01/2024 | Related Policies Removed reference link to the Medicare Advantage Policy Guideline titled Laboratory Tests and Services (retired Aug. 1, 2024) Updated reference link for the Medicare Advantage Medical Policy titled Pharmacogenomics Testing |
| 04/10/2024 | Applicable Codes Non-Covered Diagnosis Codes Added Z02.84 Administrative Archived previous policy version MPG388.09 |

Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the <u>References</u> section above to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

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*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.