

## Clinical Diagnostic Lab Policy, Professional

### **IMPORTANT NOTE ABOUT THIS REIMBURSEMENT POLICY**

*You are responsible for submission of accurate claims. This reimbursement policy is intended to ensure that you are reimbursed based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Individual Exchange reimbursement policies may 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.*

*This reimbursement policy applies to all health care services billed on CMS 1500 form. Coding methodology, industry-standard reimbursement logic, regulatory requirements, benefits design and other factors are considered in developing reimbursement policy.*

*This information is intended to serve only as a general reference resource regarding UnitedHealthcare Individual Exchange’s reimbursement policy for the services described and is not intended to address every aspect of a reimbursement situation. Accordingly, UnitedHealthcare Individual Exchange may use reasonable discretion in interpreting and applying this policy to health care services provided in a particular case. Further, the policy does not address all issues related to reimbursement for health care services provided to UnitedHealthcare Individual Exchange enrollees. Other factors affecting reimbursement may supplement, modify or, in some cases, supersede this policy. These factors may include, but are not limited to: legislative mandates, the physician or other provider contracts, the enrollee’s benefit coverage documents and/or other reimbursement, medical or drug policies. Finally, this policy may not be implemented exactly the same way on the different electronic claims processing systems used by UnitedHealthcare Individual Exchange due to programming or other constraints; however, UnitedHealthcare Individual Exchange strives to minimize these variations.*

*UnitedHealthcare Individual Exchange may modify this reimbursement policy at any time by publishing a new version of the policy on this Website. However, the information presented in this policy is accurate and current as of the date of publication.*

*\*CPT Copyright American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association.*

| Table of Contents               |                              |
|---------------------------------|------------------------------|
| <b>Application</b>              | <b>1</b>                     |
| <b>Policy</b>                   | <b>2</b>                     |
| <b>Overview</b>                 | <b>2</b>                     |
| <b>Reimbursement Guidelines</b> | <b>2</b>                     |
| <b>Definitions</b>              | <b>10</b>                    |
| <b>Questions and Answers</b>    | <b>10</b>                    |
| <b>Attachments</b>              | Error! Bookmark not defined. |
| <b>Resources</b>                | <b>11</b>                    |
| <b>History</b>                  | <b>11</b>                    |

| Application   |
|---|
| <p><b>This reimbursement policy applies to UnitedHealthcare Individual Exchange products.</b></p> <p>This reimbursement policy applies to services reported using the 1500 Health Insurance Claim Form (a/k/a CMS-1500) or its electronic equivalent or its successor form. This policy applies to all products, all network and non-network physicians and other qualified health care professionals, including, but not limited to, non-network authorized and percent of charge contract physicians and other qualified health care professionals.</p> |

**Applicable States:**

This reimbursement policy applies to Individual Exchange benefit plans in all states except for Colorado, Massachusetts, Mississippi, Nevada, New Jersey, New Mexico, New York, South Carolina and Wisconsin.

**Policy****Overview**

Based on the CMS National Coverage Determination (NCD) coding policy manual, services that are excluded from coverage include routine physical examinations and services that are not reasonable and necessary for the diagnosis or treatment of an illness or injury. CMS interprets these provisions to prohibit coverage of screening services, including laboratory tests furnished in the absence of signs, symptoms, or personal history of disease or injury. A national coverage policy for diagnostic laboratory test(s) is a document stating CMS's policy with respect to the circumstances under which the test(s) will be considered reasonable and necessary, and not screening.

**Reimbursement Guidelines**

This edit will allow clinical diagnostic lab procedure(s) when submitted with a diagnosis code found on the allowed diagnosis code list. When the clinical diagnostic lab procedure is billed as a routine screening service, as evidenced by the diagnosis code **not found** on the allowed diagnosis code list, the procedure code will deny.

**Carcinoembryonic Antigen (CEA)**

Carcinoembryonic antigen (CEA) is a protein polysaccharide found in some carcinomas. It is effective as a biochemical marker for monitoring the response of certain malignancies to therapy. UnitedHealthcare Individual Exchange reimburses for Carcinoembryonic antigen (CEA) (CPT codes 82378) when one of the diagnosis codes listed on a claim indicates a malignancy found on the list of approved diagnosis codes for this test. UnitedHealthcare Individual Exchange will not reimburse when the treatment rendered is without inclusion of one of the ICD-10CM diagnostic codes being included on the claim accurately reflecting the member's condition.

[See Attachment Section for ICD-10 Codes approved with CPT code 82378 \(CEA\)](#)

**Alpha-fetoprotein (AFP)**

Alpha-fetoprotein (AFP) is a polysaccharide found in some carcinomas. It is effective as a biochemical marker for monitoring the response of certain malignancies to therapy. AFP is useful for the diagnosis of hepatocellular carcinoma in high-risk patients (such as alcoholic cirrhosis, cirrhosis of viral etiology, hemochromatosis, and alpha 1-antitrypsin deficiency) and in separating patients with benign hepatocellular neoplasms or metastases from those with hepatocellular carcinoma and, as a non-specific tumor associated antigen, serves in marking germ cell neoplasms of the testis, ovary, retro peritoneum, and mediastinum. UnitedHealthcare Individual Exchange reimburses for Alpha-fetoprotein; serum (82105) when one of the diagnosis codes listed on a claim is found on the list of approved diagnosis codes for this test. UnitedHealthcare Individual Exchange will not reimburse when the treatment rendered is without inclusion of one of the ICD-10-CM diagnostic codes being included on the claim accurately reflecting the member's condition.

[See Attachment Section for ICD-10 Codes approved with CPT code 82105 \(AFP\)](#)

**Partial Thromboplastin Time (PTT)**

Basic plasma coagulation function is readily assessed with a few simple laboratory tests: The Partial Thromboplastin Time (PTT), Prothrombin Time (PT), Thrombin Time (TT), or a quantitative fibrinogen determination. The PTT test is an in vitro laboratory test used to assess the intrinsic coagulation pathway and monitor heparin therapy. UnitedHealthcare Individual Exchange reimburses for Partial Thromboplastin Time (PTT) (CPT code 85730), when one billed with one of the approved diagnosis codes for this test. UnitedHealthcare Individual Exchange will not reimburse when the treatment

rendered is without inclusion of one of the and ICD-10-CM diagnostic codes being included on the claim accurately reflecting the member's condition.

[See Attachment Section for ICD-10 Codes approved with CPT code 85730 \(PTT\)](#)

### **Prostate Specific Antigen (PSA)**

Prostate Specific Antigen (PSA), a tumor marker for adenocarcinoma of the prostate, can predict residual tumor in the post-operative phase of prostate cancer. Three to 6 months after radical prostatectomy, PSA is reported to provide a sensitive indicator of persistent disease. Six months following introduction of antiandrogen therapy, PSA is reported of distinguishing patients with favorable response from those in whom limited response is anticipated.

PSA when used in conjunction with other prostate cancer tests, such as digital rectal examination, may assist in the decision-making process for diagnosing prostate cancer. PSA also, serves as a marker in following the progress of most prostate tumors once a diagnosis has been established. This test is also an aid in the management of prostate cancer patients and in detecting metastatic or persistent disease in patients following treatment. UnitedHealthcare Individual Exchange reimburses for Prostate Specific Antigen (PSA) (CPT code 84153), when the claim indicates a code found on the list of approved diagnosis codes for this test. UnitedHealthcare Individual Exchange will not reimburse when the treatment rendered is without inclusion of one of the ICD-10-CM diagnostic codes being included on the claim accurately reflecting the member's condition.

[See Attachment Section for ICD-10 Codes approved with CPT code 84153 \(PSA\)](#)

### **Urine Culture, Bacterial**

A bacterial urine culture is a laboratory procedure performed on a urine specimen to establish the probable etiology of a presumed urinary tract infection. It is common practice to do a urinalysis prior to a urine culture. A urine culture may also be used as part of the evaluation and management of another related condition. The procedure includes aerobic agar-based isolation of bacteria or other cultivable organisms present, and quantitation of types present based on morphologic criteria. Isolates deemed significant may be subjected to additional identification and susceptibility procedures as requested by the ordering physician. The physician's request may be through clearly documented and communicated laboratory protocols. UnitedHealthcare Individual Exchange reimburses for Urine Culture, Bacterial (CPT codes 87086 and 87088), when the claim indicates a code found on the list of approved diagnosis codes for this test. UnitedHealthcare Individual Exchange will not reimburse when the treatment rendered is without inclusion of one of the ICD-10-CM diagnostic codes being included on the claim accurately reflecting the member's condition.

[See Attachment Section for ICD-10 Codes approved with CPT code 87086 and 87088 \(Urine Culture, Bacterial\)](#)

### **Serum Iron Studies**

Serum iron studies are useful in the evaluation of disorders of iron metabolism, particularly iron deficiency and iron excess. Iron studies are best performed when the patient is fasting in the morning and has abstained from medications that may influence iron balance.

Iron deficiency is the most common cause of anemia. In young children on a milk diet, iron deficiency is often secondary to dietary deficiency. In adults, iron deficiency is usually the result of blood loss and is only occasionally secondary to dietary deficiency or malabsorption. Following major surgery, the patient may have iron deficient erythropoietin for months or years if adequate iron replacement has not been given. High doses of supplemental iron may cause the serum iron to be elevated. Serum iron may also be altered in acute and chronic inflammatory and neoplastic conditions.

Total Iron Binding Capacity (TIBC) is an indirect measure of transferrin, a protein that binds and transports iron. TIBC quantifies transferrin by the amount of iron that it can bind. TIBC and transferrin are elevated in iron deficiency, and with oral contraceptive use, and during pregnancy. TIBC and transferrin may be decreased in malabsorption syndromes or in those affected with chronic diseases. The percent saturation represents the ratio of iron to the TIBC.

Assays for ferritin are also useful in assessing iron balance. Low concentrations are associated with iron deficiency and are highly specific. High concentrations are found in hemosiderosis (iron overload without associated tissue injury) and hemochromatosis (iron overload with associated tissue injury). In these conditions the iron is elevated, the TIBC and

transferrin are within the reference range or low, and the percent saturation is elevated. Serum ferritin can be useful for both initiating and monitoring treatment for iron overload.

Transferrin and ferritin belong to a group of serum proteins known as acute phase reactants and are increased in response to stressful or inflammatory conditions and can occur with infection and tissue injury due to surgery, trauma, or necrosis. Ferritin and iron/TIBC (or transferrin) are affected by acute and chronic inflammatory conditions, and in patients with these disorders, tests of iron status may be difficult to interpret. UnitedHealthcare Individual Exchange reimburses for Serum Iron Studies (CPT codes 82728, 83540, 83550, and/or 84466), when the claim indicates a code found on the list of approved diagnosis codes for this test. UnitedHealthcare Individual Exchange will not reimburse when the treatment rendered is without inclusion of one of the ICD-10-CM diagnostic codes being included on the claim accurately reflecting the member's condition.

[See Attachment Section for ICD-10 Codes approved with CPT code 82728, 83540, 83550, and/or 84466 \(Serum Iron Studies\)](#)

### **Human Chorionic Gonadotropin (hCG)**

Human Chorionic Gonadotropin (hCG) is useful for monitoring and diagnosis of germ cell neoplasms of the ovary, testis, mediastinum, retroperitoneum, and central nervous system. In addition, hCG is useful for monitoring pregnant patients with vaginal bleeding, hypertension and/or suspected fetal loss.

UnitedHealthcare Individual Exchange reimburses for Human Chorionic Gonadotropin (hCG) (CPT code 84702), when the claim indicates a code found on the list of approved diagnosis codes for this test. UnitedHealthcare Individual Exchange will not reimburse when the treatment rendered is without inclusion of one of the ICD-10CM diagnostic codes being included on the claim accurately reflecting the member's condition.

[See Attachment Section for ICD-10 Codes approved with CPT code 84702 \(hCG\)](#)

### **Lipids Testing**

Lipoproteins are a class of heterogeneous particles of varying sizes and densities containing lipid and protein. These lipoproteins include cholesterol esters and free cholesterol, triglycerides, phospholipids and A, C, and E apoproteins. Total cholesterol comprises all the cholesterol found in various lipoproteins.

Factors that affect blood cholesterol levels include age, sex, body weight, diet, alcohol and tobacco use, exercise, genetic factors, family history, medications, menopausal status, the use of hormone replacement therapy, and chronic disorders such as hypothyroidism, obstructive liver disease, pancreatic disease (including diabetes), and kidney disease.

In many individuals, an elevated blood cholesterol level constitutes an increased risk of developing coronary artery disease. Blood levels of total cholesterol and various fractions of cholesterol, especially low-density lipoprotein cholesterol (LDL -C) and high-density lipoprotein cholesterol (HDL-C) are useful in assessing and monitoring treatment for that risk in patients with cardiovascular and related diseases. Blood levels of the above cholesterol components including triglyceride have been separated into desirable, borderline, and high-risk categories by the National Heart, Lung, and Blood Institute in their report in 1993. These categories form a useful basis for evaluation and treatment of patients with hyperlipidemia. Therapy to reduce these risk parameters includes diet, exercise and medication, and fat weight loss, which is particularly powerful when combined with diet and exercise.

UnitedHealthcare Individual Exchange reimburses for Lipids Testing (CPT codes 80061, 82465, 83700, 83701, 83704, 83718, 83721, and 84478), when the claim indicates a code found on the list of approved diagnosis codes for this test. UnitedHealthcare Individual Exchange will not reimburse when the treatment rendered is without inclusion of one of the and ICD-10-CM diagnostic codes being included on the claim accurately reflecting the member's condition.

[See Attachment Section for ICD-10 Codes approved with CPT code 80061, 82465, 83700, 83701, 83704, 83718, 83721, and/or 84478 \(Lipids Testing\)](#)

**Thyroid Testing**

Thyroid function studies are used to delineate the presence or absence of hormonal abnormalities of the thyroid and pituitary glands. These abnormalities may be either primary or secondary and often but not always accompany clinically defined signs and symptoms indicative of thyroid dysfunction.

Laboratory evaluation of thyroid function has become more scientifically defined. Tests can be done with increased specificity, thereby reducing the number of tests needed to diagnose and follow treatment of most thyroid disease. Measurements of serum sensitive thyroid-stimulating hormone (TSH) levels complemented by determination of thyroid hormone levels [free thyroxine (fT-4) or total thyroxine (T4) with Triiodothyronine (T3) uptake] are used for diagnosis and follow-up of patients with thyroid disorders. Additional tests may be necessary to evaluate certain complex diagnostic problems or on hospitalized patients, where many circumstances can skew tests results. When a test for total thyroxine (total T4 or T4 radioimmunoassay) or T3 uptake is performed, calculation of the free thyroxine index (FTI) is useful to correct for abnormal results for either total T4 or T3 uptake due to protein binding effects.

UnitedHealthcare Individual Exchange reimburses for Thyroid Testing (CPT codes 84436, 84439, 84443, and 84479), when the claim indicates a code found on the list of approved diagnosis codes for this test. UnitedHealthcare Individual Exchange will not reimburse when the treatment rendered is without inclusion of one of the ICD-10CM diagnostic codes being included on the claim accurately reflecting the member's condition.

[See Attachment Section for ICD-10 Codes approved with CPT code 84436, 84439, 84443, and/or 84479 \(Thyroid Testing\)](#)

**Prothrombin Time (PT)**

Basic plasma coagulation function is readily assessed with a few simple laboratory tests: The Partial Thromboplastin Time (PTT), Prothrombin Time (PT), Thrombin Time (TT), or a quantitative fibrinogen determination. The PT test is one in-vitro laboratory test used to assess coagulation. While the PTT assesses the intrinsic limb of the coagulation system, the PT assesses the extrinsic or tissue factor dependent pathway. Both tests also evaluate the common coagulation pathway involving all the reactions that occur after the activation of factor X. Extrinsic pathway factors are produced in the liver and their production is dependent on adequate vitamin K activity. Deficiencies of factors may be related to decreased production or increased consumption of coagulation factors. The PT/INR is most commonly used to measure the effect of warfarin and regulate its dosing. Warfarin blocks the effect of vitamin K on hepatic production of extrinsic pathway factors.

A PT is expressed in seconds and/or as an international normalized ratio (INR). The INR is the PT ratio that would result if the WHO reference thromboplastin was used in performing the test. Current medical information does not clarify the role of laboratory PT testing in patients who are self-monitoring. Therefore, the indications for testing apply regardless of whether or not the patient is also PT self-testing.

UnitedHealthcare Individual Exchange reimburses for Prothrombin Time (CPT code 85610), when the claim indicates a code found on the list of approved diagnosis codes for this test. UnitedHealthcare Individual Exchange will not reimburse when the treatment rendered is without inclusion of one of the ICD-10CM diagnostic codes being included on the claim accurately reflecting the member's condition.

[See Attachment Section for ICD-10 Codes approved with CPT code 85610 Prothrombin Time \(PT\)](#)

**Tumor Antigen by Immunoassay CA 125**

Immunoassay determinations of the serum levels of certain proteins or carbohydrates serve as tumor markers. When elevated, serum concentration of these markers may reflect tumor size and grade.

This portion of the policy specifically addresses tumor antigen CA 125. These services are not covered for the evaluation of patients with signs or symptoms suggestive of malignancy. The service may be ordered at times necessary to assess either the presence of recurrent disease or the patient's response to treatment with subsequent treatment cycles.

UnitedHealthcare Individual Exchange reimburses for Tumor Antigen by Immunoassay CA 125 (CPT code 86304), when the claim indicates a code found on the list of approved diagnosis codes for this test. UnitedHealthcare Individual Exchange will not reimburse when the treatment rendered is without inclusion of one of the ICD-10-CM diagnostic codes being included on the claim accurately reflecting the member's condition.

[See Attachment Section for ICD-10 Codes approved with CPT code 86304 Tumor Antigen by Immunoassay CA125](#)

#### **Tumor Antigen by Immunoassay CA 15-3/CA 27.29**

Immunoassay determinations of the serum levels of certain proteins or carbohydrates serve as tumor markers. When elevated, serum concentration of markers may reflect tumor size & grade.

This portion of the policy specifically addresses the following tumor antigens: CA 15-3 and CA 27.29. These services are not covered for the evaluation of patients with signs or symptoms suggestive of malignancy. The service may be ordered at times necessary to assess either the presence of recurrent disease or the patient's response to treatment with subsequent treatment cycles.

UnitedHealthcare Individual Exchange reimburses for Tumor Antigen by Immunoassay CA 15-3/CA 27.29 (CPT code 86300), when the claim indicates a code found on the list of approved diagnosis codes for this test. UnitedHealthcare Individual Exchange will not reimburse when the treatment rendered is without inclusion of one of the ICD-10-CM diagnostic codes being included on the claim accurately reflecting the member's condition.

[See Attachment Section for ICD-10 Codes approved with CPT code 86300 Tumor Antigen by Immunoassay CA15-3/CA 27.29](#)

#### **Tumor Antigen by Immunoassay CA 19-9**

Immunoassay determinations of the serum levels of certain proteins or carbohydrates serve as tumor markers. When elevated, serum concentration of these markers may reflect tumor size and grade.

This portion of the policy specifically addresses the following tumor antigen: CA19-9. These services are not covered for the evaluation of patients with signs or symptoms suggestive of malignancy. The service may be ordered at times necessary to assess either the presence of recurrent disease or the patient's response to treatment with subsequent treatment cycles.

UnitedHealthcare Individual Exchange reimburses for Tumor Antigen by Immunoassay CA 19-9 (CPT code 86301), when the claim indicates a code found on the list of approved diagnosis codes for this test. UnitedHealthcare Individual Exchange will not reimburse when the treatment rendered is without inclusion of one of the ICD-10-CM diagnostic codes being included on the claim accurately reflecting the member's condition.

[See Attachment Section for ICD-10 Codes approved with CPT code 86301 Tumor Antigen by Immunoassay CA 19-9](#)

#### **Gamma Glutamyl Transferase (GGT)**

Gamma glutamyl transferase (GGT) is an intracellular enzyme that appears in blood following leakage from cells. Renal tubules, liver, and pancreas contain high amounts, although the measurement of GGT in serum is almost always used for assessment of Hepatobiliary function. Unlike other enzymes which are found in heart, skeletal muscle, and intestinal mucosa as well as liver, the appearance of an elevated level of GGT in serum is almost always the result of liver disease or injury. It is specifically useful to differentiate elevated alkaline phosphatase levels when the source of the alkaline

phosphatase increase (bone, liver, or placenta) is unclear. The combination of high alkaline phosphatase and a normal GGT does not, however, rule out liver disease completely.

As well as being a very specific marker of Hepatobiliary function, GGT is also a very sensitive marker for hepatocellular damage. Abnormal concentrations typically appear before elevations of other liver enzymes or biliuria are evident. Obstruction of the biliary tract, viral infection (e.g., hepatitis, mononucleosis), metastatic cancer, exposure to hepatotoxins (e.g., organic solvents, drugs, alcohol), and use of drugs that induce microsomal enzymes in the liver (e.g., cimetidine, barbiturates, phenytoin, and carbamazepine) all can cause a moderate to marked increase in GGT serum concentration. In addition, some drugs can cause or exacerbate liver dysfunction (e.g., atorvastatin, troglitazone, and others as noted in FDA Contraindications and Warnings.)

GGT is useful for diagnosis of liver disease or injury, exclusion of hepatobiliary involvement related to other diseases, and patient management during the resolution of existing disease or following injury.

UnitedHealthcare Individual Exchange reimburses for Gamma Glutamyl Transferase (CPT code 82977), when the claim indicates a code found on the list of approved diagnosis codes for this test. UnitedHealthcare Individual Exchange will not reimburse when the treatment rendered is without inclusion of one of the ICD-10CM diagnostic codes being included on the claim accurately reflecting the member's condition.

[See Attachment Section for ICD-10 Codes approved with CPT code 82977 Gamma Glutamyl Transferase \(GGT\)](#)

### **Hepatitis Panel/Acute Hepatitis Panel**

This panel consists of the following tests:

- Hepatitis A antibody (HAAb), IgM antibody;
- Hepatitis B core antibody (HBcAb), IgM antibody;
- Hepatitis B surface antigen (HBsAg) and;
- Hepatitis C antibody.

Hepatitis is an inflammation of the liver resulting from viruses, drugs, toxins, and other etiologies. Viral hepatitis can be due to one of at least five different viruses, designated hepatitis A, B, C, and E. Most cases are caused by hepatitis A virus (HAV), hepatitis B virus (HBV), or hepatitis C virus (HCV).

HAV is the most common cause of hepatitis in children and adolescents in the United States. Prior exposure is indicated by a positive IgG anti-HAV. Acute HAV is diagnosed by IgM anti-HAV, which typically appears within four weeks of exposure, and which disappears within three months of its appearance. IgG anti-HAV is similar in the timing of its appearance, but it persists indefinitely. Its detection indicates prior effective immunization or recovery from infection. Although HAV is spread most commonly by fecal-oral exposure, standard immune globulin may be effective as a prophylaxis.

HBV produces three separate antigens (surface, core, and e (envelope) antigens) when it infects the liver, although only hepatitis B surface antigen (HBsAg) is included as part of this panel. Following exposure, the body normally responds by producing antibodies to each of these antigens; one of which is included in this panel: hepatitis B surface antibody (HBsAb)-IgM antibody. HBsAg is the earlier marker, appearing in serum four to eight weeks after exposure, and typically disappearing within six months after its appearance. If HBsAg remains detectable for greater than six months, this indicates chronic HBV infection. HBcAb, in the form of both IgG and IgM antibodies, are next to appear in serum, typically becoming detectable two to three months following exposure. The IgM antibody gradually declines or disappears entirely one to two years following exposure, but the IgG usually remains detectable for life. Because HBsAg is present for a relatively short period and usually displays a low titer, a negative result does not exclude an HBV diagnosis. HBcAb, on the other hand, rises to a much higher titer and remains elevated for a longer period of time, but a positive result is not diagnostic of acute disease, since it may be the result of a prior infection. The last marker to appear in the course of a typical infection is HBsAb, which appears in serum four to six months following exposure to infected blood or body fluids; in the U.S., sexual transmission accounts for 30% to 60% of new cases of HBV infection.

The diagnosis of acute HBV infection is best established by documentation of positive IgM antibody against the core antigen (HBcAb-IgM) and by identification of a positive hepatitis B surface antigen (HBsAg). The diagnosis of chronic HBV infection is established primarily by identifying a positive hepatitis B surface antigen (HBsAg) and demonstrating positive IgG antibody directed against the core antigen (HBcAb-IgG). Additional tests such as hepatitis B e antigen (HBeAg) and hepatitis B e antibody (HBeAb), the envelope antigen and antibody, are not included in the hepatitis panel, but may be of importance in assessing the infectivity of patients with HBV. Following completion of a HBV vaccination series, HBsAb alone may be used monthly for up to six months, or until a positive result is obtained, to verify an adequate antibody response.

HCV is the most common cause of post-transfusion hepatitis; overall HCV is responsible for 15% to 20% of all cases of acute hepatitis and is the most common cause of chronic liver disease. The test most commonly used to identify HCV measures HCV antibodies, which appear in blood two to four months after infection. False positive HCV results can occur. For example, a patient with a recent yeast infection may produce a false positive anti-HCV result. For this reason, at present positive results usually are confirmed by a more specific technique. Like HBV, HCV is spread exclusively through exposure to infected blood or body fluids.

This panel of tests is used for differential diagnosis in a patient with symptoms of liver disease or injury. When the time of exposure or the stage of the disease is not known, a patient with continued symptoms of liver disease despite a completely negative hepatitis panel may need a repeat panel approximately two weeks to two months later to exclude the possibility of hepatitis. Once a diagnosis is established, specific tests can be used to monitor the course of the disease.

UnitedHealthcare Individual Exchange reimburses for Hepatitis Panel/Acute Hepatitis Panel (CPT code 80074), when the claim indicates a code found on the list of approved diagnosis codes for this test. UnitedHealthcare Individual Exchange will not reimburse when the treatment rendered is without inclusion of one of the ICD-10-CM diagnostic codes being included on the claim accurately reflecting the member's condition.

[See Attachment Section for ICD-10 Codes approved with CPT code 80074 Hepatitis Panel/Acute Hepatitis Panel](#)

### **Digoxin Therapeutic Drug Assay**

A digoxin therapeutic drug assay is useful for diagnosis and prevention of digoxin toxicity, and/or prevention for under dosage of digoxin.

Digoxin levels may be performed to monitor drug levels of individuals receiving digoxin therapy because the margin of safety between side effects and toxicity is narrow or because the blood level may not be high enough to achieve the desired clinical effect.

Clinical indications may include individuals on digoxin:

- With symptoms, signs, or electrocardiogram (ECG) suggestive of digoxin toxicity
- Taking medications that influence absorption, bioavailability, distribution, and/or elimination of digoxin
- With impaired renal, hepatic, gastrointestinal, or thyroid function
- With pH and/or electrolyte abnormalities
- With unstable cardiovascular status, including myocarditis
- Requiring monitoring of patient compliance

Clinical indications may include individuals:

- Suspected of accidental or intended overdose
- Who have an acceptable cardiac diagnosis (as listed) and for whom an accurate history of use of digoxin is unobtainable

The value of obtaining regular serum digoxin levels is uncertain, but it may be reasonable to check levels once yearly after a steady state is achieved. In addition, it may be reasonable to check the level if:

- Heart failure status worsens
- Renal function deteriorates



- Additional medications are added that could affect the digoxin level
- Signs or symptoms of toxicity develop

Steady state will be reached in approximately 1 week in patients with normal renal function, although 2-3 weeks may be needed in patients with renal impairment. After changes in dosages or the addition of a medication that could affect the digoxin level, it is reasonable to check the digoxin level one week after the change or addition. Based on the clinical situation, in cases of digoxin toxicity, testing may need to be done more than once a week.

Digoxin is indicated for the treatment of patients with heart failure due to systolic dysfunction and for reduction of the ventricular response in patients with atrial fibrillation or flutter. Digoxin may also be indicated to treat other supraventricular arrhythmias, particularly with heart failure.

UnitedHealthcare Individual Exchange reimburses for Digoxin Therapeutic Drug Assay Testing (CPT code 80162), when the claim indicates a code found on the list of approved diagnosis codes for this test. UnitedHealthcare Individual Exchange will not reimburse when the treatment rendered is without inclusion of one of the ICD-10-CM diagnostic codes being included on the claim accurately reflecting the member's condition.

[See Attachment Section for ICD-10 Codes approved with CPT code 80162 \(Digoxin Therapeutic Drug Assay\)](#)

### **Glycated Hemoglobin/Glycated Protein**

The management of diabetes mellitus requires regular determinations of blood glucose levels. Glycated hemoglobin/protein levels are used to assess long-term glucose control in diabetes. Alternative names for these tests include glycated or glycosylated hemoglobin or Hgb, hemoglobin glycated or glycosylated protein, and fructosamine.

Glycated hemoglobin (equivalent to hemoglobin A1) refers to total glycosylated hemoglobin present in erythrocytes, usually determined by affinity or ion-exchange chromatographic methodology. Hemoglobin A1c refers to the major component of hemoglobin A1, usually determined by ion-exchange affinity chromatography, immunoassay, or agar gel electrophoresis. Fructosamine or glycated protein refers to glycosylated protein present in a serum or plasma sample. Glycated protein refers to measurement of the component of the specific protein that is glycated usually by colorimetric method or affinity chromatography.

Glycated hemoglobin in whole blood assesses glycemic control over a period of 4-8 weeks and appears to be the more appropriate test for monitoring a patient who can maintain long-term, stable control. Measurement may be medically necessary every 3 months to determine whether a patient's metabolic control has been on average within the target range. More frequent assessments, every 1-2 months, may be appropriate in the patient whose diabetes regimen has been altered to improve control or in whom evidence is present that intercurrent events may have altered a previously satisfactory level of control (for example, post-major surgery or as a result of glucocorticoid therapy). Glycated protein in serum/plasma assesses glycemic control over a period of 1-2 weeks. It may be reasonable and necessary to monitor glycated protein monthly in pregnant diabetic women. Glycated hemoglobin/protein test results may be low, indicating significant, persistent hypoglycemia, in nesidioblastosis or insulinoma, conditions which are accompanied by inappropriate hyperinsulinemia. A below normal test value is helpful in establishing the patient's hypoglycemic state in those conditions.

UnitedHealthcare Individual Exchange reimburses for Glycated Hemoglobin/Glycated Protein Testing (CPT codes 82985 and 83036), when the claim indicates a code found on the list of approved diagnosis codes for this test. UnitedHealthcare Individual Exchange will not reimburse when the treatment rendered is without inclusion of one of the ICD-10-CM diagnostic codes being included on the claim accurately reflecting the member's condition.

[See Attachment Section for ICD-10 Codes approved with CPT code 82985 and 83036 \(Glycated Hemoglobin/Glycated Protein\)](#)

| Definitions      |   |
|------------------|---|
| <b>Screening</b> | The testing for disease or disease precursors so that early detection and treatment can be provided for those who test positive for the disease. Screening tests are performed when no specific sign, symptom, or diagnosis is present, and the patient has not been exposed to a disease. The testing of a person to rule out or to confirm a suspected diagnosis because the patient has a sign and/or symptom is a diagnostic test, not a screening. |

| Questions and Answers |   |
|-----------------------|---|
| <b>1</b>              | <p><b>Q:</b> What is a National Coverage Policy?</p> <p><b>A:</b> A national coverage policy for diagnostic laboratory test(s) is a document stating CMS's policy with respect to the circumstances under which the test(s) will be considered reasonable and necessary, and not screening, for Medicare purposes. Such a policy applies nationwide. A national coverage policy is neither a practice parameter nor a statement of the accepted standard of medical practice.</p> |

| Attachments  |  |
|--|--|
| <a href="#"><u>ICD-10 Codes approved with CPT code 82378 (CEA)</u></a>   | List of ICD-10 codes for which CPT code 82378 will be reimbursed.  |
| <a href="#"><u>ICD-10 Codes approved with CPT code 82105 (AFP)</u></a>   | List of ICD-10 codes for which CPT code 82105 will be reimbursed.  |
| <a href="#"><u>ICD-10 Codes approved with CPT code 85730 (PTT)</u></a>   | List of ICD-10 codes for which CPT code 85730 will be reimbursed.  |
| <a href="#"><u>ICD-10 Codes approved with CPT code 84153 (PSA)</u></a>   | List of ICD-10 codes for which CPT code 84153 will be reimbursed.  |
| <a href="#"><u>ICD-10 Codes approved with CPT codes 87086 and 87088 (Urine Culture, Bacterial)</u></a>                                     | List of ICD-10 codes for which CPT codes 87086 and 87088 will be reimbursed.   |
| <a href="#"><u>ICD-10 Codes approved with CPT codes 82728, 83540, 83550, and/or 84466 (Serum Iron)</u></a>                                 | List of ICD-10 codes for which CPT codes 82728, 83540, 83550, and/or 84466 will be reimbursed.                             |
| <a href="#"><u>ICD-10 Codes approved with CPT code 84702 (hCG)</u></a>   | List of ICD-10 codes for which CPT code 84702 will be reimbursed.  |
| <a href="#"><u>ICD-10 Codes approved with CPT codes 80061, 82465, 83700, 83701, 83704, 83718, 83721, and/or 84478 (Lipids Testing)</u></a> | List of ICD-10 codes for which CPT codes 80061, 82465, 83700, 83701, 83704, 83718, 83721, and/or 84478 will be reimbursed. |
| <a href="#"><u>ICD-10 Codes approved with CPT codes 84436, 84439, 84443, and/or 84479 (Thyroid Testing)</u></a>                            | List of ICD-10 codes for which CPT codes 84436, 84439, 84443, and/or 84479 will be reimbursed.                             |
| <a href="#"><u>ICD-10 Codes approved with CPT codes 85610 Prothrombin Time (PT)</u></a>  | List of ICD-10 codes for which CPT code 85610 will be reimbursed   |

| Attachments  |  |
|--|--|
| <a href="#"><u>ICD-10 Codes approved with CPT code 86304 Tumor Antigen by Immunoassay (CA125)</u></a>              | List of ICD-10 codes for which CPT code 86304 will be reimbursed.            |
| <a href="#"><u>ICD-10 Codes approved with CPT code 86300 Tumor Antigen by Immunoassay (CA15-3/CA 27.29)</u></a>    | List of ICD-10 codes for which CPT code 86300 will be reimbursed.            |
| <a href="#"><u>ICD-10 Codes approved with CPT code 86301 Tumor Antigen by Immunoassay (CA 19-9)</u></a>            | List of ICD-10 codes for which CPT code 86301 will be reimbursed.            |
| <a href="#"><u>ICD-10 Codes approved with CPT code 82977 Gamma Glutamyl Transferase (GGT)</u></a>                  | List of ICD-10 codes for which CPT code 82977 will be reimbursed.            |
| <a href="#"><u>ICD-10 Codes approved with CPT code 80074 (Hepatitis Panel/Acute Hepatitis Panel)</u></a>           | List of ICD-10 codes for which CPT code 80074 will be reimbursed.            |
| <a href="#"><u>ICD-10 Codes approved with CPT code 80162 (Digoxin Therapeutic Drug Assay)</u></a>                  | List of ICD-10 codes for which CPT code 80162 will be reimbursed.            |
| <a href="#"><u>ICD-10 Codes approved with CPT codes 82985 and 83036 (Glycated Hemoglobin/Glycated Protein)</u></a> | List of ICD-10 codes for which CPT codes 82985 and 83036 will be reimbursed. |

| Resources  |
|--|
| American Medical Association, <i>Current Procedural Terminology (CPT®) Professional Edition</i> and associated publications and services |
| Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services                                    |
| Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets                       |

| History           |  |
|-------------------|--|
| <b>1/1/2024</b>   | Policy Version Change<br>Update policy template<br>Added New 2024 States that are excluded from this policy  |
| <b>12/1/2022</b>  | Policy Version Change<br>Attachments Section: ICD-10 Codes approved with CPT code 82105 (AFP)  |
| <b>3/4/2022</b>   | Policy Version Change<br>Lipids Testing section: Corrected by adding CPT code 82465<br>Attachments Section: ICD-10 Codes approved with CPT codes 80061, 82465, 83700, 83701, 83704, 83718, 83721, and/or 84478 (Lipids Testing) corrected to include 82465 |
| <b>1/1/2022</b>   | Policy Version Change<br>Update policy template<br>Attachment Section: Converted table(s) to list(s) and added to Attachment Section   |
| <b>10/31/2021</b> | Policy Version Change  |



|            |  |
|------------|--|
|            | Attachments Section: Updated the ICD-10 Codes approved with CPT code 82105 (AFP) list and moved list from a table in the policy into the attachment section  |
| 10/24/2021 | Policy Version Change<br>Attachments Section: Update to the ICD-10 Codes approved with CPT code 84702 - Human Chorionic Gonadotropin (hCG) list  |
| 10/10/2021 | Policy Version Change<br>Reimbursement Guidelines: Update to the ICD-10 Codes approved with CPT code 82378 (CEA), CPT code 82105 (AFP), CPT code 86304 Tumor Antigen by Immunoassay CA125, CPT code 80074 Hepatitis Panel/Acute Hepatitis Panel, and CPT code 80162 (Digoxin Therapeutic Drug Assay)<br>Attachments Section: Update to the ICD-10 Codes approved with CPT code 85730 (PTT), CPT codes 87086 and 87088 (Urine Culture, Bacterial), CPT codes 82728, 83540, 83550, and/or 84466 (Serum Iron), CPT codes 80061, 83700, 83701, 83704, 83718, 83721, and/or 84478 (Lipids Testing), CPT codes 84436, 84439, 84443, and/or 84479 (Thyroid Testing), CPT codes 85610 Prothrombin Time (PT), and CPT code 82977 Gamma Glutamyl Transferase (GGT), lists. |
| 8/8/2021   | Policy Version Change<br>ICD-10 Codes approved with CPT code 82105 (AFP) updated   |
| 5/28/2021  | Policy Version Change<br>Attachments Section: Removed attachment(s) and converted to table(s)  |
| 3/1/2021   | Policy implemented by UnitedHealthcare Value & Balance Exchange  |