BlueCross BlueShield of South Carolina and BlueChoice® HealthPlan of South Carolina

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Laboratory Summary:
Common Medical Policy Edits

This guide is designed to summarize specific medical policy guidelines for certain laboratory services commonly provided to our members. Use this as a guide after reading the complete policy when ordering lab tests. Please visit the Medical Policies and Clinical Guidelines pages on **www.SouthCarolinaBlues.com** and **www.BlueChoiceSC.com** frequently to read all laboratory policies in their entirety and to stay abreast of all policy changes. From the Categorical List, choose Laboratory to search for any of the ten medical policies included in this summary. Note: procedure codes on each Medical Policy document are not a guarantee of payment and are included only as a general reference tool. They may not be all-inclusive.

Use this guide as a quick reference tool only. Refer to the complete medical policy for specific details. Coverage criteria may vary, no guarantee of payment is implied. Visit **www.SouthCarolinaBlues.com** or **www.BlueChoiceSC.com**, and then go to the Education Center for the Medical Policies page.

Laboratory Medical Policy Denial Reasons

These are the policy rule criteria used to determine coverage of laboratory services.

POLICY RULE	DEFINITION
Experimental and Investigational	Procedure is not covered under the member's benefit due to exclusion
Demographic Limitations	Limitations based on patient age
Excessive Procedure Units	Total units within and across claims for a single date of service more than necessary
Excessive Units per Period of Time	Maximum allowable units within a defined period of time has been exceeded
Insufficient Time Between Procedures	Minimum time required before a second procedure is warranted
Rendering Provider Limitations	Providers/Procedures not permitted in combination
Diagnosis Does Not Support Test Requested	Procedure was not appropriate for the clinical situation
Mutually Exclusive Codes	The procedure is not valid with other procedures on the same date of service

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MEDICAL POLICY SUMMARY
Vitamin B12

PROCEDURE CODE(S)		CAM POLICY
82607	83921	130

TIP! Using the appropriate procedure codes and diagnosis codes are essential when rendering laboratory services.

MEDICALLY NECESSARY

Individuals being evaluated for clinical manifestations of vitamin B12 including:

- Cutaneous
  - Hyperpigmentation
  - Jaundice
  - Vitiligo
- Hematologic
  - Anemia
  - Leukopenia
  - Pancytopenia
  - Thrombocytopenia
  - Thrombocytosis
- Gastrointestinal
  - Glossitis
- Neuropsychiatric
  - Areflexia
  - Cognitive impairment
  - Gait abnormalities
  - Irritability
  - Loss of proprioception and vibratory sense
  - Olfactory impairment
  - Peripheral neuropathy

Individuals with one or more of the following risk factors:

- Decreased ileal absorption
  - Crohn's disease
  - Ileal resection
  - Tapeworm infection
- Decreased Intrinsic Factor
  - Atrophic gastritis
  - Pernicious anemia
  - Post gastrectomy syndrome
- Genetic
  - Trans cobalamin II deficiency
- Inadequate Intake
  - Alcohol abuse
  - Patients older than 75 years or elderly individuals being evaluated for dementia
  - Vegans or strict vegetarians
- Prolonged medication use
  - Histamine H2 blocker use for more that 12 months
  - Metformin use for more than 4 months
  - Proton pump inhibitor use for more than 12 months

When performed no sooner than 3 months after initiation of therapy for individuals undergoing treatment for vitamin B12 deficiency.

Methylmalonic acid testing to confirm vitamin B12 deficiency in individuals with borderline-low vitamin B12 levels.

Methylmalonic acid testing for the evaluation of inborn errors of metabolism, which is out of scope for this policy.

NOT MEDICALLY NECESSARY

In healthy, asymptomatic individuals.

Methylmalonic acid testing for diagnosis of vitamin B12 deficiency in the absence of an abnormally low vitamin B12 result.

Homocysteine testing for the confirmation of vitamin B12 deficiency.

Holotranscolbalamin testing for the screen or confirmation of vitamin B12 deficiency.

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MEDICAL POLICY SUMMARY

Diagnosis Vaginitis/PCR Testing

PROCEDURE CODE(S)			CAM POLICY
82120	87480	87512	20416
83986	87481	87660	
87070	87482	87661	
87149	87510	87800	
87150	87511	87808	
		87905	

TIP! Using the appropriate procedure codes and diagnosis codes are essential when rendering laboratory services.

MEDICALLY NECESSARY
Direct Probe DNA-based identification of Gardnerella, Trichomonas, and Candida in patients with symptoms of vaginitis..
Vaginal cultures for Candida species for the diagnosis of vulvovaginal candidiasis in patients with clinical signs and symptoms of vaginitis and negative findings on wet-mount preparations and a normal pH test.
Measurement of sialidase activity in vaginal fluid is for the diagnosis of bacterial vaginosis in women with symptoms of vaginitis.
Nucleic Acid Amplification Test (NAAT) or Polymerase Chain Reaction (PCR)-based identification of Trichomonas in patients with symptoms of vaginitis.
Screening for Trichomonas for women with risk factors including: new or multiple partners; history of sexually transmitted diseases (STDs), exchange of sex for payment; or injection drug use.
Testing of pH, testing for the presence of amines, saline wet mount, hydrogen peroxide (KOH) wet mount and microscopic examination of vaginal fluids in patients with symptoms of vaginitis.
NOT MEDICALLY NECESSARY
Screening for trichomoniasis and bacterial vaginosis in asymptomatic patients, including asymptomatic pregnant patients at average or high risk for premature labor.
INVESTIGATIONAL
Polymerase Chain Reaction (PCR) based identification of Candida species for any indication.
Rapid identification of Trichomonas by enzyme immunoassay is in patients with symptoms of vaginitis.
PCR testing and Multi-target polymerase chain reaction (PCR) testing for diagnosis of bacterial vaginosis.

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MEDICAL POLICY SUMMARY
Vitamin D Testing

PROCEDURE CODE(S)		CAM POLICY
82306	82652	126

TIP! Laboratory tests performed by any provider type are subject to frequency limitations.

Current as of January 2019

MEDICALLY NECESSARY

Twenty-five hydroxy-vitamin D serum testing for individuals with an underlying disease or condition that is specifically associated with vitamin D deficiency or decreased bone density.

D2 and D3 fractions of 25 hydroxy-vitamin D as part of the total 25 hydroxy-vitamin D analysis.

Repeat serum testing for individuals who have documented vitamin D deficiency, **at least 12 weeks** after initiation of vitamin D supplementation therapy. 1,25-dihydroxy serum testing for the evaluation or treatment of conditions that are associated with defects in vitamin D metabolism.

- Repeat testing for monitoring of supplementation therapy **should not exceed 2 testing instances per year** until the therapeutic goal is achieved.
- Once therapeutic range has been reached, annual testing meets coverage criteria.

Indications That Support Coverage Criteria For Serum Measurement Of 25 Hydroxy-Vitamin D:

- Biliary cirrhosis and other specified disorders of the biliary tract
- Blind loop syndrome
- Celiac disease
- Coronary artery disease where risk of disease progression is considered against benefits of chronic vitamin D and calcium therapy
- Dermatomyositis
- Hypercalcemia, hypocalcemia or other disorders of calcium metabolism
- Hyperparathyroidism or hypoparathyroidism
- Individuals receiving hyperalimentation
- Intestinal malabsorption
- Liver cirrhosis
- Long-term use of anticonvulsants, glucocorticoids and other medications known to lower vitamin D levels
- Lymphoma
- Malnutrition
- Myalgia and other myositis not specified
- Myopathy related to endocrine diseases
- Obesity
- Osteogenesis imperfecta
- Hypervitaminosis of vitamin D
- Osteomalacia
- Osteopetrosis
- Osteoporosis
- Pancreatic steatorrhea
- Primary or miliary tuberculosis
- Psoriasis
- Regional enteritis
- Renal, ureteral or urinary calculus
- Rickets
- Sarcoidosis
- Stage III-V Chronic Kidney Disease and End Stage Renal Disease
- Systemic lupus erythematosus

Indications That Support Medical Necessity For Serum Testing Of 1,25 Dihydroxy-Vitamin D:

- Disorders of calcium metabolism
- Familial hypophosphatemia
- Fanconi syndrome
- Hyperparathyroidism or hypoparathyroidism
- Rickets
- Neonatal hypocalcemia
- Osteogenesis imperfecta
- Osteomalacia
- Osteopetrosis
- Primary or miliary tuberculosis
- Renal, ureteral or urinary calculus
- Individuals receiving hyperalimentation
- Sarcoidosis
- Stage III-V Chronic Kidney Disease and End Stage Renal Disease

NOT MEDICALLY NECESSARY

1,25 dihydroxy serum testing and screening of vitamin D deficiency.	Routine screening for vitamin D deficiency with serum testing.

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MEDICAL POLICY SUMMARY
Hemoglobin A1C

PROCEDURE CODE(S)			CAM POLICY
81506	83036	83037	133

TIP! Laboratory tests performed by any provider type are subject to frequency limitations.

MEDICALLY NECESSARY

For individuals with a diagnosis of either Type 1 or Type 2 diabetes as follows:

- Upon initial diagnosis to establish a baseline value and to determine treatment goals.
- **Quarterly** in individuals who are not meeting treatment goals for glycemic control.
- **Quarterly** in individuals whose pharmacologic therapy has changed.
- **Twice a year (every six months)** in individuals who are meeting treatment goals and who, based on daily glucose monitoring, appear to have stable glycemic control.

Once a year for pre-diabetic individuals with either a fasting plasma glucose test or hemoglobin A1c test

To help in detection and diagnosis of pre-diabetes or Type 2 diabetes in the following populations once every three years:

- Asymptomatic individuals at increased risk, as defined by the ADA (individuals who are overweight or obese (BMI ≥ 25 or ≥ 23 in Asian Americans) and have who have one or more of the following risks:
  - First degree relative with diabetes; or
  - High-risk race/ethnicity; or
  - History of cariovascular disease; or
  - Hypertension; or
  - Women with polycystic ovary syndrome; or
  - HDL cholesterol level <35 mg/dL (0.90 mmol/L) and/or a triglyceride level >250 mg/dL (2.82 mmol/L); or
  - Physical inactivity; or
  - Other clinical conditions associated with insulin resistance
- Women who were previously diagnosed with gestational diabetes.

Once every three years for children 10 years and older or after the onset of puberty with the following characteristics:

- Overweight or obese as defined by ADA ; and
- Must have one or more of the following additional risk factors:
  - Maternal history of diabetes or gestational diabetes mellitus during the child's gestation; or
  - Overweight or obese as defined by ADA ; and
  - Family history of type 2 diabetes in first- or second-degree relative; or
  - High-risk race/ethnicity
  - Signs of insulin resistance or conditions associated with insulin resistance

NOT MEDICALLY NECESSARY

For individuals who have been transfused within the past 120 days.

For individuals with a condition that is associated with increased blood cell turnover.

Measurement of hemoglobin A1C in conjunction with measurement of fructosamine.

To diagnose the acute onset of type 1 diabetes in individuals with symptoms of hyperglycemia.

As a screening test for cystic fibrosis related illnesses.

INVESTIGATIONAL

Panel testing of biochemical markers for Type 2 diabetes risk.

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MEDICAL POLICY SUMMARY
Hepatitis C Testing

PROCEDURE CODE(S)		CAM POLICY
86803	87521	127
86804	87522	
87520	87902	

MEDICALLY NECESSARY

A **one-time screening** for Hepatitis C infection for adults born between 1945 and 1965.

Testing for the following situations:

- Illicit drug use: Injection or intranasal
- Receipt of clotting factor concentrates produced before 1987
- History of or current hemodialysis
- Evidence of liver disease
- Presence of HIV infection
- Receipt of organ transplant
- Receipt of blood transfusion or blood component before 1992
- History of incarceration
- Receipt of tattoo in unregulated setting

HCV testing based on a recognized exposure and meets coverage criteria for:

- Health care, emergency medical and public safety workers after needle sticks, sharps or mucosal exposures to HCV-positive blood.
- Children born to HCV-positive women.
- Current sexual partners of HCV-infected persons.

A **one-time testing** for HCV genotype prior to initiation of treatment to guide selection of the most appropriate antiviral regimen.

For patients with acute HCV infection, monitoring HCV RNA to determine spontaneous clearance of HCV infection versus persistence of infection. **Testing can be performed every four to eight weeks for six to 12 months**.

Testing for HCV viral load, using a quantitative nucleic acid test n the following situations:

- **Prior to initiation of HCV therapy, and**
- **After four weeks of therapy AND**
- **At the end of treatment and**
- **12 weeks and 24 weeks after completion of treatment**

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MEDICAL POLICY SUMMARY
Allergy Testing

PROCEDURE CODE(S)			CAM POLICY
82784	83520	86021	051
82785	86001	86343	
82787	86003	86352	
83516	86005	88184	

MEDICALLY NECESSARY – See Medical Policy for a complete list of all allergy testing modalities

Direct Skin Testing (for immediate hypersensitivity)

- Percutaneous or epicutaneous (scratch, prick or puncture) — The number of tests required may vary widely depending on the patient's age and the degree of hypersensitivity.
- Intradermal testing is considered to be a more sensitive, but less specific, testing method than percutaneous testing for the detection of IgE antibodies. The number of intradermal tests may also vary from patient to patient.
- The evaluation of inhalant allergy may require up to 70 prick/puncture tests followed by up to 40 intradermal tests, which are ordinarily performed when prick/puncture tests are negative. Under special circumstances and in certain geographic areas, a greater number of prick/puncture and/or intradermal tests may be appropriate. However, in many parts of the country and probably in most cases, fewer tests are required.

Patch Testing for evaluation of possible allergic contact dermatitis. A limited series of patch tests may be an ap- propriate initial step. Standard panels of allergens for patch testing are available from various commercial sources, the most commonly used being the T.R.U.E. TEST® by Allerderm. Each T.R.U.E. TEST® patch test unit includes 35 common allergens and a negative control. In-vitro specific IgE testing is limited to 20 allergen specific antibodies per year. Additional testing beyond this number will require individual review for coverage criteria.

- The patient has persistent allergic contact dermatitis (ACD) after being previously evaluated and treated (including six weeks of avoidance of any allergens that were positive on initial patch testing, and use of topical steroid products if appropriate) or the patient has any of the following:
  - At least eight weeks of dermatitis without resolution with treatment.
  - A dermatitis that may be implanted device-related.
  - Is undergoing pre-testing for medical or dental device placement.
  - Requires extensive patch testing to determine if persistent dermatitis is allergic contact dermatitis.
  - Has seen at least one other physician who has requested specialty patch testing.

  AND
- The dermatitis interferes with the patient's normal activities of daily living, such as occupational or work activities (use of hands), sleep patterns (due to itching), bathing or social interactions.

Photo-patch test: This test reflects contact photosensitization. A photosensitivity (sensitivity to sunlight) reaction may be suspected when a rash appears only in areas exposed to sunlight. The reaction may be caused by various drugs, substances applied to the skin (drugs or cosmetics), chemicals, etc. Photo-patch testing involves applying two identical sets of allergens to the back on day one. One of the sets is exposed to UVA light, and the sites are then examined as usual. A positive photo-patch test is recorded when an allergic reaction appears only on the light- exposed site.

Specific IgE In Vitro Testing: the detection of specific IgE antibodies in the patient's blood serum.

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NOT MEDICALLY NECESSARY
Routine re-testing for allergies to the same allergens in the absence of a new clinical presentation.
Nasal Challenge Test called nasal mucous membrane test; nasal challenge/ provocation test)
Leukocyte Histamine Release Test (LHRT)
Rebuck Skin Window Test
Passive Transfer of P-X (Prausnitz-Kustner Test)
Cytotoxic Food Testing (Leukocytotoxic Test)
Provocation Neutralization Testing (sometimes referred to as the Rinkel Test)
Serum IgG levels, as part of allergy evaluation
Conjunctival Challenge Testing (ophthalmic mucous membrane test)
Mediator Release Test (MRT)
In Vitro Metal Allergy Testing
Antigen Leukocyte Cellular Antibody (ALCAT) Automated Food Allergy Testing
Electrodermal Testing
Applied Kinesiology
Reaginic Pulse Testing
Cytotoxic Test
The food immune complex assay (FICA)
Body Chemical Analysis
INVESTIGATIONAL – See Medical Policy for a complete list of all allergy testing modalities
In-vitro testing of allergen-specific IgG in the evaluation of suspected allergy.
Basophil Activation flow cytometry testing (BAT) for measuring hypersensitivity to allergens.
Various allergy tests.

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MEDICAL POLICY SUMMARY
Thyroid Disease Testing

PROCEDURE CODE(S)			CAM POLICY
80438	84439	84480	135
80439	84442	84481	
84432	84443	84482	
84436	84445	86376	
84437	84479	86800	

MEDICALLY NECESSARY

Individuals with symptoms consistent with hyporthyroidism

- TSH to confirm or rule out primary hypothyroidism.
- Free total T4 as a followup to abnormal TSH findings.
- Free T4 as a follow-up in cases of suspected secondary hypothyroidism when TSH is normal.
- TSH to distinguish between primary and secondary hypothyroidism.
- TSH, free T4 and total T4 for monitoring individuals being treated for hypothyroidism **every 6-12 weeks** upon dosage change and annually in stable individuals.

Individuals with symptoms consistent with hyperthyroidism

- TSH to confirm or rule out primary hyperthyroidism.
- Testing for total or free T3 is considered medically necessary and meets coverage criteria for individuals being evaluated for hyperthyroidism.
- Free and/or total T4 to distinguish between primary and secondary hyperthyroidism.
- TSH and free T4 should be measured for monitoring individuals being treated for hyperthyroidism **every six to 12 weeks.**
- Monitoring individuals closely after treatment for hyperthyroidism.
  - Close monitoring first three months post-treatment.
  - **Annual monitoring after first year**, even if asymptomatic, for risk of relapse or late-onset hypothyroidism.

Asymptomatic individuals 60 years of age and older, **every five years**.

Asymptomatic individuals at high risk for thyroid disease.

- A personal or family history of thyroid dysfunction (**limited to one time**).
- Personal or family history of Type 1 diabetes or other autoimmune disorder (**limited to one time**).
- Prescribed drugs that can interfere with thyroid function (annually or when dosage or medication changes). Drugs interfering with thyroid function include, but are not limited to:
  - Amiodarone, interferon, iodine, lithium, tyrosine kinase inhibitors, sulfonamides.
- Women undergoing evaluation for infertility.
- Monitoring of pregnant women in pregnancy and postpartum.
  - Monitoring of pregnant women being treated for hypothyroidism, **every four weeks.**
  - T4 testing for management of thyroid disease during pregnancy.
  - FT4 measurements in all patients in first trimester in the presence of a suppressed serum TSH.
  - Measurement of serum total T3 (TT3) and thyrotropin receptor antibodies (TRAb) for establishing a diagnosis of hyperthyroidism.
  - TSH testing if there is a thyroid nodule.
  - TSH to evaluate first year hypothyroidism.

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PROCEDURE CODE(S)			CAM POLICY
80438	84439	84480	135
80439	84442	84481	
84432	84443	84482	
84436	84445	86376	
84437	84479	86800	

MEDICALLY NECESSARY Cont.

- Serum TSH in early pregnancy if history of:
  - Thyroid dysfunction or prior thyroid surgery
  - Age >30 years
  - Symptoms of thyroid dysfunction or the presence of goiter
  - TPOAb positivity
  - Type 1 diabetes or other autoimmune disorders
  - History of head or neck radiation
  - Family history of thyroid dysfunction
  - Morbid obesity (BMI ≥ 40 kg/m²)
  - Use of amiodarone or lithium, or recent administration of iodinated radiologic contrast
  - Infertility
  - Residing in an area of known moderate to severe iodine insufficiency
- TSH, FT4 and TPOAb tests in postpartum depression.
- Patients with disease or neoplasm of the thyroid or other endocrine glands.

Testing for thyroid antibodies for the evaluation of autoimmune thyroiditis.

Testing for serum thyroglobulin and anti-thyroglobulin antibody levels for individuals with thyroid cancer.

Evaluation of the cause of hyperthyroidism or hypothyroidism.

Hyperthyroid Signs And Symptoms

Sudden weight loss when appetite, amount and type of food eaten remains the same or increases.	Tremor — a fine trembling in your hands and fingers.	Fatigue, muscle weakness.
Rapid heartbeat (tachycardia) — commonly more than 100 beats a minute – irregular heartbeat (arrhythmia) or pounding of heart.	Changes in bowel patterns, especially more frequent bowel movements.	An enlarged thyroid gland (goiter), which may appear as a swelling at the base of your neck.
Increased appetite.	Increased sensitivity to heat	Difficulty sleeping.
Nervousness, anxiety and irritability.	Changes in menstrual patterns.	Skin thinning.
Sweating.		Fine, brittle hair.

Hypothyroidism Signs And Symptoms

Fatigue	Puffy face	Pain, stiffness or swelling in joints
Increased sensitivity to cold	Hoarseness	Heavier than normal or irregular menstrual periods
Constipation	Muscle weakness	Muscle aches, tenderness and stiffness
Dry skin	Elevated blood cholesterol level	Slowed heart rate
Unexplained weight gain	Thinning hair	Depression

NOT MEDICALLY NECESSARY

Testing of Reverse T3, T3 uptake and total T4.

Measurement of total and/or T3 uptake testing in the assessment of hypothyroidism.

Measurement of a total or free T3 level when assessing levothyroxine dose in hypothyroid patients.

Testing for thyroid dysfunction in asymptomatic non-pregnant individuals for thyroid disease during general exam.

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MEDICAL POLICY SUMMARY
Testosterone Testing

PROCEDURE CODE(S)		CAM POLICY
82642	84403	131
84402	84410	

TIP! Laboratory tests performed by any provider type are subject to frequency limitations. Also, using the appropriate procedure codes and diagnosis codes are essential when rendering laboratory services.

Current as of January 2019

MEDICALLY NECESSARY
For symptomatic individuals being evaluated for conditions associated with androgen deficiency.
Repeat testing for serum total testosterone in individuals with low initial serum testosterone results. Sample collection should occur in early morning, and at least one week after the initial test.
Measurement of serum free testosterone and/or bioavailable testosterone if total testosterone is confirmed as borderline or low.
Testing for serum total testosterone for symptomatic individuals being evaluated for conditions associated with androgen excess. For infants and pre-pubescent individuals, the technology used for testing should be sensitive and specific enough to quantify accurately the low concentrations normally found in that population.
Testing for serum total testosterone for symptomatic individuals being evaluated for conditions associated with androgen excess.(e.g., polycystic ovary syndrome). The technology used for testing should be sensitive enough to detect the low concentrations normally found in this population.
Measurement of serum free testosterone and/or bioavailable testosterone for in individuals suspected of having a disorder that is accompanied by increased or decreased SHBG levels.
Testosterone measurements for monitoring treatment response in individuals taking enzyme inhibitors for prostate cancer.
Testing for individuals receiving testosterone replacement therapy every three to six months for the first year after initiation of therapy, and annually thereafter.
NOT MEDICALLY NECESSARY
Testing for serum total testosterone, free testosterone, and/or bioavailable testosterone in asymptomatic individuals or in individuals with non-specific symptoms.
For the identification of androgen biologic females.
INVESTIGATIONAL
Salivary testing for testosterone.

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MEDICAL POLICY SUMMARY
Cervical Cancer Screening

PROCEDURE CODE(S)			CAM POLICY
87623	88147	88164	20409
87624	88148	88165	
87625	88150	88166	
88141	88152	88167	
88142	88153	88174	
88143	88155	88175	
		0500T	

MEDICALLY NECESSARY – May be covered annually based on group benefits.

For women under 21 years of age who meet one of the following criteria:

- History of HIV and other immunocompromised conditions
- Previous diagnosis of cervical cancer
- Previous diagnosis of cervical dysplasia
- History of an organ transplant

For women 21 – 29 years of age, using conventional or liquid-based Papanicolaou (Pap) smears at a frequency of **every three years**.

For women 30 – 65 years of age, using conventional or liquid-based Pap smear at a frequency of **every three years**, or using the high risk HPV test alone at a frequency of **every five years**, or co-testing (cytology with concurrent high-risk HPV testing) at a frequency of **every five years**.

For women >65 years of age who are considered high risk (women with a high-grade precancerous lesion or cervical cancer, women with in-utero exposure to diethylstilbestrol or women who are immunocompromised).

Repeat cervical cancer screening by Pap smear and/or HPV testing in **one year** if a previous cervical cancer screen had an abnormal cytology and/or was positive for HPV or woman is at high risk for cervical cancer (organ transplant, exposure to the drug DES, immunocompromised women).

NOT MEDICALLY NECESSARY

Routine cervical cancer screening does not meet coverage criteria in women >65 years of age who are not considered high risk and have an adequate screening history:

- Three consecutive negative Pap smears, or
- Two consecutive negative HPV tests within 10 years before cessation of screening, with the most recent test occurring within five years.

Cervical cancer screening (at any age) for women who have undergone surgical removal of uterus and cervix and have no history of cervical cancer or pre-cancer.

INVESTIGATIONAL

Inclusion of low-risk strains of HPV in co-testing, as the clinical utility has not been established.

Other technologies for cervical cancer screening, because of insufficient evidence of clinical utility.

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MEDICAL POLICY SUMMARY
Flow Cytometry

PROCEDURE CODE(S)		CAM POLICY
88182	86355	120
88184	86356	
88185	86357	
88187	86359	
88188	86360	
88189	86361	
88199	86367	

MEDICALLY NECESSARY

Flow cytometry immunophenotyping of cell surface markers for any of the following conditions:

- Cytopenias, lymphomas, leukemia and lymphoproliferative disorders or myelodysplastic syndrome.
- B-cell monitoring for immunosuppressive disorders.
- T-cell monitoring for HIV infection and AIDS.
- Paroxysmal nocturnal hemoglobinuria.
- Postoperative monitoring of members who have undergone organ transplantation.
- Primary immunodeficiencies (PIDs) and PIDs involving T.
- Plasma cell disorders.
- Hypercellular hematolymphoid disorders.
- Chronic lymphocytic leukemia (CLL).
- Chronic myeloproliferative disorders (CMPDs).
- Minimal residual disease (MRD).
- Molar pregnancy.
- Primary platelet disorders, non-neoplastic.
- Red cell and white cell disorders, non-neoplastic.
- Mast cell neoplasms.

The following reimbursement limitations apply for flow cytometry:

- For flow cytometric immunophenotyping for the assessment of potential hematolymphoid neoplasia, use codes 88184-88189.
- Code 88184 should be used for the first marker and is reimbursable as a single unit.
- Code 88185 should be used for each additional marker, and is reimbursable up to 24 units. Note that medical necessity for the number of markers tested must be included in the medical record.
- Additional units of 88185 (i.e., greater than 24 units) require prior authorization, based on documented medical necessity.
- In patients with a neoplasm with an established immunophenotype, subsequent tests for that neoplasm should be limited to diagnostically relevant markers.
- Codes 88187, 88188 and 88189 should not be used together in any combination. They are mutually exclusive and reimbursable as a single unit only.
- Codes 88187-88189 should not be used in conjunction with codes 86355, 86356, 86357, 86359, 86360, 86361 or 86367.
- Use codes 86355, 86356, 86357, 86359, 86360, 86361 or 86367 for cell enumeration. These codes are reimbursable as single units only.

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MEDICAL POLICY SUMMARY
Venous Thrombosis Risk Testing

PROCEDURE CODE(S)		CAM POLICY
81240	81291	20482
81421	85307	

MEDICALLY NECESSARY

Testing for Factor V Leiden and Prothrombin gene G20210A mutations in patients without recurrent VTE risk factors in any of the following situations:

- Age <50, any venous thrombosis
- Venous thrombosis in unusual sites
- Recurrent venous thrombosis
- Venous thrombosis in pregnant women or women taking oral contraceptives
- First and second degree relatives of individuals with venous thrombosis under age 50.
- Myocardial infarction in female smokers under age 50.
- Before administration of oral contraceptives, targeted testing of women with a personal or family history of venous thrombosis.

Testing for protein C deficiency, protein S deficiency and antithrombin III deficiency in patients without recurrent VTE risk factors (for example, surgery, prolonged immobilization, collagen vascular disease, malignancy, certain hematologic disorders) in any of the following situations. Testing should be performed **at least six weeks** after acute thrombotic event and while the patient is not taking anticoagulants

- Age <50, any venous thrombosis
- Venous thrombosis in unusual sites
- Recurrent venous thrombosis
- Venous thrombosis and a strong family history of thrombotic disease
- Venous thrombosis in pregnant women or women taking oral contraceptives
- Individuals with warfarin induced skin necrosis
- Relatives of individuals with venous thrombosis under age 50
- Myocardial infarction in female smokers under age 50.
- Before administration of oral contraceptives, targeted testing of women with a personal or family history of venous thrombosis
- Infants who develop Neonatal Puroura Fulminans

NOT MEDICALLY NECESSARY

MTHFR genetic testing is for hypercoagulable evaluation or for “at risk” family members.

INVESTIGATIONAL

Genetic testing for inherited thrombophilia for the following situations:

- Evaluation of recurrent fetal loss, placental abruption, pre-eclampsia or fetal growth restriction.
- Evaluation of arterial thrombosis not attributable to paradoxical emboli.
- Routine screening in the general population.
- Routine newborn screening
- Routine screening of asymptomatic women considering oral contraceptive use or hormone replacement therapy.
- Routine screening of asymptomatic pregnant women.
- Prenatal or preimplantation testing.

Testing for other factors, including the factor V HR2 variant or prothrombin G1199A variant, or factor VII R353Q variant or factor 13B V34L variant or PAI-1, as well as multi-gene panel testing.

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MEDICAL POLICY SUMMARY
Helicobacter Pylori Testing

PROCEDURE CODE(S)		CAM POLICY
78267	87150	20406
78268	87181	
83009	87186	
83013	87205	
83014	87338	
86677	87339	
87077	88305	
87081	87153	
87149	0008U	

MEDICALLY NECESSARY

Urea breath testing or stool antigen testing for Helicobacter Pylori infection for adult patients (>18).
In the evaluation of suspected infection with the following symptoms:

- Dyspeptic symptoms or
- Active peptic ulcer disease (PUD) or
- Past history of PUD without H. pylori history or
- Low-grade gastric mucosa-associated lymphoid tissue (MALT) lymphoma, or
- A history of endoscopic resection of early gastric cancer (EGC), or
- Patients with uninvestigated dyspepsia who are **under the age of 60 years** and without alarm features, or
- Patients initiating chronic treatment with a non-steroidal anti-inflammatory drug (NSAID).
- Patients with unexplained iron deficiency anemia.
- In the evaluation of a patient with chronic immune thrombocytopenic purpura (ITP) and suspected H. Pylori infection.

Re-evaluation to measure success of eradication of H. Pylori infection, **at least 4 weeks** post treatment.

- Any patients with an H. Pylori-associated ulcer.
- As part of the follow-up of patients with persistent symptoms of dyspepsia following appropriate antibiotic treat for H. Pylori.
- In patients with Gastric MALT Lymphoma.
- In individuals who have undergone resection of early gastric cancer.

Urea Breath or stool antigent testing for H. Pylori infection for pediatric patients (<18) in the following situations:

- In the evaluation of a patient with chronic immune thrombocytopenic purpura (ITP) and suspected H. Pylori infection.
- Re-evaluation to measure success of eradication of H. Pylori infection, **at least 4 weeks** post-treatment.

Biopsy-based endoscopic histology test and Rapid Urease Test or culture in pediatric patients (<18) with gastric or duodenal ulcers or with refractory IDA in which other causes have been ruled out; and in adult patients (>18) undergoing endoscopic examination or in those with alarm symptoms for the diagnosis of H. Pylori infection.

NOT MEDICALLY NECESSARY

Urea Breath or stool antigen testing for H. Pylori infection for asymptomatic pediatric (<18) and asymptomatic adult (>18) patients in all other situations; and adult patients with typical symptoms of gastroesophageal reflux disease (GERD) who do not have a history of PUD.

Serologic testing for H. Pylori infection in adult and pediatric patients as it does not distinguish between currently active infection with past exposure and an infection that has been cured.

Biopsy-based endoscopic histology test and Rapid Urease Test or culture in pediatric patients (<18) for the diagnosis of H. Pylori infection when investigating the following:

- Children with functional abdominal pain
- Causes of short stature
- As part of initial investigation in children with iron deficiency anemia

Testing with the Urea Breath Test and/or stool antigen and/or biopsy-based test in patients with recent use of antibiotics, PPIs or bismuth.

Concurrent testing with the Urea Breath Test and/or stool antigen and/or biopsy-based testing as simultaneous use of both methods does not improve clinical understanding.

The use of nucleic acid testing for H. pylori, including polymerase chain reaction (PCR), 16S rRNA, 23S rRNA, and next-generation sequencing (NGS) of H. pylori, as it is not practical for routine diagnosis.

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MEDICAL POLICY SUMMARY
Fecal Analysis
Diagnosis of Intestinal Dysbiosis

PROCEDURE CODE(S)			CAM POLICY
82239	83986	87045	20426
82542	87311	87046	
82710	87102	87075	
82715	87328	87177	
82725	87329	87209	
83520	87336	82272	
83630	89160	82273	
		82274	

Current as of May 2019

INVESTIGATIONAL
Fecal analysis as a diagnostic test for the evaluation of intestinal dysbiosis, irritable bowel syndrome, malabsorption or intestinal overgrowth of bacteria.

MEDICAL POLICY SUMMARY
MUC16 (CA-125)
Expression in Ovarian Cancer

PROCEDURE CODE(S)	CAM POLICY
86304	20427

Current as of November 2018

MEDICALLY NECESSARY
Patients with symptoms suggestive of ovarian cancer to establish a baseline.
Patients with known ovarian cancer as an aid in the monitoring of disease, response to treatment, detection of recurrent disease, or assessing value of performing second-look surgery.
Patients with other suspected pelvic mass or gynecologic malignancies, such as endometrial cancer.
INVESTIGATIONAL
Asymptomatic patients as a screening technique for ovarian cancer.

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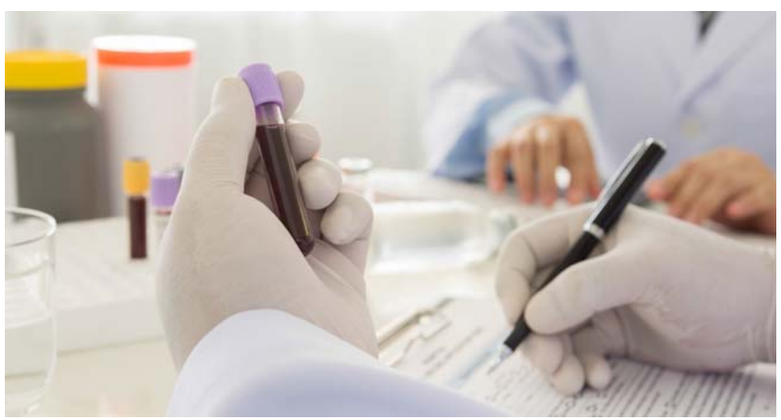
MEDICAL POLICY SUMMARY
Lyme Disease Testing

PROCEDURE CODE(S)		CAM POLICY
86617	0041U	159
86618	0042U	
87475	0043U	
87576	0044U	



MEDICALLY NECESSARY

Serologic testing (two-tier testing strategy) for all patients with a history of travel to a Lyme region (with or without a history of a tick bite) with compatible symptoms of Lyme disease.

NOT MEDICALLY NECESSARY

Serologic testing:
- In patients with an erythema migrans (EM) rash. Patients with skin rashes consistent with EM who live in or have recently traveled to an endemic area should be treated for Lyme disease.
- For screening of asymptomatic patients living in endemic areas.
- For patients with non-specific symptoms only (e.g., fatigue, myalgias/arthralgias). The use of serologic testing in populations with a low pre-test probability of Lyme disease results in a greater likelihood of false positive test results than true positive test results.

PCR-based direct detection of Borrelia burgdorferi.

Testing of the individual tick for the diagnosis of Lyme disease.

INVESTIGATIONAL

Repeat PCR-based direct detection of Borrelia burgdorferi:
- As a justification for continuation of IV antibiotics beyond one month in patients with persistent symptoms.
- As a technique to follow a therapeutic response.
- Via urine sample.

Other testing for Borrelia burgdorferi:
- Genotyping and phenotyping.
- Determination of levels of the B lymphocyte chemoattractant $CXCL_{13.}$

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MEDICAL POLICY SUMMARY

Prenatal Screening

PROCEDURE CODE(S)			CAM POLICY
80055	81479	86850	119
80081	81507	86900	
81001	81508	86901	
81002	81509	87081	
81003	81510	87086	
81007	81511	87088	
81171	81512	87270	
81172	82677	87320	
81200	82731	87490	
81209	82947	87491	
81220	82951	87590	
81221	83020	87591	
81241	83021	87592	
81242	83036	87653	
81243	83080	87662	
81244	84999	87800	
81251	85004	87810	
81252	85007	87850	

MEDICALLY NECESSARY

The following routine prenatal screening meets coverage criteria for all pregnant women:

- Screening for HIV infection
- Screening for Chlamydia trachomatis infection
- Screening for N. gonorrhea infection
- Screening for hepatitis B
- Screening for syphilis
- Screening for hepatitis C for pregnant women deemed to be at high risk, defined as meeting one of the following criteria for infection: past or current injection or intranasal drug use, long-term hemodialysis, being born to an HCV-infected mother, incarceration, individuals getting unregulated tattoos
- Screening for bacteriuria
- Screening for fetal aneuploidy and/or neural tube defects with biochemical markers
- Screening for Type 2 diabetes at the first prenatal visit
- Screening for gestational diabetes during gestational weeks 24 – 28
- Determination of blood type, RhD status and antibody status
- Screening for anemia meets coverage criteria with a CBC or hemoglobin and hematocrit
- Screening for Group B strep once during gestational weeks 35 to 37
- Screening for fetal aneuploidy with non-invasive evaluation of circulating cell-free fetal DNA for pregnant women at high risk.

For pregnant women and those women seeking pre-conception care, any of the following testing of carrier status:

- Carrier testing for cystic fibrosis.
- Carrier testing for Canavan disease, Tay-Sachs disease, familial dysautonomia, Gaucher disease, Niemann-Pick type A, Bloom syndrome and mucolipidosis IV in Ashkenazi Jewish women.
- Carrier screening for Tay-Sachs disease in women of French-Canadian or Cajun heritage.
- Carrier screening for Fragile X syndrome when there is a family history of Fragile X syndrome (or a family history of undefined mental retardation/ developmental delay).
- Carrier screening for SMA when there is a family history of SMA (or an undefined SMA-like disorder).
- Carrier screening for hemoglobinopathies in women of African, Southeast Asian and Mediterranean descent.
- Carrier testing for other genetic disorders when there is a family history of a genetic disorder and a properly validated test is available. When there is a known familial mutation, testing should be limited to that mutation, when possible. See General Genetic Testing policy for more details on appropriate criteria for genetic testing.
- Genetic testing for hereditary hearing loss mutations (GJB2, GJB6 and other hereditary hearing loss- related mutations) in individuals with hearing loss to confirm the diagnosis of hereditary hearing loss meets coverage criteria. Preconception genetic testing (carrier testing) for hereditary hearing loss mutations (GJB2, GJB6 and other hereditary hearing loss-related mutations) in parents meets coverage criteria when at least one of the following conditions has been met:
  - Offspring with hereditary hearing loss
  - One or both parents with suspected hereditary hearing loss
  - First- or second-degree relative affected with hereditary hearing loss
  - First-degree relative with offspring who is affected with hereditary hearing loss
  - Genetic testing for hereditary hearing loss mutations is investigational for all other situations, including, but not limited to, testing in patients without hearing loss.

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PROCEDURE CODE(S)			CAM POLICY
81253	85014	G0307	119
81254	85018	G0432	
81255	85025	G0433	
81257	85027	G0435	
81260	85041	G0472	
81290	86480	S3652	
81329	86481	S3844	
81330	86592	S3845	
81336	86593	S3846	
81337	86631	S3849	
81400	86632	S3850	
81401	86701	009M	
81403	86702		
81404	86703		
81405	86780		
81406	86787		
81420	86794		
81430	86803		
81431	86804		
81443	G0306		

MEDICALLY NECESSARY Cont.

Third trimester re-screening of Chlamydia trachomatis, Neisseria gonorrhea and/or HIV infections for pregnant women who meet any one of the following high-risk criteria:

- Sexually active individuals under 25 years of age.
- New or multiple sexual partners.
- Current sex workers.
- Past or current injection drug use.
- Past history of sexually transmitted diseases (bacterial vaginosis, chancroid, chlamydia, gonorrhea, genital sherpes, hepatitis B, hepatitis C, HIV/AIDS, human papillomavirus, lymphogranuloma venereum, syphilis, trichomoniasis).

Carrier screening of the biological father meets coverage criteria when the mother is known or found to be a carrier of a recessively inherited disorder. Carrier testing limitations:

- Repeat carrier screening for the same disorder does not meet coverage criteria.
- Carrier screening should be limited to once per lifetime per disorder for which the individual is at risk.
- Panel testing is considered experimental and investigational.
- Carrier screening for a recessively inherited disorder with a carrier frequency of less than one in 50 in the specific population being tested does not meet coverage criteria.

Fetal Fibronectin (FFN) assays meet coverage criteria for pregnant women who meet all of the following criteria:

- Singleton or twin gestations
- Intact membranes
- Cervical dilation <3 cm
- Patient experiencing symptoms suggestive of preterm labor between 24 and less than 35 weeks of gestation

Testing pregnant women for thyroid dysfunction if they have any of the following:

- Symptoms of thyroid disease
- Personal history of thyroid disease
- Personal history of other medical conditions associated with thyroid disease (e.g., diabetes mellitus, goiter, iodine deficiency).

Fetal RHD genotyping using maternal plasma.

Zika virus testing for pregnant women who have potentially been exposed to Zika virus (i.e., via travel, residence or sexual contact), regardless of whether they present with Zika signs or symptoms.

INVESTIGATIONAL

All other applications of the FFN assay, including, but not limited to, the following:

- As part of routine pregnancy monitoring in asymptomatic women with singleton gestation and no risk factors for preterm birth.
- As part of clinical monitoring of asymptomatic women at high risk for preterm birth, including, but not limited to, those with multiple gestations, history of preterm birth, uterine malformation, cervical incompetence or history of two or more spontaneous second trimester abortions.
- As part of clinical monitoring in women with triplet or higher-order gestations, intact membranes, cervical dilation <3 cm and who are experiencing symptoms suggestive of preterm labor.
- As a test to identify women at term being considered for induction who are likely to deliver within 24 – 48 hours and, therefore, do not require induction.

Serial monitoring of salivary estriol levels as a technique of risk assessment for preterm labor or delivery.

Pre-conceptional or prenatal genetic testing for inherited medical disorders that do not meet policy criteria.

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MEDICAL POLICY SUMMARY
Toxicology

PROCEDURE CODE(S)			CAM POLICY
80305	G0477	G0480	140
80306	G0478	G0481	
80307	G0479	G0482	
		G0483	

MEDICALLY NECESSARY

Presumptive Urine Drug Tests (UDT)

- At initial entrance into a non-cancer chronic pain management program, when starting treatment with a controlled substance; or
- To assess a patient when clinical evaluation suggests the patient's use of non-prescribed medications or illegal substances; or
- Randomly to verify compliance with treatment, identify undisclosed drug use or abuse or evaluate aberrant behavior as part of a routine random-monitoring program for individuals who are receiving treatment for non-cancer chronic pain with prescription opioid or other potentially abused medications.
- In pregnant individuals at high risk for substance abuse in whom suspicion of drug use exists as a result of the answers to substance abuse screening questions or indicated by information from the PDMP, as documented in the medical record.
- In newborns when there is a history of maternal substance abuse or agitated/altered mental status in the mother.
- In candidates for organ transplant who have a history of substance abuse, to demonstrate abstinence prior to transplant.
- The diagnosis, management and compliance monitoring of a member under treatment for substance abuse or dependence. The random testing frequency after baseline at initial evaluation must meet medical necessity and be documented in the patient's medical record:
  - For patients with zero to 90 consecutive days of abstinence, qualitative drug testing at a frequency of one to two per week meets coverage criteria.
  - For patients with >90 consecutive days of abstinence, qualitative drug testing at a frequency of one to three in one month meets coverage criteria.

Definitive/Non-Immunoassay UDT

- Presumptive UDT shows inconsistent or unexpected results; and
- Further laboratory-based specific drug identification testing is specifically requested by the patient's treating physician, documented in the medical record and is based on inconsistencies or unexpected results in the initial presumptive UDT results.
- The patient's treating physician must document in the patient's medical record the specific drugs or drug classes that are likely to be present in a definitive UDT based on the patient's medical history and current clinical presentation.
- A qualitative test does not exist or does not adequately detect the specific drug or metabolite to be tested (for example, specific drugs within the amphetamine, barbiturate, benzodiazepine, tricyclic antidepressants and opiate/opioid drug classes, as well as synthetic/analog or "designer" drugs).

NOT MEDICALLY NECESSARY

Presumptive UDT

- Testing for the same drug with both a blood and urine test simultaneously.
- Random testing at every visit.

INVESTIGATIONAL

Quantitative UDT

- Quantitative reporting as a component of a definitive UDT does not provide enough information to determine the patient's drug exposure time, dose or frequency of use, and there is currently no scientifically validated relationship between the concentrations reported in the patient's urine and the doses taken of prescribed drugs.

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MEDICAL POLICY SUMMARY

Saturation Biopsy

Diagnosis and Staging of Prostate Cancer

PROCEDURE CODE(S)		CAM POLICY
55700	55706	701121
76942	G0416	

Current as of April 2019

MEDICALLY NECESSARY

Prostate biopsy involving 12 core extended sampling in the initial diagnosis of prostate cancer as a follow up to abnormal PSA results, presence of a palpable nodule on digital rectal examination, or suspicious radiologic findings.

INVESTIGATIONAL

Prostate s saturation biopsy in the diagnosis, staging and management of prostate cancer.

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MEDICAL POLICY SUMMARY

Diagnosis and Management of

Idiopathic Environmental Intolerance

CAM POLICY

20101

Current as of April 2019

INVESTIGATIONAL

Laboratory tests designed to affirm the diagnosis of idiopathic environmental illness.

Screening blood, saliva, serum, plasma, urine, and/or stool samples for volatile solvents, organic acids, and organophosphates in all circumstances including but not limited to the following compounds:

- 2-methylhippurate
- 2-methylpentane
- 3-methylpentane
- 3,4-dihydroxyphenylpropionate
- 4-nonylphenol
- alpha-keto-beta-methylvalerate
- alpha-ketoisovalerate
- Arabinitol
- atrazine or atrazine mercapturate
- benzene
- benzoate
- bisphenol A (BPA)
- diethydithiophosphate (DEDTP), diethylthiophosphate (DETP), dimethyldithiophosphate (DMDTP), dimethylthiophosphate (DMTP)
- ethylbenzene
- hexane
- Hippurate
- Indican
- Picolinate
- Polychlorinated biphenyls (PCBs)
- Quinolinate
- Styrene
- Taurine
- Toluene
- Triclosan
- Xylene

Phthalates and parabens profiling using a blood, serum, plasma, saliva, urine, and/or stool sample.

Chlorinated pesticides, including DDE and DDT, profiling in asymptomatic patients using a blood, serum, plasma, saliva, urine, and/or stool sample .

Testing blood, serum, plasma, saliva, urine, and/or stool samples for carnitine sufficiency, oxidative stress and antioxidant sufficiency, detoxification adequacy, methylation sufficiency status, lipoic acid and CoQ10 sufficiency, and/or intestinal hyperpermeability in asymptomatic individuals and/or during general encounters. Tests include, but are not limited to:

- Amino acid testing except for newborn screening and for documented metabolic disorders
- Carotene/beta-carotene
- Vanillylmandelic acid (VMA) testing except for use in diagnosis of neuroblastoma or neuroendocrine tumors or for monitoring effectiveness of treatment of cancer
- Homovanillic acid (HVA) testing except for use in diagnosis and evaluating neuroblastomas
- 5-hydroxyindolacetic acid (5-HIAA) testing except for use in diagnosis and evaluating carcinoid syndrome or for staging, treatment, and surveillance of suspected neuroendocrine tumors
- Elastase except for pancreatic insufficiency
- Fat differentiation testing, qualitative and quantitative
- Citrate
- CoQ10

Testing blood, serum, plasma, saliva, urine, and/or stool samples for vitamin sufficiency, mineral sufficiency, and/or nutritional analysis in asymptomatic individuals and/or during general encounters without abnormal findings. These tests include, but are not limited to, the following:

- Amino acid testing except for newborn screenings or for documented metabolic disorders
- Allergen-specific IgG testing for screening food sensitivities, vitamin sufficiency, or mineral sufficiency
- Carotene/beta-carotene
- Citrate
- Vanillylmandelic acid (VMA) testing except for use in diagnosis of neuroblastoma or neuroendocrine tumors or for monitoring effectiveness of treatment of cancer
- Homovanillic acid (HVA) testing except for us in diagnosis and evaluating neuroblastomas
- 5-hydroxyindolacetic acid (5-HIAA) testing except for use in diagnosis and evaluating carcinoid syndrome or for staging, treatment, and surveillance of suspected neuroendocrine tumors
- Lipid peroxides
- Behenic acid
- Lignoceric acid
- Fat differentiation testing, qualitative and quantitative

Testing blood, serum, urine, cerebrospinal fluid, fingernails, hair, and/or stool sample for metals, including but not limited to, aluminum, arsenic, cadmium, chromium, copper, lead, magnesium, manganese, mercury, molybdenum, nickel, zinc, and heavy metals not otherwise specified in asymptomatic individuals and/or general encounters without abnormal findings.

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MEDICAL POLICY SUMMARY

Genetic Testing

Cystic Fibrosis

PROCEDURE CODE(S)			CAM POLICY
81220	81223	81412	044
81221	81224	81479	
81222			

MEDICALLY NECESSARY

Carrier screening for cystic fibrosis, using a panel containing mutations proven as causative of CF (as defined by the CFTR2 project) and including the ACMG-recommended panel of the most common mutations in all of the following situations:

- For all pregnant women.
- For all women seeking pre-conception counseling.
- For the male reproductive partners of women who have been identified as cystic fibrosis carriers.
- For the reproductive partners of individuals diagnosed with cystic fibrosis.
- For individuals who have a family history of cystic fibrosis or have a first-degree relative who is a known carrier of cystic fibrosis. Testing needs to include any known familial mutations if not already included in the panel.

Testing of a fetus for mutations in the CFTR gene (including all known parental mutations) when:

- Both biological parents are cystic fibrosis carriers.
- One or both biological parents are affected with cystic fibrosis.
- One biological parent is a cystic fibrosis carrier and the other parent is not available for testing.
- Echogenic bowel is detected by fetal ultrasound.

Testing for mutations in the CFTR gene, using a panel containing mutations proven as causative of CF (as defined by the CFTR2 project) and including the ACMG-recommended panel of the most common mutations in order to make the diagnosis in a newborn or confirm the diagnosis after an abnormal newborn screening result using immunoreactive trypsinogen.

Testing for mutations in the CFTR gene as an adjunct to sweat testing in an individual presenting with symptoms of cystic fibrosis, as follows:

- When there are known familial mutations, testing needs to include the familial mutations.
- When there are no known familial mutations, or if only one familial mutation is known, testing needs to be done with a panel containing mutations proven as causative of CF (as defined by the CFTR2 project), as well as include the ACMG-recommended panel of the most common mutations. If the known familial mutation is not included in that panel, then testing for the known mutation needs to be performed additionally.
- Sequencing of the CFTR gene meets coverage criteria if no mutations or only one mutation are found using the above panel, and the clinical suspicion of cystic fibrosis remains.
- If sequencing of the CFTR gene does not reveal two disease-causing mutations, and the clinical suspicion of cystic fibrosis remains, testing for deletions and duplications in the CFTR gene meets coverage criteria.

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PROCEDURE CODE(S)			CAM POLICY
81220	81223	81412	044
81221	81224	81479	
81222			

MEDICALLY NECESSARY Cont.

Testing for mutations in the CFTR gene, using a panel containing mutations proven as causative of CF (as defined by the CFTR2 project) and including the ACMG-recommended panel of the most common mutations, along with testing for the IVS8 5T/7T/9T variant, in males with CBAVD. If mutations are not detected with the standard panel, and a diagnosis of cystic fibrosis-related CBAVD remains a consideration, sequencing of the CFTR gene meets coverage criteria.

Testing for the IVS8 5T/7T/9T variant for cystic fibrosis carrier screening only as a reflex test when the R117H mutation is detected on carrier screening.

Genetic counseling is recommended for:

- Individuals found to be cystic fibrosis carriers.
- Individuals with a diagnosis of cystic fibrosis.
- Individuals with a family history of cystic fibrosis.
- Individuals who are the reproductive partner of a cystic fibrosis carrier.
- Individuals who are the reproductive partner of a person diagnosed with cystic fibrosis or CBAVD.

NOT MEDICALLY NECESSARY

Sequencing of the CFTR gene for cystic fibrosis carrier screening.

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MEDICAL POLICY SUMMARY

Diagnostic Testing of Influenza

PROCEDURE CODE(S)			CAM POLICY
87400	86710	87631	134
87501	87254	87632	
87502	87275	87633	
87503	87276	87804	

Current as of November 2018

MEDICALLY NECESSARY

One single rapid flu test including either a point-of-contact rapid nucleic acid amplification test (NAAT) or a rapid antigen test or one single traditional NAAT in an outpatient setting for a patient in a single visit (not both an antigen and NAAT for a single patient in a single visit) for patients who present signs and symptoms consistent with influenza disease when influenza activity has been documented in the community or geographic area.

Fever: 100.4 °F or higher temperature or feeling feverish/chills and one or more of the following:

- Cough
- Sore throat
- Headaches and/or body aches
- Difficulty breathing or shortness of breath
- Fatigue
- Runny or stuffy nose.

NOT MEDICALLY NECESSARY

Viral culture testing for influenza in an outpatient setting

Outpatient influenza testing, including rapid antigen flu tests, rapid NAAT or RT-PCR tests, traditional RT-PCR tests, and viral culture testing.

Serology testing for influenza.

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MEDICAL POLICY SUMMARY

Diagnosis of Active or Latent Tuberculosis

PROCEDURE CODE(S)			CAM POLICY
0010T	87077	87190	20428
81099	87116	87206	
81425	87149	87550	
81426	87150	87551	
82945	87153	87552	
83615	87181	87555	
84157	87184	87556	
84311	87185	87557	
86352	87186	87560	
86480	87187	87561	
87070	87188	87562	

MEDICALLY NECESSARY

To diagnose latent tuberculosis infection in:
- Individuals five years or older who are likely to be infected with Mtb.
- Individuals who are unlikely to be infected with Mtb, when screening is obliged by law.

Acid fast bacilli (AFB) smear/stain for all suspected tuberculosis infections.

Culture and culture-based drug susceptibility testing of Mycobacteria spp. for all suspected tuberculosis infections.

Direct probe or amplified probe nucleic acid-based testing, including PCR, for the following :
- Mycobacteria spp
- M. tuberculosis
- M. avium intracellulare

Molecular-based drug susceptibility testing for patients whose sputum is AFB smear positive or Hologic Amplified MTD positive and who meet one of the following criteria:
- Treated for tuberculosis in the past
- Born in or have lived for at least 1 year in a foreign country with at least a moderate tuberculosis incidence (≥20 per 100,000) or a high primary MDR-TB prevalence (≥2%)
- Contacts of patients with MDR-TB
- HIV infected

Cell counts, protein, glucose, and lactate dehydrogenase (LDH) concentrations of cerebrospinal, pleural, peritoneal, pericardial and other fluids in patients with pleural effusion, pericardial effusion, or ascites and suspected tuberculosis infection, respectively.

Urine-based detection of mycobacterial cell wall glycolipid lipoarabinomannan (LAM) in HIV-infected patients with CD4 cell counts ≤100 cells/microL who have signs and symptoms of tuberculosis.

NOT MEDICALLY NECESSARY

For patients with active tuberculosis.

To diagnose latent tuberculosis infection in healthy children less than five years of age for whom it has been decided that diagnostic testing is warranted. Tuberculosis Skin Test is recommended.

The technique for quantification of nucleic acid includes both amplification and direct probes; therefore, simultaneous coding for both amplification or direct probes.

INVESTIGATIONAL

Quantitative nucleic acid testing for Mycobacteria spp, M. tuberculosis, and M. avium intracellulare .

Whole genome sequencing of mycobacterium spp. for detection of drug resistance.

Genotyping of Mycobacterium spp is considered.

Adenosine deaminase (ADA) and interferon-gamma (IFN- γ) levels in cerebrospinal, pleural, peritoneal, pericardial and other fluids for the diagnosis of extrapulmonary TB.

Serum protein biomarkers or panels of biomarkers for the detection and diagnosis of TB disease.