SANFORD Laboratories

Commercial Insurance Patient Waiver of Liability (Non-Medicare)

Do not use this waiver for BCBS ND members or Medicare beneficiaries. Separate payer-specific waiver required.

Patient Name (Print) _____ **E# or Chart#** _____

____Insured patients of commercial payers – includes BCBS Minnesota (check if applicable)

The laboratory testing ordered by your provider may not be considered medically necessary as defined by your health insurance plan **(Health Plan Name – required)** _____. Your insurance plan may not pay for services it does not consider medically necessary or not meeting the qualifications under your policy.

Testing (required) _____ **Cost (required)** _____ **Date Service Provided (required)** _____

____BCBS Wellmark patients only (check if applicable): City and State where provider located (required): _____

As a BCBS Wellmark covered member, your insurer has medical policies to guide ordering providers in requesting medically necessary tests. BCBS Wellmark medical policies may not support your ordering provider's reasons for ordering certain tests. Medical policies exist with BCBS Wellmark for the tests indicated in the table below. Policy summaries can be found on the back of the form.

Testing Considered Not-Medical Necessary or Investigational and May Not Be Covered By Your Health Plan When Ordered for Reasons Indicated Below				
Testing	**Select Test (X) (Required)**	**Order Code**	**Signs/Symptoms/Diagnosis NOT COVERED Screening / Routine codes: Z00.00 and Z13.9 never covered**	**Estimated Cost**
Urinalysis Testing		NBLD0001	Routine Exam, Wellness Exam	$33.00
CBC, Hemograms		BLOD0632	Routine Exam, Wellness Exam	$29.00
CA 125		BLOD0608	Screening for Ovarian Cancer, or ordered due to flatulence, gas pain, plaise/fatigue, genital organ hypertroph	$127.00
CEA		BLOD0587	Screening for abdominal pain and swelling, diagnosis, staging, or routine surveillance of breast cancer	$115.00
CGH/Microarray		BLOD1440	Pre-Authorization required - this test is considered investgational in most circumstances	$1,782.00
Cystic Fibrosis 97		BLOD0505	Pre-Authorization required - this test is not covered in many circumstances	$1,046.00
Genetics Testing			Pre and Post genetic evaluation and prior approval required (Enter charge estimate to the right)	$_____
Homocystine		BLOD0579	The screening , diagnosis, and management of cardiovascular disease or a recurrent pregnancy loss without current pregnancy	$103.00
PSA		BLOD0594	Screening not considered medically necessary for asymptomatic men under 50 years of age not on testosterone therapy	$112.00
Vitamin D (for 1,25 dihydroxy or 25 hydroxy)		BLOD0409	Not medically necessary for routine or intital screening in the absence of clinical documentation associated with deficiency.	$180.00
OVA-1		BLOD1302	Considered experiental and/or investigational	$1,374.00
Allergy Testing		Varies	Skin testing is suggested to be the first line of testing - it would be inappropriate to use in vtro testing for majority of patients for first line testing. (86003 and/or 86005 and/or 86008 each allergen approx $29 - Enter charge estimate to the right)	$_____

Patient Agreement: (Must be understood and signed by all patients acknowledging financial responsibility regardless of insurer)

I understand that my health insurance may have medical policies regarding testing that has been ordered. I understand Sanford Laboratories will file a claim on my behalf as long as the billing information provided is valid and complete. I have elected to receive the services ordered and agree to pay for services if my insurance plan deems the services non-covered.*

Patient or Responsible Party Signature (required): _____ **Date** _____

Phlebotomist or Facility Representative Signature (required): _____ **Date** _____

☐ **I choose to decline testing indicated (member signature and date)** _____ **Date** _____

Phlebotomist or other facility representative signature indicates a meeting with the patient and an explanation regarding non-coverage was discussed and understood. **While an explanation of benefits may indicate otherwise, a valid, signed waiver constitutes financial liability on behalf of the policy holder**

Summaries of BCBS Wellmark Medical Policies

Vitamin D Policy: 25-hydroxyvitamin D [25(OH)D] serum testing may be considered **medically necessary** in patients with a clinically documented underlying disease or condition which is specifically associated with vitamin D deficiency or decreased bone density/osteoporosis

25-hydroxyvitamin D [25(OH)D] serum testing is considered **not medically necessary** for routine or initial screening in the absence of clinical documentation of an underlying disease or condition specifically associated with vitamin D deficiency

Testing and screening for vitamin D deficiency with 1,25 dihydroxyvitamin D [1,25$(OH)_2$D] serum testing is considered **not medically necessary** for all indications.

Chromosomal Microarray/CGH Policy: Chromosomal microarray analysis (CMA) testing is considered medically necessary as a first line test in the postnatal evaluation of individuals with the following: -- Multiple anomalies not specific to a well-delineated genetic syndrome, OR Apparently non-syndromic DD/ID (developmental delay/intellectual delay), OR Autism spectrum disorders AND

- Any indicated biochemical test for metabolic disease have been performed, and results are non-diagnostic, AND
- FMR1 gene analysis (for Fragile X syndrome), when clinically appropriate, is negative.

Chromosomal microarray analysis is considered **investigational** in all other cases of suspected genetic abnormality in children with developmental delay/intellectual disability or autism spectrum disorder.

Chromosomal microarray analysis to confirm the diagnosis of a disorder or syndrome that is routinely diagnosed based on clinical evaluation alone is considered **not medically necessary.**

Chromosomal microarray analysis is considered **investigational** for the screening, diagnosis, and management of hematologic and oncologic malignancies.

Chromosomal microarray analysis is considered **investigational** as a means to predict or evaluate pregnancy loss.

Chromosomal microarray analysis is considered **investigational** for screening for prenatal genetic mutations.

Homocysteine Policy: Measurement of plasma homocysteine is considered **not medically necessary** in the screening, diagnosis, and management of cardiovascular disease or recurrent pregnancy loss without current pregnancy. Due to the large amount of evidence from placebo-controlled RCTs that homocysteine-lowering interventions do not have a statistically significant effect on the rate of major cardiovascular events, routine testing of homocysteine for cardiovascular indications is considered not medically necessary.

Microarray-Based Gene Expression Policy: Microarray-based gene expression testing to evaluate the site of origin of a tumor of unknown primary is considered **investigational.**

Microarray-based gene expression testing to distinguish a primary from a metastatic tumor is considered **investigational.**

PSA Policy: Annual total PSA testing for prostate cancer screening may be considered **medically necessary** for either of the following:

- Asymptomatic men at any age who are at high risk of prostate cancer due to any of the following factors:
  - African-American race
  - First degree relative(s) (father, brother, or son) diagnosed with prostate cancer at age 65 or younger
- Asymptomatic men age 50 and over with a life expectancy of at least 10 years.
- Asymptomatic men age 40-50 who are receiving **medically necessary** testosterone replacement therapy
- All other screening indications are considered **not medically necessary**.

SERUM TUMOR MARKERS Policy: AFP, β-hCG, and LDH are considered **not medically necessary** to screen for germ cell tumors, to determine whether orchiectomy is indicated, or to guide treatment decisions for patients with cancer of unknown primary (CUP) All other applications of serum tumor markers are considered **investigational** including but not limited to the following:

- CEA for screening or abdominal pain and swelling, diagnosis, staging, or routine surveillance of breast cancer
- CA 19-9 as a screening or diagnostic test for gastrointestinal cancers including pancreatic and colorectal cancers, and liver, breast, esophageal and uterine cancer
- CA 15-3 and CA 27.29 for screening, diagnosis, staging, or routine surveillance of breast cancer
- CA-125 as a solitary test to screen for ovarian cancer, or ordered due to flatulence, gas pain, malaise, genital organ hypertrophy.
- HE4 for screening, diagnosing, or monitoring disease progression or recurrence in women with ovarian cancer.
- All other applications of serum tumor markers are considering investigational including but not limited to the following as the peer reviewed medical literature does not support these tests having sufficient sensitivity or specificity to define their clinical role:
  - Ova-1 (CA-125, apolipoprotein A1, beta 2 microglobulin transferin and pre-albumin) and ROMA (CA-125 and HE4). See Medical Policy Proteomics Based Testing for Evaluation of Ovarian Cancer

Allergy Testing Policy: The management of an allergic patient should include a comprehensive history, physical examination and should include confirming the cause of allergies. Once the agent is identified, treatment is provided by avoidance, medication or immunotherapy. Skin testing would be the first line of testing for the majority of patients. In vitro testing would be appropriate necessary for those with the inability to stop specific medications and those that have had severe allergic responses to medicine, food, inhalants, and insects. It would be inappropriate to use in vitro testing for the majority of patients as the first line of testing.

BCBS Wellmark medical policies: http://www.wellmark.com/Provider/MedPoliciesAndAuthorizations/MedicalPolicies/MedicalPoliciesAlphabetical.aspx

BCBS Minnesota medical policies: http://notes.bluecrossmn.com/web%5Cmedpolman.nsf/($All)?OpenView