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 ivestigational or not medically necessary may not be covered by your health plan when ordered for reasons 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	$39.00
CBC, Hemograms		BLOD0632	Routine Exam, wellness Exam	$35.00
CEA		BLOD0587	Screening for abdominal pain and swelling, staging or routine surveillance of breast cancer	$115.00
Homocysteine		BLOD0579	the screening/diagnosis/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
CA 125		BLOD0608	Screening for ovarian cancer or ordered due to flatulence, gas pain, malaise/fatigue, genital organ hypertrophy	$127.00
Fibrinogen		BLOD0666	in many cases not medically necessary	$43.00
CA 19-9		BLOD0312	includes but is not limited to screening or diagnostic tests for gastrointestinal cancers	$79.00
B. Pertussis NAD		NBLD0274	in many cases not medically necessary	$300.00
CA 15-3		BLOD0311	screening, diagnosis, staging or routine surveillance of breast cancer	$127.00
Myotonic Dystrophy PCR		BLOD1076	in many cases not medically necessary	$460.00
Cystic Fibrosis 97		BLOD0505	Pre-authorization/liability form required as test is not covered in many circumstances	$2,898.00
OVA-1		BLOD1302	Considered experimental or investigational	$2,960.00
Vitamin D (1,25 hydroxy or 25 hydroxy)		BLOD0409 or BLOD0171	Not medically necessary for routine or initial screening in the absence of clinical documentation associated with deficiency	$136.00 - $180.00
Factor V Leiden		BLOD0379	in many cases not medically necessary	$244.00
Factor II (G20210A)		BLOD0364	in many cases not medically necessary	$240.00
Allergy Testing		Varies	Skin testing is suggested to be the first line of testing (86003 and/or 86005 and/or 86008 each allergen approx $29 - enter charge estimate to the right)	$_____
Other Testing				$_____
Other Genetics Testing			Pre and post genetic evaluation and prior authorization where required (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**

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Summaries of Blue Cross Blue Shield Medical Policies

Vitamin D Policy: The use of vitamin D deficiency with 1,25-hydroxyvitamin D and 25-hydroxyvitamin D serum testing is considered not medically necessarydue to general population screening and routine testing where monitoring the condition is not associated with vitamin D metabolism.

Pharmacogentic Testing: Pharmacogenetic testing is considered investigational and experimental to determine medication dose for mental health disorders, drug metabolizer status for pain medication and warfarin (Coumadin) dosing.

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.

Whole Exome Sequencing: Whole exome sequencing is considered investigational for screening and evaluating disorders where extensive pre-genetic evaluation not performed, screening asymptomatic individuals for genetic disorders, molecular profiling of tumors for the diagnosis, prognosis or management of cancer

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