Commercial Insurance Patient Waiver of Liability  
(Non-Medicare)

Patient Name (Print) ______________________________________________________________

___ BCBS/Wellmark Patients Only (check if applicable):

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. If your ordering provider requests any of the tests below for the symptoms indicated or other symptoms deemed non-covered by BCBS/Wellmark, you may be responsible for the charges.

___ Insured Patients of All Other Commercial Health Plans (other than BCBS/Wellmark) (check if applicable):

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

City & State where provider located (required): ______________________________________________

<table>
<thead>
<tr>
<th>Testing^</th>
<th>Select Test (X) (Required)</th>
<th>Signs/Symptoms/ Diagnoses NOT COVERED</th>
<th>(estimated cost)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urinalysis Testing</td>
<td>Routine Exam, Wellness Exam</td>
<td>Routine Exam, Wellness Exam</td>
<td>($39.00)</td>
</tr>
<tr>
<td>CBC, Hemograms</td>
<td>Routine Exam, Wellness Exam</td>
<td>Screening for ovarian cancer, or ordered due to flatulence, gas pain, malaise/fatigue, genital organ hypertrophy</td>
<td>($209.00)</td>
</tr>
<tr>
<td>CA 125</td>
<td>Screening or abdominal pain and swelling, diagnosis, staging, or routine surveillance of breast cancer</td>
<td>($121.00)</td>
<td></td>
</tr>
<tr>
<td>CGH/Chromosome Microarray</td>
<td>Pre-Authorization Required - this test is considered investigational in most circumstances.</td>
<td>($1,900.00)</td>
<td></td>
</tr>
<tr>
<td>Cystic Fibrosis 97</td>
<td>Pre-Authorization Required - this test is not covered in many circumstances.</td>
<td>($619.00)</td>
<td></td>
</tr>
<tr>
<td>Genetics Testing</td>
<td>Pre and Post Genetic Evaluation, and Prior Approval Required</td>
<td>(variable)</td>
<td></td>
</tr>
<tr>
<td>Homocysteine</td>
<td>The screening, diagnosis, and management of cardiovascular disease or a recurrent pregnancy loss without current pregnancy</td>
<td>($243.00)</td>
<td></td>
</tr>
<tr>
<td>PSA</td>
<td>Screening indications are considered not medically necessary for asymptomatic men under 50 years of age not on testosterone therapy</td>
<td>($68.00)</td>
<td></td>
</tr>
<tr>
<td>Vitamin D (for 1,25 dihydroxy or 25 hydroxy)</td>
<td>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</td>
<td>($165.00 - $215.00)</td>
<td></td>
</tr>
</tbody>
</table>

Patient Agreement:

I have read and understand the above information. 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 accurate, 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 Other Clinic Representative Signature (required): __________________________ Date __________________

* Summaries of BCBS medical policies indicated in above table are located on the back of this form. A link to Wellmark policies is also provided if needed. While an explanation of benefits may indicate otherwise, a valid, signed waiver constitutes financial liability on behalf of the policy holder.

^Testing indicated in this table is not an all inclusive list. Your provider may order other testing deemed non-covered by your insurance plan.
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)₂D] 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 nonsyndromic DD/ID (developmental delay/intellectual delay), OR Autism spectrum disorders AND

- Any indicated biochemical test for metabolic disease have been performed, and results are nondiagnostic, 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 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

Full BCBS/Wellmark medical policies can be accessed at:
http://www.wellmark.com/Provider/MedPoliciesAndAuthorizations/MedicalPolicies/MedicalPoliciesAlphabetical.aspx

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