CAPITAL WOMEN'S CARE

Obstetrics & Gynecology

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Patient Informed Consent
Prenatal Screening Tests

The American Congress of Obstetricians and Gynecologists recommends that prenatal screening be offered to all pregnant (or soon to be pregnant) women, regardless of their age. These are some of the tests that will be offered to you:

<table>
<tr><td>Carrier Screening</td><td>Carrier screening is performed by a blood test for genetic conditions that are passed from parents to their children. This often occurs even when neither parent has the clinical disease or syndrome. Identifying if you or your partner are carriers of various genetic disorders can help define your risk of having a child with that disorder. Carrier screening can be performed prior to a pregnancy or after becoming pregnant. There are several panel sizes to choose from:
<table>
<tr><td>Trio (3 gene Panel)</td><td>Recommended by the American College of Obstetrics and Gynecologists (ACOG), screens for Cystic Fibrosis (CF), Spinal Muscular Atrophy (SMA) and Fragile X Syndrome. CF is the most commonly inherited condition that affects children and young adults. It is a progressive disease that affects many different organs in the body, including the lungs, pancreas, and liver, lining them with abnormally thick, sticky mucus. CF may cause chronic breathing problems and lung infections and CF patients have a lower life expectancy. Some treatments can increase the life span of patients with CF into their 30s. SMA causes certain nerves in the brain and spinal cord to die, impairing the person's ability to move. SMA is the most commonly inherited cause of early childhood death. Fragile X syndrome causes serious intellectual impairment and behavioral problems and is the most common form of inherited intellectual disability. Individuals with Fragile X syndrome can have a wide range of challenges in learning and behavior, including autism spectrum disorders. If a woman is a carrier, she has approximately a 50% chance of having a child with Fragile X syndrome. Boys tend to be more severely affected than girls.</td></tr>
<tr><td>Targeted (27 gene Panel)</td><td>Targeted carrier testing includes the above plus an additional 24 conditions that have a higher prevalence rate in the following ethnicities: Asian, Greek, Mediterranean, African/African American and Ashkenazi Jewish descent</td></tr>
<tr><td>Expanded (274 gene panel)</td><td>Expanded carrier testing includes the above plus 200+ additional rare genetic disorders. This type of screening is done without regard to race or ethnicity.</td></tr>
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These are non-invasive tests that require a blood sample. If the mother is a carrier for any of the conditions tested, the next step is to test the father, as both parents must be carriers (in most cases) for a child to have a risk of being affected by the condition. Having the awareness of risk for a condition can prepare both parents and healthcare providers as to future testing or follow up needed for the child.</td></tr>
<tr><td>Non-Invasive Prenatal Testing (NIPT)</td><td>NIPT is a simple, prenatal blood test that detects the presence of non-inherited genetic disorders such as Down syndrome, Edwards syndrome, Patau syndrome, Monosomy X, sex chromosome aneuploidies and several microdeletions. NIPT is a highly sensitive screening test (99% accurate) and can be performed as early as 10 weeks in pregnancy. It is recommended for pregnant women with certain risk factors, including those age 35 and over and those who have been determined by their doctors to have other high-risk factors.</td></tr>
<tr><td>Early Genetic/ Nuchal Translucency Sonogram</td><td>FTS is performed between 11-14 weeks of pregnancy to identify mothers whose babies may be at an increased risk for Down syndrome or other chromosomal abnormalities. It includes an ultrasound examination to measure excess fluid accumulation under the skin on the back of the fetus' neck and assessment for early cardiac, brain, bowel or other defects. This ultrasound is *not* diagnostic, but it can help to estimate pregnancy risks for certain birth defects and determine whether further evaluation of the pregnancy may be needed.</td></tr>
<tr><td>Maternal Serum Screening</td><td>Maternal serum screening is a group of screening tests performed in the second trimester (between 15-21 weeks) that help you find out if your unborn baby is at greater risk of Down syndrome, Edwards syndrome and neural tube defects. This testing helps evaluate the risk a fetus may have these conditions but is not diagnostic meaning further evaluation may be needed if results are abnormal. If you have had the NIPT test, only one component of this, the Alpha-fetoprotein, which assesses for neural tube defects.</td></tr>
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natera

NATERA PATIENT ACKNOWLEDGMENT

I have been informed of and understand the details of the test ordered for me by my health care provider, including the risks, benefits and alternatives and I have consented to testing. I understand that the test results may inform me of a genetic condition that is present in myself or my partner that may require medical follow-up. I also understand that negative results do not rule out the possibility of a genetic condition in the fetus, myself and/or partner. I authorize Natera or another provider to share the information on this form and my test results with my health insurer/health plan on my behalf with all benefits of my plan made payable directly to Natera or another provider. I understand that I am **responsible** for costs not paid by my plan directly to Natera for test ordered, including, without limitation, any copayments, deductibles, or amount deemed 'patient responsibility" and any amounts paid to me by my plan. This testing will not be covered by my plan if it is outside of the plan's coverage guidelines or is deemed not medically necessary - (e.g. where prior authorization is required but not obtained) and I will be responsible for the cost of such testing at **$99** per test, discounts may apply. I assign Natera the right to appeal on my behalf negative coverage decisions made by my plan and to assert all rights and claims reserved to me as beneficiary thereof. I authorize Natera to charge my credit card for any balance I might owe with regards to my tests. The information obtained from my tests may be used in scientific publications or presentations, but my specific identity will not be revealed. Natera may contact my healthcare provider to obtain more information regarding clinical correlation and confirmatory testing. My leftover samples may be de-identified and used for research and development. I and my heirs will not receive payments, benefits, or rights to any resulting products or discoveries. If I do not want my samples to be used, I may send a request in writing to Natera Sample Retention Department at the address below within 60 days after test results have been issued and my samples will be destroyed.

PLEASE MAKE A SELECTION AND SIGN BELOW:

Carrier Screening (select 1)

- ☐ Trio Carrier Screening (CF, SMA, Fragile X)
- ☐ Targeted Carrier Screening (27 gene panel)
- ☐ Expanded Carrier Testing (274 gene panel)
- ☐ Decline Carrier Screening

NIPT (Non-invasive prenatal testing)

- ☐ Yes, I want the NIPT testing
  - ☐ Yes I want the gender
  - ☐ No I don't want the gender
- ☐ No, I decline the NIPT testing

Patient name: _____ Date of birth: _____

Patient signature: _____ Date: _____