

### Medical Policy: MEDICAL POLICY FOR NONINVASIVE PRENATAL TESTING FOR FETAL ANEUPLOIDY (NIPT)

Effective Date: 05/08/14

Reviewed/No Updates: 02/12/15, 02/11/16, 2/9/17, 2/8/18,

2/14/19, 2/13/20, 2/17/22, 2/2/23, 2/8/24 Reviewed/Updated: 2/11/21, 8/10/23, 2/20/25

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Noninvasive prenatal testing uses cell free fetal DNA from the plasma of pregnant women processed through a technology known as massively parallel genomic sequencing to detect trisomy 13, trisomy 18 and trisomy 21 as early as the 10<sup>th</sup> week of pregnancy. Because this is a simple blood draw for the mother, it is considered a safe, noninvasive test compared to invasive testing of chorionic villus sampling (CVS) or amniocentesis. Detection rates for trisomy 13, 18 and 21 are greater than 98% with very low false positive rates (less than 0.5%).

Ventura County Health Care Plan (VCHCP) has adopted the following recommendations of the American College of Obstetricians and Gynecologists (ACOG):

- 1. Primary prenatal screening, consisting of ultrasound for nuchal translucency and alpha fetoprotein testing, is to be offered to all pregnant women at fetal gestational age between 10 and 13 weeks for blood test and between 11 and 14 weeks for ultrasound.
- Cell-free DNA (cfDNA) screening as a first-line screening option for all pregnant women
  regardless of age. ACOG also recognizes cfDNA screening as the most sensitive and
  specific screening test for fetal aneuploidies. cfDNA screening can be performed in twin
  pregnancies.
- 3. Cell free fetal DNA testing can also be used as a follow-up test for women with positive first-trimester or second-trimester screening test result.

Additional recommendations from The American College of Obstetricians and Gynecologists (ACOG):

- cfDNA screening can be performed in twin pregnancies.
- NIPT results which include fetal fraction measurements are preferable.
- Technical failures of cfDNA screening (no-call results)\* are associated with a higher risk of aneuploidy. Women who receive a no-call NIPT result should have genetic counseling and be offered ultrasound and diagnostic testing. In some cases, repeat NIPT may be considered.
- Multiple an euploidy screening tests performed simultaneously should not be used.

\* A no-call result means that the lab was not able to run the test, or that the test did not produce a result, possibly due to poor DNA quality or due to a problem with the sample itself.



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**NOTE**: Expanded NIPT for microdeletions, rare autosomal aneuploidies, or genome-wide changes are not recommended and therefore are not covered.

**Exclusions:** Cell free fetal DNA testing is not approved for prenatal gender identification.

#### **History:**

Reviewed/No Updates: Catherine Sanders, MD

Committee Review: UM: February 12, 2015; OAC: February 24, 2015 Reviewed/No Updates: Faustine Dela Cruz, RN & Catherine Sanders, MD Committee Review: UM: February 11, 2016; QAC: February 23, 2016 Reviewed/No Updates: Catherine Sanders, MD & Robert Sterling, MD Committee Review: UM: February 9, 2017; QAC: February 28, 2017 Reviewed/No Updates: Catherine Sanders, MD & Robert Sterling, MD Committee Review: UM: February 8, 2018; QAC: February 27, 2018 Reviewed/No Updates: Catherine Sanders, MD & Robert Sterling, MD Committee Review: UM: February 14, 2019; QAC: February 26, 2019 Reviewed/No Updates: Howard Taekman, MD & Robert Sterling, MD Committee Review: UM: February 13, 2020; QAC: February 25, 2020 Reviewed/Updated: Howard Taekman, MD & Robert Sterling, MD Committee Review: UM: February 11; 2021; QAC: February 23, 2021 Reviewed/No Updates: Howard Taekman, MD & Robert Sterling, MD Committee Review: UM: February 17, 2022; QAC: February 22, 2022 Reviewed/No Updates: Howard Taekman, MD & Robert Sterling, MD Committee Review: UM: February 2, 2023; QAC: February 7, 2023 Reviewed/ Updated: Howard Taekman, MD & Robert Sterling, MD Committee Review: UM: August 10, 2023; QAC: August 29, 2023 Reviewed/ Updated: Howard Taekman, MD & Robert Sterling, MD Committee Review: UM: February 8, 2024; QAC: February 27, 2024 Reviewed/Updated by: Howard Taekman, MD & Robert Sterling, MD Committee Review: UM: February 20, 2025; QAC: February 25, 2025



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Revision Date	Content Revised (Yes/No)	Contributors	Review/Revision Notes
2/9/17	No	Catherine Sanders, MD; Robert Sterling, MD	Annual Review
2/8/18	No	Catherine Sanders, MD; Robert Sterling, MD	Annual Review
2/14/19	No	Catherine Sanders, MD; Robert Sterling, MD	Annual Review
2/13/20	No	Howard Taekman, MD; Robert Sterling, MD	Annual Review
2/11/21	Yes	Howard Taekman, MD; Robert Sterling, MD	Expanded information regarding the use of cell-free DNA (cfDNA) in all patients, regardless of maternal age or baseline risk.
2/17/22	No	Howard Taekman, MD; Robert Sterling, MD	Annual Review
2/2/23	No	Howard Taekman, MD; Robert Sterling, MD	Annual Review
8/10/23	Yes	Howard Taekman, MD; Robert Sterling, MD	Updated with: Ventura County Health Care Plan (VCHCP) has adopted the following recommendations of the American College of Obstetricians and Gynecologists (ACOG):



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2/8/24	No	Howard Taekman, MD; Robert Sterling, MD	Annual Review
2/20/25	Yes	Howard Taekman, MD; Robert Sterling, MD	Added "A no-call
			result means that
			the lab was not
			able to run the
			test, or that the
			test did not
			produce a result,
			possibly due to
			poor DNA quality
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			problem with the
			sample itself."