

Clinical Policy: Genetic Testing for Non-Invasive Prenatal Screening (NIPS)

Reference Number: CP.MP.231

Date of Last Revision: 02/22

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Non-invasive prenatal screening (NIPS) is a sequencing test performed on placental cell-free DNA found in maternal serum and is most commonly used to screen for fetal aneuploidy (trisomy 21, trisomy 13, and trisomy 18); sex chromosomes are also screened for fetal sex determination and sex chromosome aneuploidy. NIPS is a screening test and does not provide definitive diagnosis for a fetus. When NIPS is positive, or high risk, for a genetic abnormality, the fetus is at increased risk for that condition. Further testing would be necessary to exclude the possibility of a false-positive.

NIPS has recently expanded to include microdeletion and microduplication syndromes, as well as single-gene disorders, although this is an area of ongoing research. NIPS has also expanded to predict twin zygosity (i.e., monozygotic versus dizygotic twins). Monozygotic twins have a higher risk for certain complications, such as twin-twin transfusion syndrome (TTTS).

Below are a list of higher volume tests and the associated laboratories for each criteria section. This list is not all inclusive.

CPT® Codes	Example Tests (Labs)	Criteria Section	Common ICD Codes
81420,0060U	Panorama (Natera)	Non-invasive Prenatal Screening (NIPS) for Trisomy 13, 18, and 21	O09, O28, O30, O35, Q90-Q99, Z34, Z36.0
81420,81479	MaterniT21 PLUS (Integrated Genetics)	Non-invasive Prenatal Screening (NIPS) for Trisomy 13, 18, and 21	O09, O28, O30, O35, Q90-Q99, Z34, Z36.0
81420,81479	Prequel Prenatal Screen (Myriad)	Non-invasive Prenatal Screening (NIPS) for Trisomy 13, 18, and 21	O09, O28, O30, O35, Q90-Q99, Z34, Z36.0
81420,81479	Invitae NIPS for Singleton Pregnancies (chromosomes 13, 18, 21) - Primary + Invitae NIPS for Singleton Pregnancies (chromosomes 13, 18, 21) (Invitae)	Non-invasive Prenatal Screening (NIPS) for Trisomy 13, 18, and 21	O09, O28, O30, O35, Q90-Q99, Z34, Z36.0
81507	Harmony (Ariosa)	Non-invasive Prenatal Screening (NIPS) for Trisomy 13, 18, and 21	O09, O28, O30, O35, Q90-Q99, Z34, Z36.0

CLINICAL POLICY

Genetic Testing Non-Invasive Prenatal Screening (NIPS)

CPT® Codes	Example Tests (Labs)	Criteria Section	Common ICD Codes
N/A	Vanadis NIPT (PerkinElmer Genomics)	Non-invasive Prenatal Screening (NIPS) for Trisomy 13, 18, and 21	O09, O28, O30, O35, Q90-Q99, Z34, Z36.0
81422,0060U	Panorama - with microdeletion syndromes (Natera)	Non-invasive Prenatal Screening (NIPS) for Microdeletions	O09, O28, O30, O35, Q90-Q99, Z34, Z36.0
81422	QNatal Advanced (Quest) MaterniT21 Plus Core + ESS (Integrated Genetics) Prequel Prenatal Screen + Microdeletions (Myriad) Invitae NIPS for Singleton Pregnancies (chromosomes 13, 18, 21) - Primary + for Select Microdeletions (1p36, 4p16.3, 5p15.2, 15q11.2, 22q11.2) (Invitae)	Non-invasive Prenatal Screening (NIPS) for Microdeletions	O09, O28, O30, O35, Q90-Q99, Z34, Z36.0
81302,81400, 81401,81402, 81403,81404, 81405,81406, 81407,81408, 81442, 81479	Vistara (Point Mutation NIPT) (Natera) PreSeek Non-invasive Prenatal Gene Sequencing Screen (Baylor Miraca Genetics Laboratories)	Non-invasive Prenatal Screening (NIPS) for Single-Gene Disorders	O09, O28, O30, O35, Q90-Q99, Z34, Z36.0
81508,81509, 81510,81511, 81512	First Trimester Serum Screening Second Trimester Serum Screening Integrated Screening	Maternal Serum Screening (MSS)	O09, O28, O30, O35, Q90-Q99, Z34, Z36.0

CLINICAL POLICY

Genetic Testing Non-Invasive Prenatal Screening (NIPS)

This policy document provides criteria for Non-Invasive Prenatal Screening (NIPS). Please refer to:

- ***CP.MP.239 Oncology: Circulating Tumor DNA and Circulating Tumor Cells (Liquid Biopsy)*** for criteria related to circulating tumor DNA (ctDNA) or circulating tumor cell testing performed on peripheral blood for cancer diagnosis, management and surveillance.
- ***CP.MP.235 Genetic Testing: Prenatal Diagnosis (via amniocentesis, CVS, or PUBS) and Pregnancy Loss*** for criteria related to prenatal and pregnancy loss diagnostic genetic testing.
- ***CP.MP.234 Genetic Testing: Prenatal and Preconception Carrier Screening*** for criteria related to carrier screening for genetic disorders.
- ***CP.MP.233 Genetic Testing: Preimplantation Genetic Testing*** for criteria related to genetic testing of embryos prior to in vitro fertilization.
- ***CP.MP.230 Genetic Testing: Multisystem Inherited Disorders, Intellectual Disability, and Developmental Delay*** for criteria related to diagnostic genetic testing in the postnatal period.
- ***CP.MP.222 Genetic Testing: General Approach to Genetic Testing*** for criteria related to non-invasive prenatal screening that is not specifically discussed in this or other non-general policies.

Policy/Criteria

Non-invasive Prenatal Screening (NIPS) for Trisomy 13, 18, and 21

- I. It is the policy of health plans affiliated with Centene Corporation® that Noninvasive Prenatal Screening (NIPS) for trisomy 13, 18, and 21 (81420, 81507, 0168U) may be considered **medically necessary** when meeting all of the following:
 - A. The member/enrollee has a singleton or twin pregnancy;
 - B. The member/enrollee has received appropriate counseling about the benefits and limitations of this test by one of the following:
 1. Qualified OBGYN
 2. Maternal-fetal medicine specialist/perinatologist
 3. Clinical geneticist
 4. Certified genetic counselor
 5. Advanced practice practitioner (e.g. APRN or Physician’s Assistant) in genetics or maternal-fetal medicine/perinatology.
- II. It is the policy of health plans affiliated with Centene Corporation® that current evidence does not support NIPS for multiple gestation pregnancies (triplets or higher) or to predict twin zygosity (see definitions) (0060U).
- III. It is the policy of health plans affiliated with Centene Corporation® that current evidence does not support NIPS for all other indications, including the following:
 - A. For all other aneuploidies (other than trisomy 13, 18, and 21)

CLINICAL POLICY

Genetic Testing Non-Invasive Prenatal Screening (NIPS)

- B. For the sole purpose of fetal sex determination
- C. NIPS performed simultaneously with maternal serum screening
- D. NIPS performed after a diagnostic test has been performed (e.g., amniocentesis, CVS, or PUBS)
- E. Use on a singleton pregnancy with a known vanishing twin

Non-invasive Prenatal Screening (NIPS) for Microdeletions

- I. It is the policy of health plans affiliated with Centene Corporation® that current evidence does not support NIPS for microdeletion and microduplications (81422).

Non-invasive Prenatal Screening (NIPS) for Single-gene Disorders

- I. It is the policy of health plans affiliated with Centene Corporation® that current evidence does not support NIPS for mutations associated with single gene disorders (81302, 81400, 81401, 81402, 81403, 81404, 81405, 81406, 81407, 81408, 81442).

Maternal Serum Screening (MSS)

- I. It is the policy of health plans affiliated with Centene Corporation® that maternal serum screening for aneuploidy using no more than one of the following one time per pregnancy is considered **medically necessary**:
 - A. First trimester screening (free or total beta-HCG and PAPP-A) (81508)
 - B. Second trimester screening (hCG, msAFP, uE3, and DIA) (81509, 81510, 81511, 81512)
 - C. Integrated, stepwise sequential, or contingent sequential screening (81508, 81509, 81510, 81511, 81512)

Notes and Definitions

Noninvasive prenatal screening (NIPS) is a screening test that is used to determine the risk of specific genetic disorders by analyzing traces of cell-free DNA (cfDNA) in a pregnant woman's blood.

Sequencing-based tests use 1 of 2 general approaches to analyze cell-free DNA. The most widely used technique to date uses massively parallel sequencing (MPS; also known as next-generation or "next gen" sequencing). The second general approach uses the single nucleotide polymorphism (SNP) method.

Twin Zygosity testing is used to predict the degree of genetic similarity within each pair (i.e., monozygotic versus dizygotic). Monozygotic (genetically identical twins) are at a higher risk for pregnancy complications, such as twin-twin transfusion syndrome (TTTS).

More than one cell-free DNA screen performed per pregnancy (defined by no more than one paid test per pregnancy) is not medically indicated.

NIPS does not assess the risk of neural tube defects (NTDs). Guidelines recommend that patients should continue to be offered screening for NTDs via ultrasound or maternal serum alpha fetoprotein (msAFP).

CLINICAL POLICY

Genetic Testing Non-Invasive Prenatal Screening (NIPS)

NIPS is a screening test and indicates an increased or decreased risk for the condition(s) being screened. NIPS is not diagnostic for any condition and pregnancy management decisions should not be based solely on the results of cell-free DNA screening. Karyotyping, FISH, or CMA would be necessary to exclude the possibility of a false-positive. Before testing, guidelines recommend that women be counseled about the risk of a false-positive result. False-positive findings have been associated with factors, including placental mosaicism, vanishing twin, maternal genetic condition, and maternal malignancy.

ACOG Practice Guideline 226 (2020) recommends that all patients receive information on the risks and benefits of various methods of prenatal screening and diagnostic testing for fetal aneuploidies, including the option of no testing. ACOG also recommends that patients with indeterminate or uninterpretable (ie, "no call") cell-free DNA test results be referred for genetic counseling and offered ultrasound evaluation and diagnostic testing because "no-call" findings have been associated with an increased risk of aneuploidy.

Background

American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine (SMFM)

The American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine (2020) released a joint practice bulletin (No. 226) with the following recommendations for screening for fetal chromosomal abnormalities:

The following recommendations and conclusions are based on good and consistent scientific evidence (Level A):

- “Prenatal genetic screening (serum screening with or without nuchal translucency [NT] ultrasound or cell-free DNA screening) and diagnostic testing (chorionic villus sampling [CVS] or amniocentesis) options should be discussed and offered to all pregnant women regardless of maternal age or risk of chromosomal abnormality. After review and discussion, every patient has the right to pursue or decline prenatal genetic screening and diagnostic testing.”
- “If screening is accepted, patients should have one prenatal screening approach, and should not have multiple screening tests performed simultaneously.”
- “Cell-free DNA is the most sensitive and specific screening test for the common fetal aneuploidies. Nevertheless, it has the potential for false-positive and false-negative results. Furthermore, cell-free DNA testing is not equivalent to diagnostic testing.”
- “All patients should be offered a second-trimester ultrasound for fetal structural defects, since these may occur with or without fetal aneuploidy; ideally this is performed between 18 and 22 weeks of gestation (with or without second-trimester maternal serum alpha-fetoprotein).”
- “Patients with a positive screening test result for fetal aneuploidy should undergo genetic counseling and a comprehensive ultrasound evaluation with an opportunity for diagnostic testing to confirm results.”
- “Patients with a negative screening test result should be made aware that this substantially decreases their risk of the targeted aneuploidy but does not ensure that the fetus is unaffected. The potential for a fetus to be affected by genetic disorders that are not evaluated by the screening or diagnostic test should also be reviewed. Even if patients

CLINICAL POLICY**Genetic Testing Non-Invasive Prenatal Screening (NIPS)**

have a negative screening test result, they may choose diagnostic testing later in pregnancy, particularly if additional findings become evident such as fetal anomalies identified on ultrasound examination.”

- “Patients whose cell-free DNA screening test results are not reported by the laboratory or are uninterpretable (a no-call test result) should be informed that test failure is associated with an increased risk of aneuploidy, receive further genetic counseling and be offered comprehensive ultrasound evaluation and diagnostic testing.”
- “If an enlarged nuchal translucency or an anomaly is identified on ultrasound examination, the patient should be offered genetic counseling and diagnostic testing for genetic conditions as well as a comprehensive ultrasound evaluation including detailed ultrasonography at 18–22 weeks of gestation to assess for structural abnormalities.”

The following recommendations and conclusions are based on limited and inconsistent scientific evidence (Level B):

- “The use of cell-free DNA screening as follow-up for patients with a screen positive serum analyte screening test result is an option for patients who want to avoid a diagnostic test. However, patients should be informed that this approach may delay definitive diagnosis and will fail to identify some fetuses with chromosomal abnormalities.”
- “In clinical situations of an isolated soft ultrasonographic marker (such as echogenic cardiac focus, choroid plexus cyst, pyelectasis, short humerus or femur length) where aneuploidy screening has not been performed, the patient should be counseled regarding the risk of aneuploidy associated with the finding and cell-free DNA, quad screen testing, or amniocentesis should be offered. If aneuploidy testing is performed and is low-risk, then no further risk assessment is needed. If more than one marker is identified, then genetic counseling, maternal–fetal medicine consultation, or both are recommended.”
- “No method of aneuploidy screening that includes a serum sample is as accurate in twin gestations as it is in singleton pregnancies; this information should be incorporated into pretest counseling for patients with multiple gestations.”
- “Cell-free DNA screening can be performed in twin pregnancies. Overall, performance of screening for trisomy 21 by cell-free DNA in twin pregnancies is encouraging, but the total number of reported affected cases is small. Given the small number of affected cases it is difficult to determine an accurate detection rate for trisomy 18 and 13.”
- “Because preimplantation genetic testing is not uniformly accurate, prenatal screening and prenatal diagnosis should be offered to all patients regardless of previous preimplantation genetic testing.”

The following recommendations and conclusions are based primarily on consensus and expert opinion (Level C):

- “The use of multiple serum screening approaches performed independently (eg, a first-trimester screening test followed by a quad screen as an unlinked test) is not recommended because it will result in an unacceptably high positive screening rate and could deliver contradictory risk estimates.”
- “In multifetal gestations, if a fetal demise, vanishing twin, or anomaly is identified in one fetus, there is a significant risk of an inaccurate test result if serum based aneuploidy screening or cell-free DNA is used. This information should be reviewed with the patient and diagnostic testing should be offered.”

CLINICAL POLICY

Genetic Testing Non-Invasive Prenatal Screening (NIPS)

- “Patients with unusual or multiple aneuploidies detected by cell-free DNA should be referred for genetic counseling and maternal–fetal medicine consultation.”

American College of Medical Genetics and Genomics (ACMG)

The American College of Medical Genetics and Genomics (2016) published a position statement on noninvasive prenatal screening (NIPS) for fetal aneuploidy. ACMG recommends:

- Informing all pregnant women that NIPS is the most sensitive screening option for traditionally screened aneuploidies (i.e., T13, T18, and T21).
- Referring patients to a trained genetics professional when an increased risk of aneuploidy is reported after NIPS.
- Offering diagnostic testing when a positive screening test result is reported after NIPS.
- Providing accurate, balanced, up-to-date information, at an appropriate literacy level, when a fetus is diagnosed with a chromosomal or genomic variation in an effort to educate prospective parents about the condition of concern. These materials should reflect the medical and psychosocial implications of the diagnosis.

ACMG recommended against using NIPS to screen for autosomal aneuploidies other than those involving chromosomes 13, 18, and 21.

The American College of Medical Genetics and Genomics (2009) published a practice guideline for screening for fetal aneuploidy and neural tube defects that recommended the following:

- First trimester screening (NT measurement, PAPP-A, and hCG) is an acceptable, effective approach for screening for fetal aneuploidy if a woman presents early in pregnancy (before 14 weeks' gestation).
- Women who decide to undergo first trimester screening and/or CVS should be offered MSAFP screening and/or an ultrasound for the detection of neural tube defects between 15 and 20 weeks' gestation.
- First trimester screening or second trimester screening can be used in multifetal pregnancies; however, women should be made aware of the limitations of screening in this setting.

National Society for Genetic Counselors (NSGC)

The National Society for Genetic Counselors adopted the following statement updated in 2021 supporting prenatal cell-free DNA (cfDNA) screening as an option for pregnant patients:

“The National Society of Genetic Counselors believes that all pregnant patients, regardless of aneuploidy risk, should have access to prenatal aneuploidy screening using cell-free DNA (cfDNA)*. Healthcare providers should present cfDNA screening for aneuploidy within the context of other available prenatal screening and diagnostic testing options. Included in this discussion should be the option of pursuing diagnostic testing as a first line approach or declining all screening/testing. Pretest counseling should also include a discussion of the individual patient’s values, preferences, and needs, as well as the benefits and limitations of cfDNA screening. Many factors influence cfDNA screening performance; therefore, it may not be appropriate for every clinical scenario. Additionally, some laboratories offer screening for conditions beyond common aneuploidies, so it is essential to consider the test’s positive predictive value, particularly when the prevalence of the disorder is low.”

CLINICAL POLICY

Genetic Testing Non-Invasive Prenatal Screening (NIPS)

“Patients who receive increased risk or inconclusive/atypical results should receive post-test genetic counseling with a knowledgeable healthcare provider, such as a genetic counselor. In such cases, confirmatory diagnostic testing may be indicated, and patients should be counseled that no irreversible actions should be taken based on the cfDNA screening alone.”

The American College of Obstetricians and Gynecologists (ACOG)

ACOG issued a practice advisory for the use of cell-free DNA to screen for single-gene disorders (February 2019, reaffirmed March 2020), which states the following:

“The continued innovation in cell-free technology combined with the desire for a maternal blood test to predict the risk for fetal genetic disorders during a pregnancy has broadened the application of cell-free DNA screening beyond aneuploidy to single-gene disorders. Examples of single-gene disorders include various skeletal dysplasias, sickle cell disease and cystic fibrosis. Although this technology is available clinically and marketed as a single-gene disorder prenatal screening option for obstetric care providers to consider in their practice, often in presence of advanced paternal age, there has not been sufficient data to provide information regarding accuracy and positive and negative predictive value in the general population. For this reason, single-gene cell-free DNA screening is not currently recommended in pregnancy.”

Society for Maternal Fetal Medicine (SMFM)

SMFM released a statement (2014) regarding maternal serum cell-free DNA screening in low risk women, which stated the following:

“At the present time, professional organizations including SMFM have recommended that NIPT is most appropriate for high-risk patients. The five high-risk criteria currently include maternal age 35 years or older at delivery, sonographic findings indicating an increased risk of aneuploidy, history of a prior pregnancy with a trisomy, positive screening results for aneuploidy, including first trimester, sequential, integrated, or quadruple screen, or parental balanced Robertsonian translocation with increased risk for trisomy 13 or 21. This recommendation has been based primarily on the more limited evidence regarding the utility of NIPT in low- or average-risk pregnant women, and validation studies that have generally been limited to high-risk populations. Understandably, there is a keen interest in performing the same type of validation studies in a low risk population.”

Coding Implications

This clinical policy references Current Procedural Terminology (CPT[®]). CPT[®] is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2021, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CLINICAL POLICY
Genetic Testing Non-Invasive Prenatal Screening (NIPS)

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed.	02/22	02/22

References

1. Gregg AR, Gross SJ, Best RG, et al. ACMG statement on noninvasive prenatal screening for fetal aneuploidy. *Genet Med.* 2013;15(5):395-398. doi:10.1038/gim.2013.29
2. Gregg AR, Skotko BG, Benkendorf JL, et al. Noninvasive prenatal screening for fetal aneuploidy, 2016 update: a position statement of the American College of Medical Genetics and Genomics. *Genet Med.* 2016;18(10):1056-1065. doi:10.1038/gim.2016.97
3. “Prenatal Cell-Free DNA Screening.” Position Statement from National Society of Genetic Counselors. <https://www.nsgc.org/Policy-Research-and-Publications/Position-Statements/Position-Statements/Post/prenatal-cell-free-dna-screening-1>. Released October 11, 2016. Revised April 2021.
4. SMFM Statement: Maternal serum cell-free DNA screening in low risk women. SMFM. <https://www.smfm.org/publications/157-smfm-statement-maternal-serum-cell-free-dna-screening-in-low-risk-women>. 2015.
5. American College of Obstetricians and Gynecologists’ Committee on Practice Bulletins—Obstetrics; Committee on Genetics; Society for Maternal-Fetal Medicine. Screening for Fetal Chromosomal Abnormalities: ACOG Practice Bulletin, Number 226. *Obstet Gynecol.* 2020;136(448-e69). doi:10.1097/AOG.0000000000004084
6. Driscoll DA, Gross SJ; Professional Practice Guidelines Committee. Screening for fetal aneuploidy and neural tube defects. *Genet Med.* 2009;11(11):818-821. doi:10.1097/GIM.0b013e3181bb267b
7. Wilson KL, Czerwinski JL, Hoskovec JM, et al. NSGC practice guideline: prenatal screening and diagnostic testing options for chromosome aneuploidy. *J Genet Couns.* 2013;22(1):4-15. doi:10.1007/s10897-012-9545-3
8. “Cell-free DNA to Screen for Single-Gene Disorders”. Practice Advisory from The American College of Obstetricians and Gynecologists. <https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2019/02/cell-free-dna-to-screen-for-single-gene-disorders> Published February 2019. Reaffirmed March 2020.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

CLINICAL POLICY

Genetic Testing Non-Invasive Prenatal Screening (NIPS)

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of member/enrollees. This clinical policy is not intended to recommend treatment for member/enrollees. Member/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, member/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, member/enrollees and their representatives agree to be bound by such terms and conditions by providing services to member/enrollees and/or submitting claims for payment for such services.

Note: For Medicaid member/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare member/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

©2016 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene[®] and Centene Corporation[®] are registered trademarks exclusively owned by Centene Corporation.