OH.CLI.1381 Noninvasive Prenatal Testing

Effective Date:	May 10, 2024	Accountable Dept.:	Medicaid Clinical Delivery Experience 10585
Last Reviewed Date:	February 15, 2024		

Summary of Changes:

Added additional codes beyond 81510. Added Brahms PIGF plus KRYPTOR information on p. 10. Added Medical Alternatives on p. 14. Added EPSDT information p. 9 4.A. Updated references.

Scope:

This policy applies to all physical and behavioral health prior authorization requests received by Humana Healthy Horizons™ in Ohio.

Policy:

Humana Healthy Horizons™ in Ohio use established criteria guidelines to make medical necessity decisions on a case-by-case basis, based on the information provided on the member's health status.

For the following Noninvasive Prenatal Testing related HCPCS Code, 81510, Humana Healthy Horizons™ in Ohio uses the below coverage determination criteria.

Providers may submit authorization request(s) through the provider portal.

Providers may access physical and behavioral clinical coverage policies and medical necessity criteria at the below links.

Physical Health:

www.humana.com/provider/medical-resources/ohio-medicaid/physical-health-clinical-coverage-policies

Behavioral Health:

www.humana.com/provider/medical-resources/ohio-medicaid/behavioral-health-clinical-coverage-policies

Members may request a copy of the medical necessity criteria by calling member services at 877-856-5702 (TTY:711), Monday-Friday, 7AM to 8PM EST.

Providers may also request a copy of the medical necessity criteria by calling provider services at 877-856-5707 (TTY:711), Monday-Friday, 7AM to 8PM EST or emailing the request to OHMCDUM@humana.com.

Description:

CPT® Code(s)	Description	Comments
76376	3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; not requiring image postprocessing on an independent workstation	Not covered if used to report routine pregnancy ultrasound
76377	3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality with image postprocessing under concurrent supervision; requiring image postprocessing on an independent workstation	Not covered if used to report routine pregnancy ultrasound
76801	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, first trimester (< 14 weeks 0 days), transabdominal approach; single or first gestation	
76802	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, first trimester (< 14 weeks 0 days), transabdominal approach; each additional gestation (List separately in addition to code for primary procedure)	
76811	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation plus detailed fetal anatomic examination, transabdominal approach; single or first gestation	Not covered if used to report first trimester ultrasound assessment of the nasal bone
76812	Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation plus detailed fetal anatomic examination, transabdominal approach; each additional gestation (List separately in addition to code for primary procedure)	Not covered if used to report first trimester ultrasound assessment of the nasal bone

76813	Ultrasound, pregnant uterus, real time with image documentation, first trimester fetal nuchal translucency measurement, transabdominal or transvaginal approach; single or first gestation	
76814	Ultrasound, pregnant uterus, real time with image documentation, first trimester fetal nuchal translucency measurement, transabdominal or transvaginal approach; each additional gestation (List separately in addition to code for primary procedure)	
76815	Ultrasound, pregnant uterus, real time with image documentation, limited (eg, fetal heart beat, placental location, fetal position and/or qualitative amniotic fluid volume), 1 or more fetuses	
76816	Ultrasound, pregnant uterus, real time with image documentation, follow-up (eg, re-evaluation of fetal size by measuring standard growth parameters and amniotic fluid volume, re-evaluation of organ system(s) suspected or confirmed to be abnormal on a previous scan), transabdominal approach, per fetus	
76999	Unlisted ultrasound procedure (eg, diagnostic, interventional)	Not covered if used to report routine pregnancy ultrasound outlined in Coverage Limitations section
81420	Fetal chromosomal aneuploidy (eg, trisomy 21, monosomy X) genomic sequence analysis panel, circulating cell-free fetal DNA in maternal blood, must include analysis of chromosomes 13, 18, and 21	Not Covered if used to report any test outlined in Coverage Limitations section
81422	Fetal chromosomal microdeletion(s) genomic sequence analysis (eg, DiGeorge syndrome, Cri-du-chat syndrome), circulating cell-free fetal DNA in maternal blood	

81479	Unlisted molecular pathology procedure	Not Covered if used to report any test outlined in Coverage Limitations section
81507	Fetal aneuploidy (trisomy 21, 18, and 13) DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy	
81508	Fetal congenital abnormalities, biochemical assays of two proteins (PAPP-A, hCG [any form]), utilizing maternal serum, algorithm reported as a risk score	Individual serum levels reported with multianalyte assays with algorithmic analysis (MAAA) for fetal congenital anomalies are not separately reimbursable
81509	Fetal congenital abnormalities, biochemical assays of three proteins (PAPP-A, hCG [any form], DIA), utilizing maternal serum, algorithm reported as a risk score	Individual serum levels reported with multianalyte assays with algorithmic analysis (MAAA) for fetal congenital anomalies are not separately reimbursable
81510	Fetal congenital abnormalities, biochemical assays of three analytes (AFP, uE3, hCG [any form]), utilizing maternal serum, algorithm reported as a risk score	Individual serum levels reported with multianalyte assays with algorithmic analysis (MAAA) for fetal congenital anomalies are not separately reimbursable

81511	Fetal congenital abnormalities, biochemical assays of four analytes (AFP, uE3, hCG [any form], DIA) utilizing maternal serum, algorithm reported as a risk score (may include additional results from previous biochemical testing)	Individual serum levels reported with multianalyte assays with algorithmic analysis (MAAA) for fetal congenital anomalies are not separately reimbursable
81512	Fetal congenital abnormalities, biochemical assays of five analytes (AFP, uE3, total hCG, hyperglycosylated hCG, DIA) utilizing maternal serum, algorithm reported as a risk score	Individual serum levels reported with multianalyte assays with algorithmic analysis (MAAA) for fetal congenital anomalies are not separately reimbursable
81599	Unlisted multianalyte assay with algorithmic analysis	Fetal gender testing is considered integral to the panel of standard blood tests that are taken when assessing for sex chromosome aneuploidies and not separately reimbursable
82105	Alpha-fetoprotein (AFP); serum	Individual serum levels (eg, AFP, hCG [duplicate form], inhibin-A, PAPP-A, uE3) reported with multianalyte assays with algorithmic analysis (MAAA) for fetal congenital anomalies (eg, 81508, 81509, 81510, 81511, 81512) are not separately reimbursable

82106	Alpha-fetoprotein (AFP); amniotic fluid	Individual serum levels (eg, AFP, hCG [duplicate form], inhibin-A, PAPP-A, uE3) reported with multianalyte assays with algorithmic analysis (MAAA) for fetal congenital anomalies (eg, 81508, 81509, 81510, 81511, 81512) are not separately reimbursable
82677	Estriol	Individual serum levels (eg, AFP, hCG [duplicate form], inhibin-A, PAPP-A, uE3) reported with multianalyte assays with algorithmic analysis (MAAA) for fetal congenital anomalies (eg, 81508, 81509, 81510, 81511, 81512) are not separately reimbursable
84163	Pregnancy-associated plasma protein-A (PAPP-A)	Individual serum levels (eg, AFP, hCG [duplicate form], inhibin-A, PAPP-A, uE3) reported with multianalyte assays with algorithmic analysis (MAAA) for fetal congenital anomalies (eg, 81508, 81509, 81510, 81511, 81512) are not separately reimbursable

84702	Gonadotropin, chorionic (hCG); quantitative	Individual serum levels (eg, AFP, hCG [duplicate form], inhibin-A, PAPP-A, uE3) reported with multianalyte assays with algorithmic analysis (MAAA) for fetal congenital anomalies (eg, 81508, 81509, 81510, 81511, 81512) are not separately reimbursable
84703	Gonadotropin, chorionic (hCG); qualitative	Individual serum levels (eg, AFP, hCG [duplicate form], inhibin-A, PAPP-A, uE3) reported with multianalyte assays with algorithmic analysis (MAAA) for fetal congenital anomalies (eg, 81508, 81509, 81510, 81511, 81512) are not separately reimbursable
84704	Gonadotropin, chorionic (hCG); free beta chain	Individual serum levels (eg, AFP, hCG [duplicate form], inhibin-A, PAPP-A, uE3) reported with multianalyte assays with algorithmic analysis (MAAA) for fetal congenital anomalies (eg, 81508, 81509, 81510, 81511, 81512) are not separately reimbursable

84999	Unlisted chemistry procedure	Not Covered if used to report any test outlined in Coverage Limitations section
86336	Inhibin A	Individual serum levels (eg, AFP, hCG [duplicate form], inhibin-A, PAPP-A, uE3) reported with multianalyte assays with algorithmic analysis (MAAA) for fetal congenital anomalies (eg, 81508, 81509, 81510, 81511, 81512) are not separately reimbursable
0060U	Twin zygosity, genomic targeted sequence analysis of chromosome 2, using circulating cell-free fetal DNA in maternal blood	
0243U	Obstetrics (preeclampsia), biochemical assay of placental-growth factor, time-resolved fluorescence immunoassay, maternal serum, predictive algorithm reported as a risk score for preeclampsia	
0247U	Obstetrics (preterm birth), insulin-like growth factor–binding protein 4 (IBP4), sex hormone– binding globulin (SHBG), quantitative measurement by LC-MS/MS, utilizing maternal serum, combined with clinical data, reported as predictive-risk stratification for spontaneous preterm birth	
0327U	Fetal aneuploidy (trisomy 13, 18, and 21), DNA sequence analysis of selected regions using maternal plasma, algorithm reported as a risk score for each trisomy, includes sex reporting, if performed	

0341U	Fetal aneuploidy DNA sequencing comparative analysis, fetal DNA from products of conception, reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplication, mosaicism, and segmental aneuploid	
0390U	Obstetrics (preeclampsia), kinase insert domain receptor (KDR), Endoglin (ENG), and retinol-binding protein 4 (RBP4), by immunoassay, serum, algorithm reported as a risk score	

First trimester noninvasive prenatal testing (NIPT) is usually done between 11 to 14 gestational weeks to check for chromosomal abnormalities and can be completed in a single combined test or in a multistep process. A blood sample, taken from a pregnant woman, is analyzed for free ß-human chorionic gonadotropin (hCG) and pregnancy-associated plasma protein A (PAPP-A) levels. In addition, an ultrasound may be performed to measure nuchal translucency (thickness of the space between the back of the fetal neck and overlying skin). The results of these tests (and consideration of maternal age) are used to calculate specific risk for fetal chromosomal disorders. If these results demonstrate a significant probability of a fetal abnormality, invasive testing such as amniocentesis or chorionic villus sampling (CVS), may be performed.

Second trimester NIPT may include maternal serum testing for alpha-fetoprotein (AFP) levels to check for neural tube defects. This test is generally performed between 16 to 18 weeks of pregnancy. Multiple marker screening (also referred to as triple screen or quad screen) may be performed during the second trimester and includes testing maternal serum levels of AFP, hCG, unconjugated estriol (uE3) and/or inhibin-A to combine screening for chromosome abnormalities and neural tube defects. This panel is usually done around 15 to 20 gestational weeks when abnormal levels could indicate that further evaluation may be needed with invasive testing.

For **NIPT for Zika virus**, please refer to the Centers for Disease Control and Prevention (CDC) for the current guidelines.

Prenatal cell-free deoxyribonucleic acid (cfDNA) noninvasive screening tests are laboratory studies that examine changes in human DNA, chromosomes, genes or gene products (such as proteins) of cfDNA sequences that are isolated in the maternal plasma during pregnancy.
Examples include:

- Genome testing (e.g., MaterniT Genome, PreSeek, Resura, VERAgene, Vistara) analyzes fetal chromosomes for extra or missing parts of chromosomes or other whole chromosome changes. (Refer to Coverage Limitations section)
- Sequencing-based trisomy tests for fetal aneuploidy detect chromosome abnormalities. These advanced screening tests are used to detect one or more of the following:
  - Aneuploidies involving chromosomes 13, 18 and 21
  - Aneuploidies involving sex chromosomes (Refer to Coverage Limitations section)
  - Microdeletions/microduplications (Refer to Coverage Limitations section)
  - Screening for single gene variants (Refer to Coverage Limitations section)

- Screening for twin zygosity (Refer to Coverage Limitations section)

Cell-based NIPT that isolates fetal DNA from rare fetal trophoblast cells, circulating in maternal blood, has also been proposed for prenatal screening and diagnosis. This method of testing is purported to detect fetal chromosomal aneuploidy and chromosomal deletions/duplications commonly linked to genetic conditions, as early as 8 weeks gestation. (Refer to Coverage Limitations section)

Pre-eclampsia is a disorder of pregnancy characterized by the onset of high blood pressure and protein in the urine which typically begins after the twentieth week of pregnancy. Monitoring of maternal blood pressure is routinely used as a screening tool to evaluate for pre-eclampsia during prenatal visits. Available tests include, but not may not be limited to:

- BRAHMS PIGF plus KRYPTOR (an automated immunofluorescent assay for quantitative placental growth factor [PlGF] in plasma) is to be used in conjunction with the BRAHMS sFlt-1 KRYPTOR (an automated immunofluorescent assay for quantitative soluble fms-like tyrosine kinase-1 [sFlt-1], also known as VEGF receptor-1) along with other laboratory tests and clinical assessments to assess pregnant women (singleton pregnancies 23 to 35 weeks gestation) who have been hospitalized for hypertensive disorders of pregnancy (preeclampsia, chronic hypertension with or without superimposed preeclampsia or gestational hypertension) to purportedly aid in the risk for progression to preeclampsia with severe features. (Refer to Coverage Limitations section)
- Mirvie RNA platform uses RNA analyses and machine-learning to identify preeclampsia risk before the clinical presentation of symptoms38 (Refer to Coverage Limitations section)
- PlGF 1-2-3 Assay is a biochemical assay of PlGF, time-resolved fluorescence immunoassay, maternal serum and predictive algorithm that is used as a risk score for preeclampsia42-(Refer to Coverage Limitations section)
- PEPredictDx evaluates a serum specimen for three biomarkers (kinase insert domain receptor, endoglin and retinol-binding protein 4) using immunoassay technique that reports a risk score for preeclampsia PE as early as 11 weeks in pregnancy (Refer to Coverage Limitations section)

Preterm birth (delivery prior to 37 weeks gestation) occurs in approximately 10% of pregnancies in the United States. The PreTRM test is purported to predict spontaneous preterm birth as early as 19 weeks of gestation in asymptomatic, singleton pregnancies by analyzing multiple maternal serum proteins and other clinical data. (Refer to Coverage Limitations section)

Ultrasonography (ultrasound) is commonly used in the second trimester of pregnancy to monitor fetal development and maternal well-being. Two-dimensional (2D) ultrasound may be performed to determine gestational age, number of fetuses, fetal cardiac activity and placental location. In addition, many congenital structural anomalies and significant abnormalities in fetal growth may be identified.

Three-dimensional (3D) ultrasound uses special probes and software to acquire a 2D static display of 3D data. Although the indications for its use have not been well defined, 3D technology can purportedly reduce scanning time and better demonstrate abnormalities previously detected with 2D sonography including facial

abnormalities and neural tube defects. Four-dimensional (4D) ultrasound (also called dynamic 3D sonography) refers to 3D images that can be viewed in real-time. Five-dimensional (5D) ultrasound (also known as high-definition live) includes a software package on the ultrasound unit that purportedly enhances facial skin tone and depth perception through lighting techniques which results in high-resolution images. (Refer to Coverage Limitations section)

Fetal magnetocardiography is a noninvasive technique for recording magnetic fields generated by the electrical activity of the fetal heart. It is a passive recording technique utilizing high sensitivity Superconducting Quantum Interference Device (SQUID) sensors. These sensors amplify signals that are naturally occurring, yet weak. (Refer to Coverage Limitations section)

Procedures:

1. The Plan covers all benefits and services required in OAC chapter 5160 in the amount, duration, and scope for the same services furnished to members under the fee-for-service (FFS) Medicaid.
2. When applying coverage policies and medical necessity criteria, the Plan will consider individual member needs and an assessment of the local delivery system.
3. The Plan uses the following hierarchy of guidelines to review for medical necessity:
   - 3.1 Federal or state regulation, including medical criteria published in the Ohio Administrative Code, Chapter 5160.
   - 3.2 Nationally accepted evidence based clinical guidelines: MCG (formerly Milliman Care Guidelines), American Society of Addiction Medicine (ASAM) Level of Care Adolescent Guidelines and American Society of Addiction Medicine (ASAM) Patient Placement Criteria (ASAM Admission Guidelines).
   - 3.3 Humana Healthy Horizons™ in Ohio clinical policies
   - 3.4 In the case of no guidance from above, additional information that the clinical reviewer will consider, when available, includes;
     - 3.4.1 Clinical practice guidelines and reports from peer reviewed medical literature, from which a higher level of evidence and study quality is more strongly considered in determinations;
     - 3.4.2 Professional standards for safety and effectiveness recognized in the US for diagnosis, care, or treatment;
     - 3.4.3 Medical association publications;
     - 3.4.4 Government-funded or independent entities that assess and report on clinical care; Decision and technology such as Agency for Healthcare Research and Quality (AHRQ), Hayes Technology Assessment, Up-To-Date, Cochrane Reviews, National Institute for Health and Care Excellence (NICE), etc.;
     - 3.4.5 Published expert opinions;
     - 3.4.6 Opinion of health professionals in the area of specialty involved;
     - 3.4.7 Opinion of attending provider;
   - 3.5 Dental: DentaQuest coverage guidelines and policies
     Dental Coverage - Humana Healthy Horizons in Ohio | Humana
   - 3.6 Vision: EyeMed coverage guidelines and policies

Vision Care - Humana Healthy Horizons - Ohio Medicaid | Humana

4. When the plan receives a request for a primary code that requires prior authorization, and the primary code is denied for lack of medical necessity, any related secondary codes submitted on the authorization request will be denied based on lack of medical necessity. When a primary code is approved, related secondary codes requiring prior authorization will be reviewed individually for medical necessity determination.

Only practitioners with the appropriate clinical expertise can make the decision to deny or reduce the amount, duration or scope of the services being requested.

Humana Healthy Horizons™ in Ohio requires prior authorization on all "Miscellaneous," "Unlisted," and "Not Otherwise Specified" codes. Medical necessity documentation and rationale must be submitted with the prior authorization request. The Medical Director adheres to the above process to align criteria based on the information provided on the member's health status.

Coverage Determination Criteria:

Any mandates from the State of Ohio for noninvasive prenatal screening take precedence over this medical coverage policy.

Humana Healthy Horizons™ in Ohio members may be eligible under the Plan for NIPT for chromosomal abnormalities using ONE of the following:

- Multiple marker screening (inhibin-A, free or total hCG, PAPP-A and/or uE3 levels) with or without 2D ultrasonography* (measurement of nuchal translucency); OR
- Sequencing-based tests in single or twin gestation pregnancies, using cfDNA to screen for fetal trisomy aneuploidy 13, 18 and 21 (81420, 81507, 0327U)

Humana Healthy Horizons™ in Ohio members may be eligible under the Plan for NIPT for neural tube defects performed in the second trimester using 2D ultrasonography* (e.g., screening for fetal anomalies) with or without maternal serum AFP.

Coverage Limitations:

Humana Healthy Horizons™ in Ohio members may NOT be eligible under the Plan for the following NIPT for any indication:

- 3D, 4D or 5D ultrasonography
- Fetal magnetocardiography
- First trimester ultrasound assessment of the nasal bone

These are considered experimental/investigational as they are not identified as widely used and generally accepted for the proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana Healthy Horizons™ in Ohio members may NOT be eligible under the Plan for cfDNA sequence-based prenatal screening for fetal trisomy aneuploidy (13, 18 and 21) (e.g., 81420, 81507, 0327U) for any indications other than those listed above in the coverage determination section including, but may not be limited to, the following:

- Duplicative or repeat (during the same pregnancy) testing for low fetal fraction or test failure); OR
- Duplicative or repeat NIPT testing for chromosomal abnormalities (e.g., multiple marker screening with or without 2D ultrasound for nuchal translucency) has been performed during the current pregnancy; OR
- Expanded testing of microdeletion/microduplication analysis (e.g., DiGeorge syndrome, Prader-Willi syndrome) (81422); OR
- Screening for monogenic disorders (e.g., beta thalassemia, hemophilia, sickle cell anemia); OR
- Screening for sex chromosome aneuploidies; OR
- Screening for single gene variants (e.g., known familial variant); OR
- Screening for trisomies other than 13, 18 and 21; OR
- Screening for twin zygosity (0060U); OR
- Testing prior to 10 weeks gestation; OR
- Triplet or higher gestation pregnancies

These are considered experimental/investigational as it is not identified as widely used and generally accepted for any other proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana Healthy Horizons™ in Ohio members may NOT be eligible under the Plan for the following NIPT for any indication:

- BRAHMS SFlt-1/ PlGF KRYPTOR Test System; OR
- Luna Prenatal Test (0341U); OR
- MaterniT GENOME; OR
- Mirvie RNA platform; OR
- PlGF 1-2-3 assay (0243U); OR
- PEPredictDx (0390U); OR
- PreSeek; OR
- PreTRM (0247U); OR
- Resura; OR
- VERAgene; OR
- Vistara

These are considered experimental/investigational as they are not identified as widely used and generally accepted for the proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana Healthy Horizons™ in Ohio members may NOT be eligible under the Plan for NIPT for any indications other than those listed above, including the detection of genetic susceptibility to adult-onset/late-onset disorders. This may be considered experimental/investigational and not clinically proven.

Fetal sex testing is considered integral to the panel of standard blood tests and is not separately reimbursable.

Individual serum levels (e.g., AFP, hCG [duplicate form], inhibin-A, PAPP-A, uE3) reported with multianalyte assays with algorithmic analysis (MAAA) for fetal congenital anomalies (81508, 81509, 81510, 81511, 81512) are not separately reimbursable.

Background:

Additional information about fetal chromosomal abnormalities may be found from the following websites:

- American College of Medical Genetics and Genomics
- American College of Obstetricians and Gynecologists
- National Library of Medicine

Medical Alternatives:

Alternatives to screening tests for preeclampsia include, but may not be limited to, the following:

- Fetal biophysical profile
- Urine analysis

Alternatives to PreTRM include, but may not be limited to, the following:

- Fetal fibronectin testing
- Transvaginal ultrasound exam

Physician consultation is advised to make an informed decision based on an individual's health needs.

Humana may offer a disease management program for this condition. The member may call the number on his/her identification card to ask about our programs to help manage his/her care.

Definitions:

1. Adverse Benefit Determination – As defined in OAC rule 5160-26-01, is a managed care entity's (MCEs):
    (1) Denial or limited authorization of a requested service, including determinations based on the type or level of service, requirements for medical necessity, appropriateness, setting, or effectiveness of a covered benefit.
    (2) Reduction, suspension, or termination or services prior to the member receiving the services previously authorized by the MCE;
    (3) Failure to provide services in a timely manner as specified in rule 5160-26-03.1 of the Administrative Code;
    (4) Failure to act within the resolution timeframes specified in rule 5160-26-08.4 of the Administrative Code;
    (5) Denial of a member's request to dispute a financial liability, including cost sharing, copayments, premiums, deductibles, coinsurance, and other member financial liabilities, if applicable; or
    (6) Denial, in whole or part, of payment for a service. A denial, in whole or in part, of a payment for a service solely because the claim does not meet the definition of a "clean claim" as defined in 42 C.F.R. 447.45(b) (October 1, 2021) is not an adverse benefit determination)
2. American Society of Addiction Medicine (ASAM) – a professional medical society representing over 7,000 physicians, clinicians, and associated professionals in the field of addiction medicine. ASAM produces a comprehensive set of standards for placement, continued stay, transfer or discharge of patients with addiction and co-occurring conditions used by clinical staff to determine whether to refer a service request for physician review based upon the clinical information submitted by the requestor.

3. MCG® – are nationally recognized guidelines used by clinical staff to determine whether to refer a service request for physician review based upon the clinical information submitted by the requestor.
4. Medically Necessary or Medical Necessity – Has the same meaning as OAC rule 5160-1-01:
    A. Medical necessity for individuals covered by early and periodic screening, diagnosis, and treatment (EPSDT) is criteria of coverage for procedures, items, or services that prevent, diagnose, evaluate, correct, ameliorate, or treat an adverse health condition such as an illness, injury, disease or its symptoms, emotional or behavioral dysfunction, intellectual deficit, cognitive impairment, or developmental disability. Providers can request prior authorization to exceed coverage or benefit limits for members under the age of 21.
    B. Medical necessity for individuals not covered by EPSDT is criteria of coverage for procedures, items, or services that prevent, diagnose, evaluate or treat an adverse health condition such as an illness, injury, disease or its symptoms, emotional or behavioral dysfunction, intellectual deficit, cognitive impairment, or developmental disability and without which the person can be expected to suffer prolonged, increased, or new morbidity; impairment of function; dysfunction of a body organ or part; or significant pain and discomfort.
    C. Conditions of medical necessity for a procedure, item, or service are met all the following apply:
        a. It meets generally accepted standards of medical practice;
        b. It is clinically appropriate in its type, frequency, extent, duration, and delivery setting;
        c. It is appropriate to the adverse health condition for which it is provided and is expected to produce the desired outcome;
        d. It is the lowest cost alternative that effectively addresses and treats the medical problem;
        e. It provides unique, essential, and appropriate information if it is used for diagnostic purposes; and
        f. It is not provided primarily for the economic benefit of the provider nor for the sole convenience of the provider or anyone else other than the recipient.
    D. The fact that a physician, dentist, or other licensed practitioner renders, prescribes, orders, certifies, recommends, approves, or submits a claim for a procedure, item, or service does not, in and of itself make the procedure, item, or service medically necessary and does not guarantee payment.
    E. The definition and conditions of medical necessity articulated in this rule apply throughout the entire medicaid program. More specific criteria regarding the conditions of medical necessity for particular categories of service may be set forth within the Ohio department of medicaid (ODM) coverage policies or rules.

References:

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2. American College of Medical Genetics and Genomics (ACMG). Laboratory screening and diagnosis of open neural tube defects, 2019 revision: a technical standard of the American College of Medical Genetics and Genomics (ACMG). https://www.acmg.net. Published November 2019. Accessed November 26, 2023.

3. American College of Medical Genetics and Genomics (ACMG). Noninvasive prenatal screening for fetal aneuploidy, 2016 update: a position statement of the American College of Medical Genetics and Genomics. https://www.acmg.net. Published October 2016. Accessed November 26, 2023.

4. American College of Medical Genetics and Genomics (ACMG). Noninvasive prenatal screening (NIPS) for fetal chromosome abnormalities in a general-risk population: an evidence-based clinical guideline of the American College of Medical Genetics and Genomics (ACMG). https://www.acmg.net. Published December 2022. Accessed November 28, 2023.

5. American College of Medical Genetics and Genomics (ACMG). Systematic evidence-based review: the application of noninvasive prenatal screening using cell-free DNA in general-risk pregnancies. https://www.acmg.net. Published May 2022. Accessed November 26, 2023.

6. American College of Obstetricians and Gynecologists (ACOG). Practice Advisory. Cell-free DNA to screen for single-gene disorders. https://www.acog.org. Published February 2019. Updated October 2022. Accessed November 26, 2023.

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15. ECRI Institute. ECRIgene Evidence Report. Panorama cell-free fetal DNA test (Natera, Inc.) for prenatal screening. https://www.ecri.org. Published May 2017. Accessed November 18, 2023.

16. ECRI Institute. ECRIgene Evidence Report. Verifi cell-free fetal DNA test (Illumina, Inc.) for prenatal screening. https://www.ecri.org. Published March 30, 2018. Accessed November 18, 2023.

17. ECRI Institute. Genetic Test Assessment. Cell-free DNA tests for prenatal screening in twin pregnancies. https://www.ecri.org. Published September 9, 2022. Accessed November 18, 2023.

18. ECRI Institute. Hotline Response (ARCHIVED). Prenatal ultrasound for monitoring routine pregnancy. https://www.ecri.org. Published April 17, 2017. Accessed November 18, 2023.

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Version Control:

11/28/2023 - Code 81510 from Humana Healthy Horizons™ in Ohio policies H1120, H1309, H1310, H1311 and H1312 was placed into this new policy (H1381) and coverage criteria was written for determining medical necessity. - M. Joyce Medicaid Clinical Delivery Experience.

2/15/2024 Review complete. Updates added, additional codes beyond 81510, Brahms PIGF plus KRYPTOR information on p. 10., Medical Alternatives on p. 14., EPSDT information p. 9 4.A., and updated references. - J. Spink Medicaid Clinical Delivery Experience.