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State of Nevada

Department of Health and Human Services

Chromosome Microarray Analysis

Division of Health Care Financing & Policy

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Helping people. It's who we are and what we do.

Objectives

- Educate MCAC on prenatal testing and which are currently covered by Nevada Medicaid
- Discuss Chromosome Microarray Analysis diagnostic test (CMA)
- Discuss Strengths, Weaknesses, Opportunities, and Threats (SWOT) of the CMA diagnostic test
- Review Fiscal Impact
- Recommendations

Prenatal Testing

Two kinds of prenatal genetic tests – Screening & Diagnostic

OPTIONAL		Medicaid Coverage*
Screening	**Identifies the chance that a fetus has an aneuploidy (abnormal number of chromosomes) and a few additional disorders. (+) higher chance, (-) lower chance, can be followed by diagnostic test.**	
1st Trimester Screening	Conducted via blood panel & ultrasound exam. Screens for Down Syndrome & Trisomy 18	√
2nd Trimester Screening "Quad Screen"	Blood test & ultrasound exam. Screens for Down Syndrome, Trisomy 18, and neuro tube defects.	√
Cell-free DNA Screening (NIPS = Non-Invasive Prenatal Screening)	Blood test. Screens for Down Syndrome, Trisomy 13 & 18, and sex chromosome abnormalities. Conducted 1st trimester or beyond.	
Diagnostic	**Determines with certainty whether a fetus has an aneuploidy or specific inherited disorder. Mostly conducted during 1st or 2nd trimester.**	
Karyotype	Cells taken from the fetus or placenta obtained through amniocentesis or chorionic villus sampling (CVS) - slight chance of miscarriage. Detects missing, extra, or damaged chromosomes by taking a picture of the chromosomes and arranging them in order from largest to smallest.	√
Fluorescence In Situ Hybridization (FISH)	Cells taken from the fetus or placenta obtained through amniocentesis or chorionic villus sampling (CVS) - slight chance of miscarriage. Detects common aneuploidies involving chromosomes 13, 18, and 21 and the X and Y chromosomes. Positive test results are confirmed with a karyotype.	√
Chromosome Microarray Analysis (CMA)	Blood test. Detects chromosome problems, including aneuploidy, throughout the entire set of chromosomes. It can find some chromosome problems that karyotyping can miss.	
DNA	Blood test. Detects specific gene mutations. For example, parents are carriers of the Cystic Fibrosis gene and request prenatal diagnostic testing for this specific mutation.	

CVS – Down Syndrome, Trisomy 13 & 18, and other inherited disorders, but not neuro tube defects. 1st Trimester.
Amniocentesis – Down Syndrome, Trisomy 13 & 18, other inherited disorders, and certain types of neuro tube defects. 2nd Trimester or beyond.
*** Medicaid Coverage** – Can be covered under EPSDT with administrative exception when medically necessary for pregnant women under the age of 21 years old.

Chromosome Microarray Analysis (CMA)

Recommended by:

- American College of Obstetricians and Gynecologists (ACOG), Dec. 2016 Committee Opinion #682
- Society for Maternal-Fetal Medicine, May 2020, Consult Series #52

CMA diagnostic test should be covered for the following:

- Recipient with a structurally normal fetus (regardless of maternal age) who is undergoing invasive prenatal diagnostic testing, either fetal karyotyping or a CMA can be performed.
- Recipient with a fetus with one or more major structural abnormalities identified on ultrasonographic examination and who are undergoing invasive prenatal diagnosis. The test typically can replace the need for fetal karyotype testing.
- CMA of fetal tissue (e.g., amniotic fluid, placenta, or products of conception) is recommended in the evaluation of intrauterine fetal death or stillbirth when further cytogenetic analysis is desired because of the test's increased likelihood of obtaining results and improved detection of causative abnormalities.
- Recipient with a fetus with fetal growth restriction is detected and a fetal malformation, polyhydramnios, or both are also present, regardless of gestational age.
- Recipient with a fetus with unexplained isolated fetal growth restriction is diagnosed at less than 32 weeks of gestation.

SWOT

STRENGTHS	WEAKNESSES
• Blood test. Amniocentesis or CVS collection method not needed. No risk of miscarriage. • Ability to diagnose chromosomal abnormalities in fetus. • Greater resolution than conventional karyotyping. CMA acts like a microscope in being able to see deletions and duplications beyond what the karyotyping test can detect. • Can detect deletions and duplications down to a 50 – 100 kb level. • 1 in 60 women with a normal fetal ultrasound and a normal fetal karyotype have a chromosome abnormality identified by microarray analysis. • 1 in 17 women with fetal structural anomalies detected by ultrasound and a normal fetal karyotype had a chromosomal abnormality identified by microarray analysis. • Replaces the need for fetal karyotype testing when fetal structural abnormalities and/or stillbirth occur. • Can detect consanguinity and nonpaternity in some cases • Not recommended as a first-line test to evaluate first-trimester pregnancy loss. • Can replace prenatal karyotype testing from amniocentesis or CVS specimens, but this is not always the case.	• Does not detect every genetic disease or syndrome. • Does not detect autosomal-recessive disorders associated with single gene point mutations. • Provider may need to order a karyotype test due to the CMA test not being able to detect balanced rearrangements.
OPPORTUNITIES	**THREATS**
• Cover standard of care prenatal tests. • Allow parents to prepare for support services that newborn may need.	• Nevada Medicaid not covering standard of care prenatal tests that ACOG recommends being available to all pregnant women. • Providers may want DNA diagnostic testing also covered. • Providers could order both karyotype tests and a CMA test due to strengths and weaknesses of both types of tests.

Fiscal Impact

- Coverage of CPT codes 81228 or 81229 at 50% of Medicare rates.

SFY 20 – 21

Calculated Total Computable costs by State Fiscal Year	
SFY20	$ 0
SFY21	$ 17,341
Total	**$ 17,341**

Projected State General Fund cost by State Fiscal Year	
SFY20	$ 0
SFY21	$ 4,157
Total	**$ 4,157**

SFY 22 – 23

Calculated Total Computable costs by State Fiscal Year	
SFY22	$ 27,866
SFY23	$ 28,759
Total	**$ 56,625**

Projected State General Fund cost by State Fiscal Year	
SFY22	$ 8,395
SFY23	$ 8,431
Total	**$ 16,826**

Fiscal impact developed by utilizing the number of women who had a karyotype test. FFS = 10 in SFY 20.

Next Steps

- Dr. Ishan Azzam, Chief Medical Officer
  - Recommended the DHCFP follow the recommendations of ACOG and Society for Maternal-Fetal Medicine
- MSM Chapter 600 Public Workshop on 1/20/2021
- MCAC recommendations

Questions?

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