Chapter 246-680 WAC
PRENATAL TESTS—CONGENITAL AND HERITABLE DISORDERS

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WAC

WAC 246-680-001 Purpose. The purpose of this chapter is to establish standards for screening and diagnostic procedures for prenatal diagnosis of congenital disorders of the fetus under RCW 48.21.244, 48.44.344, and 48.46.375; and to establish criteria and timelines regarding the availability and use of prenatal tests for health care providers to share with pregnant women and couples as required under RCW 70.54.220.

[Statutory Authority: RCW 43.20.050, 70.54.220. WSR 03-11-031, § 246-680-001, filed 5/15/03, effective 6/15/03. Statutory Authority: RCW 43.20.050. WSR 91-02-051 (Order 124B), recodified as § 246-680-001, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 48.21.244, 48.44.344 and 48.46.375. WSR 90-02-094 (Order 024), § 248-106-001, filed 1/3/90, effective 2/3/90.]

WAC 246-680-010 Definitions. The definitions in this section apply throughout this chapter unless the context clearly requires otherwise:

(1) "Amniocentesis" means a procedure to remove a small amount of amniotic fluid from the uterus of a pregnant person in order to perform one or more of the following laboratory tests:

(a) Measure the level of alpha-fetoprotein;

(b) Measure the level of acetylcholinesterase;

(c) Cytogenetic studies on fetal cells including chromosome analysis, cytogenomic microarray analysis (CMA), and fluorescent in-situ hybridization (FISH);

(d) Biochemical studies on fetal cells or amniotic fluid;

(e) Deoxyribonucleic acid (DNA) studies on fetal cells for single gene disorders or fetal genotyping for isoimmunization studies; and

(f) Infectious disease studies.

(2) "Carrier screening" means a procedure to remove blood or other tissue from one or both parents in order to perform laboratory analysis to establish chromosome constitution or recessive or X-linked genetic carrier status of the parents.

(3) "Chorionic villus sampling" means a procedure to remove a small number of cells from the developing placenta, in order to perform one or more of the following laboratory tests:

(a) Cytogenetic studies on fetal cells including chromosome analysis, cytogenomic microarray analysis (CMA), and fluorescent in-situ hybridization (FISH);

(b) Biochemical studies on placental cells; and

(c) DNA studies on placental cells for single gene disorders.

(4) "Hepatitis B surface antigen (HBsAg) screening" means a procedure involving obtaining blood from a pregnant person to test for maternal hepatitis B infection.

(5) "Maternal serum marker screening" means a procedure involving obtaining blood from a pregnant person in order to measure through

laboratory tests the level of certain products that are associated with increased risks to the fetus or pregnancy such as alpha-fetoprotein, unconjugated estriol, human gonadotropin, inhibin, or PAPP-A.

(6) "Percutaneous umbilical blood sampling" means a procedure to obtain blood from the fetus, in order to perform one or more of the following laboratory tests:

(a) Cytogenetic studies on fetal cells including chromosome analysis, cytogenomic microarray analysis (CMA), and fluorescent in-situ hybridization (FISH);

(b) Viral titer studies;

(c) Fetal blood typing for isoimmunization studies;

(d) Prenatal diagnostic tests for hematological disorders;

(e) DNA studies on fetal cells for single gene disorders; and

(f) Biochemical studies on fetal blood.

(7) "Postprocedure genetic counseling" means individual counseling that may be part of another procedure, or service involving a health care provider and a pregnant person with or without other family members, to discuss the results of the prenatal tests done, any further testing or procedures available or referrals for further consultation or counseling.

(8) "Prenatal cell free DNA screening," sometimes called noninvasive prenatal screening, means drawing blood from the pregnant person to perform laboratory analysis on the cell free DNA circulating in the maternal blood stream.

(9) "Prenatal test" means any test or procedure to screen for or diagnose congenital or heritable disorders of a fetus.

(10) "Prenatal ultrasonography" means a procedure resulting in visualization of the uterus, the placenta, the fetus, and internal structures through use of sound waves.

(11) "Preprocedure genetic counseling" means individual counseling that may be part of another procedure, or service, involving a health care provider and a pregnant person with or without other family members, to assess and identify increased risks for congenital abnormalities or pregnancy complications, offer specific carrier screening or diagnostic tests, discuss the purposes, risks, accuracy, and limitations of a prenatal testing procedure, aid in decision making and to assist, when necessary, in obtaining the desired testing or procedure.

[Statutory Authority: RCW 43.20.050, 48.21.244, 48.44.344, 48.46.375 and 70.54.220. WSR 21-16-076, § 246-680-010, filed 7/30/21, effective 7/1/22. Statutory Authority: RCW 48.21.244, 48.44.344, 48.46.375, 70.54.220. WSR 03-11-031, § 246-680-010, filed 5/15/03, effective 6/15/03. Statutory Authority: RCW 43.20.050. WSR 91-02-051 (Order 124B), recodified as § 246-680-010, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 48.21.244, 48.44.344 and 48.46.375. WSR 90-02-094 (Order 024), § 248-106-010, filed 1/3/90, effective 2/3/90.]

WAC 246-680-020 Board of health standards for screening and diagnostic tests during pregnancy. (1) For the purpose of RCW 48.21.244, 48.44.344, and 48.46.375, the following are standards of medical necessity for insurers, health care service contractors, and health maintenance organizations to use when authorizing requests or claims for prenatal screening or diagnosis without the requirement of a case-by-case determination:

(a) Hepatitis B surface antigen (HBsAg) screening for all pregnant persons during the first trimester of pregnancy and the last trimester of pregnancy if the person is at high risk for hepatitis B infection.

(b) Group B strep screening through prenatal vaginorectal cultures at thirty-five to thirty-seven weeks of gestation. Pregnant persons who are currently colonized with Group B strep, or who have unknown Group B strep status should receive intrapartum treatment in accordance with the current standard of practice in order to reduce risk to the newborn.

(2) For the purpose of RCW 48.21.244, 48.44.344, and 48.46.375, the following are standards of medical necessity for insurers, health care service contractors, and health maintenance organizations to use when authorizing requests or claims for prenatal screening or diagnosis without the requirement of a case-by-case determination and including preprocedure and postprocedure genetic counseling:

(a) Maternal serum marker screening for all pregnant persons at the beginning of prenatal care if initiated before the twenty-second completed week of gestation.

(b) Prenatal ultrasonography:

(i) During the first trimester to establish viability, gestational age, and determine if singleton or multiple births; and

(ii) During second trimester for fetal morphology.

(c) Additional prenatal ultrasonography can be done at any time during a pregnancy if one or more of the following criteria are met:

(i) A person is undergoing amniocentesis, chorionic villus sampling, percutaneous umbilical blood sampling, or fetal tissue biopsy;

(ii) The results of a maternal serum marker screening or prenatal cell free DNA test indicate an increased risk to the fetus or pregnancy;

(iii) There is an increased risk of a congenital abnormality due to:

(A) An environmental exposure;

(B) A medical evaluation indicating the possibility of polyhydramnios, oligohydramnios, or poor or accelerated fetal growth; or

(C) A personal or family history of a congenital abnormality that is potentially detectable by prenatal ultrasound.

(d) Amniocentesis after fourteen weeks of gestation.

(e) Chorionic villus sampling between ten and fourteen weeks of gestation.

(f) Fetal diagnostic testing including:

(i) Cytogenetic studies on fetal cells including chromosome analysis, targeted cytogenomic microarray analysis (CMA), and fluorescent in-situ hybridization (FISH) for any person undergoing amniocentesis or chorionic villus sampling; and

(ii) DNA testing, biochemical testing, or testing for infectious diseases if medically indicated because of an abnormal ultrasound finding, intrauterine fetal demise, or known family history; and

(iii) Cytogenomic microarray analysis in the case of recurrent intrauterine fetal demise.

(g) Prenatal cell free DNA testing performed after nine weeks of gestation for the detection of aneuploidy including trisomy 21, 18, 13, or the sex chromosomes if the following criteria are met:

(i) There is documentation of preprocedure genetic counseling;

(ii) There is documentation of how postprocedure genetic counseling will be provided; and

(iii) Testing the sex chromosomes is not solely for the purposes of determining the sex of the fetus.

(h) Carrier screening at any time during the pregnancy for:

(i) Recessive or X-linked conditions if indicated by a positive family history; and

(ii) Any of the following conditions irrespective of family history:

(A) Alpha-thalassemia (HBA1/HBA2);
(B) Beta-thalassemia;
(C) Bloom syndrome;
(D) Canavan disease;
(E) Cystic fibrosis;
(F) Familial dysautonomia (IKBKAP);
(G) Fanconi anemia type C (FANCC);
(H) Gaucher disease (GBA);
(I) Mucolipidosis IV (MCOLN1); or
(J) Niemann-Pick disease (SMPD1);
(K) Sickle cell disease;
(L) Spinal muscular atrophy (SMN1);
(M) Tay-Sachs disease (HEXA);
(N) Fragile-X Syndrome.

(iii) Carrier screening under (h)(i) and (ii) of this subsection may be limited to once per lifetime.

(i) Molecular genetic or cytogenetic testing of parents to allow for definitive fetal testing, or parental testing to better inform results that are suggestive of, but do not identify a unifying diagnosis and when the results of the parental testing will be used to guide treatment, reproductive decisions, or care planning that would not otherwise be made.

(3) The following procedures are for use by insurers, health service contractors, and health maintenance organizations in determining medical necessity on a case-by-case basis to use when authorizing requests for claims for prenatal screening and diagnosis:

(a) Percutaneous umbilical cord blood sampling after fifteen weeks of gestation if one or more of the following criteria are met:

(i) A medical evaluation indicates rapid or specific submicroscopic chromosomal diagnosis or DNA diagnosis is required to predict prognosis for the fetus;

(ii) A medical evaluation indicates the possibility of a prenatally diagnosable fetal infection;

(iii) Fetal blood studies are medically indicated for isoimmunization studies or therapy;

(iv) Fetal blood is the only means to provide biochemical genetic diagnosis;

(v) Prenatal diagnosis of a hematological disorder is medically indicated.

(b) Prenatal tissue biopsy if the nature of the disorder in question indicates that fetal liver, skin, or other tissue biopsy is the only means to provide biochemical genetic diagnosis to protect the health of the pregnant person or predict the prognosis of the fetus.

(c) Cytogenomic microarray analysis (CMA) if medically indicated because of an abnormal ultrasound finding or known family history.

[Statutory Authority: RCW 43.20.050, 48.21.244, 48.44.344, 48.46.375 and 70.54.220. WSR 21-16-076, § 246-680-020, filed 7/30/21, effective 7/1/22. Statutory Authority: RCW 48.21.244, 48.44.344, 48.46.375. WSR 03-11-031, § 246-680-020, filed 5/15/03, effective 6/15/03. Statutory

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