

Chapter 246-680 WAC

PRENATAL TESTS—CONGENITAL AND HERITABLE DISORDERS

WAC

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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, 03-11-031, § 246-680-001, filed 5/15/03, effective 6/15/03. Statutory Authority: RCW 43.20.050, 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, 90-02-094 (Order 024), § 248-106-001, filed 1/3/90, effective 2/3/90.]

WAC 246-680-010 Definitions. For the purpose of this chapter, the following definitions apply:

(1) "Department" means the Washington state department of health.

(2) "Health care providers" means persons licensed or certified by the state of Washington under Title 18 RCW to provide prenatal care or to practice medicine and qualified genetic counselors.

(3) "Prenatal carrier testing" 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 genetic carrier status of the parents.

(4) "Prenatal test" means any test to predict congenital or heritable disorders that may harm or endanger the health, safety, or welfare of members of the public if improperly utilized and includes preprocedure and postprocedure genetic counseling, laboratory tests, and procedures as follows:

(a) Maternal serum marker screening is a procedure involving obtaining blood from a pregnant woman during the fifteenth to twenty-second week of gestation, in order to measure through laboratory tests the level of certain analytes that are associated with increased risks to the fetus or pregnancy such as alpha-fetoprotein, unconjugated estriol, human gonadotropin, inhibin, and/or PAPP-A.

(b) Maternal hepatitis B surface antigen (HBsAg) screening is a procedure involving obtaining blood from a pregnant woman during the first trimester of pregnancy to test for maternal hepatitis B infection. HBsAg screening should be repeated during the last trimester of pregnancy if a woman is at high risk for hepatitis B infection.

(c) Group B strep screening per vaginorectal culture at 35-37 weeks gestation is used to screen pregnant women for

Group B strep colonization. The swab culture specimen must be grown in selective broth media.

(d) Amniocentesis is a procedure performed after fourteen weeks of gestation to remove a small amount of amniotic fluid from the uterus of a pregnant woman, in order to perform one or more of the following laboratory tests:

- (i) Measure the level of alpha-fetoprotein;
- (ii) Measure the level of acetylcholinesterase;
- (iii) Cytogenetic studies on fetal cells including fluorescent in-situ hybridization (FISH) if indicated;
- (iv) Biochemical studies on fetal cells or amniotic fluid;
- (v) Deoxyribonucleic Acid (DNA) studies on fetal cells including fetal genotyping for isoimmunization studies; and
- (vi) Infectious disease studies.

(e) Chorionic villus sampling is a procedure performed from ten to twelve weeks of gestation to remove a small amount of cells from the developing placenta, in order to perform one or more of the following laboratory tests:

- (i) Cytogenetic studies on fetal cells including fluorescent in-situ hybridization (FISH) if indicated;
- (ii) Biochemical studies on fetal cells; and
- (iii) DNA studies on fetal cells.

(f) Percutaneous umbilical cord blood sampling is a procedure performed typically after fifteen weeks of gestation to obtain blood from the fetus, in order to perform one or more of the following laboratory tests:

- (i) Cytogenetic studies including fluorescent in-situ hybridization (FISH) if indicated;
- (ii) Viral titer studies;
- (iii) Fetal blood typing for isoimmunization studies;
- (iv) Prenatal diagnostic tests for hematological disorders;

(v) DNA studies on fetal cells;

(vi) Biochemical studies on fetal blood.

(g) Prenatal ultrasonography is a procedure performed at any time during pregnancy resulting in visualization of the uterus, the placenta, the fetus, and internal structures through use of sound waves.

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

(i) "Postprocedure genetic counseling" means, when test results are available, individual counseling, which may be part of another procedure or service, involving a health care provider or a qualified genetic counselor under the direction

of a physician and a pregnant woman with or without other family members, to discuss the results of the prenatal tests done, any further testing or procedures available and/or referrals for further consultation or counseling.

(j) "Qualified genetic counselor" means an individual eligible for certification or certified as defined by the American Board of Medical Genetics, Inc., or the American Board of Genetic Counseling.

[Statutory Authority: RCW 48.21.244, 48.44.344, 48.46.375, 70.54.220. 03-11-031, § 246-680-010, filed 5/15/03, effective 6/15/03. Statutory Authority: RCW 43.20.050. 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. 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 and/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 women beginning prenatal care before the twentieth completed week of gestation.

(b) Maternal hepatitis B surface antigen (HBsAg) screening for all pregnant women during the first trimester of pregnancy and the last trimester of pregnancy if the woman is at high risk for hepatitis B infection.

(c) Information about Group B strep should be provided to all pregnant women, including the risk to the newborn, if the woman is identified through screening as potentially colonized with Group B strep. Screening is done through prenatal vaginorectal cultures, although specific clinical indicators may preclude screening. Pregnant women 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.

(d) Prenatal ultrasonography if one or more of the following criteria are met:

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

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

(iii) A woman or the biological father of the fetus has a personal or family history of a congenital abnormality detectable by prenatal ultrasound;

(iv) An increased risk of a congenital abnormality is present due to an environmental exposure including maternal exposure to alcohol; or

(v) A medical evaluation indicates the possibility of polyhydramnios or oligohydramnios.

(e) Amniocentesis if one or more of the following criteria are met:

(i) A woman is thirty-five years of age or older at the time of delivery;

(ii) A woman or the biologic father of the fetus has a previous child or fetus with a chromosomal abnormality or other prenatally diagnosable disorder;

(iii) A woman or the biologic father of the fetus has a family history that includes birth defects or developmental delays;

(iv) A woman or the biologic father of the fetus is a carrier of a chromosomal rearrangement;

(v) A woman and/or the biologic father of the fetus are carriers of, or affected with, a prenatally diagnosable inherited disorder;

(vi) The results of a maternal serum marker screening test indicate an increased risk to the pregnancy or fetus;

(vii) A woman has a documented history of three or more miscarriages of unknown cause when circumstances prevent parental chromosomal testing;

(viii) There is an ultrasound diagnosis of fetal anomaly;

(ix) A medical evaluation indicates an increased risk of fetal infection;

(x) Fetal blood studies are indicated for isoimmunization studies or therapy.

(f) Chorionic villus sampling with preprocedure and postprocedure genetic counseling if one or more of the following criteria are met:

(i) A woman is thirty-five years of age or older at the time of delivery;

(ii) A woman or the biologic father of the fetus has a previous child or fetus with a chromosomal abnormality or other prenatally diagnosable inherited disorder;

(iii) A woman or the biologic father of the fetus is a carrier of a chromosomal rearrangement;

(iv) A woman or the biologic father of the fetus is a carrier of, or affected with, a prenatally diagnosable inherited disorder;

(v) A woman has a documented history of three or more miscarriages of unknown cause when circumstances prevent parental chromosomal testing; or

(vi) Fetal genotyping is indicated to determine risks for isoimmunization.

(g) Fluorescent in-situ hybridization (FISH) if a medical evaluation indicates a rapid or specific submicroscopic chromosomal diagnosis is required to predict the prognosis for the fetus.

(2) The board recommends the following additional procedures for use by insurers, health service contractors, and health maintenance organizations in determining medical necessity on a case-by-case basis:

(a) Percutaneous umbilical cord blood sampling with preprocedure and postprocedure genetic counseling 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 mother or predict the prognosis of the fetus.

[Statutory Authority: RCW 48.21.244, 48.44.344, 48.46.375. 03-11-031, § 246-680-020, filed 5/15/03, effective 6/15/03. Statutory Authority: RCW 43.20.050. 91-02-051 (Order 124B), recodified as § 246-680-020, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 48.21.244, 48.44.344 and 48.46.375. 90-02-094 (Order 024), § 248-106-020, filed 1/3/90, effective 2/3/90.]