## (Effective until July 1, 2022)

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. WSR 03-11-031, § 246-680-020, filed 5/15/03, effective 6/15/03. Statutory Authority: RCW 43.20.050. WSR 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. WSR 90-02-094 (Order 024), § 248-106-020, filed 1/3/90, effective 2/3/90.]

## (Effective July 1, 2022)

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 Authority: RCW 43.20.050. WSR 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. WSR 90-02-094 (Order 024), § 248-106-020, filed 1/3/90, effective 2/3/90.]