Chapter 246-680 WAC – Prenatal Tests – Congenital and Heritable Disorders

Informal Comment Summary, March 2021

General Comments
Throughout the rule, request to not change references of “woman” to “person”.
Informed consent and shared decision making are important elements and should be specified in the rule for all the prenatal tests identified throughout the rule.
Request for clarification on why pre- and post-procedure genetic counseling requirements were removed or not consistent for all non-invasive and invasive tests.
WAC 246-680-010 Definitions
Throughout the definitions section, WAC 246-680-010, the repeated use of the term procedure may be confusing. Suggest in several definitions that the term "test" be used.
In WAC 246-680-010(7) and (11), the definitions of post-procedure genetic counseling and pre-procedure genetic counseling, it is unreasonable to exclude telephone or telemedicine and unreasonable to expect to wait for next scheduled appoint if results are abnormal.
In WAC 246-680-010(7) and (11), the definitions of post-procedure genetic counseling and pre-procedure genetic counseling, the specificity of individual does not reflect current practice.
Suggest adding timeline for testing be added to cell-free DNA definition.
Recommend changing the definition of ultrasonography to: “Prenatal ultrasonography is an imaging test performed using sound waves to produce an image(s) of the uterus, maternal ovaries, placenta, fetus, and amount of amniotic fluid.”
The American College of Gynecologists and Obstetricians clinical guidance does not recommend the triple screen and the definition of maternal serum screening should reflect that.
WAC 246-680-020(2)(e); Fetal diagnostic testing

Request to amend WAC 246-680-020(2)(e)(iii) to include cytogenomic microarray analysis (CMA) for recurrent intrauterine fetal demise, which is based on the American Society for Reproductive Medicine recommendations.
Chromosomal microarray in the absence of looking for a specific condition is neither sensitive nor always specific.
Abnormal ultrasound finding for CMA should be specified as high-risk ultrasound finding or multiple anomalies.
WAC 246-680-020(2)(f); Cell-free DNA testing
Request to amend to remove cell-free DNA testing for sex chromosomes.
Requirements to document pre-procedure genetic counseling and an appointment for post-procedure genetic counseling a significant and unnecessary administrative burden on the healthcare provider and payer alike.
Recommend providing coverage for non-invasive prenatal tests for all patients and without prior authorization.
Concerned that this blanket allowance for cell-free DNA is not supported by strong evidence of benefit at the costs being currently charged.
WAC 246-680-020(2)(h); Molecular genetic or cytogenetic testing of parents
Recommend amending WAC 246-680-020(2)(h), molecular genetic or cytogenetic testing of parents to section 3 to allow for case-by-case review. This is current practice for many commercial carriers. If retained in section 2, recommend adding the following language "when the results of the parental testing will be used to guide treatment or reproductive decisions that would not otherwise be made".
Payment for the non-pregnant parent would not be covered by the issuer and this will result in out-of-pocket costs of $1,000-$4,000 for individuals.