Clinical Policy: Testing for Rupture of Fetal Membranes

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Coding Implications
Revision Log

Description
Premature rupture of membranes is a complication in pregnancy that can lead to preterm delivery. The purpose of this policy is to define medical necessity criteria for testing for rupture of fetal membranes using AmniSure®, Actim® PROM and the ROM Plus Fetal Membranes Rupture Test for the diagnostic evaluation for premature rupture of membranes.

Policy/Criteria
It is the policy of PA Health & Wellness that AmniSure, Actim PROM and the ROM Plus Fetal Membranes Rupture Test (tests billed with CPT® code 84112) are considered **not medically necessary** for members as they have not been shown to improve clinical outcomes over standard methods of diagnosis.

Background
Preterm delivery is a major contributing factor to perinatal morbidity and mortality. According to the American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin: Premature Rupture of Membranes, premature rupture of membranes (PROM) complicates approximately 3% of all pregnancies in the United States.[1] Membrane rupture prior to 37 weeks of gestation is referred to as preterm PROM. There are many pathologies that can influence PROM, although intraamniotic infection is commonly related to preterm PROM.[1]

The ACOG Practice Bulletin states that test kits should be considered ancillary to standard methods of diagnosis.[1] PROM is diagnosed through several methods, including: (1) the visualization of amniotic fluid pooling in the vagina from the cervical canal; (2) a pH test of the vaginal fluid; (3) ferning of dried vaginal fluid through microscopic evaluation.[1] The pH of normal vaginal secretions is 4.5 – 6.0, whereas the pH of amniotic fluid is 7.1 – 7.3.[1]

The AmniSure test measures the presence of placental alpha macroglobulin-1 (PAMG-1) protein in the amniotic fluid using an immunochromotographic assay from a vaginal swab. This test has been reported to have a high sensitivity for detecting the PAMG-1 protein.[2] However, the clinical significance of the positive outcomes reported in other studies (evaluating women with term labor and women with preterm labor) should be measured against the small sample sizes (n= 125 and n=90), as well as high false positive rates of 19-30%.[1,3-4]

Actim PROM rapid test detects insulin-like growth factor binding protein-1 (IGFBP-1) present in amniotic fluid as a marker of the presence of amniotic fluid in a cervicogenic sample. IGFBP-2 is synthesized in the fetal liver and detected in the amniotic fluid throughout pregnancy and the rupture of membranes would cause its displacement. Recent studies utilizing this test have reported a sensitivity and a specificity to as low as 89.3 and 82.7%.[5] Moreover, the positive

predictive value of the Actim test was determined to be less than that of the AmniSure test in a recent meta-analysis study.[6]

ROM Plus Fetal Membranes Rupture Test detects the presence of insulin-like growth factor binding protein-1 (IGFBP-1) and alpha fetoprotein (AFP) as markers of membrane rupture. To date, no published studies have established the clinical effectiveness of this test.

Coding Implications

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CPT Codes considered Not Medically Necessary

CPT® Codes	Description
84112	Evaluation of cervicovaginal fluid for specific amniotic fluid protein(s) (eg, placental alpha microglobulin-1 [PAMG-1], placental protein 12 [PP12], alpha-fetoprotein), qualitative, each specimen

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD-10-CM Code	Description
N/A	

Reviews, Revisions, and Approvals	Date	Approval Date
Policy created	04/18	06/18
References reviewed and updates	09/18	

References

1. American College of Obstetricians and Gynecologists (ACOG) "Practice Bulletin no. 188: Premature Rupture of MembranesClinical Management Guidelines for Obstetrician-Gynecologists." Obstet Gynecol. 2018 Jun;131(6):1163-1164.
2. Cousins LM, Smok DP, Lovett Sm, Poelte DM. AmniSure placental alpha microglubuin-1 rapid immunoassay versus standard diagnostic methods for detection of rupture of membrans. *Am J Perinatol*. 2005; 22: 317- 20.

3. Lee, Seung Mi, et al. "The clinical significance of a positive Amnisure test™ in women with term labor with intact membranes." *The Journal of Maternal-Fetal & Neonatal Medicine* 22.4 (2009): 305-310.
4. Mi Lee, Seung, et al. "The clinical significance of a positive Amnisure test in women with preterm labor and intact membranes." *The Journal of Maternal-Fetal & Neonatal Medicine* 25.9 (2012): 1690-1698.
5. Abdelazim, Ibrahim A. "Insulin-like growth factor binding protein-1 (Actim PROM test) for detection of premature rupture of fetal membranes." *Journal of Obstetrics and Gynaecology Research* 40.4 (2014): 961-967.
6. Palacio, Montse, et al. "Meta-analysis of studies on biochemical marker tests for the diagnosis of premature rupture of membranes: comparison of performance indexes." *BMC pregnancy and childbirth* 14.1 (2014): 183.