Clinical Policy: Testing for Rupture of Fetal Membranes
Reference Number: PA.CP.MP.149
Effective Date: 05/18
Last Review Date: 09/18

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
CLINICAL POLICY
Rupture of Fetal Membranes Testing
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
This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2018, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuais and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT Codes considered Not Medically Necessary

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<tr>
<td>84112</td>
<td>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</td>
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ICD-10-CM Diagnosis Codes that Support Coverage Criteria

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Reviews, Revisions, and Approvals

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<td>09/18</td>
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References

CLINICAL POLICY
Rupture of Fetal Membranes Testing

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

   preterm labor and intact membranes." The Journal of Maternal-Fetal & Neonatal Medicine

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

   diagnosis of premature rupture of membranes: comparison of performance indexes." BMC