Clinical Policy: Non-invasive Testing for Rupture of Fetal Membranes

Reference Number: CP.MP.149
Effective Date:
Last Review Date: 08/17

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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 the non-invasive testing for rupture of fetal membranes testing (*e.g.* AmniSure®, Actim® PROM and the ROM Plus Fetal Membranes Rupture Test) for the diagnostic evaluation of premature rupture of membranes.

Policy/Criteria

I. It is the policy of health plans affiliated with Centene Corporation that non-invasive testing for rupture of fetal membranes is considered **not medically necessary** for members as it has 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 pregnancy 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	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	08/17	

References

1. American College of Obstetricians and Gynecologists (ACOG) "Practice Bulletin no. 80: Premature Rupture of Membranes. Clinical Management Guidelines for Obstetrician-Gynecologists." *Obstet Gynecol* 109 (2007): 1007-1019.
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.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.