Clinical Policy: Testing for Rupture of Fetal Membranes

Reference Number: CP.MP.149 Coding Implications
Last Review Date: 06/20 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 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 health plans affiliated with Centene Corporation® that AmniSure, Actim PROM and the ROM Plus Fetal Membranes Rupture Test (tests billed with CPT® code 84112) are considered **not medically necessary** 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: Prelabor Rupture of Membranes, premature rupture of membranes (PROM) complicates approximately 2-3% 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]

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.[1,9] The pH of normal vaginal secretions is 3.8-4.5, whereas the pH of amniotic fluid is 7.1 – 7.3.[9] According to an ACOG Practice Bulletin, several commercially available tests for amniotic proteins report high sensitivity for PROM. However, false-positive test result rates of 19–30% have been reported in patients with clinically intact membranes and symptoms of labor. ACOG notes that the studies evaluating these protein tests are problematic because most of them use conventional clinical assessment (pooling, ferning, pH) as controls or gold standards for the diagnosis of rupture of membranes, calling into question their utility in equivocal cases.[9]

According to the U.S. Food and Drug Administration, health care providers should not use these tests without other clinical assessments because of concerns about "misuse, overreliance, and inaccurate interpretation of lab test results from rupture of membranes tests used to detect rupture of membranes in pregnant women. These can lead to serious adverse events, including fetal death, infection, and other health complications in pregnant women."[10]

Per ACOG, if the diagnosis remains unclear after a full evaluation, and if the benefits of the procedure outweigh the risks, membrane rupture can be diagnosed with ultrasonographically guided transabdominal instillation of indigo carmine dye, followed by the passage of blue-dyed

fluid into the vagina, which is documented by a stained tampon or pad that is removed 20–30 minutes later. It is important to note that maternal urine also will turn blue or blue-green and should not be confused with amniotic fluid. Recent shortages of indigo carmine dye have complicated the availability of this procedure, and alternatives, such as fluorescein, have been suggested.[9]

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, there is a paucity of published studies evaluating 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 2020, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals 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

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	08/17
References reviewed and updated	06/18	06/18
References reviewed and updated. Specialist review	05/19	06/19
Background updated with no impact to position statement. References reviewed and updated.	05/20	06/20

References

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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.
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8. Tchirikov M, Schlabritz-Loutsevitch N, Maher J, et al. Mid-trimester preterm premature rupture of membranes (PPROM): etiology, diagnosis, classification, international recommendations of treatment options and outcome. J Perinat Med. 2018 Jul 26;46(5):465-488.
9. American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin no.217, Prelabor Rupture of Membranes March 2020 (Replaces #188, January 2018)
10. U.S. Food and Drug Administration. Risks associated with use of rupture of membranes tests—letter to health care providers. Silver Spring, MD: FDA; 2018. Available at: https://www.fda.gov/medical-devices/letters-health-care-providers/risks-associated-use-rupture-membranes-tests-letter-health-care-providers.
11. Hayes Molecular Assessment. AmniSure ROM Test for Detection of Fetal Membrane Rupture. Mar, 20, 2018. Update May 4, 2020.

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.

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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.