Medical Policy

Premature Rupture of Membranes (PROM) Testing

MEDICAL POLICY NUMBER: 97

Effective Date: 2/1/2024

Last Review Date: 1/2024

Next Annual Review: 1/2025

INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☐ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

Notice to Medicaid Policy Readers: For comprehensive rules and guidelines pertaining to this policy, readers are advised to consult the Oregon Health Authority. It is essential to ensure full understanding and compliance with the state's regulations and directives. Please refer to OHA's prioritized list for the following coverage guidelines:

Premature Ruptured Membrane Test:

This service is considered new and emerging medical technologies that are considered investigational, and therefore are not covered, because the current scientific evidence is not yet sufficient to establish the impact of these technologies on health outcomes.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

I. Tests for the evaluation of premature rupture of fetal membranes are considered **not medically necessary.** Tests include, but are not limited to the following (A.-D.):

   A. Actim® ROM
   B. AmniSure® ROM
   C. PartoSure™
   D. ROM Plus® Fetal Membrane Rupture Test

Link to Evidence Summary

POLICY CROSS REFERENCES

None

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

BACKGROUND

During pregnancy, the fetal membrane protects the developing fetus and its surrounding fluid from infection. Although tearing or rupture of membranes (ROM) normally occurs during labor, in approximately 12% of pregnancies that are at term (≥ 37 weeks of development), the membrane ruptures before initiation of labor, which is called premature ROM (PROM). PROM that occurs at < 37 weeks of development is referred to as preterm premature ROM (PPROM), which complicates approximately 3% of all pregnancies in the United States.[1] Early detection of PROM and PPROM is important, since physicians must respond quickly to the substantial increase in risks after these conditions.[2]

The optimal approach to clinical assessment and treatment of women with term and preterm PROM remains controversial. Management hinges on knowledge of gestational age and evaluation of the relative risks of delivery versus the risks of expectant management (e.g., infection, abruptio placentae, and umbilical cord accident).[1] Standard methods for detection of PROM include the following: visual pooling of amniotic fluid, sterile speculum examination, nitrazine test to assess the pH of vaginal secretions, microscopic evaluation of crystallization of amniotic fluid into fernlike patterns, ultrasonographic examination to assess amniotic fluid levels, and ultrasonographically guided transabdominal instillation of indigo carmine dye. However, a speculum examination can cause patient discomfort and standard vaginal fluid analysis techniques may give inaccurate results.[2]

There are a number of commercially available tests intended to detect rupture of fetal membranes:

- Actim® PROM test (manufactured by Medix Biomedica, Espoo, Finland, and distributed in the United States by Cooper Surgical, Inc., Trumbull, CT) is a rapid, point-of-care, qualitative immunoassay intended to detect premature rupture of fetal membranes in pregnant women with symptoms suggestive of fetal membrane rupture. The test detects the presence of human IGFBP-1 in cervicovaginal secretions.
- AmniSure® ROM (rupture of membrane) test (AmniSure International, LLC, Boston, MA, a Qiagen Sciences company) is a noninvasive immunoassay intended to detect premature rupture of fetal membranes in pregnant women with symptoms suggestive of fetal membrane rupture. The test detects the presence of human PAMG-1 (Placental Alpha Microglobulin-1, a protein found in amniotic fluid) in vaginal secretions.
- PartoSure™ (Parsagen Diagnostics, Inc.) is a noninvasive test for predicting preterm birth by detecting levels of PAMG-1 in patient vaginal discharge. According to the company, "the PartoSure Test is intended to be used as an aid to rapidly assess the risk of preterm delivery in ≤ 7 or ≤ 14 days from the time of cervicovaginal sample collection in pregnant women with signs and symptoms of early preterm labor, intact amniotic membranes and minimal cervical dilation (≤3 cm) sampled between 20 weeks, 0 days and 36 weeks, 6 days gestation."[3]
- ROM Plus® test (Clinical Innovations, LLC, Murray, UT) is a rapid, noninvasive, immunochromatographic, point-of-care test intended to detect premature rupture of fetal

membranes (PROM) in pregnant women with symptoms suggestive of membrane rupture. The test detects the presence of alpha-fetoprotein (AFP) and insulin-like growth factor binding protein-1 (IGFBP-1) in vaginal secretions using monoclonal antibodies.

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of tests for the evaluation of premature membrane rupture. Below is a summary of the available evidence identified through December 2023.

Comparison of Tests

Systematic Reviews

In 2017 (archived 2019), Hayes published a systematic review which evaluated the use of the Actim PROM-POC PROM Test, AmniSure ROM Test, and the ROM Plus Test.[4] The evidence review did not find any head-to-head comparative studies. The review did include 7 studies, including prospective comparative studies, a meta-analysis, and comparative in vitro studies. The Hayes review concluded evidence continues to be insufficient to inform definitive conclusions about the superiority of any of the requested tests for premature rupture of membranes (PROM) during pregnancy."[4]

AmniSure

Of all the commercially available tests for PROM, AmniSure was the first to be approved by the U.S. Federal Drug Administration (FDA) and there have been a large number of studies published on the accuracy of AmniSure. Therefore, the evidence section below for this test is limited to systematic reviews that evaluated the test performance of AmniSure on its own, or compared to clinical tests or other commercially available PROM tests. Importantly, no studies were identified that reported on the clinical utility of this test. Studies are needed to determine if the use of the AmniSure test impacts health outcomes and changes in management.

Systematic Reviews

- In 2013, Ramsauer et al. published a meta-analysis that evaluated the accuracy of the Actim® PROM test compared to AmniSure®.[5] Of the 12 studies that met inclusion criteria, four studies utilized Actim PROM (N=648), six utilized AmniSure (N=501), and two studies compared both biomarker tests (N=261). Pooled analysis included only those women with suspected ROM who had later confirmation of the diagnosis through standard clinical tests. When the two tests were compared with respect to their test performance in similar groups (i.e., patients presenting with suspected ROM but for whom leakage from the cervical os could not be visualized = unknown membrane status), AmniSure performed better than Actim PROM, with significantly higher sensitivity (96.0 % vs. 73.9%) and specificity (98.9% versus 77.8%). The studies included in this meta-analysis were heterogeneous in terms of study protocols, the clinical characteristics of included patients, and the gold standard used for confirming PROM diagnosis. In addition, women with bleeding were excluded from most of the included studies, making it unclear

whether the findings were representative of the broader population of women presenting with suspected PROM. Lastly, clinical utility was not reported and, therefore, it remains unclear whether the use of these tests resulted in improved health outcomes for the mother or baby.

- In 2014, Palacio et al. published a meta-analysis that compared the accuracy of Actim PROM and AmniSure tests.[6] including 17 studies; 10 for Actim PROM (N = 1,066), four for AmniSure (n = 1,081) and three studies in which both biomarker tests were compared directly. Analysis included women with suspected ROM who were later diagnosed through standard clinical tests. Among women whose membrane rupture status was known, AmniSure was not significantly different from Actim PROM in terms of test performance (Actim PROM: sensitivity: 98.2%, specificity: 95.8%, PPV: 96%, NPV 98%; AmniSure: sensitivity: 96.5%, specificity: 98.2%, PPV: 98.2%, NPV 96.5%). Among women whose rupture status was unknown, AmniSure performed significantly better than Actim PROM (Actim PROM: sensitivity: 92.1%, specificity: 90.5%, PPV: 87.9%, NPV 93.9%; AmniSure: sensitivity: 96.8%, specificity: 98.3%, PPV: 98.4%, NPV 96.7%). Pooled showed no significant differences in sensitivity or NPV between tests, but AmniSure had superior specificity and PPV compared with Actim PROM. The reviewers concluded that there was no difference in test performance in studies where they were used under the same clinical conditions or in women with known membrane status, and that further studies were needed, since the exclusion of bleeding patients may not be representative of women clinically presenting with suspected PROM.

- In 2018 (updated 2022), Hayes published a systematic review of the AmniSure test to evaluate the sensitivity, specificity, negative/positive predictive value, accuracy, and clinical utility of testing to detect fetal membrane rupture.[2] A total of 18 tests were included in the review; 17 studies evaluated the capacity of AmniSure to detect PROM and 1 study assessed the clinical utility of testing. The review found the sensitivity of testing to be 89-100% and specificity to be 88-100%. However, the Hayes review noted, "(w)hen comparing the results of diagnostic tests, it is essential to remember that overall test accuracy relies on both the sensitivity (correct detection of patients who do have the condition) and the specificity (correct exclusion of patients who do not have the condition). Although some of these studies found that the AmniSure test is somewhat better than the usual combined methods for diagnosis of PROM, the available studies have not provided consistent evidence that the AmniSure test is more accurate than the nitrazine test or ferning test, which are often combined with sterile speculum examination for detection of PROM. In addition, the available studies have not demonstrated that the AmniSure test is more accurate than other available immunoassays for diagnosis of PROM." In addition, the review indicated there was insufficient evidence to evaluate the clinical utility of testing. Hayes issued a "**C rating**" to the AmniSure test, stating, "additional studies are needed to determine the accuracy of the AmniSure test relative to established testing methods."[2]

- In 2014 (updated 2022), ECRI published a systematic review assessing the clinical validity and utility of the AmniSure ROM Test for detecting ruptured fetal membranes.[7] In total, one systematic review and 3 clinical validity studies were included for review. The systematic review (n = 2,147) assessed the accuracy of Actim PROM and AmniSure to diagnose ROM. Of the 17 included therein, 4 studies (n=1,081) assessed AmniSure. Overall, AmniSure sensitivity (96.5%) and specificity (98.2%) did not differ significantly from Actim PROM sensitivity (98.2%) and specificity (95.8%). However, in patients with suspected membrane rupture, AmniSure

sensitivity (96.8%) and specificity (98.3%) were higher than Actim PROM sensitivity (92.1%) and specificity (90.5%). Two clinical validity studies (n=435) compared AmniSure to ROM Plus to diagnose ROM and reported sensitivity and specificity, and reported that AmniSure and ROM Plus tests had sensitivities of 96.4% and 89.3%, respectively, and specificities of 98.8% and 100%, respectively, with no significant difference between tests. An additional clinical validity study (n = 151) reported AmniSure and Actim PROM tests had sensitivities of 97.8% and 91.0%, respectively, and specificities of 91.5% and 75%, respectively. The specificity difference was statistically significant. Significantly more Actim PROM test were discarded due to blood smears. Investigators concluded that evidence supporting the AmniSure ROM Test was "somewhat favorable." Limitations included variation in the reference standard used to confirm the ROM diagnosis and a lack of studies assessing clinical utility.

Nonrandomized Studies

In 2019, Sean-Esplin and colleagues conducted a prospective, comparative study evaluating two immunoassays, ROM Plus and Amnisure, designed to diagnose SROM.[8] In total, 324 subjects with singleton pregnancy ≥ 15 weeks' and suspected SROM. Immunoassays were run by independent providers that were blinded to results of SSE. The primary outcome of interest was a final diagnosis of SROM at 48-hour follow-up. Authors reported that both tests were statistically equivalent to SSE and ultrasound (>91% vs. >95%). Investigators concluded that while immunoassays may be used as an alternative to the standard clinical evaluation with SSE, additional studies are necessary to evaluate the performance of these tests among women with specific presenting symptoms that may be associated with an increased a priori risk of ROM.

Actim PROM

Since the systematic reviews described were published, several studies have been published which have evaluated the Actim PROM test. These studies are summarized below. Importantly, no studies were identified that reported on the clinical utility of this test, in that health outcomes and changes in management as a result of the Actim PROM test have not been addressed.

Randomized Controlled Trials

In 2014, Liang et al. conducted an RCT that compared the accuracy of placental α-microglobulin-1 (PAMG-1, AmniSure), insulin-like growth factor binding protein-1 (IGFBP-1, Actim PROM) and nitrazine test to diagnose PROM, including 120 pregnant women between 11 and 42 weeks with signs/symptoms of PROM.[9] The authors reported that AmniSure was the most accurate test to diagnose premature rupture of membranes with the highest sensitivity, specificity, positive predictive value and negative predictive value. However, statistical analyses were not reported, making it difficult to draw conclusions.

Nonrandomized Studies

In 2013, Abdelaizm and Makhouf published a study that compared the performance of placental alpha microglobulin-1 (PAMG-1, AmniSure) versus insulin-like growth factor binding protein-1 (IGFBP-1, Actim PROM) to diagnose PROM, including 150 women who were divided into two groups according to presence or absence of PROM.[10] In this study, no significant differences in sensitivity, specificity, NPV, PPV or accuracy were found between the two tests.

In 2014, Abdelazim published a case-control study which evaluated the accuracy of the Actim PROM test, compared to nitrazine testing and the ferning test in diagnosing PROM in 150 pregnant women after 37 weeks gestation.[11] The women were divided into two groups according to presence or absence of premature rupture of the membranes (PROM); 75 patients with PROM were included in group I and 75 patients without PROM were included in group II as controls. In this study, the sensitivity and the specificity of IGFBP-1 (Actim PROM test) in diagnosing PROM were 89.3% and 82.7%, respectively, as compared with 84% sensitivity and 78.7% specificity for the Ferning test, and 86.7% sensitivity and 81.3% specificity for the Nitrazine test. The positive predictive value (PPV) and negative predictive value (NPV) of IGFBP-1 were 83.8% and 88.6%, respectively, as compared with 79.7% PPV and 83.1% NPV for the Ferning test, and 82.2% PPV and 85.9% NPV for the Nitrazine test. Although the authors stated that the Actim PROM test was more accurate than the two standard clinical tests it was measured against, it was unclear if the test performance parameters reported were significantly different between the tests.

ROM Plus Test

No RCTs were identified that compare the test performance of the ROM Plus test with any of the other commercially available PROM tests or the standard clinical tests such as the nitrazine or ferning test. Importantly, no studies were identified that reported on the clinical utility of this test. Studies are needed to determine if the use of the ROM Plus test impacts health outcomes and changes in patient management. Only studies identified are on test performance, and are described below.

Nonrandomized Studies

In 2013, Thomasino et al. published a multicenter prospective observational comparative study that evaluated the accuracy of the PROM Plus test compared to current conventional clinical assessment for diagnosis of ROM.[12] The study included 285 patients (15-42 weeks of gestation) presenting with signs or symptoms of ruptured amniotic membranes. The false positive rate for the ROM Plus test was 9% and the false negative rate was 0.5%. The sensitivity and specificity were 99% and 91%, respectively; and the positive and negative predictive values were 95% and 99%, respectively. Although the author's stated that the ROM Plus test detects PP12 and AFP with an efficacy comparable to conventional testing and better than the individual components of conventional testing (ferning, nitrazine), statistical analyses were not reported, making it difficult to draw conclusions.

In 2016, Rogers et al. published a study which compared the diagnostic performance characteristics between the ROM Plus test and the ferning test as measured in the same patient.[13] Both tests were run on 75 pregnant patients who presented to labor and delivery with complaints of leaking amniotic fluid. The ROM Plus test performance measures were higher than that of the fern test: sensitivity (100% vs. 77.8%), specificity (94.8% vs. 79.3%), PPV (75% vs. 36.8%), NPV (100% vs. 95.8%), and accuracy (95.5% vs. 79.1%). Although the author's stated that the ROM Plus test provides improved diagnostic accuracy for the detection of ROM compared to fern testing, statistical analyses were not reported, making it difficult to draw conclusions.

PartoSure Test

In 2021, Pirjani and colleagues published a systematic review and meta-analysis on the placental alpha microglobulin-1 (PartoSure) test for the prediction of preterm birth.[14] Seventeen observational cohort

studies were included (n=35-635), totalling 2590 women. The meta-analysis included 15 of the studies (n=1906) and found a pooled sensitivity of 66.2% (95% CI: 59.1-72.7) and a specificity or 96.1% (95% CI: 95.1-97.0). The summary receiver operating characteristic was 0.97 (95% CI: 0.95-0.98) for prediction of delivery within 7 days of testing. Limitations of the review included:

- No randomized, comparative studies were identified
- Exclusion criteria was not explicit in included studies
- Interventions post-testing were not considered in the review, which could affect outcomes.

The authors concluded that PartoSure had high specificity and relatively high sensitivity to predict preterm birth within 7 to 14 days of testing in symptomatic pregnant women.

CLINICAL PRACTICE GUIDELINES

American College of Obstetricians and Gynecologists (ACOG)

- In 2016, ACOG updated their Practice Bulletin on Premature Rupture of Membranes,[1] stating that the optimal approach to clinical assessment and treatment of women with term and preterm PROM remains controversial. According to ACOG, most cases of PROM can be diagnosed on the basis of the patient's history and physical examination. The guideline further states that several tests for amniotic proteins are currently available with high reported sensitivity for PROM. However, these tests should be considered ancillary to standard diagnostic methods due to reported false-positive rates of 19%–30% in patients with clinically intact membranes and symptoms of labor.

- In 2020, ACOG updated the practice bulletin on premature rupture of membranes.[15] The bulletin noted the false-positive test rate and stated that PROM testing should not replace standard testing techniques. The guideline also quoted the FDA's concern over "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."[15]

National Institute for Health and Care Excellence (NICE)

In 2015 (updated 2019), NICE published guidelines addressing preterm labor and birth.[16] The guideline made the following recommendations:

- Offer a speculum examination to check for pooling of amniotic fluid.
    - If pooling is seen, do not conduct diagnostic tests but rather provide care consistent for a woman having PPROM.
    - If pooling is not seen, consider performing an AmniSure or Actim Prom test.
- If the AmniSure or Actim PROM test results are positive, do not use the test results in isolation, but rather use the test results in conjunction with the clinical condition, medical and pregnancy history, ad gestational age, to determine what care to provide and;
    - Offer care consistent with the woman having PPROM; or
    - Reevaluate the woman's diagnostic status at a later time point.
- If the AmniSure or Actim PROM test results are negative and no amniotic fluid is observed.
    - Do not provide prophylactic antenatal antibiotics

    - Explain to the woman that the likelihood of PPROM is low, but if she has further symptoms suggestive of PPROM or preterm labor then she should return.
- Do not use the Nitrazine test for diagnosis of PPROM.
- Do not use diagnostic tests for PPROM in a woman who is reporting symptoms suggestive of PPROM and who is in established labor.

EVIDENCE SUMMARY

There is insufficient evidence to support the use of Premature Rupture of Membranes (PROM) testing as an alternative to standard testing. Additionally, clinical practice guidelines do not support the use of PROM testing noting the false-positive rates and concern for "misuse, overreliance, and inaccurate interpretation of lab test results" which can lead to serious adverse events, including fetal death, infection, and other health complications in pregnant women.

BILLING GUIDELINES AND CODING

CODES*		
CPT	~~0066U~~	**TERMED 9/30/2023** ~~Placental alpha-micro globulin-1 (PAMG-1), immunoassay with direct optical observation, cervico-vaginal fluid, each specimen~~
	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
	84999	Unlisted chemistry procedure

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.

3/2023	Interim update. Changed investigational criteria to not medically necessary.
4/2023	Annual review, no changes. Separated into Company & Medicare policies.
10/2023	Interim update. 10/1 code set.
2/2024	Annual review. No changes to criteria