Medicare Medical Policy

Premature Rupture of Membranes (PROM) Testing

MEDICARE MEDICAL POLICY NUMBER: 383

Effective Date: 2/1/2024

Last Review Date: 1/2024

Next Annual Review: 1/2025

INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. 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.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

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

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Service	Medicare Guidelines
Premature Rupture of Membranes (PROM) Testing	Company medical policy for Premature Rupture of Membranes (PROM) Testing I. These services are considered **not medically necessary** for Medicare based on the Company medical policy. *See Policy Guidelines below.*

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

None

The full Company portfolio of Medicare 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. While tearing or rupture of membranes (ROM) normally occurs during labor, at times the membrane ruptures before initiation of labor. This is called premature ROM (PROM). If PROM occurs at < 37 weeks of development, this is referred to as preterm premature ROM (PPROM).

Early detection of PROM and PPROM is important, since physicians must respond quickly to the substantial increase in risks after these conditions. However, 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). 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.

Commercially available tests intended to detect rupture of fetal membranes include the following:

- 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."
- 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.

MEDICARE AND MEDICAL NECESSITY

Medicare requires diagnostic laboratory tests be ordered by a provider who is treating the member for a specific medical problem **and** who will use the test results in the direct management of that specific medical problem.[1,2] Thus, diagnostic testing must have established clinical utility and analytic validity.

Only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*.

The Company policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development. In the absence of Medicare coverage policies (e.g., manual, national coverage determination [NCD], local coverage determination [LCD], article [LCA], etc.) which addresses the medical necessity of a given medical service, Medicare regulatory guidelines do allow Medicare Advantage Organizations (MAOs) to make their own coverage determinations.

During the MAO review, an evidence-based process must be used. This includes using authoritative evidence, such as studies performed by government agencies (i.e., the FDA), well-designed clinical studies that appeared in peer reviewed journals, and evaluations performed by independent technology assessment groups. *(Medicare Managed Care Manual, Ch. 4, §90.5)* In addition to review of the quality of the body of studies and the consistency of the results, additional consideration may be given to determine if the evidence can be generalized to the Medicare population.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

CODES*		
CPT	~~0066U~~	**CODE 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
HCPCS	None	

***Coding Notes:**

- The code list above 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. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*

- 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.

REFERENCES

1. 42 CFR §410.32(a); Available at: https://www.govinfo.gov/content/pkg/CFR-2011-title42-vol2/pdf/CFR-2011-title42-vol2-sec410-32.pdf
2. Medicare Benefit Policy Manual, Ch. 15 – Covered Medical and Other Health Services, §80.1 - Clinical Laboratory Services; Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
3/2023	New Medicare Advantage medical policy
10/2023	Q4 2023 Code Updates
2/2024	Annual review, no criteria change