

Testing of Premature Rupture of Membrane in Pregnancy, OB 12

Table of Content
Purpose
Description & Definitions
Criteria
Coding
Document History
References
Special Notes
Keywords

<u>Effective Date</u>	12/2012
<u>Next Review Date</u>	5/2025
<u>Coverage Policy</u>	OB 12
<u>Version</u>	3

All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member’s condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

Purpose:

This policy addresses Testing of Premature Rupture of Membrane in Pregnancy.

Description & Definitions:

Testing of Premature Rupture of Membrane in Pregnant is individual using a swab to collect a sample of fluid from the cervix or vagina, aiding in determining Premature Rupture of Membranes (PROM).

- These tests include, but are not limited to, Amnisure ROM and PartoSure - placental alpha-microglobulin-1(PAMG-1), Actim PROM - insulin-like growth factor binding protein IGFBP-1, ROM Plus - placental protein 12(PP12)/ insulin-like growth factor binding protein (IGFBP-1).

Criteria:

Testing of Premature Rupture of Membrane in Pregnancy is considered **not medically necessary** for any indications.

Coding:

Medically necessary with criteria:

Coding	Description
	None

Considered Not Medically Necessary:

Coding	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
-------	--

U.S. Food and Drug Administration (FDA) - approved only products only.

Document History:

Revised Dates:

- 2022: May
- 2020: January
- 2016: January, April
- 2015: January, February, October
- 2014: July, December
- 2013: January, February, March, July, August, September

Reviewed Dates:

- 2024: May
- 2023: May
- 2021: June
- 2020: July
- 2019: May
- 2018: April
- 2016: June, July

Effective Date:

- December 2012

References:

Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

Code of Federal Regulations. Title 32. Subtitle A. Chapter I. Subchapter M. Part 199. § 199.2. Retrieved 4.17.2024. <https://www.ecfr.gov/current/title-32/subtitle-A/chapter-I/subchapter-M/part-199/section-199.2>

U.S. Food and Drug Administration. FDA alerts healthcare providers, women about risks associated with improper use of rupture of membranes tests. 8.8.2018. Retrieved 4.17.2024. <https://www.fda.gov/news-events/press-announcements/fda-alerts-healthcare-providers-women-about-risks-associated-improper-use-rupture-membranes-tests>

Hayes. A symplr Company. Molecular Test Assessment. Mar 20, 2018. Annual Review: Jun 13, 2022. AmniSure ROM Test for Detection of Fetal Membrane Rupture. Retrieved 4.17.2024. <https://evidence.hayesinc.com/report/dir.amnisure1790>

Centers for Medicare and Medicaid Services. CMS.gov. Retrieved 4.19.2024. <https://www.cms.gov/search/cms?keys=premature+rupture+of+membranes>

Commonwealth of Virginia. Department of Medical Assistance Services. Procedure Fee File & CPT Search. Retrieved 4.19.2024. <https://www.dmas.virginia.gov/for-providers/rates-and-rate-setting/procedure-fee-files-cpt-codes/#searchCPT>

National Comprehensive Cancer Network. Retrieved 4.19.24. <https://www.nccn.org/search-result?indexCatalogue=nccn-search-index&searchQuery=premature%20rupture%20of%20membranes>

Carelon Clinical Pathway Guidelines. Retrieved 4.19.2024. https://www.google.com/search?q=carelon+premature+rupture+of+membrane+testing&rlz=1C1GCEA_enUS951_US951&oq=carelon+premature+rupture+of+membrane+testing&gs_lcrp=EgZjaHJvbWUyCQgAEEUYORigATIGCAEQRRhA0gEKMTA3MThqMGoxNagCCLACAQ&sourceid=chrome&ie=UTF-8

Avalon. Laboratory Testing Policies. Retrieved 4.19.2024. <https://www.avalonhcs.com/policies-sentarahealth/>

The American College of Obstetrics and Gynecology. Pre-labor Rupture of Membranes. Practice Bulletin. PB Number 217. March 2020. Retrieved 4.19.2024. <https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/03/prelabor-rupture-of-membranes>

Thumm, B., Walsh, G., & Heyborne, K. D. (2020). Diagnosis of rupture of membranes: AmniSure, clinical assessment, and the Food and Drug Administration warning. *American journal of obstetrics & gynecology MFM*, 2(4), 100200. Retrieved 4.19.2024. <https://doi.org/10.1016/j.ajogmf.2020.100200>

MCG Informed Care Strategies. 27th Edition. Retrieved 4.19.2024. <https://careweb.careguidelines.com/ed27/index.html>

Special Notes: *

This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to "correct or ameliorate" (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member's condition. *Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

Keywords:

Testing of Premature Rupture of Membrane in Pregnancy, Amnisure, Obstetrics 12, OB, Premature Rupture of Membranes, PROM, ROM, Amnisure ROM, PartoSure, placental alpha-microglobulin-1, PAMG-1, Actim PROM, insulin-like growth factor binding protein IGFBP-1, ROM Plus, placental protein 12, PP12, insulin-like growth factor binding protein, IGFBP-1