BlueCross BlueShield Arizona

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EVIDENCE-BASED CRITERIA	**ORIGINAL EFFECTIVE DATE: 01/03/23**
SECTION: OB/GYN/REPRODUCTION	**LAST REVIEW DATE: 04/02/24**
	CURRENT EFFECTIVE DATE: 11/05/24
	LAST CRITERIA REVISION DATE:
NEXT ANNUAL REVIEW DATE: 2ND QTR 2025	**ARCHIVE DATE:**

MATERNAL SERUM BIOMARKERS FOR PREDICTION OF ADVERSE OBSTETRIC OUTCOMES

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Improved accuracy of the identification of women at risk of preeclampsia and spontaneous preterm birth has the potential to reduce maternal and perinatal morbidity and mortality. Assessment of historical risk and clinical factors represents the traditional approach to diagnosis and planning interventions. Maternal serum biomarker test with or without additional algorithmic analysis is proposed as an adjunct to standard screening to identify women at risk of preeclampsia and spontaneous preterm birth.

Preeclampsia is defined as new onset maternal hypertension and proteinuria or new onset hypertension and significant end-organ dysfunction (with or without proteinuria) after the 20th week of gestation.

Preterm birth is defined as birth occurring between the 20th and 37th week of pregnancy and can be spontaneous following preterm labor and rupture of membranes or iatrogenic due to clinical interventions for maternal or fetal medical indications.

The B·R·A·H·M·S sFlt-1/ PlGF KRYPTOR Test System (Thermo Fisher Scientific) was cleared for marketing by the FDA as a prognostic test in May 2023. The Test System includes quantitative determination of Placental Growth Factor (PlGF) and soluble fms-like tyrosine kinase-1 (sFlt-1) in human serum and plasma. The Test System is to be used along with other laboratory tests and clinical assessments to aid in the risk assessment of pregnant women (singleton pregnancies between gestational age 23+0 to 34+6/7 weeks) hospitalized for hypertensive disorders of pregnancy (preeclampsia, chronic hypertension with or without superimposed preeclampsia, or gestational hypertension) for progression to preeclampsia with severe features (as defined by the American College of Obstetricians and Gynecologists (ACOG) guidelines) within 2 weeks of presentation.

The PreTrm™ test (Sera Prognostics) use maternal serum biomarkers (insulin-like growth factor binding protein-4 [IBP4] and sex hormone binding globulin [SHBG]) in combination with biometric measures to assess the risk of spontaneous preterm birth.

Criteria:

- The use of maternal serum biomarker tests with or without additional algorithmic analysis for the prediction of preeclampsia or spontaneous preterm birth is considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met:

  1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or
  5. Insufficient evidence to support improvement outside the investigational setting

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Resources:

Literature reviewed 04/02/24. We do not include marketing materials, poster boards and non-published literature in our review.

Resources prior to 04/02/24 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. Agrawal S, Cerdeira AS, Redman C, Vatish M. Meta-Analysis and Systematic Review to Assess the Role of Soluble FMS-Like Tyrosine Kinase-1 and Placenta Growth Factor Ratio in Prediction of Preeclampsia: The SaPPPhirE Study. *Hypertension*. Feb 2018;71(2):306-316. doi:10.1161/hypertensionaha.117.10182

2. Agrawal S, Shinar S, Cerdeira AS, Redman C, Vatish M. Predictive Performance of PlGF (Placental Growth Factor) for Screening Preeclampsia in Asymptomatic Women: A Systematic Review and Meta-Analysis. *Hypertension*. Nov 2019;74(5):1124-1135. doi:10.1161/hypertensionaha.119.13360

3. American College of Obstetrics and Gynecology and The Society for Maternal-Fetal Medicine. Practice Advisory: Low-Dose Aspirin Use for the Prevention of Preeclampsia and Related Morbidity and Mortality. December, 2021. Accessed January 12, 2024.

4. Andersen LB, Frederiksen-Møller B, Work Havelund K, et al. Diagnosis of preeclampsia with soluble Fms-like tyrosine kinase 1/placental growth factor ratio: an inter-assay comparison. *J Am Soc Hypertens*. Feb 2015;9(2):86-96. doi:10.1016/j.jash.2014.11.008

5. Branch DW, VanBuren JM, Porter TF, et al. Prediction and Prevention of Preterm Birth: A Prospective, Randomized Intervention Trial. *Am J Perinatol*. Jul 2023;40(10):1071-1080. doi:10.1055/s-0041-1732339

6. Cerdeira AS, O'Sullivan J, Ohuma EO, et al. Randomized Interventional Study on Prediction of Preeclampsia/Eclampsia in Women With Suspected Preeclampsia: INSPIRE. *Hypertension*. Oct 2019;74(4):983-990. doi:10.1161/hypertensionaha.119.12739

7. Chaemsaithong P, Sahota DS, Poon LC. First trimester preeclampsia screening and prediction. *Am J Obstet Gynecol*. Feb 2022;226(2s):S1071-S1097.e2. doi:10.1016/j.ajog.2020.07.020

8. Chaiworapongsa T, Romero R, Savasan ZA, et al. Maternal plasma concentrations of angiogenic/anti-angiogenic factors are of prognostic value in patients presenting to the obstetrical triage area with the suspicion of preeclampsia. *J Matern Fetal Neonatal Med*. Oct 2011;24(10):1187-207. doi:10.3109/14767058.2011.589932

9. Cobo T, Kacerovsky M, Jacobsson B. Risk factors for spontaneous preterm delivery. *Int J Gynaecol Obstet*. Jul 2020;150(1):17-23. doi:10.1002/ijgo.13184

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10. Conde-Agudelo A, Papageorghiou AT, Kennedy SH, Villar J. Novel biomarkers for the prediction of the spontaneous preterm birth phenotype: a systematic review and meta-analysis. *Bjog*. Aug 2011;118(9):1042-54. doi:10.1111/j.1471-0528.2011.02923.x

11. Davidson KW, Barry MJ, Mangione CM, et al. Aspirin Use to Prevent Preeclampsia and Related Morbidity and Mortality: US Preventive Services Task Force Recommendation Statement. *Jama*. Sep 28 2021;326(12):1186-1191. doi:10.1001/jama.2021.14781

12. De Oliveira L, Roberts JM, Jeyabalan A, et al. PREPARE: A Stepped-Wedge Cluster-Randomized Trial to Evaluate Whether Risk Stratification Can Reduce Preterm Deliveries Among Patients With Suspected or Confirmed Preterm Preeclampsia. *Hypertension*. Oct 2023;80(10):2017-2028. doi:10.1161/hypertensionaha.122.20361

13. Dröge LA, Höller A, Ehrlich L, Verlohren S, Henrich W, Perschel FH. Diagnosis of preeclampsia and fetal growth restriction with the sFlt-1/PlGF ratio: Diagnostic accuracy of the automated immunoassay Kryptor®. *Pregnancy Hypertens*. Apr 2017;8:31-36. doi:10.1016/j.preghy.2017.02.005

14. Duhig KE, Myers J, Seed PT, et al. Placental growth factor testing to assess women with suspected pre-eclampsia: a multicentre, pragmatic, stepped-wedge cluster-randomised controlled trial. *Lancet*. May 4 2019;393(10183):1807-1818. doi:10.1016/s0140-6736(18)33212-4

15. Executive summary: Workshop on Preeclampsia, January 25-26, 2021, cosponsored by the Society for Maternal-Fetal Medicine and the Preeclampsia Foundation. *Am J Obstet Gynecol*. Sep 2021;225(3):B2-b7. doi:10.1016/j.ajog.2021.05.043

16. Ford ND, Cox S, Ko JY, et al. Hypertensive Disorders in Pregnancy and Mortality at Delivery Hospitalization - United States, 2017-2019. *MMWR Morb Mortal Wkly Rep*. Apr 29 2022;71(17):585-591. doi:10.15585/mmwr.mm7117a1

17. Gestational Hypertension and Preeclampsia: ACOG Practice Bulletin, Number 222. *Obstet Gynecol*. Jun 2020;135(6):e237-e260. doi:10.1097/aog.0000000000003891

18. Hamilton BE, Martin JA, Osterman MJK. Births: Provisional Data for 2020. National Center for Health Statistics. Accessed January 12, 2024. https://www.cdc.gov/nchs/data/vsrr/vsrr012-508.pdf

19. Hayes-Ryan D, Khashan AS, Hemming K, et al. Placental growth factor in assessment of women with suspected pre-eclampsia to reduce maternal morbidity: a stepped wedge cluster randomised control trial (PARROT Ireland). *Bmj*. Aug 13 2021;374:n1857. doi:10.1136/bmj.n1857

20. Henderson JT, Vesco KK, Senger CA, Thomas RG, Redmond N. Aspirin Use to Prevent Preeclampsia and Related Morbidity and Mortality [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2021 Sep. (Evidence Synthesis, No. 205.) Available from: https://www.ncbi.nlm.nih.gov/books/NBK574449/.

21. Henderson JT, Webber EM, Thomas RG, Vesco KK. Screening for Hypertensive Disorders of Pregnancy: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force. *Jama*. Sep 19 2023;330(11):1083-1091. doi:10.1001/jama.2023.4934

22. Honest H, Forbes CA, Durée KH, et al. Screening to prevent spontaneous preterm birth: systematic reviews of accuracy and effectiveness literature with economic modelling. *Health Technol Assess*. Sep 2009;13(43):1-627. doi:10.3310/hta13430

23. Lim S, Li W, Kemper J, Nguyen A, Mol BW, Reddy M. Biomarkers and the Prediction of Adverse Outcomes in Preeclampsia: A Systematic Review and Meta-analysis. *Obstet Gynecol*. Jan 1 2021;137(1):72-81. doi:10.1097/aog.0000000000004149

24. Lucaroni F, Morciano L, Rizzo G, et al. Biomarkers for predicting spontaneous preterm birth: an umbrella systematic review. *J Matern Fetal Neonatal Med*. Mar 2018;31(6):726-734. doi:10.1080/14767058.2017.1297404

25. Magee LA, Brown MA, Hall DR, et al. The 2021 International Society for the Study of Hypertension in Pregnancy classification, diagnosis & management recommendations for international practice. *Pregnancy Hypertens*. Mar 2022;27:148-169. doi:10.1016/j.preghy.2021.09.008

26. Markenson GR, Saade GR, Laurent LC, et al. Performance of a proteomic preterm delivery predictor in a large independent prospective cohort. *Am J Obstet Gynecol MFM*. Aug 2020;2(3):100140. doi:10.1016/j.ajogmf.2020.100140

27. Mazaki-Tovi S, Romero R, Kusanovic JP, et al. Recurrent preterm birth. *Semin Perinatol*. Jun 2007;31(3):142-58. doi:10.1053/j.semperi.2007.04.001

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35. Prediction and Prevention of Spontaneous Preterm Birth: ACOG Practice Bulletin, Number 234. *Obstet Gynecol*. Aug 1 2021;138(2):e65-e90. doi:10.1097/aog.0000000000004479

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42. U.S. Food & Drug Administration. DEN220027: BRAHMS sFlt-1/ PlGF KRYPTOR Test System. Accessed January 8, 2024. https://www.accessdata.fda.gov/cdrh_docs/pdf22/DEN220027.pdf

43. van Helden J, Weiskirchen R. Analytical evaluation of the novel soluble fms-like tyrosine kinase 1 and placental growth factor assays for the diagnosis of preeclampsia. *Clin Biochem*. Nov 2015;48(16-17):1113-9. doi:10.1016/j.clinbiochem.2015.06.020

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44. von Dadelszen P, Payne B, Li J, et al. Prediction of adverse maternal outcomes in pre-eclampsia: development and validation of the fullPIERS model. *Lancet*. Jan 15 2011;377(9761):219-27. doi:10.1016/s0140-6736(10)61351-7

Coding:

CPT: 0243U, 0247U, 0482U

History:	**Date:**	**Activity:**
Medical Policy Panel	04/02/24	Review with revisions
Medical Policy Panel	01/02/24	Review with no revisions
Medical Policy Panel	01/03/23	Approved guideline
Medical Director (Dr. Deering)	11/13/22	Development

Policy Revisions:

11/05/24	Added:	CPT code: 0482U
04/02/24	Revised:	Description section; Resource section

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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1–800–368–1019, 800–537–7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nílínigíí Blue Cross Blue Shield of Arizona haada yit'éego bína'ídíłkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yína'ídíłkidgo beehaz'áanii hólǫ díí t'áá hazaadk'ehjí háká a'doowołgo bee haz'ą doo bąąh íłínígóó. Ata' halne'ígíí kojį' bich'į' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:
إن كان لديك أو لدى شخص تساعده أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون اية تكلفة. للتحدث مع مترجم اتصل ب 877-475-4799.

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Multi-Language Interpreter Services:

Tagalog: Kung ikaw, o ang iyong tinutulangan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 전화하십시오.

French: Si vous, ou quelqu'un que vous êtes en train d'aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizona についてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi:
اگر شما، یا کسی که شما به او کمک میکنید ، سوال در مورد Blue Cross Blue Shield of Arizona ، داشته باشید حق این را دارید که کمک و
اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799
[تماس حاصل نمایید.

Assyrian:
[illegible] Blue Cross Blue Shield of Arizona، [illegible]
[illegible] 877-475-4799.

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคณ หรอคนทคณกาลงชวยเหลอมคาถามเกยวกบ Blue Cross Blue Shield of Arizona
คณมสทธทจะไดรบความชวยเหลอและขอมลในภาษา ของคณไดโดยไมมคาใชจาย พดคยกบลาม โทร 877-475-4799