



An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA
SECTION: LABORATORY

ORIGINAL EFFECTIVE DATE: 07/01/25
LAST REVIEW DATE: 04/29/26
CURRENT EFFECTIVE DATE: 04/29/26
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

NEXT ANNUAL REVIEW DATE: 2ND QTR 2027

GENESIGHT PSYCHOTROPIC TEST

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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GENESIGHT PSYCHOTROPIC TEST

Description:

Pharmacogenomic tests are germline genetic tests that are developed to aid in assessing an individual's response to a drug treatment or to predict the risk of toxicity from a specific drug treatment. Testing may be performed prior to initiation of treatment to identify if an individual has genetic variants that could either affect response to a particular drug and/or increase the risk of adverse drug reactions. Testing may also be performed during treatment to assess an individual who has had an adverse drug reaction or to assess response to treatment.

The GeneSight Psychotropic test analyzes how an individual's genes may affect their outcomes with medications commonly prescribed to treat depression, anxiety, ADHD, and other mental health conditions. The GeneSight Psychotropic test is intended to provide the treating clinician with information about which medications may require dose adjustments, may be less likely to work for an individual or may have an increased risk of side effects based on the individual's genetic makeup.

Criteria:

- The GeneSight Psychotropic test is considered **medically necessary** with documentation of **ALL** of the following:
 1. The individual has a diagnosis of major depressive disorder or generalized anxiety disorder
 2. The individual has failed at least one prior medication to treat their condition
 3. Treating clinician is considering (or already administering) medication that meets **ALL** of the following:
 - Medically necessary, appropriate, and approved for use in the individual's condition
 - Known to have a gene(s)-drug interaction demonstrated to be clinically actionable as defined by the FDA (pharmacogenomics testing information required for safe drug administration) or Clinical Pharmacogenetic Implementation Consortium (CPIC) guidelines (category A and B) ¹
 4. The results of the GeneSight Psychotropic test are necessary for the physician's decision-making process regarding safely administering or dosing the drug
 5. Clinical record reflects the treating clinician has already considered non-genetic factors to make a preliminary drug selection as documented by **ALL** of the following:
 - Individual's diagnosis
 - Individual's other medical conditions
 - Other medications individual is taking
 - Professional judgment
 - Clinical science and basic science pertinent to drug (eg, mechanism of action, side effects)
 - Individual's past medical history

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- Pertinent family history
 - Individual's preferences and values
- The GeneSight Psychotropic test for all other indications not previously listed or if above criteria not met 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
- ¹ Refer to Resources section for website address to FDA and CPIC website.

Resources:

Literature reviewed 04/29/26. We do not include marketing materials, poster boards and non-published literature in our review.

1. Ariz. Rev Stat, §20-841.13 (2025). Accessed March 30, 2026.
2. Ariz. Rev Stat, §20-1057.19 (2025). Accessed March 30, 2026.
3. Brown L, Vranjkovic O, Li J, et al. The clinical utility of combinatorial pharmacogenomic testing for patients with depression: a meta-analysis. *Pharmacogenomics*. Jun 2020;21(8):559-569. doi:10.2217/pgs-2019-0157
4. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD) MoIDX: Pharmacogenomics Testing (L38337). 2024. Updated October 2, 2025. Accessed March 5, 2026. <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38337&ver=10&bc=0>
5. Clinical Pharmacogenetics Implementation Consortium (CPIC). Genes-Drugs. 2024. Accessed March 5, 2026. <https://cpicpgx.org/genes-drugs/>
6. Dagar A, Cherlopalle S, Ahuja V, et al. Real-world experience of using combinatorial pharmacogenomic test in children and adolescents with depression and anxiety. *J Psychiatr Res*. Feb 2022;146:83-86. doi:10.1016/j.jpsychires.2021.12.037
7. Greden JF, Parikh SV, Rothschild AJ, et al. Impact of pharmacogenomics on clinical outcomes in major depressive disorder in the GUIDED trial: A large, patient- and rater-blinded, randomized, controlled study. *J Psychiatr Res*. Apr 2019;111:59-67. doi:10.1016/j.jpsychires.2019.01.003



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8. Jablonski MR, Lorenz R, Li J, Dechairo BM. Economic Outcomes Following Combinatorial Pharmacogenomic Testing for Elderly Psychiatric Patients. *J Geriatr Psychiatry Neurol.* Nov 2020;33(6):324-332. doi:10.1177/0891988719892341
9. Multi-gene Pharmacogenomic Testing That Includes Decision-Support Tools to Guide Medication Selection for Major Depression: A Health Technology Assessment. *Ont Health Technol Assess Ser.* 2021;21(13):1-214.
10. Myriad Genetics. The GeneSight Psychotropic test. 2024. Accessed March 5, 2026. <https://genesight.com/product/>
11. Parikh SV, Law RA, Hain DT, et al. Combinatorial pharmacogenomic algorithm is predictive of sertraline metabolism in patients with major depressive disorder. *Psychiatry Res.* Feb 2022;308:114354. doi:10.1016/j.psychres.2021.114354
12. Rothschild AJ, Parikh SV, Hain D, et al. Clinical validation of combinatorial pharmacogenomic testing and single-gene guidelines in predicting psychotropic medication blood levels and clinical outcomes in patients with depression. *Psychiatry Res.* Feb 2021;296:113649. doi:10.1016/j.psychres.2020.113649
13. Shelton RC, Parikh SV, Law RA, et al. Combinatorial Pharmacogenomic Algorithm is Predictive of Citalopram and Escitalopram Metabolism in Patients with Major Depressive Disorder. *Psychiatry Res.* Aug 2020;290:113017. doi:10.1016/j.psychres.2020.113017
14. Tantisira K, Weiss ST. Overview of pharmacogenomics. In: Tirnauer JS, Shah SM, eds. *UpToDate.* UpToDate; 2026. Accessed March 5, 2026. <https://www.uptodate.com/contents/overview-of-pharmacogenomics>
15. U.S. Food & Drug Administration (FDA). Table of Pharmacogenomic Biomarkers in Drug Labeling. 2024. Updated March 3, 2026. Accessed March 5, 2026. <https://www.fda.gov/drugs/science-and-research-drugs/table-pharmacogenomic-biomarkers-drug-labeling>

Coding:

CPT: 0345U

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<u>History:</u>	<u>Date:</u>	<u>Activity:</u>
Medical Policy Panel	04/29/26	Review with revisions
Legal Review	03/30/26	Review with no revisions
Medical Director (Dr. Raja)	03/12/26	Review with no revisions
Medical Policy Panel	04/15/25	Approved guideline (effective 07/01/25)
Medical Director (Dr. Raja)	03/20/25	Development
Legal Review	02/20/25	Development
Medical Director (Dr. Raja, Dr. Sutanto)	01/09/25	Development
Medical Director (Dr. Raja, Dr. Sutanto)	11/22/24	Development

Policy Revisions:

04/29/26 Updated: Resources 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 nilinigií Blue Cross Blue Shield of Arizona haada yit'éego bina'idilkidgo éí doodago Háida bį́ą́ anilyeedigií t'áadoo le'é yina'idilkidgo beehaz'ánii hóloq díí t'áá hazaadk'ehjí háká a'doowołgo bee haz'ą́ doo baqah ilinígóó. Ata' halne'ígíí kojį' bich'į́' hodilnih 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 تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 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:

Blue Cross Blue Shield of Arizona... 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: หากคน หรือคนทดกลางช่วยเหลื่อมคาตามเกยวกับ Blue Cross Blue Shield of Arizona คมมสททจะไดรบความช่วยเหลอมและขอมลในภาษา ของคนไดโดยไมมคาไจจาย พดคยภมลาม โทร 877-475-4799