



MEDICAL COVERAGE GUIDELINES
SECTION: LABORATORY

ORIGINAL EFFECTIVE DATE: 08/08/18
LAST REVIEW DATE: 09/18/18
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

URINE AND SERUM DRUG TESTING FOR DRUG-DRUG INTERACTION, COMPLIANCE AND ADHERENCE AND URINE SPECIMEN DNA AUTHENTICATION TESTING

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 Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline 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.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Urine Drug Testing for Drug-Drug Interactions:

Pain, behavioral and primary care providers assess the individual's risk for drug interactions if the individual experiences any of the following:

- Adverse effects or intolerance to therapy
- A reduced response to therapy
- A need for dose escalation for effective therapy
- A risk of morbidity due to age, organ dysfunction, polypharmacy or multiple health conditions

The Drug-to-Drug Interaction Test (DDI) InterAct Rx™ by Aegis Sciences is a laboratory analysis by mass spectrometry that has been investigated for identifying common drugs, herbal supplements and foods that may alter a response to therapy. These drugs include antiarrhythmics, antidepressants/antipsychotics, antimicrobials/antiretrovirals, antiemetics/gastric reflux, antiepileptics, antihypertensives, chemotherapeutic agents, foods/supplements, steroids/hormones and other miscellaneous drugs. This test is performed separately from the medication compliance test. The lab report will detect any contraindications or adverse drug effects.

Urine Specimen DNA Authentication Testing:

Has been investigated for determining if the urine specimen submitted for drug testing matches the donor's DNA. A one-time cheek swab of buccal cells is collected and sent to laboratory with the urine specimen. By utilizing the donor's unique genetic markers, the laboratory will compare the buccal cells and urine cellular DNA for a match. Test will also determine if specimen is synthetic or substitute human urine. Tests include, *but are not limited to*:

- ToxProtect™ by Genotox Laboratories
- ToxLok™ by InSource Diagnostics

Serum Drug Testing:

Has been investigated for reporting therapeutic and toxic ranges of prescription drugs with steady state ranges of prescribed doses when detected, reports whether an individual is consistent with prescribed dose per date of service. This testing methodology includes a well established correlation between the dosage prescribed and the level of drug in the individuals blood. The test can be utilized alone or used along with a traditional urine drug testing program. Tests include, *but are not limited to*:

- AssuranceRx Micro Serum by Firstox Laboratories, LLC.

Urine Drug Testing for Prescription Drug Monitoring:

Has been investigated for prescription drug monitoring evaluation of drugs present by liquid chromatography mass spectrometry (LC-MS/MS), urine, 31 drug panel, reported as quantitative results, detected or not detected. Tests include, but are not limited to the UCompliDX test by Elite Medical Laboratory Solutions.



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Definitions:

Presumptive (e.g., Immunoassay) Drug Screen:

A test used to detect the presence of a drug in the body that is generally reported as either positive or negative.

Definitive (e.g., Confirmatory) Drug Screen:

A test used to confirm the presence of a specific drug identified by a screening test and can identify drugs that cannot be isolated by currently available immunoassays.

Criteria:

For urine drug testing for pain medication and substance abuse monitoring, see BCBSAZ Medical Coverage Guideline #O895, "*Drug Testing in Pain Management and Substance Abuse Disorder(s) Treatment*".

- Urine drug testing for drug-drug interactions is considered **experimental or investigational** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 4. Insufficient evidence to support improvement outside the investigational setting.

- Urine specimen DNA authentication testing is considered **experimental or investigational** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 4. Insufficient evidence to support improvement outside the investigational setting.

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Criteria: (cont.)

- Serum drug testing for prescription drug monitoring is considered ***experimental or investigational*** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 4. Insufficient evidence to support improvement outside the investigational setting.

- Urine drug testing for prescription drug monitoring is considered ***experimental or investigational*** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 4. Insufficient evidence to support improvement outside the investigational setting.

These tests include, *but are not limited to*:

- UCompliDX test

Resources:

Literature reviewed 09/18/18. We do not include marketing materials, poster boards and non-published literature in our review.

1. Gregg K, McCarty M, Rhodes R, et al. American Academy of Pain Management 2016 AAPM Annual Meeting Presentation, ToxID: A New and Valuable Validity Test for Urine Drug Testing. Accessed 08/04/2017.
2. Matt McCarty M. Whose Urine is It? A New Approach to Expose Other Human and Synthetic Urine Substitution in Outpatient Medication/Sobriety Monitoring. 2016 *Pain Physician Journal*. Accessed 08/04/2017:E795-E827.
3. McEvoy J, Millet RA, Dretchen K, Morris AA, Corwin MJ, Buckley P. Quantitative levels of aripiprazole parent drug and metabolites in urine. *Psychopharmacology (Berl)*. Dec 2014;231(23):4421-4428.



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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: Dii kwe'é atah nilinigií Blue Cross Blue Shield of Arizona haada yit'éego bina'idilkidgo éi doodago Háida bį́ą́ anilyeedigií t'áadoo le'é yina'idilkidgo beehaz'áanii hólo dii t'áá hazaadk'ehjí háká a'doowołgo bee haz'ą́ doo baqah ilinígóó. Ata' halne'ígíí kojį' bich'į́' hodiilnih 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.

