

Direct-to-Consumer and Over-the-Counter Testing

MEDICAL POLICY NUMBER: 73

Effective Date: 2/1/2023
Last Review Date: 1/2022
Next Annual Review: 1/2024
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INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. 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.

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

PLAN PRODUCT AND BENEFIT APPLICATION

Commercial

Medicaid/OHP*

Medicare**

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered “**not medically necessary**” for Medicare members.

COVERAGE CRITERIA

Note:

- Prior to May 11, 2023, there were temporary provisions in place for this Medicare medical policy during the COVID-19 public health emergency. See [Policy Guidelines](#) below for information regarding these emergency provisions.
 - This policy does not address home prothrombin time/international normalized ratio (PT/INR) monitoring for anticoagulation management, with may be considered medically necessary.
- I. Direct-to-consumer (DTC) tests are considered **investigational and not covered** for any situation or indication, including but not limited to any of the following (A.-F.):
- A. Genetic
 - B. Saliva
 - C. Urine
 - D. Vaginal health screens (e.g., SmartJane™ test by uBiome)
 - E. Microbiome (e.g., SmartGut™ test by Ubiome)
 - F. Vitamin levels

Link to [Evidence Summary](#)

POLICY CROSS REFERENCES

None

The full Company portfolio of current Medical Policies is available online and can be [accessed here](#).

POLICY GUIDELINES

NEED AND DURATION OF EMERGENCY PROVISIONS

1. **Need for the temporary Provisions: COVID-19 public health emergency**
2. **Documents or source relied upon: Families First Coronavirus Response Act (FFCRA) and the Coronavirus Aid, Relief, and Economic Security (CARES) Act¹⁻⁴**
3. **Initial Effective Date: 8/1/2020**
4. **Re-review dates: 9/23/2020; 11/30/2020; 2/1/2021; 3/31/2021; 6/1/2021; 12/8/2021; 7/20/2022; 10/4/2022; 12/16/2022**
5. **Termination Date: 5/11/2023**
6. **Next Reassessment Date determined at Companies sole discretion: 4/29/2023, or sooner if regulations or clinical practice guidelines change.**

POLICY ADDENDUM

Applies To: Commercial, ASO, and Medicare

Effective for Dates of Service: 2/26/2021 onward

COVID-19 Public Health Emergency

Under section 6001 of the Families First Coronavirus Response Act (FFCRA) and section 4201 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, health plans must provide coverage of in vitro diagnostic products for the detection or diagnosis of SARS-CoV-2 or COVID-19 that are approved by the U.S. Food and Drug Administration (FDA).^{1,2} On June 23, 2020, the Department of Labor (DOL), Department of Health and Human Services (DHHS), and the Department of the Treasury (collectively, the Departments) jointly released an FAQ around the FFCRA and CARES act implementation.³ This FAQ (see question 4) indicates that COVID-19 tests intended for at-home testing must be covered. Therefore, the following temporary emergency policy provisions are enacted:

Direct-to-Consumer Testing for *Diagnosing SARS-CoV-2/COVID-19*

Defined as: test collection performed in the member's home, but the sample must be sent off to be processed by an external laboratory. Test results are provided by the laboratory.

- I. Direct-to-consumer testing for diagnosing SARS-CoV-2/COVID-19 is considered medically necessary and covered.

Over-the-Counter Testing for Diagnosing SARS-CoV-2/COVID-19

Defined as: test collection and test processing is performed in the member's home. Test results are received within minutes and this testing does not require processing by an external laboratory.

II. Over-the-counter (OTC) testing for diagnosing SARS-CoV-2/COVID-19 is considered **medically necessary and covered** when the test is EUA/FDA approved for OTC use. This includes, but is not limited to, the following tests:

- Quidel QuickVue At-Home OTC COVID-19 test
- Ellume COVID-19 Home Test
- Abbott BinaxNOW (multiple configurations)
 - Abbott BinaxNOW COVID-19 Antigen Self Test
 - Abbott BinaxNOW COVID-19 Ag Card 2 Home Test
 - Abbott BinaxNOW COVID-19 Ag 2 Card
- BD Veritor System for Rapid Detection of SARS-CoV-2
- Cue Health COVID-19 Test for Home and Over The Counter (OTC) Use
- Lucira COVID-19 All-In-One Test Kit

Notes:

- Effective 1/15/2022: Members are limited to 8 tests per rolling 30-day period.
- If the test is not listed above, please see the FDA’s complete list of in vitro diagnostic EUA approvals for SARS-CoV-2 linked below. The authorized setting must be “Home” for the test to be authorized for OTC use.

- [Molecular Diagnostic Tests for SARS-CoV-2](#)
- [Antigen Diagnostic Tests for SARS-CoV-2](#)
- [Serology and Other Adaptive Immune Response Tests for SARS-CoV-2](#)
- [In vitro Diagnostics for Management of COVID-19 Patients](#)

III. If criterion II. above is not met, OTC testing for diagnosing SARS-CoV-2/COVID-19 is considered **investigational and not covered**.

POLICY ADDENDUM REFERENCES

1. Families First Coronavirus Response Act (FFCRA). Established into law March 18, 2020. Last accessed: December 8, 2022. URL: <https://www.congress.gov/116/plaws/publ127/PLAW-116publ127.pdf>
2. Coronavirus Aid, Relief, and Economic Security (CARES) Act. Established into law March 19, 2020. Last accessed: December 8, 2022. URL: <https://www.congress.gov/116/bills/s3548/BILLS-116s3548is.pdf>
3. FAQs About Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation. Part 43. Publication date: June 23, 2020. Last accessed: December 8, 2022. URL: <https://www.cms.gov/files/document/FFCRA-Part-43-FAQs.pdf>
4. Centers for Medicare & Medicaid Services (CMS). Laboratories: Medicare Flexibilities to Fight COVID-19. Published: April 29, 2020. Last accessed: December 8, 2022. URL: <https://www.cms.gov/files/document/laboratories-cms-flexibilities-fight-covid-19.pdf>

BACKGROUND

Direct-to-consumer (DTC) Testing

Direct-to-consumer (DTC) testing, also known as self-testing, at-home testing, or over the counter testing, are tests that are sold directly to individuals via the Internet, television, print advertisements or other marketing materials. Typically, DTC tests are bought and performed without a prescription, and with little to no involvement of a physician, genetic counselor, or other certified healthcare professional. However, DTS tests may be ordered by a medical provider. After the individual purchases a test kit, they collect a sample via finger-stick, buccal swab, saliva collection or other method, depending on the sample-type required. The sample is sent by mail to the testing laboratory and the results are provided directly to the individual via a website, mail or telephone. Most companies offering DTC genetic testing will ask the consumer to consent to using his or her genetic data for further voluntary research studies.

Currently, there are several types of DTC currently offered, including but not limited to:

- Hereditary risk genetic testing, which proposes to evaluate an individual's predisposition to complex diseases such as hereditary cancers, cardiovascular disease or depression
- Pharmacogenomic testing, which proposes to predict an individual's response to specific medication
- Carrier testing, which proposes to predict the likelihood of an individual carrying genetic information that may be passed on to offspring
- Whole exome or genome sequencing, which proposes to evaluate a broad range of health status from nutrition to fitness and overall wellness
- Diagnostic testing, which proposes to identify sexually transmitted infection (STI) status for conditions such as human papillomavirus (HPV)
- Microbiome testing, which proposes to evaluate health status based on various body locations such as the gut, mouth, nose, or genitalia

There are several companies offering DTC testing. Examples of these companies include:

- 23andMe, Inc. (Sunnyvale, CA)
- AncestryHealth® (San Francisco, CA)
- Dante Labs (New York, NY)
- Pathway Genomics (San Diego, CA)
- Veritas Genetics (Danvers, MA)

Concerns Regarding DTC Testing

Government agencies, including the U.S. Food & Drug Administration, Centers for Disease Control and Prevention (CDC), the National Institutes of Health: National Library of Medicine (NIH:NLM), and the Federal Trade Commission (FTC) have expressed concerns regarding the risks and limitations of DTC tests.¹⁻⁴ These concerns are expressed by major medical associations, including the American Medical Association (AMA), the American College of Human genetics and Genomics (ACMG) and the Association for Molecular Pathology (AMP).^{5,6} See Clinical Practice Guidelines section below for the official guidance published by major U.S.-based medical associations. Recent statements of concern by agencies and associations are summarized here.

Federal Laws and Regulations

Major U.S. medical associations recommend that all DTC testing be performed in Clinical Laboratory Improvement Amendments (CLIA) accredited laboratories, which are regulated through the Centers for Medicare & Medicaid Services (CMS).^{7,8} However, some of the laboratories offering DTC tests have not gone through the accreditation process, and therefore, the analytical validity and quality of some DTC tests cannot be determined. Of note, the CLIA process only accredits laboratories based on minimal analytical and technical test performance measures and does not evaluate or regulate the clinical validity or clinical utility of tests offered by accredited laboratories. CLIA accreditation does not indicate that the components of a test are associated with a disease or that the test will lead to improved health outcomes.

Qualifications of Medical Professionals

Because laboratory testing, particularly genetic testing, and the interpretation of results are highly technical and complex, it is important that personnel performing the tests, analyzing the results, and disseminating the results to patients, have the appropriate qualifications. The CLIA process only enforces these personnel qualification requirements in the context analytical and technical test performance measures. However, analyzing the results, preparing reports and communicating the results to the patient requires appropriately educated (and board-certified) medical professionals. There are concerns that many of the DTC testing laboratories may not have the medical staff with the appropriate certifications/credentials to analyze and disseminate laboratory results.

As stated by the American Association of Clinical Chemistry:⁹

“Laboratory reports have been developed to provide specific information to highly trained and knowledgeable healthcare providers. As such, the reports typically provide a numeric value and a reference interval, and may also include a brief description of the result. This minimal information, when considered with all other factors such as any symptoms of disease that may be present, is sufficient for healthcare professionals to make clinical decisions. An individual consumer likely will need far greater context to fully understand the meaning of the test and to determine next steps. For example, an abnormal test result outside the reference interval may or may not indicate an underlying health problem. Alternatively, an individual may be falsely reassured by a test result in the normal range even when signs and symptoms warrant medical attention.”

Therefore, it is standard medical practice that laboratory and genetic tests not only be ordered, but also interpreted by the physician or other health care provider currently overseeing a patient’s care. Furthermore, the results of these tests should be evaluated as part of an overall health assessment with a healthcare provider.

Tests not ordered and interpreted by a healthcare professional as part of ongoing patient care, such as some direct-to-consumer tests, have a number of risks, including being misinterpreted and/or not understood by patients. These risks are described below.

Interpretation of Results

Interpretation of laboratory and genetic test results can difficult to interpret for a number of reasons. For some laboratory tests, what is considered the “normal” range has not been demonstrated. While for others, appropriate medical management for individuals with “low” or “high” values has not been established. In addition, laboratory and genetic test results must be interpreted in the context of the

patient's other health factors, like family history, environmental characteristics, other health conditions and current medications.

Concerns regarding genetic DTC tests, in particular, have been raised, as a positive result does not always indicate a diagnosis, but may indicate an increased risk for developing a disease. Conversely, a negative result may not preclude an individual from being at risk of developing a disease. Therefore, there are also concerns that the results and limitations of DTC tests will not be adequately explained to consumers, thereby allowing for medical and reproductive decisions to be made without a complete understanding of the risks/benefits.

Test Accuracy

Recent reports of DTC test inaccuracy indicate that there may be a high false positive rate for results reported by DTC genetic tests. A recent case series published by Ambry Genetics, a diagnostic genetics laboratory, reported that 40% of variants in a variety of genes reported in DTC raw data were false positives.¹⁰ The authors reported that some variants designated with the "increased risk" classification in DTC raw data or by a third-party interpretation service were classified as benign at Ambry Genetics as well as several other clinical laboratories, and have been determined to be common variants in publicly available population frequency databases. Of the 40% of false-positive calls, 94.1% (n = 16/17) were in cancer-related genes and the remaining 5.9% (n = 1) was in a connective-tissue disorder gene. Additionally, the DTC tests did not examine all the potential genetic risk factors, so there was also a possibility of false negatives. The authors also reported that the genes reported out for any given condition by the DTC tests were not comprehensively sequenced or analyzed, and stated "therefore, the consumer is not provided with a comprehensive genetic risk assessment."

Security and Privacy

Lastly, there are also security concerns raised by U.S. medical associations regarding privacy and safety of personal and family information. DTC testing laboratories may not clearly communicate, "who will have access to test results, what processes are in place to protect these results, what will happen to the DNA sample once testing is complete, and whether the test results may have any personal or family-related implications for life, long-term care, or disability insurance."⁶ In addition, it is unclear, "whether data generated from testing will be sold to or shared with third parties should be clearly disclosed, as should ownership of the sample and generated data."

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

In order to "provide reasonable assurance of safety and effectiveness", the FDA reviews DTC test kits and claims in order to determine if the test meets the FDA's definition of an *in vitro* diagnostic (IVD)

test.⁴ This review process must be completed before a commercial IVD product can be placed on the market. DTC tests reviewed to date fall under two different IVD categories:

- Nucleic Diagnostic Tests (e.g., 23&Me)
- Home Use Tests for various conditions such as hepatitis, HPV and STIs.

However, review of any test by the FDA as an IVD does not demonstrate definitive safety, efficacy, or clinical utility; nor does it indicate medical necessity.

CLINICAL LITERATURE REVIEW

American College of Obstetricians and Gynecologists (ACOG)

A 2021 ACOG Committee Opinion stated the following regarding consumer testing for disease risk:¹¹

- The American College of Obstetricians and Gynecologists discourages direct-to-consumer genetic testing without appropriate counseling.
- Pretest counseling for direct-to-consumer genetic testing should include a discussion of privacy concerns, including who may have access to the results; what systems are in place to provide protection of confidential health information; how the sample will be handled after testing is complete; whether the test results will have an effect on issues related to life, long-term care, or disability insurability; and how genetic information will be handled if the company closes or is purchased.
- Direct-to-consumer genetic testing may suggest an increased or decreased risk for a disorder but can neither prove nor eliminate disease potential. Direct-to-consumer testing also may identify unanticipated information or results that may have implications for other family members.
- Patients may present after direct-to-consumer testing already has been performed, and clinicians should be prepared to review these results or refer to a health care professional with the appropriate knowledge, training, and experience in interpreting test results.
- In most circumstances, when a patient presents with a direct-to-consumer test result that putatively assesses the risk of specific diseases, the patient should be referred to an obstetrician-gynecologist or other health care professional who is skilled in risk assessment for the diseases or conditions of interest and who can interpret genetic testing results in the context of the individual's genetic testing results in the context of the individual's relevant medical and family history.
- When a patient presents with a direct-to-consumer test result, medical intervention should wait for confirmatory testing in a clinical laboratory.
- Given the insufficient data to support the use of single nucleotide polymorphisms (SNP) testing for medical purposes, SNP testing to provide individual risk assessment for a variety of diseases or to tailor drug therapy outside of an institutional review board-approved research protocol is not recommended. The American College of Obstetricians and Gynecologists recommends that the use of these technologies be viewed as investigational at this time.

American College of Medical Genetics and Genomics (ACMG)

In 2019, the ACMG published guidance regarding direct-to-consumer genetic testing.⁵ The ACMG stated support for genomic testing for clinically-meaningful tests, meeting a comprehensive list of conditions. The list included well-established clinical validity, supported by strong scientific evidence in the peer reviewed literature, laboratory compliance in accordance with CLIA statute and regulations, test validation and interpretation supported by appropriately licensed and credentialed, board-certified individuals, amongst numerous other requirements.

EVIDENCE SUMMARY

There is insufficient evidence that the use of direct-to-consumer (DTC) tests improve overall health outcomes, including confirming a diagnosis or altering medical management. Emerging evidence indicates that DTC tests may have high false positive rates and have the potential for false negatives. In addition, while some tests may have minimum measures of analytical validity and test performance, there is a paucity of evidence on the clinical validity and utility of DTC tests. Furthermore, prominent government agencies and major medical associations have published numerous concerns regarding the risks of DTC testing, including lack of comprehensive testing for included conditions and misinterpretation of results, both of which may have a negative impact on medical management.

BILLING GUIDELINES AND CODING

Depending on the type of test, the test components, the indication, and other factors, DTC test requests may come in with one or more specific codes and/or various unlisted codes.

Note: Codes addressed by this policy, may include, but are not limited to, the following:

CODES*		
CPT	81479	Unlisted molecular pathology procedure
	81599	Unlisted multianalyte assay with algorithmic analysis
	84999	Unlisted chemistry procedure

*Coding Notes:

- The above code list 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.
- 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

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2. Federal Trade Commission. Consumer Information. Direct-to-Consumer Genetic Tests. <https://www.consumer.ftc.gov/articles/0166-direct-consumer-genetic-tests>. Published 2018. Accessed 12/8/2022.
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10. Tandy-Connor S, Guiltinan J, Krempely K, et al. False-positive results released by direct-to-consumer genetic tests highlight the importance of clinical confirmation testing for appropriate patient care. *Genet Med.* 2018. <https://www.ncbi.nlm.nih.gov/pubmed/29565420>
11. American College of Obstetricians and Gynecologists. ACOG committee opinion: Consumer testing for disease risk. *Obstetrics & gynecology.* 2021;137(1):e1-e6. <https://www.acog.org/-/media/project/acog/acogorg/clinical/files/committee-opinion/articles/2021/01/consumer-testing-for-disease-risk.pdf>

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.

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