MEDICAL POLICY	**Temporary Policy Emergency Provisions for:** **Direct-to-Consumer (DTC) and Over-the-Counter (OTC) Testing** **(Medicare Only)**
Effective Date: 7/1/2022  7/1/2022 Medical Officer Date	Medical Policy Number: 520 Medical Policy Committee Approved Date: 2/2022

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

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) Act[1-4]**
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: 4/30/2023**
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 1/15/22: 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**.

MEDICAL POLICY	Temporary Policy Emergency Provisions for: Direct-to-Consumer (DTC) and Over-the-Counter (OTC) Testing (Medicare Only)

POLICY ADDENDUM REFERENCES

1. Families First Coronavirus Response Act (FFCRA). Established into law March 18, 2020. Last accessed: August 4, 2020. 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: August 4, 2020. 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: August 4, 2020. 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: August 4, 2020. URL: https://www.cms.gov/files/document/covid-19-laboratories.pdf

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").

APPLIES TO:

Medicare Only

MEDICARE POLICY CRITERIA

The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.

Service	Medicare Guidelines
Direct-to-Consumer (DTC) Testing (aka, self-testing, at-home testing, or over-the-counter testing)	Medicare Benefit Policy Manual, Ch. 15 – Covered Medical and Other Health Services, §80.1 - Clinical Laboratory Services **NON-COVERAGE POSITION SUMMARY:** Clinical laboratory services must be ordered and used promptly by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements and test

	results must be used in the direct management of a specific medical problem. Tests that are not ordered by a treating provider as noted above are denied as **not medically reasonable or necessary**.[1-3]

POLICY GUIDELINES

Medicare and Medical Necessity

Medicare coverage of diagnostic laboratory services requires the services meet certain requirements to determine medical necessity. In order to be considered a medically necessary test, Medicare requires that the service in question:

- Be ordered by a physician who is treating the beneficiary;[1-3]
- Provide data that would be directly used in the management of a beneficiary's specific medical problem. [1-3]
- Fall within a defined Medicare benefit category;[4,5]
- Be considered medically necessary, as defined by the *Social Security Act, §1862(a)(1)(A)*. This means the service must be considered reasonable and necessary in the diagnosis or treatment of an illness or injury, or to rule out or confirm a suspected diagnosis because the patient has signs and/or symptoms;[6,7]

According to Medicare, "Tests that are not ordered by a treating physician or other qualified treating nonphysician practitioner acting within the scope of their license and in compliance with Medicare requirements will be denied as not reasonable and necessary."[2] Therefore, direct-to-consumer (DTC) or over-the-counter (OTC) testing is **not medically necessary**.

CPT/HCPCS CODES

Medicare Only	
Unlisted Codes All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then it will be **denied as not covered.**	
81479	Unlisted molecular pathology procedure
81599	Unlisted multianalyte assay with algorithmic analysis
84999	Unlisted chemistry procedure

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 Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

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.

REGULATORY STATUS

Mental Health Parity Statement

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.

REFERENCES

1. Medicare Benefit Policy Manual, Ch. 15 – Covered Medical and Other Health Services, §80.1 - Clinical Laboratory Services; Last Updated 11/19/2007; Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf
2. Federal Register / Vol. 66, No. 226 / Friday, November 23, 2001; Available at: https://www.cms.gov/Medicare/Coverage/CoverageGenInfo/downloads/lab2.pdf
3. 42 CFR §410.32(a); Available at: https://www.govinfo.gov/content/pkg/CFR-2011-title42-vol2/pdf/CFR-2011-title42-vol2-sec410-32.pdf
4. Medicare Coverage Determination Process; Last Updated: 12/01/2021; Available at: https://www.cms.gov/medicare/coverage/determinationprocess
5. Medicare Managed Care Manual, Ch. 4 - Benefits and Beneficiary Protections, §10.2 - Basic Rule; Last Updated: 04/22/2016; Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c04.pdf
6. *Title XVIII of the Social Security Act, §1862(a)(1)(A)*; Available at: https://www.ssa.gov/OP_Home/ssact/title18/1862.htm

7. Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §20 - Services Not Reasonable and Necessary; Last Updated 10/01/2003; Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c16.pdf