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<b>Title</b>	<b>COVID-19 Testing: Diagnostic, Surveillance and Over the Counter</b>		
<b>Number</b>	<b>CP.PP.421.v1.5</b>		
<b>Last Approval Date</b>	11/12/24	<b>Original Effective Date</b>	03/04/22
<b>Cross Reference</b>			

Coverage of any service is determined by a member's eligibility, benefit limits for the service or services rendered and the application of the Plan's Medical Policy. Final payment is subject to the application of claims adjudication edits common to the industry and the **Plan's professional or facility services claims coding policies**. Reimbursement is restricted to the provider's scope of practice as well as the fee schedule applicable to that provider.

<b>Purpose/ Application</b>	To define/identify COVID-19 testing for general workplace health and safety, occupational, school, travel or public health surveillance purposes or any other purpose not primarily intended for diagnosis or treatment that is submitted on a CMS 1500 paper claim, an 837P electronic claim form or a member submitted claim.
<b>Scope</b>	Applies to all Premera Blue Cross, Premera Blue Cross Blue Shield of Alaska, LifeWise Health Plan of Washington, LifeWise Assurance Company and Premera Blue Cross HMO lines of business and products
<b>Definitions</b>	<ul style="list-style-type: none"> <li>• <b>Diagnostic Testing:</b> Testing primarily intended for individualized diagnosis or treatment of current infection in individuals when a person is displaying signs and symptoms of COVID-19, or when a person is not symptomatic but has been recently exposed to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), either a confirmed or suspected case of COVID-19. The two main types of diagnostic testing:             <ul style="list-style-type: none"> <li>○ <b>Molecular Tests</b> – diagnostic viral test; nasal swab testing to identify the virus RNA present in a patient</li> <li>○ <b>Antigen Tests</b> – diagnostic viral test; tests look for specific viral proteins that are known to be part of the SARS-CoV-2 virus. Antigen tests are easier and quicker to run but they are not as sensitive as molecular tests</li> </ul> </li> <li>• <b>Screening Testing:</b> Testing to identify people who are not exhibiting symptoms of COVID-19 and who have not had a known or suspected exposure to SARS-CoV-2. Screening testing is used to identify persons who may be contagious so that measures can be taken to prevent further transmission of the virus (e.g., testing of a skilled nursing facility, prison, employer testing employees, or schools testing students, faculty, and staff)</li> <li>• <b>Surveillance Testing:</b> Testing for public health surveillance is an ongoing, systematic collection, analysis, and interpretation of health-related data for planning, implementation, and evaluation of public health practice. Surveillance testing for SARS-CoV-2 is used to monitor the community or population level infection and disease rather than that of an individual, or to gain the incidence and prevalence of disease. Surveillance testing results are returned in aggregate to the requesting institution as the testing is performed only on de-identified specimens. Surveillance testing is not used to return a diagnostic test result to an individual or for individual decision-making (e.g., a public health department randomly selects and samples a percentage of all persons in a city at intervals to assess local infection rates and trends)</li> </ul>

	<ul style="list-style-type: none"> <li>• <b>Viral Testing:</b> checks samples from your respiratory system (such as swabs of the inside of the nose) to tell you if you currently have an infection with SARS-CoV-2, the virus that causes COVID-19</li> <li>• <b>Antibody Testing:</b> checks your blood by looking for antibodies, which can show if you had a past infection with the virus that causes COVID-19. Antibodies are proteins that help fight off infections and usually provide protection against getting that disease again (immunity). Antibodies are disease specific. Depending on when someone was infected and the timing of the test, the test may not find antibodies in someone with a current COVID-19 infection. Antibody tests should not be used to diagnose COVID-19</li> <li>• <b>Attending Provider:</b> An attending provider means an individual who is licensed under applicable state law, who is acting within the scope of the provider’s license, and who is responsible for providing care to a patient. An attending provider is not a plan, issuer, hospital, or managed care organization</li> </ul>
<p><b>Policy</b></p>	<p><b><u>Diagnostic Testing</u></b></p> <p>Diagnostic Testing for COVID-19 using molecular and antigen tests for the detection of SARS-CoV-2 is reimbursed when the following criteria are met:</p> <ul style="list-style-type: none"> <li>• the test is approved, cleared, or authorized under section 510(k), 513, 515, or 564 of the Federal Food, Drug, and Cosmetic Act, the developer has requested, or intends to request Emergency Use Authorization (EUA) under section 564 of the Federal Food, Drug, and Cosmetic Act, is developed in and authorized by a State that has notified the Secretary of Health and Human Services (HHS) of its intention to review tests intended to diagnose COVID–19, and is another test the Secretary of HHS determines appropriate in guidance.</li> <li>• an attending provider as defined in applicable federal guidance has made an individualized determination that the test is medically necessary for diagnosis or treatment of COVID-19</li> <li>• the test is used to diagnose and/or treat an individual suspected of having a coronavirus infection.</li> </ul> <p><b><u>Surveillance and Screening Testing</u></b></p> <p>When COVID-19 testing is performed solely for data collection, analysis, and public health surveillance to determine if an individual was previously infected with COVID-19, such testing will not be reimbursed since this type of testing is not used to diagnose or treat an illness or disease.</p> <p>Testing for return to work or school, occupational, travel, public health screening, and vaccine accommodation <b>is not covered or reimbursed</b> under any Company plan.</p> <p>Documentation in the member’s medical record should identify the purpose of the COVID-19 test and be available for review upon request.</p> <p><b><u>Over the Counter (OTC) COVID-19 Tests</u></b></p> <p>Self-administered and self-read at home/elsewhere OTC tests will not be reimbursed as member-submitted claims.</p>

	<p>OTC COVID-19 tests for SARS-CoV-2 infections for surveillance testing will not be reimbursed under a member’s coverage or as a member-submitted claim.</p>
<p><b>Codes and Coding Guidelines</b></p>	<p><b><u>MOLECULAR test codes:</u></b></p> <ul style="list-style-type: none"> <li>• <b>0202U</b> - Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected</li> <li>• <b>0223U</b> - Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected</li> <li>• <b>0225U</b> - Infectious disease (bacterial or viral respiratory tract infection) pathogen-specific DNA and RNA, 21 targets, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected</li> <li>• <b>0240U</b> - Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 3 targets (severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), influenza A, influenza B), upper respiratory specimen, each pathogen reported as detected or not detected</li> <li>• <b>0241U</b> - Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 4 targets (severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), influenza A, influenza B, respiratory syncytial virus (RSV)), upper respiratory specimen, each pathogen reported as detected or not detected</li> <li>• <b>87635</b> - Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique</li> <li>• <b>87636</b> - Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease COVID-19) and influenza virus types A and B, multiplex amplified probe technique</li> <li>• <b>87637</b> - Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease (COVID-19), influenza virus types A and B, and respiratory syncytial virus, multiplex amplified probe technique</li> <li>• <b>U0001</b> - CDC 2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel</li> <li>• <b>U0002</b> - 2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC</li> </ul> <p><b><u>ANTIGEN test codes:</u></b></p> <ul style="list-style-type: none"> <li>• <b>87426</b> - Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay – EIA, enzyme-linked immunosorbent assay – ELISA, fluorescence immunoassay (FIA), immunochemiluminometric assay – IMCA) qualitative or semiquantitative, multiple-step method; severe acute respiratory syndrome coronavirus (e.g., SARS-CoV-2, SARS-CoV-2 COVID-19)</li> <li>• <b>87428</b> - Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay (EIA), enzyme-linked immunosorbent assay (ELISA), fluorescence immunoassay (FIA), immunochemiluminometric assay (IMCA) qualitative or semiquantitative; severe acute respiratory syndrome coronavirus</li> </ul>

	<p>(e.g., SARS-CoV-2, SARS-CoV-2 COVID-19) and influenza virus types A and B</p> <ul style="list-style-type: none"> <li>• <b>87449</b> - Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay – EIA, enzyme-linked immunosorbent assay – ELISA, fluorescence immunoassay (FIA), immunochemiluminometric assay – IMCA), qualitative or semiquantitative; multiple-step method, not otherwise specified, each organism</li> <li>• <b>87811</b> - Infectious agent antigen detection by immunoassay with direct optical (i.e., visual) observation; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease COVID-19)</li> </ul> <p><b><u>ANTIBODY test codes:</u></b></p> <ul style="list-style-type: none"> <li>• <b>0224U</b> - Antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), includes titer(s), when performed</li> <li>• <b>86328</b> - Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single step method (e.g., reagent strip); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])</li> <li>• <b>86413</b> - severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]) antibody, quantitative,</li> <li>• <b>86769</b> - Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])</li> </ul> <p><b><u>NEUTRALIZING ANTIBODY test codes:</u></b></p> <ul style="list-style-type: none"> <li>• <b>86408</b> - Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease COVID-19); screen</li> <li>• <b>86409</b> - Neutralizing antibody, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease COVID-19); titer</li> <li>• <b>0226U</b> - Surrogate viral neutralization test (sVNT), severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease COVID-19), ELISA, plasma, serum</li> </ul> <p><b><u>Over the Counter (OTC) Test kit code:</u></b></p> <ul style="list-style-type: none"> <li>• <b>K1034</b> - Provision of COVID-19 test, nonprescription self-administered and self-collected use, FDA approved, authorized or cleared, one test count</li> </ul> <p><b><u>ICD-10-CM Diagnosis Code Description</u></b></p> <ul style="list-style-type: none"> <li>• <b>U07.1</b> – COVID-19</li> <li>• <b>Z20.822</b> – Contact with and suspected exposure to COVID-19</li> <li>• <b>Z03.89</b> - Encounter for observation of other suspected diseases and condition rule out</li> <li>• <b>Z11.52</b> – Encounter for screening for COVID-19</li> </ul>
<b>Violations of Policy</b>	<p>Violations of this policy by any party that enters a written arrangement with the Plan may result in increased auditing and monitoring, performance guarantee contractual penalties and/or termination of the contract. Disciplinary actions will be determined at the Plan’s sole discretion.</p> <p>Violations of this policy may be grounds for corrective action, up to and including termination of employment.</p>
<b>Exceptions</b>	

<b>Laws, Regulations &amp; Standards</b>	<ul style="list-style-type: none"> <li>• Families First Coronavirus Response Act (FFCRA) Pub. L. No. 116-127 (2020)</li> <li>• Coronavirus Aid, Relief, and Economic Security Act (CARES Act) Pub. L. No. 116-136 (2020)</li> <li>• FAQs ABOUT FAMILIES FIRST CORONAVIRUS RESPONSE ACT AND CORONAVIRUS AID, RELIEF, AND ECONOMIC SECURITY ACT IMPLEMENTATION PART 42, April 11, 2020</li> <li>• FAQs ABOUT FAMILIES FIRST CORONAVIRUS RESPONSE ACT AND CORONAVIRUS AID, RELIEF, AND ECONOMIC SECURITY ACT IMPLEMENTATION PART 43, June 23, 2020</li> <li>• FAQs ABOUT FAMILIES FIRST CORONAVIRUS RESPONSE ACT AND CORONAVIRUS AID, RELIEF, AND ECONOMIC SECURITY ACT IMPLEMENTATION PART 44, February 26, 2021</li> <li>• FAQs ABOUT AFFORDABLE CARE ACT IMPLEMENTATION PART 51, FAMILIES FIRST CORONAVIRUS RESPONSE ACT AND CORONAVIRUS AID, RELIEF AND ECONOMIC SECURITY ACT IMPLEMENTATION, JANUARY 10, 2022</li> <li>• Centers for Disease Control and Prevention (CDC)</li> </ul>
<b>References and Resources</b>	<ul style="list-style-type: none"> <li>• Food and Drug Administration, Individual EUAs for Antigen and Molecular Diagnostic Tests for SARS-CoV-2: <ul style="list-style-type: none"> <li>○ <a href="#">In Vitro Diagnostics EUAs - Antigen Diagnostic Tests for SARS-CoV-2   FDA</a></li> <li>○ <a href="#">In Vitro Diagnostics EUAs - Molecular Diagnostic Tests for SARS-CoV-2   FDA</a></li> </ul> </li> <li>• ICD-10-CM Official Coding Guidelines for Coding and Reporting FY 2023 (October 2, 2022-September 30, 2023)</li> <li>• American Medical Association Current Procedural Terminology (AMA CPT), 2023 edition</li> </ul>

<b>Policy Owner Review</b>	Payment Integrity Oversight Committee	
<b>Contact</b>	Any questions regarding the contents of this policy or its application should be directed to the Payment Integrity Department	
<b>Annual Review Dates</b>	11/12/24; 03/04/24; 05/19/23; 03/13/23; 05/12/22	
<b>Version History</b>	03/04/22	Creation of policy
	05/12/22	<ul style="list-style-type: none"> <li>• Revised policy Title</li> <li>• Removed diagnosis codes under the Surveillance Testing section due to configuration in claims processing system.</li> <li>• Added the new OTC COVID-19 Test code K1034 to the Over-the-Counter section of the policy and in the Codes/Coding Guidelines section.</li> </ul>
	03/13/23	At the beginning of the section Over the Counter COVID-19 Tests (OTC COVID 19) of the policy, added a paragraph indicating that OTC tests purchased on and after May 11, 2023, will no longer be reimbursed as member submitted claims due to the federal government declaration that the PHE is ending May 11, 2023. Member submitted claims will be reimbursed for purchase dates through May 10, 2023 only.
	05/19/23	CORRECTION: A correction was made to the date that Over the Counter (OTC) COVID 19 tests will no longer be reimbursed. OTC

		tests purchased on and after <b>May 12, 2023</b> , will no longer be reimbursed as member submitted claims due to the end of the Public Health Emergency on May 11, 2023.
	03/04/24	In the Codes/Coding Guideline section, code termination dates added to codes U0003, U0004 and U0005.
	11/12/24	<p>Removed from the Policy section:</p> <ul style="list-style-type: none"> <li>○ In response to the Federal government declaration that the COVID public health emergency (PHE) ended May 11, 2023, effective with <b>purchase dates</b> on and after May 12, 2023, self-administered and self-read at home/elsewhere OTC tests will no longer be reimbursed as member-submitted claims.</li> <li>○ Effective with purchase dates of January 15, 2022, through May 11, 2023, self-administered and self-read at home/elsewhere tests <b>without the involvement of a health care provider</b> (self-tests or at-home tests) will be reimbursed for each participant or enrollee <b>up to 8 individual tests per 30-day period</b>.</li> <li>○ Such OTC COVID-19 tests, purchased prior to May 12, 2023, will be processed for reimbursement as a member-submitted claim using a separate claim form for each covered family member with the following information supplied by each member on the claim form as follows: <ul style="list-style-type: none"> <li><b>Procedure codes:</b> <ul style="list-style-type: none"> <li>○ <b>K1034</b> - Provision of COVID-19 test, nonprescription self-administered and self-collected use, FDA-approved, authorized, or cleared, one test count (code effective April 4, 2022, through May 11, 2023)</li> <li>○ <b>C0019</b> – COVID Home Test Kits (code effective January 15, 2022 through May 11, 2023)</li> </ul> </li> <li><b>Place of Service code 12 – HOME</b></li> <li><b>One of the following diagnosis codes:</b> <ul style="list-style-type: none"> <li>○ <b>Z20.822 – Contact with and suspected exposure to COVID-19</b></li> <li>○ <b>Z03.89 - Encounter for observation of other suspected diseases and condition rule out</b></li> <li>○ <b>Z11.52 – Encounter for screening for COVID-19</b></li> </ul> </li> </ul> </li> <li>○ The test purchased is one approved or granted EUA by the Food and Drug Administration (FDA) and <b>labeled for home use</b>. The FDA EUA list of approved home test kits can be found using the links in the References section of this policy</li> <li>○ A copy of the purchase receipt and/or shipping receipt indicating amount paid, the specific test purchased, and the total number of “individual” tests purchased. If the individual tests were ordered via an online source, the claim should be held until the actual tests have been received</li> <li>○ A copy or photo of the barcode from the test package</li> </ul> <p>Removed from the coding section:</p> <ul style="list-style-type: none"> <li>○ <b>U0003</b> -Infectious agent detection by nucleic acid (DNA or RNA); Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique, making use of high throughput technologies</li> </ul>

		<p>as described by CMS-2020-01-R (code terminated May 12, 2023)</p> <ul style="list-style-type: none"> <li>○ <b>U0004</b> - 2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19), any technique, multiple types or subtypes (includes all targets), non-CDC, making use of high throughput technologies as described by CMS-2020-01-R (code terminated May 12, 2023)</li> <li>○ <b>U0005</b> - Infectious agent detection by nucleic acid (DNA or RNA); Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus disease (COVID-19), amplified probe technique, CDC or non-CDC, making use of high throughput technologies, completed within 2 calendar days from date of specimen collection (list separately in addition to either HCPCS code U0003 or U0004) (code terminated May 12, 2023)</li> <li>○ <b>C0019</b> - COVID Home Test Kits (effective January 15, 2022 through May 12, 2023)</li> </ul>
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