Circulating Tumor DNA and Circulating Tumor Cells for Cancer Management (Liquid Biopsy)

**Introduction**

Liquid biopsy is a method when a blood sample (rather than a piece of tissue) is used to test for cancer cells or small genetic cancer pieces mixing in the blood. The blood sample is taken from the arm and is tested for cells or genetic pieces that cancers shed into the bloodstream. Identifying tumor cell material in the blood might help to diagnose cancer, track changes in a cancer over time or help select the right type of cancer treatment. However, there is not enough information from clinical studies to be certain that this works as well as a tissue biopsy in most people, because we don’t yet know that this works as well as tissue biopsy. This treatment is not yet proven.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can
be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

**Policy Coverage Criteria**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Circulating Tumor DNA, Circulating Tumor Cells</td>
<td>The use of circulating tumor DNA and/or circulating tumor cells is considered investigational for all indications (see Table 1 for examples of liquid biopsy tests).</td>
</tr>
</tbody>
</table>

**Coding**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>Description</td>
</tr>
<tr>
<td>81479</td>
<td>Unlisted molecular pathology procedure</td>
</tr>
<tr>
<td>86152</td>
<td>Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood);</td>
</tr>
<tr>
<td>86153</td>
<td>Cell enumeration using immunologic selection and identification in fluid specimen (eg, circulating tumor cells in blood); physician interpretation and report, when required</td>
</tr>
</tbody>
</table>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

**Related Information**

This policy does not address the use of blood-based testing for epidermal growth factor receptor variants in non-small-cell lung cancer or the use of AR-V7 circulating tumor cells for metastatic prostate cancer.

**Evidence Review**
Description

Circulating tumor DNA (ctDNA) and circulating tumor cells (CTCs) in peripheral blood, referred to as “liquid biopsy,” have several potential uses for guiding therapeutic decisions in patients with cancer or being screened for cancer. This policy evaluates uses for liquid biopsies not addressed in a separate policy. If a separate policy exists, then conclusions reached there supersede conclusions here.

Background

Liquid biopsy refers to analysis of circulating tumor DNA (ctDNA) or circulating tumor cells (CTCs) as methods of noninvasively characterizing tumors and tumor genome from the peripheral blood.

Circulating Tumor DNA

Normal and tumor cells release small fragments of DNA into the blood, which is referred to as cell-free DNA (cfDNA). cfDNA from nonmalignant cells is released by apoptosis. Most cell-free tumor DNA is derived from apoptotic and/or necrotic tumor cells, either from the primary tumor, metastases, or CTCs. Unlike apoptosis, necrosis is considered a pathologic process, and generates larger DNA fragments due to incomplete and random digestion of genomic DNA. The length or integrity of the circulating DNA can potentially distinguish between apoptotic and necrotic origin. ctDNA can be used for genomic characterization of the tumor.

Circulating Tumor Cells

Intact CTCs are released from a primary tumor and/or a metastatic site into the bloodstream. The half-life of a CTC in the bloodstream is short (1-2 hours), and CTCs are cleared through extravasation into secondary organs. Most assays detect CTCs through the use of surface epithelial markers such as EpCAM and cytokeratins. The primary reason for in detecting CTCs is prognostic, through quantification of circulating levels.
Detecting ctDNA and CTCs

Detection of ctDNA is challenging because ctDNA is diluted by nonmalignant circulating DNA and usually represents a small fraction (<1%) of total cfDNA. Therefore, more sensitive methods than the standard sequencing approaches (e.g., Sanger sequencing) are needed.

Highly sensitive and specific methods have been developed to detect ctDNA, for both single-nucleotide mutations (e.g., BEAMing [which combines emulsion polymerase chain reaction [PCR] with magnetic beads and flow cytometry] and digital PCR) and copy-number variants. Digital genomic technologies allow for enumeration of rare mutant variants in complex mixtures of DNA.

Approaches to detecting ctDNA can be considered targeted, which includes the analysis of known genetic mutations from the primary tumor in a small set of frequently occurring driver mutations, which can impact therapy decisions or untargeted without knowledge of specific variants present in the primary tumor, and include array comparative genomic hybridization, next-generation sequencing, and whole exome and genome sequencing.

CTC assays usually start with an enrichment step that increases the concentration of CTCs, either by biologic properties (expression of protein markers) or physical properties (size, density, electric charge). CTCs can then be detected using immunologic, molecular, or functional assays.

Table 1. Examples of Liquid Biopsy Tests

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Test</th>
<th>Type of Liquid Biopsy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biocept</td>
<td>Liquid Biopsies for breast, colorectal, gastric, prostate, and melanoma</td>
<td>ctDNA</td>
</tr>
<tr>
<td>CellMax Life</td>
<td>CellMax-LBx Liquid Biopsy</td>
<td>CTC plus ctDNA</td>
</tr>
<tr>
<td>CellMax Life</td>
<td>CellMax-CRC Colorectal Cancer Early Detection Test</td>
<td>CTC</td>
</tr>
<tr>
<td></td>
<td>CellMax-PanCa Monitoring Test</td>
<td>CTC</td>
</tr>
<tr>
<td>CellMax Life</td>
<td>CellMax-Prostate Cancer Test</td>
<td>CTC</td>
</tr>
<tr>
<td>Cynvenio</td>
<td>ClearID® Solid Tumor Panel</td>
<td>ctDNA</td>
</tr>
<tr>
<td></td>
<td>ClearID® HER2 Expression Liquid Biopsy</td>
<td>CTC</td>
</tr>
<tr>
<td>Foundation Medicine</td>
<td>FoundationACT®</td>
<td>ctDNA</td>
</tr>
<tr>
<td>Guardant Health</td>
<td>Guardant360®</td>
<td>ctDNA</td>
</tr>
</tbody>
</table>
Summary of Evidence

For individuals who have advanced cancer who receive testing of ctDNA to select targeted treatment, the evidence includes observational studies. Relevant outcomes are overall survival, disease-specific survival, test accuracy and validity, morbid events, and medication use. Given the breadth of methodologies available to assess ctDNA, the clinical validity of each commercially available test must be established independently, and these data are lacking. Published studies reporting clinical outcomes and/or clinical utility are lacking. The uncertainties concerning clinical validity and clinical utility preclude conclusions about whether variant analysis of ctDNA can replace variant analysis of tissue. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have advanced cancer who receive testing of CTCs to select targeted treatment, the evidence includes observational studies. Relevant outcomes are overall survival, disease-specific survival, test accuracy and validity, morbid events, and medication use. Given the breadth of methodologies available to assess CTCs, the clinical validity of each commercially available test must be established independently, and these data are lacking. Published studies reporting clinical outcomes and/or clinical utility are lacking. The uncertainties concerning clinical validity and clinical utility preclude conclusions about whether the use of CTCs can replace variant analysis of tissue. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have cancer who receive testing of ctDNA to monitor treatment response, the evidence includes observational studies. Relevant outcomes are overall survival, disease-specific survival, test accuracy and validity, morbid events, and medication use. Given the breadth of methodologies available to assess ctDNA, the clinical validity of each commercially available test must be established independently, and these data are lacking. Published studies reporting clinical outcomes and/or clinical utility are lacking. The uncertainties concerning clinical validity and clinical utility preclude conclusions about whether the use of ctDNA should

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<tr>
<th>Manufacturer</th>
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</tr>
</thead>
<tbody>
<tr>
<td>IVDiagnostics</td>
<td>Velox™</td>
<td>CTC</td>
</tr>
<tr>
<td>Pathway Genomics</td>
<td>CancerIntercept® Detect</td>
<td>ctDNA</td>
</tr>
<tr>
<td>Personal Genome Diagnostics</td>
<td>PlasmaSELECT™</td>
<td>ctDNA</td>
</tr>
<tr>
<td>Sysmex Inostics</td>
<td>OncoBEAM™</td>
<td>ctDNA</td>
</tr>
<tr>
<td>Circulogene</td>
<td>Theranostics</td>
<td>ctDNA</td>
</tr>
</tbody>
</table>

CTC: circulating tumor cell; ctDNA: circulating tumor DNA.
be used to monitor treatment response. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have cancer who receive testing of CTCs to monitor treatment response, the evidence includes a randomized controlled trial, observational studies, and systematic reviews of observational studies. Relevant outcomes are overall survival, disease-specific survival, test accuracy and validity, morbid events, and medication use. Given the breadth of methodologies available to assess CTCs, the clinical validity of each commercially available test must be established independently, and these data are lacking. The available randomized controlled trial found no effect on overall survival when patients with persistently increased CTC levels after first-line chemotherapy were switched to an alternative cytotoxic therapy. Other studies reporting clinical outcomes and/or clinical utility are lacking. The uncertainties concerning clinical validity and clinical utility preclude conclusions about whether the use of CTCs should be used to monitor treatment response. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have received curative treatment for cancer who receive testing of ctDNA to predict risk of relapse, the evidence includes observational studies. Relevant outcomes are overall survival, disease-specific survival, test accuracy and validity, morbid events, and medication use. Given the breadth of methodologies available to assess ctDNA, the clinical validity of each commercially available test must be established independently, and these data are lacking. Published studies reporting clinical outcomes and/or clinical utility are lacking. The uncertainties concerning clinical validity and clinical utility preclude conclusions about whether the use of ctDNA should be used to predict relapse response. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have received curative treatment for cancer who receive testing of CTCs to predict risk of relapse, the evidence includes observational studies. Relevant outcomes are overall survival, disease-specific survival, test accuracy and validity, morbid events, and medication use. Given the breadth of methodologies available to assess CTCs, the clinical validity of each commercially available test must be established independently, and these data are lacking. Published studies reporting clinical outcomes and/or clinical utility are lacking. The uncertainties concerning clinical validity and clinical utility preclude conclusions about whether the use of CTCs should be used to predict relapse response. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are asymptomatic and at high risk for cancer who receive testing of ctDNA to screen for cancer, no evidence was identified. Relevant outcomes are overall survival, disease-specific survival, test accuracy, and test validity. Published data on clinical validity and clinical
utility are lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are asymptomatic and at high risk for cancer who receive testing of CTCs to screen for cancer, the evidence includes observational studies. Relevant outcomes are overall survival, disease-specific survival, test accuracy, and test validity. Given the breadth of methodologies available to assess CTCs, the clinical validity of each commercially available test must be established independently, and these data are lacking. Published studies reporting clinical outcomes and/or clinical utility are lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in the Table 2.

Table 2. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01349842</td>
<td>CirCe01 Study: Evaluation of the Use of Circulating Tumour Cells to Guide</td>
<td>265</td>
<td>Jan 2018</td>
</tr>
<tr>
<td></td>
<td>Chemotherapy From the 3rd Line of Chemotherapy for Metastatic Breast Cancer</td>
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<tr>
<td>NCT01710605</td>
<td>Randomized Trial to Evaluate the Medico-economic Interest of Taking Into</td>
<td>819</td>
<td>Sep 2018 (ongoing)</td>
</tr>
<tr>
<td></td>
<td>Account Circulating Tumor Cells (CTC) to Determine the Kind of First Line</td>
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<td></td>
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<tr>
<td></td>
<td>Treatment for Metastatic, Hormone-receptors Positive, Breast Cancers.</td>
<td></td>
<td></td>
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<tr>
<td>NCT02140463</td>
<td>Next generation personalized therapy with plasma DNA Trial 2 in refractory</td>
<td>260</td>
<td>Dec 2018</td>
</tr>
<tr>
<td></td>
<td>solid tumors (The NEXT-2 Trial)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02035813</td>
<td>DETECT IV - A Prospective, Multicenter, Open-label, Phase II Study in</td>
<td>520</td>
<td>Dec 2019</td>
</tr>
<tr>
<td></td>
<td>Patients With HER2-negative Metastatic Breast Cancer and Persisting</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HER2-negative Circulating Tumor Cells (CTCs).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT01619111</td>
<td>DETECT III - A Multicenter, Randomized, Phase III Study to Compare Standard</td>
<td>120</td>
<td>Mar 2020</td>
</tr>
<tr>
<td></td>
<td>Therapy Alone Versus Standard</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT No.</td>
<td>Trial Name</td>
<td>Planned Enrollment</td>
<td>Completion Date</td>
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</tr>
<tr>
<td></td>
<td>Therapy Plus Lapatinib in Patients With Initially HER2-negative Metastatic Breast Cancer and HER2-positive Circulating Tumor Cells</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT03038217</td>
<td>Investigation of the Value of ctDNA Analysis in the Diagnosis, Treatment, and Surveillance of Patients With Surgically Resectable Colorectal Cancer</td>
<td>300</td>
<td>Dec 2021</td>
</tr>
<tr>
<td>NCT02137837</td>
<td>Fulvestrant Alone Versus Fulvestrant and Everolimus Versus Fulvestrant, Everolimus and Anastrozole: A Phase III Randomized Placebo-Controlled Trial in Postmenopausal Patients</td>
<td>825</td>
<td>May 2022</td>
</tr>
<tr>
<td>NCT03182634</td>
<td>A Multiple Parallel Cohort, Multi-centre Phase IIa Trial Aiming to Provide Proof of Principle Efficacy for Designated Targeted Therapies in Patients With Advanced Breast Cancer Where the Targetable Mutation is Identified Through ctDNA</td>
<td>1000</td>
<td>Nov 2023</td>
</tr>
</tbody>
</table>

**Unpublished**

| NCT01701050 | COMETI Phase 2: Characterization of Circulating Tumor Cells (CTC) From Patients With Metastatic Breast Cancer Using the CTC-Endocrine Therapy Index | 121                | Nov 2016        |

NCT: national clinical trial

**Practice Guidelines and Position Statements**

National Comprehensive Cancer Network (NCCN) guidelines for colon cancer (v.2.2018)\(^{34}\) and melanoma (v.2.2018)\(^{35}\), non-small-cell lung cancer (v.4.2016), and prostate cancer (v.2.2016) do not address CTCs or ctDNA. NCCN guidelines for breast cancer (v.1.2018) state that the use of CTCs in metastatic breast cancer is not yet included in algorithms for disease assessment and monitoring.\(^{36}\)

**Medicare National Coverage**

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers. Palmetto GBA has issued a local noncoverage determination (L35071) for all circulating tumor cell assay.\(^{37}\)
Regulatory Status

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests (LDTs) must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments (CLIA). Laboratories that offer LDTs must be licensed by CLIA for high-complexity testing. To date, the U.S. Food and Drug Administration (FDA) has chosen not to require any regulatory review of this test.

The CellSearch® System (Janssen Diagnostics, formerly Veridex) is the only FDA-approved device for monitoring patients with metastatic disease and CTCs. In 2004, the CellSearch® System was cleared by FDA for marketing through the 510(k) process for monitoring metastatic breast cancer, in 2007 for monitoring metastatic colorectal cancer, and in 2008 for monitoring metastatic prostate cancer. The system uses automated instruments manufactured by Immucor for sample preparation (CellTracks® AutoPrep) and analysis (CellSpotter Analyzer®), together with supplies, reagents, and epithelial cell control kits manufactured by Veridex. FDA product code: NQI.

References


## History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>08/01/16</td>
<td>New policy, approved July 12, 2016; add to Pathology/Laboratory section. Policy created with a literature review through March 10, 2016. Policy statement that the use of circulating tumor DNA and circulating tumor cells is considered investigational for all indications. Policy incorporates policy statement and other information from 2.04.37 Circulating Tumor Cells, which is now deleted.</td>
</tr>
<tr>
<td>10/01/16</td>
<td>Interim Update, approved September 13, 2016. Information regarding screening/diagnostic tests ColoVantage, ColoSentry and Epi proColon extracted from medical policy 12.04.121 and added as examples of ctDNA tests. Title revised to include “Diagnosis”, reflecting the expanded scope of the policy. CPT code 88399 added with supporting information for Target Selector Test. Policy moved into new format and renumbered/moved to Genetic Testing section; previously 2.04.141 and now 12.04.141 – previous version is now deleted.</td>
</tr>
<tr>
<td>01/01/17</td>
<td>Coding update; added new CPT code 81327 effective 1/1/17.</td>
</tr>
<tr>
<td>12/01/17</td>
<td>Annual Review, approved November 9, 2017. Policy updated with literature review through October 2017; no references added. No change to policy statement.</td>
</tr>
<tr>
<td>02/09/18</td>
<td>Minor update. Added test names, FoundationACT and Guardant360, to the policy statement as they were noted only under the Regulatory Information.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>--------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>08/01/18</td>
<td>Annual Review, approved July 25, 2018. Policy updated with a literature review through March 2018. References updated. Clarifying edit to policy statement, add ‘or’ to the following sentence: “The use of circulating tumor DNA and/or circulating tumor cells...” Regulatory status test names updated. Some test names removed as they are addressed in a related policy. Removed CPT codes 81327 and 86849.</td>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2018 Premera All Rights Reserved.

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  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
• Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

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Toll free 855-332-6396, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@LifeWiseHealth.com

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through LifeWise Health Plan of Oregon. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-596-3440 (TTY: 800-842-5357).

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LifeWise Health Plan of Oregon

The information is very important. This notification contains very important information.

If you do not dial 800-596-3440 (TTY: 800-842-5357), you may lose your health coverage.

If you have the right to obtain this information and help in your language

You also have the right to request information and assistance in the language of your choice.

La vida de salud plan of Oregon

Este aviso contiene información importante. Este aviso contiene información importante privada que puede ser recogida a través de LifeWise Health Plan of Oregon. Pueda estar pensado para usted en un momento de tiempo a menudo menú y acercamiento si alguien de seguro o asistencia gratuita a los costos. Araigtre el derecho a ofrecer estos servicios y aliento para serle benevolente.

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To ogłoszenie może zawierać ważne informacje. To ogłoszenie może zawierać ważne informacje, które powinny być zawarte w tym ogłoszeniu aby nie przekroczyć terminów w przypadku utraty prawa. Zawiadomienie we własnym języku. Zadzwonie pod 800-596-3440 (TTY: 800-842-5357)

Português (Portuguese):

Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do LifeWise Health Plan of Oregon. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-596-3440 (TTY: 800-842-5357)

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Русский (Russian):

Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через LifeWise Health Plan of Oregon. В настоящем уведомлении могут быть указаны ключевые даты. В этом случае, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-596-3440 (TTY: 800-842-5357).

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Este aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de LifeWise Health Plan of Oregon. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-596-3440 (TTY: 800-842-5357).

Tagalog (Tagalog):


ไทย (Thai):

ปัญญาญน์ให้คุณรู้ข้อมูลอย่างแย่ในกรณีที่คุณต้องการมีการประกันสุขภาพหรือเพื่อการประกันสุขภาพของคุณ

คุณมีสิทธิ์ที่จะได้รับข้อมูลและช่วยเหลือในกรณีที่คุณต้องการมีการประกันสุขภาพหรือเพื่อการประกันสุขภาพของคุณ

Telephone: 800-596-3440 (TTY: 800-842-5357).

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Ukrainian (Ukrainian):

Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про ваше звернення щодо страхувального покриття через LifeWise Health Plan of Oregon. Зверніть увагу на ключові дати, які можуть бути вказані в цьому повідомленні.

Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дзвоніть за номером телефону 800-596-3440 (TTY: 800-842-5357).

Tiếng Việt (Vietnamese):