MEDICAL POLICY – 12.04.510
Molecular Markers in Fine Needle Aspirates of the Thyroid

BCBSA Ref. Policy: 2.04.78
Effective Date: Feb. 1, 2017
Last Revised: July 28, 2017
Replaces: 12.04.78 and 2.04.78

RELATED MEDICAL POLICIES: None

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

A thyroid nodule is a clump of unusual cells in the thyroid gland. Most thyroid nodules are not cancerous. Obtaining a sample of a thyroid nodule to see if it contains cancerous cells requires a test called a fine need aspiration. A thin needle is inserted through the skin and into the nodule, a sample is drawn into the needle, and the needle is then removed. Several samples may be taken at one appointment, with a new needle used for each sample. Reviewing the samples under a microscope is usually enough to determine if cancer is present. In those cases where the results are uncertain, an additional test, known as a gene expression classifier, may be done. This test looks at the activity of about 100 genes in the needle sample. This medical policy describes when a gene expression classifier may be medically necessary. Genetic tests that look for other types of genetic mutations in specific genes to try to diagnose thyroid cancer are unproven (investigational). More studies are needed to determine if these types of genetic tests are useful.

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>Testing</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gene expression classifier (GEC) in fine needle aspirates (FNA) of the thyroid</td>
<td>The use of a gene expression classifier (GEC) in fine needle aspirates (FNA) of the thyroid (eg, Afirma®, ThyraMIR™) may be considered medically necessary for assessing fine needle aspiration samples from thyroid nodules that are indeterminate, atypical or suspicious for malignancy.</td>
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<table>
<thead>
<tr>
<th>Testing</th>
<th>Investigational</th>
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<tr>
<td>Mutation analysis in fine-needle aspirates of the thyroid</td>
<td>Mutation analysis in fine-needle aspirates of the thyroid including BRAF (eg, miRInform® Thyroid, ThyGenX® Thyroid Oncogene Panel) is considered to be investigational.</td>
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### Commercially Available Tests

<table>
<thead>
<tr>
<th>Gene expression classifier (GEC)</th>
<th>Comments</th>
</tr>
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<tbody>
<tr>
<td>Afirma® (Veracyte)</td>
<td>May be considered medically necessary when criteria are met. (see the Medical Necessity section above) Specific details about the test are found in the Description section.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>ThyGenX® Thyroid Oncogene Panel (Interpace Diagnostics)</th>
</tr>
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<tr>
<td>• formerly miRInform™ Thyroid (Asuragen)</td>
</tr>
<tr>
<td>Considered to be investigational. Specific details about the tests are found in the Description section.</td>
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</tbody>
</table>

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<thead>
<tr>
<th>ThyroSeq® v.2 Next Generation Sequencing (CBLPath)</th>
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<td>Considered to be investigational. Specific details about the test are found in the Description section.</td>
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<table>
<thead>
<tr>
<th>Thyroid Cancer Mutation Panel (Quest Diagnostics)</th>
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<tbody>
<tr>
<td>Considered to be investigational. Specific details about the test are found in the Description section.</td>
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Coding

<table>
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<th>Code</th>
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<tbody>
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<td></td>
</tr>
<tr>
<td>81445</td>
<td>Targeted genomic sequence analysis panel, solid organ neoplasm, DNA analysis, and RNA analysis when performed, 5-50 genes (eg, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed</td>
</tr>
<tr>
<td>81479</td>
<td>Unlisted molecular pathology procedure</td>
</tr>
<tr>
<td>81545</td>
<td>Oncology (thyroid), gene expression analysis of 142 genes, utilizing fine needle aspirate, algorithm reported as a categorical result (eg, benign or suspicious)</td>
</tr>
<tr>
<td>81599</td>
<td>Unlisted multianalyte assay with algorithmic analysis</td>
</tr>
<tr>
<td>84999</td>
<td>Unlisted chemistry procedure</td>
</tr>
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</table>

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Related Information

In patients who do not undergo surgical biopsy or thyroidectomy on the basis of gene expression classifier results, regular active surveillance is indicated.

Evidence Review

Description

Cytologic examination of fine needle aspirate (FNA) samples from a thyroid lesion to identify which patients need thyroid resection has diagnostic limitations. Assays using molecular markers have been developed in an attempt to improve the accuracy of thyroid FNA biopsies.

Although not entirely conclusive, clinical input has supported the use of a gene expression classifier (GEC) with a high negative predictive value (NPV) for individuals whose FNA was found
to be cytologically indeterminate (follicular lesion of undetermined significance or suspicious for follicular neoplasm).

**Background**

*Fine needle aspiration (FNA) of the thyroid*

Thyroid nodules are common, present in 5-7% of the U.S. adult population. The vast majority of these nodules are benign, and most cases of thyroid cancer are curable by surgery if it was detected early. Fine needle aspiration (FNA) of the thyroid is currently the most accurate procedure to distinguish benign thyroid lesions from malignant ones, reducing the rate of unnecessary thyroid surgery for patients with benign nodules and triaging patients with thyroid cancer to appropriate surgery.

About 60% to 70% of thyroid nodules are classified cytologically as benign, and 4% to 10% of nodules are cytologically deemed malignant. However, the remaining 20% to 30% have equivocal findings, usually due to overlapping cytologic features between benign and malignant nodules, and these nodules usually require surgery for a final diagnosis. Thyroid FNA cytology is classified by Bethesda System criteria into the following groups: nondiagnostic; benign; follicular lesion of undetermined significance (FLUS) or atypia of undetermined significance (AUS); follicular neoplasm (or suspicious for follicular neoplasm); suspicious for malignancy; and malignant. Lesions with FNA cytology in the AUS or FLUS or follicular neoplasm categories are often considered indeterminate.

There is some individualization of management for patients with FNA-indeterminate nodules, but many patients will require a surgical biopsy, typically thyroid lobectomy, with intraoperative pathology. Consultation would typically be the next step in diagnosis. Approximately 80% of patients with indeterminate cytology undergo surgical resection; postoperative evaluation has revealed a malignancy rate ranging from 6% to 30%, making this a clinical process with very low specificity. Thus, if analysis of FNA samples could reliably identify the risk of malignancy as low, there is potential for patients to avoid surgical biopsy.

Preoperative planning of optimal surgical management of patients with equivocal cytological results is challenging. Depending on several factors, different thyroid malignancies may require different surgical procedures (e.g., unilateral lobectomy vs total or subtotal thyroidectomy with or without lymph node dissection). These factors include histologic subtype and risk-stratification strategies (tumor size, patient age). If a diagnosis cannot be made intraoperatively, a lobectomy
is typically performed. If postoperative histology shows the lesion is malignant, a second surgical intervention may be necessary to remove additional tissue.

**Thyroid Cancer**

Most thyroid cancers originate from thyroid follicular cells and include well-differentiated papillary thyroid carcinoma (PTC) (80% of all thyroid cancers) and follicular carcinoma (15%). Poorly differentiated and anaplastic thyroid carcinomas are uncommon and can arise de novo or from preexisting well-differentiated papillary or follicular carcinomas. Medullary thyroid carcinoma originates from parafollicular or C cells, and accounts for about 3% of all thyroid cancers.

The diagnosis of PTC is primarily based on cytologic features. If FNA of the nodule is indeterminate, surgical biopsy with intraoperative pathology is most often diagnostic, although its efficacy and therefore its use will vary across institutions, surgeons, and pathologists.

For follicular carcinoma, invasion of the tumor capsule or blood vessels is diagnostic and cannot be determined by cytology, because tissue sampling is necessary to observe these histologic characteristics. Intraoperative diagnosis of follicular carcinoma is challenging and often not feasible, because extensive sampling of the tumor and capsule is usually necessary and performed on postoperative permanent sections.

Two new approaches for improving the diagnostic accuracy of thyroid FNA include mutation analysis and gene expression classifiers. Mutation analysis may be used to more accurately classify which patients need to proceed to surgery and may include the extent of surgery necessary. Gene expression classifiers may be used to identify patients who do not need any surgery and can be safely followed.

**Mutations Associated with Thyroid Cancer**

Various mutations have been discovered in thyroid cancer. Papillary carcinomas may carry point mutations of the BRAF and RAS genes, as well as RET/PTC and TRK rearrangements, all of which are able to activate the mitogen-activated protein kinase pathway. These mutually exclusive mutations are found in more than 70% of papillary carcinomas. BRAF mutations are highly specific for PTC. Follicular carcinomas harbor either RAS mutations or PAX8/PPARγ rearrangement. These mutations have been identified in 70% to 75% of follicular carcinomas. Genetic alterations involving the PI3K/AKT signaling pathway also occur in thyroid tumors,
although they are rare in well-differentiated thyroid cancers and have higher prevalence in less differentiated thyroid carcinomas. Additional mutations known to occur in poorly differentiated and anaplastic carcinomas involve the TP53 and CTNNB1 genes. Medullary carcinomas, which can be familial or sporadic, frequently possess point mutations located in the RET gene.

Studies have evaluated the association between various genes and cancer phenotype in individuals with diagnosed thyroid cancer.4-6

**Available Molecular Diagnostic Testing**

**Mutation and Rearrangement Testing**

Point mutations in specific genes, including BRAF, RAS, and RET, and evaluation for rearrangements associated with thyroid cancers can be accomplished by gene sequencing with Sanger sequencing, pyrosequencing, or by real-time polymerase chain reaction (rtPCR). Panels of tests for mutations associated with thyroid cancer are also available. For example, Quest Diagnostics offers a Thyroid Cancer Mutation Panel, which includes BRAF and RAS mutation analysis and testing for RET/PTC and PAX8/PPARγ rearrangements.

The ThyroSeq® v.2 Next Generation Sequencing panel (CBLPath, Ocala, FL) is a panel that looks at more than 60 genes. According to the CBLPath’s website, the test is indicated for indeterminate thyroid FNAs.

The ThyGenX™ Thyroid Oncogene Panel (formerly miRInform® Thyroid; Interpace Diagnostics, Parsippany, NJ; testing done at Asuragen Clinical Laboratory) is another NGS sequencing panel designed to be used in patients with indeterminate thyroid FNA results. It includes sequencing of 8 genes associated with papillary thyroid carcinoma and follicular carcinomas.

**Gene Expression Profiling**

Genetic alterations associated with thyroid cancer can be assessed using gene expression profiling, which refers to simultaneous analysis of messenger RNA (mRNA) expression levels of many genes. Several gene expression profiling tests are now available to biologically stratify tissue from thyroid nodules.

The Afirma® Gene Expression Classifier (Afirma GEC; Veracyte, South San Francisco, CA) analyzes the expression of 142 different genes for patterns associated with benign findings on
surgical biopsy. It is designed to evaluate thyroid nodules that have an “indeterminate” classification on FNA as a method to select patients (“rule out”) who are at low risk for cancer.

Veracyte also markets 2 “malignancy classifiers” that use mRNA expression-based classification to evaluate for BRAF mutations or mutations associated with medullary thyroid carcinoma (Afirma BRAF and Afirma MTC, respectively). The Afirma BRAF is designed to be used for nodules with “suspicious” results on Afirma GEC. The Afirma MTC is an option when the Afirma GEC is ordered for thyroid nodules with an “intermediate” classification on FNA, and can also be used for thyroid nodules with “malignant” or “suspicious” results on Afirma GEC.

ThyraMIR™ (Interpace Diagnostics, Parsippany, NJ) is a micro-RNA classifier intended for use in thyroid nodules with indeterminate cytology on FNA.

Other gene expression profiles have been reported in investigational settings, but have not been widely validated or used commercially (eg, Barros-Filho et al [2015], Zheng et al [2015]); these are not addressed in this policy.

**Summary of Evidence**

For individuals with thyroid nodule(s) that have indeterminate findings on fine needle aspirate (FNA) who undergo testing with the Afirma Gene Expression Classifier (GEC) to determine their risk for malignancy, the evidence includes 1 prospective clinical validity study with the marketed test, and an indirect chain of evidence to support clinical utility. Relevant outcomes are disease-specific survival, test accuracy and validity, morbid events, and resource utilization. In 1 multicenter validation study, the Afirma GEC was reported to have a high negative predictive value (NPV; range, 90%-95%). These results are supported by an earlier development and clinical validation study (Chudova et al), but the classifiers used in the 2 studies do not appear to be identical. In an additional multicenter and multiple single-center studies, there is suggestive evidence that rates of malignancy are low in Afirma benign patients, but the exact NPV is unknown. The available evidence has suggested that physician decision making about surgery is affected by GEC results, although long-term follow-up of patients with thyroid nodules who avoided surgery based on GEC results is limited. An indirect chain of evidence can be constructed to establish the potential for clinical utility of GEC testing in cytologically indeterminate lesions, but with only 1 study of the marketed test reporting a true NPV, the clinical validity is uncertain. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with thyroid nodule(s) and indeterminate findings on FNA who receive FNA sample testing with molecular markers to predict malignancy, the evidence includes prospective
and retrospective studies of clinical validity. Relevant outcomes are disease-specific survival, test accuracy and validity, morbid events, and resource utilization. Mutation analysis has the potential to improve the accuracy of an equivocal FNA of the thyroid and may play a role in preoperative risk stratification and surgical planning. Single-center studies have suggested that testing for a panel of mutations associated with thyroid cancer may allow for the appropriate selection of patients for surgical management with an initial complete thyroidectomy. Prospective studies in additional populations are needed to validate these results. Mutation analysis does not achieve a high enough NPV to identify which patients can undergo active surveillance over thyroid surgery. Although the presence of certain mutations may predict more aggressive malignancies, the management changes that would occur as a result of identifying higher risk tumors are not well-established. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in November 2016 did not identify any ongoing or unpublished trials that would likely influence this review.

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may provide appropriate reviewers who collaborate with and make recommendations during this process, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2016 Input

In response to requests, input was received from 2 physician specialty societies (1 of which provided 3 responses) and 1 academic medical center while this policy was under review in 2016. Input focused on the use of gene expression classifiers with a high negative predictive value (NPV) in nodules shown to be indeterminate on fine needle aspirate (FNA). Although individual uses of a gene expression classifier with NPV in these situations varied, there was general agreement that the tests are considered standard in the evaluation of some indeterminate cases of FNA.
2013 Input

In response to requests, input was received from 1 physician specialty society (4 reviewers) and 6 academic medical centers, for a total of 10 reviewers, while this policy was under review in 2013. There was general agreement with the policy statements that mutation analysis and use of the gene expression classifier is investigational. Input was mixed as to whether either test changes patient management and whether prospective randomized trials are necessary to establish the clinical utility of these tests.

Practice Guidelines and Position Statements

American Thyroid Association (ATA)

In 2016, the American Thyroid Association (ATA) updated its guidelines on the management of thyroid nodules and differentiated thyroid cancer in adults. These guidelines made the following statements on molecular diagnostics in thyroid nodules that are atypia of undetermined significance (AUS) or follicular lesion of undetermined significance (FLUS) on cytology:

For nodules with AUS/FLUS cytology, after consideration of worrisome clinical and sonographic features, investigations such as repeat FNA [fine needle aspirate] or molecular testing may be used to supplement malignancy risk assessment in lieu of proceeding directly with a strategy of either surveillance or diagnostic surgery. Informed patient preference and feasibility should be considered in clinical decision-making.” (Weak recommendation, Moderate-quality evidence)

If repeat FNA cytology, molecular testing, or both are not performed or inconclusive, either surveillance or diagnostic surgical excision may be performed for an AUS/FLUS thyroid nodule, depending on clinical risk factors, sonographic pattern, and patient preference. (Strong recommendation, Low-quality evidence)

The guidelines made the following statements on molecular diagnostics in thyroid nodules that are follicular neoplasm (FN) or suspicious for follicular neoplasm (SFN) on cytology:

Diagnostic surgical excision is the long-established standard of care for the management of FN/SFN cytology nodules. However, after consideration of clinical and sonographic features, molecular testing may be used to supplement malignancy risk assessment data in lieu of
proceeding directly with surgery. Informed patient preference and feasibility should be considered in clinical decision-making. (Weak recommendation, Moderate-quality evidence)

The guidelines also stated, “there is currently no single optimal molecular test that can definitively rule in or rule out malignancy in all cases of indeterminate cytology, and long-term outcome data proving clinical utility are needed.”

**National Comprehensive Cancer Network (NCCN)**

National Comprehensive Cancer Network (NCCN) guidelines on the treatment of thyroid cancer (v1.2016) make the following comments on the use of molecular diagnostics in thyroid cancer\textsuperscript{50}:

For thyroid nodules evaluated with FNA, molecular diagnostics may be employed in the following cases (category 2B recommendation):

- Follicular or Hürthle cell neoplasms
- Atypia of undetermined significance or follicular lesion of undetermined significance

The guidelines also state: “Molecular testing (both the Gene Expression Classifier and individual mutation analysis) was available in the majority of NCCN Member Institutions (>75%). About 70% of the panelists would recommend using a gene expression classifier in the evaluation of follicular lesions.”

**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**

Palmetto GBA determines coverage and reimbursement for laboratories that perform molecular diagnostic testing and submit Medicare claims in Medicare Jurisdiction E (California, Nevada, and Hawaii). Palmetto GBA’s decisions apply for all molecular diagnostic tests for Medicare.

Palmetto GBA has completed an assessment of the Afirma GEC and determined that the test meets criteria for analytical and clinical validity, and clinical utility as a reasonable and necessary
Medicare benefit. Effective January 1, 2012, Palmetto GBA will reimburse Afirma services for patients with the following conditions:

1. Patients with one or more thyroid nodules with a history or characteristics suggesting malignancy such as:
   - Nodule growth over time
   - Family history of thyroid cancer
   - Hoarseness, difficulty swallowing or breathing
   - History of exposure to ionizing radiation
   - Hard nodule compared with rest of gland consistency
   - Presence of cervical adenopathy

2. Have an indeterminate follicular pathology on fine needle aspiration

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). Thyroid mutation testing and gene expression classifiers are available under the auspices of 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.

In 2013, the THxID™-BRAF kit (bioMérieux, Marcy l'Etoile, France), an in vitro diagnostic device, was approved by FDA through the premarket approval process to assess specific BRAF mutations in melanoma tissue via real-time polymerase chain reaction. However, there are currently no diagnostic tests for thyroid cancer mutation analysis with approval from FDA.

References


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**History**

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<th>Comments</th>
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<tr>
<td>04/14/14</td>
<td>New PR policy; replaces 12.04.78. Literature review performed through February 27, 2014. Policy statement revised from that of 12.04.78: The use of a gene expression classifier may be considered medically necessary (previously investigational). References 9, 15, 17, 18, 20, 21, 23, 24 and 25 added.</td>
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<td>07/24/14</td>
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<td>06/17/15</td>
<td>Annual Review. Policy updated to state mutation analysis in fine-needle aspirates of the thyroid including BRAF is considered to be investigational. Policy updated with literature review through March 2, 2015. References 5-9, 15, 18, 20-24, 28, 29 added.</td>
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<td>Coding update. Added 81545, effective 1/1/16.</td>
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<td>Annual review, approved November 8, 2016. Added reference 27. No change to policy statements.</td>
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<td>Annual Review, approved January 10, 2017. Policy updated with literature review and results of clinical input; references 10-11, 18-20, 24, 28, 34, 43-45, and 48-49 added. Removed Appendix table. No change to policy statements.</td>
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<td>Policy moved into new format, no changes to policy statement.</td>
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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 Premera Blue Cross. Es posible que haya fechas claras 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 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog):
Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon. Ang paunawa na ito ay may mga impormasyon importante para sa solicitude o cobertura a travers Premera Blue Cross. Es posible que haya fechas claras 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 800-722-1471 (TTY: 800-842-5357).

ไทย (Thai):
ประกาศนี้อาจมีข้อมูลที่สําคัญเกี่ยวกับการสมัครหรือขอบเขตประกันสุขภาพของคุณผ่าน Premera Blue Cross หรือการรับความช่วยเหลือที่คุณมีสิทธิที่จะได้รับข้อมูลและความช่วยเหลือนี้ในภาษาของคุณโดยไม่มีค่าใช้จ่าย 800-722-1471 (TTY: 800-842-5357).

Čeština (Czech):

Українська (Ukrainian):
Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страхувального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існують інші обставини, в яких Вами буде зобов’язано виконати бажані дії в конкретний кінцевий строк 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. Дозвоніться за номером телефону 800-722-1471 (TTY: 800-842-5357).

Tiếng Việt (Vietnamese):