Introduction

Tumor treating fields (TTF) is a new treatment being studied for use in certain cancers. The therapy consists of low-level electrical currents that arise from small insulated electrodes placed on the skin surface. TTF is believed to cause cell death during a later stage of development. Currently this therapy is covered as one treatment option for people who have a deadly form of brain cancer called glioblastoma multiforme. People wear a helmet with small electrodes attached to the scalp for at least 18 hours per day during TTF therapy. This treatment requires pre-approval by the plan, and this policy describes when this treatment is covered. TTF is considered investigational for other types of cancer (therefore not covered), as there is not yet enough scientific data that shows it works for other diagnoses.

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.
<table>
<thead>
<tr>
<th>Condition</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glioblastoma- initial therapy</td>
<td>Tumor treating fields (TTF) to treat glioblastoma is considered investigational:</td>
</tr>
<tr>
<td></td>
<td>• As an alternative to standard chemotherapy for patients with advanced or recurrent glioblastoma</td>
</tr>
</tbody>
</table>
| All other diagnoses           | Tumor treating fields (TTF) is considered investigational for all other indications.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Medical Necessity</th>
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</thead>
<tbody>
<tr>
<td>Glioblastoma- adjuvant therapy</td>
<td>Tumor treating fields (TTF) to treat glioblastoma is medically necessary when all of the following are met:</td>
</tr>
<tr>
<td></td>
<td>• Initial treatment with debulking surgery or biopsy, followed by concurrent temozolamide AND</td>
</tr>
<tr>
<td></td>
<td>• Radiotherapy, with no documented tumor progression AND</td>
</tr>
<tr>
<td></td>
<td>• TTF is used with temozolamide AND</td>
</tr>
<tr>
<td></td>
<td>• TTF is begun within 7 weeks of final radiation treatment</td>
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**Coding**

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>A4555</td>
<td>Electrode/transducer for use with electrical stimulation device used for cancer treatment, replacement only</td>
</tr>
<tr>
<td>A9900</td>
<td>Miscellaneous DME supply, accessory, and/or service component of another HCPCS code</td>
</tr>
<tr>
<td>E0766</td>
<td>Electrical stimulation device used for cancer treatment, includes all accessories, any type</td>
</tr>
<tr>
<td>E1399</td>
<td>Durable medical equipment, miscellaneous</td>
</tr>
</tbody>
</table>

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Background

Glioblastome Multiforme

Glioblastomas, also known as glioblastoma multiforme (GBM), are the most common form of malignant primary brain tumor in adults. They comprise approximately 15% of all brain and central nervous system tumors, and more than 50% of all tumors that arise from glial cells.\(^1\) The peak incidence for GBM occurs between the ages of 45 and 70 years. GBMs are grade IV astrocytomas, the most deadly type of glial cell tumor, and are often resistant to standard chemotherapy.\(^1\) According to the National Comprehensive Cancer Network, "only a third of patients [with GMB] surviv[e] for 1 year and less than 5% liv[e] beyond 5 years."\(^2\)

Treatment of Glioblastoma Multiforme

The primary treatment for initial GBM is debulking surgery to remove as much of the tumor as possible. At that time, some patients may undergo implantation of the tumor cavity with a carmustine (bis-chloroethylnitrosourea [BCNU]).impregnated wafer.\(^2\) Depending on the patient’s physical condition, adjuvant radiotherapy, chemotherapy (typically temozolomide), or a combination of the 2 are sometimes given. After adjuvant therapy, some patients may undergo maintenance therapy with temozolomide.

No standard treatment exists for recurrent GBM. After these initial treatments, additional debulking surgery may be used if recurrence is localized. Other treatment options for recurrent disease include various forms of systemic medications such as bevacizumab, bevacizumab plus chemotherapy (e.g., irinotecan, BCNU/chloroethylNitrosourea [CCNU], temozolomide), temozolomide, nitrosourea, PCV (procarbazine, CCNU, vincristine), cyclophosphamide, and platinum-based agents.\(^2\) External beam radiotherapy also may be used. Response rates in
recurrent disease are less than 10%, and progression-free survival rates at 6 months are less than 20%.²³

**Tumor Treating Fields**

TTF therapy is a new, noninvasive technology intended to treat GBM on an outpatient basis using electrical fields.³⁵ TTF therapy exposes cancer cells to alternating electric fields of low intensity and intermediate frequency, which are purported to both selectively inhibit tumor growth and reduce tumor angiogenesis. TTF are proposed to inhibit rapidly dividing tumor cells by two mechanisms: arrest of cell proliferation and destruction of cells while undergoing division.⁴⁵

The NovoTTF-100A System has received marketing approval from the U.S. Food and Drug Administration to deliver TTF therapy. TTF therapy via the NovoTTF-100A System is delivered by a battery-powered, portable device that generates the fields via disposable electrodes noninvasively attached to the patient’s shaved scalp over the site of the tumor.³⁴ The device is used by the patient at home on a continuous basis (20-24 h/d) for the duration of treatment, which can last for several months. The device is covered under the DME benefit. Patients can carry the device in a backpack or shoulder pack while carrying out activities of daily living.³⁴

**Evidence Review**

This evidence review was created in August 2013 and has been updated periodically through literature searches of the MEDLINE database. The most recent literature review was through March 24, 2016.

Following is a summary of the key literature. Tumor treating fields (TTF) therapy is proposed as a treatment for glioblastoma multiforme (GBM). For this review, 2 indications will be considered: (1) TTF therapy as an alternative to chemotherapy in advanced or recurrent GBM and (2) TTF therapy as an adjunct to maintenance treatment in patients following early treatment. Comparative trials are essential to determine efficacy in this area, and randomized controlled trials (RCTs) are needed to control for heterogeneity in the patient populations and other confounders of outcome. This evidence review will include both RCTs and nonrandomized comparative trials.
TTF Therapy as an Alternative to Chemotherapy in Advanced or Recurrent GBM

Randomized Controlled Trials

The U.S. Food and Drug Administration (FDA) approval of the NovoTTF-100A system was based on a Phase III, multinational prospective randomized controlled trial (RCT) (EF11) which was published in 2012 by Stupp et al. The Stupp study, which was sponsored and funded by the manufacturer of the device (NovoCure), compared tumor-treating fields (TTF) therapy (delivered by the NovoTTF-100A System) with the best standard of care chemotherapy (active control). Twenty-eight clinical centers (across 7 countries) enrolled 237 adult participants with relapsed or progressive glioblastoma multiforme (GBM), despite conventional radiotherapy. Other prior treatments may have included surgery and/or chemotherapy. Patient characteristics were balanced in both groups, with median age of 54 years and median Karnofsky performance status score of 80%. More than 80% of participants had failed 2 or more prior chemotherapy regimens (≥second recurrence), and 20% had failed bevacizumab before study enrollment.

Two-hundred thirty-seven patients were randomized in a 1:1 ratio to receive TTF therapy only (n=120) or active control (n=117). The choice of chemotherapy regimens varied, reflecting local practice at each of the participating clinical centers. Chemotherapy agents considered as active control during the trial included platinum-based chemotherapy (i.e., carboplatin); nitrosoureas; procarbazine; combination of procarbazine, lomustine and vincristine (PCV); temozolomide; and bevacizumab. For patients assigned to the TTF group, uninterrupted treatment was recommended, and a period of 28 days of treatment with TTF was considered one full treatment course.

The primary study endpoint in this RCT was overall survival (OS). Secondary endpoints included progression-free survival (PFS) at 6 months, TTP, one-year survival rate, quality of life (QOL), and radiologic response.

Ninety-seven percent (116) of 120 participants in the TTF group started treatment and 93 participants (78%) completed one cycle (4 weeks) of therapy. Discontinuation of TTF therapy occurred in 27 participants (22%) due to noncompliance or the inability to handle the device. For each TTF treatment month, the median compliance was 86% (range, 41%-98%), which equaled a mean use of 20.6 hours per day. In the active control group, 113 (97%) of the 117 assigned participants received chemotherapy and all except one individual completed a full treatment course. Twenty-one participants (18%) in the active control group did not return to the treating site and details on disease progression and toxicity were not available.
Outcomes of this study are summarized in Table 1. The trial failed to reach its primary endpoint of improved survival compared with active chemotherapy. With a median follow-up of 39 months, 220 participants (93%) had died. Median survival was 6.6 months in the TTF group compared with 6.0 months in the active control group (hazard ratio [HR], 0.86; 95% confidence interval [CI], 0.66 to 1.12; p=0.27). For both groups, one-year survival was 20%.

Longitudinal QOL data were available in 63 participants (27%). There were no meaningful differences observed between the groups in the domains of global health and social functioning. However, cognitive, emotional, and role functioning favored TTF therapy, whereas physical functioning favored chemotherapy. Symptom scale analysis was in accordance to treatment-associated toxicity; appetite loss, diarrhea, constipation, nausea, and vomiting were directly related to the chemotherapy administration.

Wong et al published a subgroup analysis of the Stupp RCT to determine characteristics of responders and nonresponders in the treatment and active control groups. Tumor response was assessed using Macdonald criteria. More patients in the TTF arm were considered responders (14/120 vs 7/117 in the chemotherapy arm.) Median response time was longer for those in the TTF arm (7.3 months) than those in the chemotherapy arm (5.6 months; p<0.001), and there was a strong correlation (Pearson r) between response and OS in the TTF arm (p<0.001) but not in the chemotherapy arm (p=0.29). Compared with the chemotherapy arm, a higher proportion of responders in the TTF arm had a prior low-grade histology (36% vs 0%). These differences in treatment responder groups suggest that TTF therapy may differentially benefit certain types of GBM; however, the small numbers of responders in both groups limits generalizations that can be drawn from this analysis.

In summary, this RCT failed to demonstrate the primary endpoint of improved survival with TTF therapy in comparison with chemotherapy. Limitations of the trial included a somewhat heterogeneous patient population, with participants included after progression of one or several lines of chemotherapy, as well as the use of different chemotherapy regimens in the control group. Another limitation is the absence of a placebo/supportive care arm. In the setting of advanced disease, the supportive care arm would have been useful to gauge the safety and efficacy of treatment for both groups of patients. Treatments used in the active control arm (best standard of care chemotherapy) in the recurrent disease setting have previously demonstrated limited efficacy, thus limiting the ability to determine the true treatment effect of TTF. Data from a trial of TTF versus placebo, or TTF plus standard chemotherapy versus standard chemotherapy alone would therefore provide a better assessment of treatment efficacy. The latter study design is being used in an ongoing trial of TTF therapy in the treatment of patients with newly diagnosed GBM (see Ongoing and Unpublished Clinical Trials).
A further limitation was high dropout rates in both groups. For example, over 20% of participants in the active control group were lost at follow-up, and this degree of the number of dropouts may have underestimated the toxicity evaluation in this group. Similarly, over 20% of participants in the TTF arm discontinued treatment within a few days due to noncompliance or inability to handle the device. This implies that compliance might be an issue with TTF, because it requires the patient to continuously wear transducers on the shaved head. Finally, the number of patients who completed the QOL data was approximately one-quarter of total enrollment, and the self-reported QOL indicators may have been subject to bias due to the lack of blinding.3,6

Table 1. Principal Efficacy Results for Randomized Trial of TTF Therapy versus Physicians’ Choice of Chemotherapy in Recurrent Glioblastoma (Stupp et al)

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>TTF</th>
<th>Chemotherapy</th>
<th>Measure of Association, Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median survival, mo</td>
<td>6.6</td>
<td>6.0</td>
<td></td>
</tr>
<tr>
<td>Hazard ratio for survival</td>
<td></td>
<td></td>
<td>0.86 (95% CI, 0.66 to 1.12) favors TTF</td>
</tr>
<tr>
<td>Radiologic response (not all patients evaluated)</td>
<td>14%</td>
<td>9.6%</td>
<td>p=0.19</td>
</tr>
<tr>
<td>Median PFS, mo</td>
<td>2.2</td>
<td>2.1</td>
<td></td>
</tr>
<tr>
<td>Hazard ratio for PFS</td>
<td></td>
<td></td>
<td>0.81 (95% CI, 0.60 to 1.09) favors TTF</td>
</tr>
</tbody>
</table>

CI: confidence interval; PFS: progression-free survival; TTF: tumor treating fields.

A second post hoc analysis of the TTF EF-11 pivotal trial data was performed to evaluate OS rates among patients who completed at least one complete course of TTF or chemotherapy.10 These investigators analyzed survival in what they referred to as a “modified ITT [intention-to-treat]” subgroup comprising 93 of 120 (78%) of the original TTF allocated group, versus 117 of 117 (100%) of the original chemotherapy allocated group. This exercise revealed median OS of 7.7 months in the TTF modified ITT (mITT) group compared with 5.9 months in the chemotherapy group (HR=0.69; 95% CI: 0.52 to 0.91; p=0.009). They also showed a trend relationship between proportion of patients with higher TTF compliance and median OS rates (p=0.039). The investigators suggest that TTF provides an OS benefit if used as intended in the
FDA-approved label when compared with best chemotherapy. This post hoc analysis has flaws in that it was not pre-specified in the study, includes only 78% of the original TTF allocated patients, and fails to control for noncompliance due to faster clinical deterioration of TTF recipients leading to treatment cessation.

**Nonrandomized Comparative Studies**

Two nonrandomized studies were identified that compared TTF treatment to standard care using historical controls. A study published in late 2014 assessed OS data from 457 patients included in the Patient Registry Dataset (PRiDe), a postmarketing registry of all recurrent GBM patients who received NovoTTF therapy in a real-world, clinical practice setting at 91 centers in the United States between October 2011 and November 2013. Median OS rate in the PRiDe clinical practice dataset (9.6 months) was reported as significantly superior to that attained in the TTF EF-11 pivotal trial (6.6 months; HR=0.66, 95% CI, 0.05 to 0.86; p<0.001). One- and 2-year OS rates for TTF in PRiDe were significantly longer than those in the TTF group in the EF-11 trial (44% vs 20% at 1 year; 30% vs 9% at 2 years, respectively). The PRiDe investigators reported no novel or unexpected treatment-related adverse events compared with the EF-11 trial.

Kirson et al (2007) reported findings of a study examining the effects of TTF therapy delivered by the NovoTTF-100A System in 10 patients with recurrent GBM. Median TTP in these patients was 26.1 weeks, and median OS was 62.2 weeks. The authors noted that these TTP and OS rates were more than double the medians reported for historical control patients. No device-related serious adverse events were seen after more than 70 months of cumulative treatment in all patients. The only device-related adverse event observed was a mild-to-moderate contact dermatitis beneath the field delivering electrodes. The primary limitation of this study was its use of historical controls, because those patients may not be comparable on major clinical and prognostic features.

**Section Summary: TTF Therapy as an Alternative to Chemotherapy in Advanced or Recurrent GBM**

The single RCT for this indication reported that outcomes following TTF therapy were similar to outcomes following standard chemotherapy. However, this RCT is not sufficient to allow conclusions on the efficacy of the device. There was no placebo control group or supportive care treatment group, and treatments used in the active control arm (best standard of care chemotherapy) have previously demonstrated limited efficacy. Thus, the comparisons made have limited ability to determine the true treatment effect of TTF. Methodologic limitations in
the study decrease its’ internal validity. There was heterogeneity in the patient populations and heterogeneity in the chemotherapy regimens for the control group. Furthermore, more patients in the TTF group than in the control group did not complete the treatment course, and patients in the TTF group received more courses of second-line chemotherapy. The number of patients who completed the QOL data was approximately one-quarter of total enrollment and the self-reported QOL indicators may have been subject to bias due to the lack of blinding.3,6 The other available published evidence, 2 nonrandomized comparative studies, are small and limited by potential differences in patient populations. Thus, the evidence base does not permit conclusions about the impact of the technology on health outcomes.

TTF Therapy as an Adjunct to Standard Maintenance Care for GBM

In 2015, Stupp et al published a planned interim analysis of a multicenter, open-label RCT that evaluated maintenance therapy with TTF for GBM.13 This trial enrolled patients with GBM who had completed standard treatment consisting of chemoradiotherapy plus surgery if indicated. Patients were randomized in a 2:1 fashion to receive TTF plus temozolomide or temozolomide alone. At the time of the interim analysis, 210 patients were randomized to TTF plus temozolomide and 105 patients randomized to temozolomide alone. The primary outcome was PFS analyzed by intention-to-treat; a secondary outcome was OS analyzed by per-protocol analysis. Planned interim analysis was performed at a median follow-up of 38 months (range, 18-60 months). Median PFS and median OS are summarized in Table 2.

Table 2. TTF Therapy as an Adjunct to Standard Maintenance Care in Glioblastoma

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>PFS (95% CI)</th>
<th>HR (98.7% CI)</th>
<th>OS (95% CI)</th>
<th>HR (99.4% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TTF + temozolomide</td>
<td>210</td>
<td>7.1 mo (5.9 to 8.2 mo)</td>
<td>0.62 (0.43 to 0.89)</td>
<td>20.5 mo (16.7 to 25 mo)</td>
<td>0.64 (0.42 to 0.98)</td>
</tr>
<tr>
<td>Temozolomide alone</td>
<td>105</td>
<td>4.0 mo (3.3 to 5.2 mo)</td>
<td></td>
<td>15.6 mo (13.3 to 19.1 mo)</td>
<td></td>
</tr>
</tbody>
</table>

CI: confidence interval; HR: hazard ratio; OS: overall survival; PFS: progression-free survival; TTF: tumor treating fields. 

* Included in per-protocol analysis.
There were a total of 35 (11%) dropouts during the trial, 14 (6.7%) of 210 patients in the TTF group and 21 (20%) of 105 in the temozolomide alone group. Adherence to treatment was defined as wearing the device for at least 18 hours a day, and 157 (75%) of 210 patients met this criteria for adherence. The number of treatment cycles with temozolomide differed between groups. The TTF group received a median of 6 cycles compared to a median of 4 cycles for the temozolomide alone group. The most common side effect of treatment was local skin irritation, which occurred in 43% of patients treated with TTF.

**Section Summary: TTF Therapy as an Adjunct to Standard Maintenance Care for GBM**

The single RCT for this indication reported that PFS improved by 3.1 months and OS improved by 4.9 months following the addition of TTF to standard maintenance therapy. Therefore, there may be a survival benefit associated with TTF therapy for this indication, but there is substantial uncertainty around this conclusion. The single RCT had methodologic limitations and the current publication is a planned interim analysis. The lack of a placebo group and the lack of blinding create the possibility of a placebo effect, even with the survival outcomes. There was a moderately high rate of dropouts overall (11%) and differential dropout between groups (6.7% in the TTF group vs 20% in standard maintenance group). Also, for outcomes evaluated on a per-protocol basis (e.g., OS), there is the possibility of an adherence bias, in that patients who complete the treatment protocol may have better outcomes than patients who do not. As a result, conclusions about the efficacy of TTF therapy for this indication cannot be made with certainty.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 3.

**Table 3. 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>
</tbody>
</table>
Summary of Evidence

Glioblastoma multiforme (GBM) is the most common and deadly malignant brain tumor. It has a very poor prognosis and is associated with low quality of life during treatment. Tumor treating fields (TTF).

For individuals who have advanced or recurrent glioblastoma multiforme (GBM) who receive tumor treating fields (TTF) therapy as an alternative to standard chemotherapy, the evidence consists of 1 randomized controlled trial (RCT) and nonrandomized comparative studies. Relevant outcomes are overall survival, disease-specific survival, quality of life, and treatment-related morbidity. The single published RCT reported no difference in outcomes between patients treated with TTF therapy and standard chemotherapy. This trial has methodologic limitations. The comparisons made included only an active control of questionable efficacy, which may not reflect current standard of care. More patients in the TTF group than in the control group did not complete the treatment course, and patients in the TTF group received more courses of second-line chemotherapy. For the quality of life outcomes, only approximately one-quarter of enrolled patients had complete data. The 2 nonrandomized studies were small, with limited validity due to differences in the patient populations treated with TTF and standard care. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have GBM on maintenance therapy following initial treatment with surgery and/or radiotherapy who receive TTF therapy as an adjunct to maintenance treatment following initial treatment with surgery and/or radiation, the evidence consists of 1 RCT. Relevant
outcomes are overall survival, disease-specific survival, quality of life, and treatment-related morbidity. The single RCT reported that patients who received TTF therapy plus temozolomide have longer progression-free survival (3.1 months) and overall survival (4.9 months) than patients who received temozolomide alone. The trial had methodologic limitations, therefore further high-quality RCTs are needed to validate the results. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Practice Guidelines and Position Statements**

The National Comprehensive Cancer Network’s Central Nervous System Tumors guidelines (v.1.2016)\(^2\) has updated the recommendation for the treatment of recurrence of glioblastoma, with the option “consider alternating electric field therapy for glioblastomas” from a Category 3 recommendation to a 2A recommendation for adjuvant therapy, and 2B for use in recurrent disease.

**Medicare National Coverage**

There is no National Coverage Decision (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

**Regulatory Status**

The NovoTTF-100A™ System (assigned the generic name of TTF) was approved by FDA in April 2011 through the premarket approval process.\(^6\) The FDA-approved label reads as follows:

“The NovoTTF-100A System is intended as a treatment for adult patients (22 years of age or older) with confirmed GBM, following confirmed recurrence in an upper region of the brain (supratentorial) after receiving chemotherapy. The device is intended to be used as a stand-alone treatment, and is intended as an alternative to standard medical therapy for recurrent GBM after surgical and radiation options have been exhausted.”\(^6\)

On September 28, 2014, FDA approved a request for Novocure to change its products name from NovoTTF-110A System to Optune™.\(^7\)
On October 15, 2015, FDA granted approval for the use of Optune in combination with temozolomide for newly diagnosed supratentorial glioblastoma, after maximal debulking surgery, radiation and standard chemotherapy.

Product code: NZK.

References


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/14/13</td>
<td>New Policy. Policy created with literature search through June 3, 2013; considered investigational.</td>
</tr>
<tr>
<td>12/06/13</td>
<td>Update Related Policies. Removed 8.01.31 as it was archived.</td>
</tr>
<tr>
<td>08/09/16</td>
<td>Annual Review. Changed statement to MN when criteria are met.</td>
</tr>
<tr>
<td>03/30/17</td>
<td>Coding correction; updated code descriptions. Minor formatting update.</td>
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Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon. Ang paunawa na ito ay naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagpakawala ng Premera Blue Cross. Maaaring may mga mahalagang petisyon o pagpapakawala na una sa 800-722-1471 (TTY: 800-842-5357).

Український (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. 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. Дозвоніться за номером телефону 800-722-1471 (TTY: 800-842-5357).