TUMOR TREATING FIELDS THERAPY

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.
TUMOR TREATING FIELDS THERAPY (cont.)

Description:

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 treatment fields (TTF) therapy is a new, noninvasive technology intended to treat glioblastoma using alternating electric fields.

Electrical field therapy also referred to as Tumor Treatment Field therapy, exposes cancer cells to alternating electric fields of low intensity and intermediate frequency using insulated electrodes placed on the skin surrounding the region of a malignant tumor to inhibit tumor growth and reduce tumor angiogenesis. TTF inhibit rapidly dividing tumor cells by arrest of cell proliferation and destruction of cells while undergoing division.

FDA-approved TTF devices, include, but are not limited to:

- NovoTTF™-100A System
- Optune®

Criteria:

- Tumor treating fields therapy (TTF) to treat glioblastoma multiforme is considered medically necessary as an adjunct to standard maintenance therapy with temozolomide with documentation of ALL of the following:
  1. Newly diagnosed glioblastoma multiforme following initial treatment with surgery, radiotherapy, and/or chemotherapy
  2. Adults ≥18 years of age
  3. Karnofsky Performance Status’ score ≥70%
  4. Supratentorial tumor
  5. Demonstrates understanding of device use, including requirement for a shaved head, and is willing to comply with use criteria according to the FDA label
TUMOR TREATING FIELDS THERAPY (cont.)

Criteria: (cont.)

- Tumor treating fields therapy for all other indications not previously listed or if criteria above not met is considered experimental or investigational based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

These indications include, but are not limited to:

- As an adjunct to standard medical therapy (e.g., bevacizumab, chemotherapy) for individuals with progressive or recurrent glioblastoma multiforme
- As an alternative to standard medical therapy for individuals with progressive or recurrent glioblastoma multiforme
- Brain metastases
- Cancer in areas other than the brain

1 Karnofsky Performance Status table is located at the end of the Criteria section.

Karnofsky Performance Score:

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>100%</td>
<td>Able to carry on normal activity, no evidence of disease.</td>
</tr>
<tr>
<td>90%</td>
<td>Able to carry on normal activity, minor signs or symptoms of disease.</td>
</tr>
<tr>
<td>80%</td>
<td>Normal activity with effort, some signs and symptoms of disease.</td>
</tr>
<tr>
<td>70%</td>
<td>Cares for self, unable to carry on normal activity or to work.</td>
</tr>
<tr>
<td>60%</td>
<td>Requires occasional assistance from others but able to care for most needs.</td>
</tr>
<tr>
<td>50%</td>
<td>Requires considerable assistance from others and frequent medical care</td>
</tr>
<tr>
<td>40%</td>
<td>Disabled, requires special care and assistance.</td>
</tr>
<tr>
<td>30%</td>
<td>Severely disabled, hospitalization indicated, death not imminent.</td>
</tr>
<tr>
<td>20%</td>
<td>Very sick, hospitalization indicated, active support treatment necessary.</td>
</tr>
<tr>
<td>10%</td>
<td>Moribund</td>
</tr>
<tr>
<td>0%</td>
<td>Dead</td>
</tr>
</tbody>
</table>
TUMOR TREATING FIELDS THERAPY (cont.)

Resources:

Literature reviewed 08/21/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.


TUMOR TREATING FIELDS THERAPY (cont.)

Resources: (cont.)


TUMOR TREATING FIELDS THERAPY (cont.)

Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ’s Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ’s Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1–800–368–1019, 800–537–7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe’ é atah nílínígíí Blue Cross Blue Shield of Arizona haada yít’éego bina’idílíkidgo éí doodago Háida bíjá anilyeedígíí t’áadoo le’e yína’idílíkidgo beehaz’àanii hólo díí t’áá hazaadk’ehií háká a’dowolgo bee haz’a doo báqah ilínígódó. Ata’ halne’igíí kojí ‘bich’íí’ hodilínih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插件項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題。您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thể thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thợirdịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو أدى شخص نسبه لائحة إصدار بخصوص تجميع المعلومات الضرورية ببلاغ من دون إية تكلفة للتحدث مع مترجم الاتصال ب 877-475-4799.
TUMOR TREATING FIELDS THERAPY (cont.)

Multi-Language Interpreter Services: (cont.)


Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 이용 가능하니 합시다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799로 전화하시십시오.

French: Si vous, ou quelqu’un que vous êtes en train d’aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d’obtenir de l’aide et l’information dans votre langue dans un coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizonaについてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799までお電話ください。

Farsi:

آگر شما، یا کسی که شما به او کمک می‌کنید، سوال ندارد باید مورد اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799.

Assyrian:

Blue Cross Blue Shield of Arizona، بابه، صالبه، عبات، صالبه، مهاب، صلاله، بابه، صالبه، مهاب، صلاله.

Serbo-Croatian: Ukoiko Vi ili neko kome Vi pomažete ima pitanja o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijate pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodcicom, nazovite 877-475-4799.

Thai: หากคุณ หรือคนที่คุณช่วยเหลือมีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณสมควรจะได้รับความช่วยเหลือและข้อมูลในภาษาของคุณโดยไม่เสียค่าใช้จ่าย โปรดโทรมาที่ 877-475-4799