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MEDICAL POLICY – 1.01.29

Tumor Treating Fields Therapy

BCBSA Ref. Policy: 1.01.29

Effective Date:	Oct. 1, 2024	RELATED MEDICAL POLICIES:
Last Revised:	Sept. 9, 2024	None
Replaces:	N/A	

Select a hyperlink below to be directed to that section.

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

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

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 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.

Policy Coverage Criteria

Condition	Medical Necessity

Glioblastoma-adjuvant therapy	**Tumor treating fields (TTF) therapy to treat newly diagnosed glioblastoma multiforme is considered medically necessary when ALL of the following are met:**
	• The individual is ≥ 18 years of age
	• The tumor is in the supratentorial region of the brain (the cerebrum)
	• The individual has a Karnofsky Performance Status score ≥ 70% (see **Table** below)
	• The individual has completed initial treatment with **ALL** of the following:
	  ○ Surgery (i.e., resection, debulking, or biopsy)
	  ○ Radiation therapy
	  ○ Chemotherapy (if applicable)
	AND
	• The individual is receiving standard maintenance therapy with Temodar (temozolomide)
	
	Note: See **Related Information** for continuation of treatment

Condition	Investigational
All other conditions	**Tumor treating fields (TTF) therapy is considered investigational in all other conditions, including but not limited to the following situations:** • As an adjunct to standard medical therapy (e.g., Avastin [bevacizumab], chemotherapy) for progressive or recurrent glioblastoma • As an alternative to standard medical therapy (e.g., Avastin [bevacizumab], chemotherapy) for progressive or recurrent glioblastoma multiforme • As an adjunct to standard medical therapy (pemetrexed and platinum-based chemotherapy) for individuals with malignant pleural mesothelioma • For brain metastases • For cancer in areas other than the brain **Note:** See **Related Information** for how progression of tumor is defined

Length of Approval	
Approval	**Criteria**
Initial authorization	Tumor treating fields (TTF) therapy may be initially approved for a 90-day rental
Re-authorization criteria	Re-authorization for TTF therapy may be approved for an additional 90-day rental until documented progression or recurrence of the tumor as documented on MRI report (See **Related Information**).

Documentation Requirements

The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:

- Location of the brain tumor
- Karnofsky Performance Status score ≥ 70%
- Documentation that member has completed initial treatment with **ALL** of the following:
  - Surgery (resection, debulking, or biopsy)
  - Radiation therapy
  - Chemotherapy (if applicable)

AND

- Documentation that the individual is receiving standard maintenance therapy with Temodar (temozolomide)

Coding

Code	Description
HCPCS	
A4555	Electrode/transducer for use with electrical stimulation device used for cancer treatment, replacement only
E0766	Electrical stimulation device used for cancer treatment, includes all accessories, any type

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

Progression was defined in the EF-14 study trial (Stupp et al [2015, 2017]) according to the MacDonald criteria as tumor growth > 25% compared with the smallest tumor area measured in the individual during the trial or the appearance of one or more new tumors in the brain that are diagnosed radiologically as glioblastoma multiforme.

Per the pivotal trial, patients ≥18 years of age were eligible for enrollment. The median patient age was about 56 years with a range of 19 to 83 years; subgroup analyses for younger age groups were not provided.

The recommended Karnofsky Performance Status (KPS) varies from the National Comprehensive Cancer Network guideline (score ≥60). In the pivotal trial the median KPS score at baseline was 90.0, with a range from 60 to 100. Subgroup analyses for patients with score 60 to 70 were not provided.

Continuation of treatment is allowed until documented progression or recurrence of the tumor. MRI report is required every 6 months to demonstrate there is no progression or recurrence of the tumor.

Individuals need to understand the device use, including the requirement for a shaved head, and is willing to comply with use criteria according to the US Food and Drug Administration (FDA) label.

The FDA label includes the following:

- Patients should use Optune for at least 18 hours a day to get the best response to treatment
- Patients should finish at least 4 full weeks of therapy to get the best response to treatment. Stopping treatment before 4 weeks lowers the chances of a response to treatment.

Karnofsky Performance Status Scale Definitions Rating (%) Criteria		
Able to carry on normal activity and to work; no special care needed	100	Normal no complaints; no evidence of disease
	90	Able to carry on normal activity; minor signs or symptoms of disease
	80	Normal activity with effort; some signs or symptoms of disease

Karnofsky Performance Status Scale Definitions	Rating (%)	Criteria
Unable to work; able to live at home and care for most personal needs; varying amount of assistance needed	70	Cares for self; unable to carry on normal activity or to do active work
	60	Requires occasional assistance, but is able to care for most of his personal needs
	50	Requires considerable assistance and frequent medical care
Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly	40	Disabled; requires special care and assistance
	30	Severely disabled; hospital admission is indicated although death not imminent
	20	Very sick; hospital admission necessary; active supportive treatment necessary
	10	Moribund; fatal processes progressing rapidly
	0	Dead

Source: http://npcrc.org/files/news/karnofsky_performance_scale.pdf. Link archived.

Evidence Review

Description

Tumor treating fields (TTF) therapy is a noninvasive technology intended to treat glioblastoma and malignant pleural mesothelioma on an outpatient basis and at home using electrical fields. 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. Malignant pleural mesothelioma is an aggressive tumor with few treatment options that is associated with significant morbidity and mortality.

Background

Glioblastoma Multiforme

Glioblastomas, also known as glioblastoma multiforme (GBM), are the most common form of malignant primary brain tumor in adults.[1] GBMs are grade IV astrocytomas, a rapidly progressing and deadly type of glial cell tumor that is often resistant to standard medical therapy (e.g., bevacizumab, chemotherapy). Together, anaplastic astrocytomas and

glioblastomas comprise approximately 49.1% of all primary malignant brain tumors. Mean age at GBM diagnosis is 65 years. Glioblastomas have the lowest survival rate of any central nervous system tumor; the 5-year survival rate and average length of survival is estimated at 6.9% and 8 months, respectively.[2]

Treatment of Newly Diagnosed GBM

The primary treatment for individuals newly diagnosed with GBM is to resect the tumor to confirm a diagnosis while debulking the tumor to relieve symptoms of increased intracranial pressure or compression. If total resection is not feasible, subtotal resection and open biopsy are options. During surgery, some individuals may undergo implantation of the tumor cavity with a carmustine (bis-chloroethylnitrosourea) (Gliadel Wafer) impregnated wafer. Due to the poor efficacy of local treatment, postsurgical treatment with adjuvant radiotherapy, chemotherapy (typically temozolomide), or a combination of these two therapies is recommended. After adjuvant therapy, individuals may undergo maintenance therapy with temozolomide. Maintenance temozolomide is given for five days of every 28-day cycle for six cycles. Response and overall survival rates with temozolomide are higher in individuals who have O^6-methylguanine-DNA methyltransferase (MGMT) gene promoter methylation.

Prognostic factors for therapy success are age, histology, performance status or physical condition of the individual, and extent of resection. National Comprehensive Cancer Network (NCCN) recommendations include patient age and Karnofsky Performance Status score as important determinants of postsurgical treatment choice.[3] For individuals with good performance status, the most aggressive treatment (standard radiotherapy [RT] plus temozolomide) is recommended. For individuals with poor performance status, only single treatment cycles or even palliative or supportive care are recommended. Hypofractionated RT is indicated for individuals with poor performance status because it is better tolerated, and more individuals are able to complete RT.

Treatment of GBM is rarely curative, and tumors will recur essentially in all individuals.

Treatment of Recurrent GBM

When disease recurs, additional debulking surgery may be used if the recurrence is localized. Due to radiation tolerances, re-radiation options for individuals with recurrent GBM who have previously received initial external-beam radiotherapy are limited. There is no standard adjunctive treatment for recurrent GBM. Treatment options for recurrent disease include various

forms of systemic medications such as the antivascular endothelial growth factor drug bevacizumab (Avastin), alkylating agents such as nitrosoureas (e.g., lomustine, carmustine), or retreatment with temozolomide. Medical therapy is associated with side effects that include hematologic toxicity, headache, loss of appetite, nausea, vomiting, and fatigue. Response rates in recurrent disease are less than 10%, and the progression-free survival rate at 6 months is less than 20%.[4] There is a need for new treatments that can improve survival in individuals with recurrent GBM or reduce the side effects of treatment while retaining survival benefits.

Malignant Pleural Mesothelioma

Malignant pleural mesothelioma (MPM) is an aggressive tumor that is associated with significant morbidity and mortality. It is associated with asbestos exposure and has a latency period of about 40 years after asbestos exposure. Recommendations for treatment are mainly chemotherapy as first line with pemetrexed (e.g., Alimta) plus platinum. Surgical cytoreduction is also recommended in selected individuals with early-stage disease. Adjuvant radiation can be offered for individuals who have resection of intervention tracts found to be histologically positive or for palliation of symptomatic individuals.

Summary of Evidence

For individuals who have newly diagnosed GBM on maintenance therapy after initial treatment who receive TTF therapy as an adjunct to standard maintenance therapy, the evidence includes a randomized controlled trial (RCT) and a systematic review. The relevant outcomes include overall survival, disease-specific survival, symptoms, functional outcomes, quality of life, and treatment-related morbidity. The EF-14 trial found a significant increase of 2.7 months in progression-free survival and an increase of 4.9 months in overall survival with the addition of TTF therapy to standard maintenance therapy (i.e., temozolomide) in individuals with newly diagnosed GBM. Although patients were not blinded to treatment assignment, progression-free survival was assessed by blinded evaluators, and the placebo effects on the objective measure of overall survival are expected to be minimal. In a systematic review that included the EF-14 trial along with other observational studies, the pooled median OS and PFS in newly diagnosed individuals who received TTF therapy was 21.7 months and 7.2 months, respectively. This technology represents a clinically significant option in the treatment of individuals with GBM, for whom options are limited. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have progressive or recurrent GBM who receive TTF therapy as an adjunct or alternative to standard medical therapy, the evidence includes an RCT, nonrandomized comparative studies, and a systematic review of these data. Relevant outcomes are overall survival, disease-specific survival, quality of life, and treatment-related morbidity. The single RCT evaluating TTF therapy for recurrent GBM did not show superiority of TTF therapy for the primary outcome (overall survival) compared with physicians' choice chemotherapy. Because no serious adverse effects have been identified with TTF therapy, this raises the possibility that treatment with TTF might reduce the toxicity associated with treatment for recurrent GBM. A reduction in chemotherapy-associated toxicity without loss of efficacy would be considered a net health benefit. However, this RCT is not sufficient to permit conclusions on the efficacy of the device. Because the trial was not designed as a noninferiority trial, no inferences of noninferiority compared with chemotherapy can be made. Also, quality of life assessment was measured in an insufficient number of individuals to reach firm conclusions on differences in quality of life between TTF therapy and medical treatment. The highest quality study of TTF combined with medical treatment for recurrent GBM is a post hoc analysis of the EF-14 trial. Two registry studies also evaluated real-world outcomes in individuals enrolled in the PRiDe registry compared to individuals in the EF-11 study. In a systematic review that included the RCT and post hoc analysis of the EF-14 trial, along with other observational studies, the pooled median overall survival and progression-free survival in individuals with recurrent GBM who received TTF therapy was 10.3 months and 5.7 months, respectively. A high quality, prospective RCT is needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have unresectable, locally advanced, or metastatic, malignant pleural mesothelioma (MPM) who receive TTF therapy as an adjunct to standard maintenance therapy, the evidence includes one single-arm prospective study conducted in 80 patients and a retrospective study of five US patients. Relevant outcomes include overall survival, disease-specific survival, symptoms, functional outcomes, quality of life, and treatment-related morbidity. In individuals who received TTF therapy in combination with pemetrexed (e.g., Alimta) and cisplatin or carboplatin, median overall survival was 18.2 months (95% CI 12.1 to 25.8 months). Because there was no comparison group, it is not possible to make conclusions about the effectiveness of the intervention compared to medical therapy alone. The retrospective study is the first publication of real-world implementation of TTF for MPM. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in **Table 1**. Of particular note are the phase 3 trials evaluating TTF therapy in non-small-cell lung cancer and pancreatic cancer. TTF therapy is an active area of research for mechanisms underlying its effects on cancer cells.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02831959[a]	Pivotal, Open-label, Randomized Study of Radiosurgery With or Without Tumor Treating Fields (TTFields) (150kHz) for 1-10 Brain Metastases From Non-small Cell Lung Cancer (NSCLC) (METIS)	270	Dec 2024
NCT02973789[a]	LUNAR: Pivotal, Randomized, Open-label Study of Tumor Treating Fields (TTFields) Concurrent With Standard of Care Therapies for Treatment of Stage 4 Non-small Cell Lung Cancer (NSCLC) Following Platinum Failure	276	Sep 2023
NCT03377491[a]	EF-27 Pivotal, Randomized, Open-label Study of Tumor Treating Fields (TTFields, 150kHz) Concomitant With Gemcitabine and Nab-paclitaxel for Front-line Treatment of Locally-advanced Pancreatic Adenocarcinoma (PANOVA-3)	556	Oct 2024
NCT04471844[a]	EF-32: Pivotal, Randomized, Open-Label Study of Optune (Tumor Treating Fields, 200kHz) Concomitant With Radiation Therapy and Temozolomide for the Treatment of Newly Diagnosed Glioblastoma	950	Aug 2026
Unpublished			
NCT02663271[a]	A Phase 2, Multi-center, Single Arm, Histologically Controlled Study Testing the Combination of TTFields and Pulsed Bevacizumab Treatment in Patients With Bevacizumab-refractory Recurrent Glioblastoma	18	Mar 2022 (terminated)
NCT03940196[a]	ENGOT-ov50 / GOG-3029 / INNOVATE-3: Pivotal, Randomized, Open-label Study of Tumor Treating Fields (TTFields, 200kHz) Concomitant With Weekly	540	May 2023 (completed)

NCT No.	Trial Name	Planned Enrollment	Completion Date
	Paclitaxel for the Treatment of Platinum-resistant Ovarian Cancer (PROC)		
NCT01971281[a]	A Phase II Study of TTFields (150 kHz) Concomitant With Gemcitabine and TTFields Concomitant With Gemcitabine Plus Nab-paclitaxel for Front-line Therapy of Advanced Pancreatic Adenocarcinoma	40	Dec 2017 (unknown)
NCT01894061[a]	A Prospective Phase II Trial of NovoTTF-100A With Bevacizumab (Avastin) in Patients With Recurrent Glioblastoma	40	Jul 2019 (completed)

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Clinical Input from Physician Specialty Societies and Academic Medical Centers

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, 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 three physician specialty societies (one of which provided six responses and two of which provided one response each) and one academic medical center (total of 9 individual responses) while this policy was under review in 2016. There was majority support, but not consensus, for the use of tumor treatment fields therapy as an adjunct to maintenance treatment following initial therapy for GBM. There was mixed support for the use of tumor treatment fields as an alternative to chemotherapy in advanced or recurrent GBM.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

National Comprehensive Cancer Network

NCCN guidelines on central nervous system cancers (v.1. 2023) include recommendations for the treatment of glioblastoma (see **Table 2**).[3] For the initial treatment of individuals with glioblastoma with good performance status and either methylated or unmethylated or indeterminate O^6-methylguanine-DNA methyltransferase promotor status, treatment with standard brain radiotherapy plus concurrent temozolomide and adjuvant temozolomide plus alternating electric field therapy is a category 1 recommendation. Alternating electric currents therapy is only an option for individuals with supratentorial disease. Consideration of alternating electric field therapy for recurrent glioblastoma is a category 2B recommendation.

Table 2. Guidelines for Adjuvant Treatment of Glioblastoma, by Age and Performance Status

Age, y	KPS Score,%	Treatment Options	Category
≤70	≥60	• Standard RT plus concurrent and adjuvant temozolomide plus TTF (preferred) • Standard RT plus concurrent and adjuvant temozolomide	1
≤70	≥60	• Standard RT alone (for unmethylated MGMT promoter status only)	2A
≤70	≥60	• Standard RT plus concurrent and adjuvant lomustine and temozolomide (for methylated or indeterminate MGMT promoter status only)	2B
≤70	<60	• Hypofractionated RT with/without concurrent or adjuvant temozolomide • Temozolomide • Palliative/best supportive care	2A
>70	≥60	• Hypofractionated RT plus concurrent and adjuvant temozolomide (for methylated or indeterminate MGMT promoter status only)	1

Age, y	KPS Score,%	Treatment Options	Category
		• Standard RT plus concurrent and adjuvant temozolomide plus TTF	
>70	≥60	• Standard RT plus concurrent and adjuvant temozolomide • Temozolomide alone (for methylated or indeterminate MGMT promoter status only) • Hypofractionated RT alone (for unmethylated MGMT promoter status only)	2A
>70	≥60	• Hypofractionated RT alone (for methylated or indeterminate MGMT promoter status only)	2B
>70	<60	• Hypofractionated brain RT alone • Temozolomide alone • Palliative/best supportive care	2A

KPS: Karnofsky Performance Status; MGMT: O6-methylguanine-DNA-methyltransferase; RT: radiotherapy; TTF: tumor treating fields.

The NCCN guidelines on MPM (v.1.2024) do not address TTF as a treatment option for MPM.[24]

Congress of Neurological Surgeons

In 2022, the Congress of Neurological Surgeons released guidelines on role of cytotoxic chemotherapy and other cytotoxic therapies in the management of progressive glioblastoma.[25] In regard to TTF use in adult patients with progressive glioblastoma, the Congress states that "the use of TTF with other chemotherapy may be considered when treating adult patients with progressive glioblastoma [pGBM]. There is insufficient evidence to recommend TTF to increase overall survival in adult patients with pGBM".

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

In April 2011, the NovoTTF-100A System (Novocure; assigned the generic name of TTF) was approved by the US Food and Drug Administration (FDA) through the premarket approval process.[5] 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."

In September 2014, FDA approved Novocure's request for a product name change from NovoTTF-110A System to Optune.[6]

In October 2015, FDA expanded the indication for Optune in combination with temozolomide to include newly diagnosed GBM.[7] The device was granted priority review status in May 2015 because there was no legally marketed alternative device available for the treatment of newly diagnosed GBM, a life-threatening condition. In July 2016, a smaller, lighter version of the Optune device, called the Optune System (NovoTTF-200A System), received FDA approval.

The FDA-approved label for newly diagnosed GBM reads as follows: "This device is indicated as treatment for adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme (GBM). Optune with temozolomide is indicated for the treatment of adult patients with newly diagnosed, supratentorial glioblastoma following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy."

In May 2019, FDA approved a modified version of the Optune System (NovoTTF-100A System), which is now called the Optune Lua System (NovoTTF-100L System), for "treatment of adult patients with unresectable, locally advanced or metastatic, malignant pleural mesothelioma (MPM) to be used concurrently with pemetrexed and platinum-based chemotherapy. The indication was modified from that granted for the Humanitarian Device Exemption designation to more clearly identify the patient population the device is intended to treat and in which the safety and probable benefit of the device is supported by the available clinical data."[8]

In September 2021, the FDA granted breakthrough designation to the NovoTTF-200T System for use together with atezolizumab and bevacizumab for the first-line treatment of individuals with unresectable or metastatic liver cancer.[9]

To date, all of the existing tumor treating fields products fall under the brand name Optune. In March 2020, the manufacturer of Optune products announced a plan to include a suffix after the brand name for newly approved indications to further delineate specific indications for individual products (e.g., Optune Lua).[10] Optune was renamed Optune Gio™ in 2023. [11]

FDA product codes: NZK; QGZ.

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History

Date	Comments
10/14/13	New Policy. Policy created with literature search through June 3, 2013; considered investigational.

Date	Comments
12/06/13	Update Related Policies. Removed 8.01.31 as it was archived.
11/20/14	Annual Review. Policy updated with literature review through June 26, 2014. References 8 and 16-17 added. Editorial revisions made to rationale section. Policy statement unchanged. New HCPCS codes A9900 and E1399 added to the policy.
10/13/15	Annual Review. Policy updated with literature review through July 8, 2015; references10-11 removed and 10-12 added. Policy statement unchanged. Removed informational ICD-9 and ICD-10 codes.
09/01/16	Annual Review, approved August 9, 2016. Changed statement to MN when criteria are met.
03/30/17	Coding correction; updated code descriptions. Minor formatting update.
11/01/17	Annual Review, approved October 3, 2017. Policy updated with literature review through June 5, 2017; no references added. Removed HCPCS codes A9900 and E1399. Policy statements rewritten for clarity.
09/01/18	Annual Review, approved August 14, 2018. Policy updated with literature review through April 2018; references 10, and 12-13 added. Title changed from "Tumor Treatment Fields Therapy for Glioblastoma" to "Tumor Treating Fields Therapy". May be considered medically necessary in conjunction with maintenance temozolomide for patients with newly diagnosed glioblastoma multiforme. Investigational for all other indications.
10/01/19	Annual Review, approved September 10, 2019. Policy updated with literature review through May 2019. Malignant pleural mesothelioma added to list of conditions for which the therapy is considered investigational.
10/01/20	Annual Review, approved September 1, 2020. Policy updated with literature review through June, 2020; references added. Regulatory Status section updated to include information differentiating between Optune and Optune Lua products. Policy statements unchanged.
10/01/21	Annual Review, approved September 23, 2021. Policy updated with literature review through May 28, 2021; no references added. Policy statements unchanged. Defined initial and reauthorization criteria for added clarity.
10/01/22	Annual Review, approved September 12, 2022. Policy updated with literature review through May 23, 2022; references added. Minor editorial refinements to policy statements; intent unchanged.
10/01/23	Annual Review, approved September 11, 2023. Policy updated with literature review through May 31, 2023; references added. Policy statements unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
10/01/24	Annual Review, approved September 9, 2024. Policy updated with literature review through May 15, 2024; no references added. Minor editorial refinements to Policy Guidelines section; intent unchanged.

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.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.