Electrical Stimulation Device Used for Cancer Treatment

OPTUNE (NOVOTTF™ – 100A SYSTEM)

For any item to be covered by The Health Plan, it must:

1. Be eligible for a defined Medicare or The Health Plan benefit category
2. Be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member
3. Meet all other applicable Medicare and/or The Health Plan statutory and regulatory requirements

For the items addressed in this medical policy, the criteria for “reasonable and necessary” are defined by the following indications and limitations of coverage and/or medical necessity. Please refer to individual product lines certificates of coverage for possible exclusions of benefit.

For an item to be covered by The Health Plan, the supplier must receive a written, signed, and dated order before a claim is submitted to The Health Plan. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not reasonable and necessary.

Suppliers are to follow The Health Plan requirements for precertification, as applicable.

OPTUNE requires precertification and medical director review.

Supplier is non-par. If authorized, the reimbursement is as follows: West Virginia Medicaid rate for Medicaid members. Please send to Provider Services to negotiate for Commercial and Self-Funded members.

<table>
<thead>
<tr>
<th>CMS National Coverage Policy</th>
<th>None</th>
</tr>
</thead>
<tbody>
<tr>
<td>DME Region LCD Covers</td>
<td>Jurisdiction B. Local Coverage Determination L34738 and Article A52678</td>
</tr>
<tr>
<td>Review/Revisions Effective Date</td>
<td>For service performed on or after 03/01/14 Revised 04/01/2017, 02/01/16, 10/08/14</td>
</tr>
</tbody>
</table>
| The Health Plan             | Medicare plans will follow Oversight Region V Coverage Determination final determination posted on the CGS Services website  
Medicaid beneficiaries will follow West Virginia Medicaid  
Commercial plans will follow The Health Plan guidelines |

DESCRIPTION

Developed by NOVOCURE, The OPTUNE is a wearable, noninvasive medical device designed for continuous use throughout the day by the patient. The device has been shown in both in-vitro and in-
vivo studies to slow and reverse tumor growth by inhibiting mitosis, the process by which cells divide and replicate. The OPTUNE, which weighs about 6 lbs. (3 kg.), creates a low intensity, alternating electric field within the tumor that exerts physical forces on electrically charged cellular components, preventing the normal mitotic process and causing cancer cell death prior to division. (1)

TTF therapy is tuned to affect only one cell type at a time. TTF therapy has not been shown to affect cells that are not undergoing division. (2)

TTF therapy is not expected to affect the normal functions of bone marrow in creating red and white blood cells since the bone marrow is naturally shielded from the fields. (2)

TTF therapy is delivered locally through a physical, nonchemical pathway. This allows TTF therapy to treat brain tumors, whereas other mitotic inhibitor treatments such as taxanes and vinca alkaloids have poor diffusion across the blood-brain barrier and are rarely used to treat brain tumors. (2)

There is no evidence of cumulative damage to healthy tissues in the body when exposed to TTF therapy. Since the fields alternate so rapidly, they have no effect on normal quiescent cells, nor do they stimulate nerves and muscles. (2)

Per the manufacturer, NOVOCURE, it is intended for use with adults, with the recommended patient age to be age 22 or above. (3)

NOVOTTF is not intended for use with other cancer treatments.


COVERAGE GUIDELINES

FOR COMMERCIAL and WEST VIRGINIA MEDICAID PLANS

Covered as monotherapy for persons with histologically confirmed glioblastoma (World Health Organization Grade IV astrocytoma), after histologically or radiologically confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy and all other treatments have been exhausted.

Coverage is for the OPTUNE ™ device by NOVOCURE. No other devices will be covered.

NONCOVERAGE STATEMENT

OPTUNE (NOVOTTF) is not covered for Medicare Beneficiaries.

OPTUNE (NOVOTTF) is not covered and will be denied as experimental and investigational in the treatment of all other malignant tumors, (e.g., breast, lung, melanoma, ovarian cancer, pancreatic cancer, and solid tumor brain metastases; etc.) and all other indications because the effectiveness has not been established.

CODING INFORMATION

CPT/HCPCS codes: The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIERS
ELECTRICAL STIMULATION DEVICE USED FOR CANCER TREATMENT

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0766</td>
<td>ELECTRICAL STIMULATION DEVICE USED FOR CANCER TREATMENT INCLUDES ALL ACCESSORIES, ANY TYPE</td>
</tr>
<tr>
<td>A4555</td>
<td>ELECTRODE /TRANSDUCER FOR USE WITH ELECTRICAL STIMULATION DEVICE, USED FOR CANCER TREATMENT, REPLACEMENT ONLY</td>
</tr>
</tbody>
</table>

**HCPCS CODES COVERED IF COVERAGE CRITERIA MET**

ICD-10 codes covered if coverage criteria are met. The presence of an ICD-9 code listed in this section is not sufficient by itself to assure coverage.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C71.0</td>
<td>MALIGNANT NEOPLASM OF CEREBRUM EXCEPT LOBES AND VENTRICLES</td>
</tr>
<tr>
<td>C71.1</td>
<td>MALIGNANT NEOPLASM OF FRONTAL LOBE</td>
</tr>
<tr>
<td>C71.2</td>
<td>MALIGNANT NEOPLASM OF TEMPORAL LOBE</td>
</tr>
<tr>
<td>C71.3</td>
<td>MALIGNANT NEOPLASM OF PARIETAL LOBE</td>
</tr>
<tr>
<td>C71.4</td>
<td>MALIGNANT NEOPLASM OF OCCIPITAL LOBE</td>
</tr>
<tr>
<td>C71.5</td>
<td>MALIGNANT NEOPLASM OF VENTRICLES</td>
</tr>
<tr>
<td>C71.6</td>
<td>MALIGNANT NEOPLASM OF CEREBELLUM NOS</td>
</tr>
<tr>
<td>C71.7</td>
<td>MALIGNANT NEOPLASM OF BRAIN STEM</td>
</tr>
<tr>
<td>C71.8</td>
<td>MALIGNANT NEOPLASM OF OTHER PARTS OF BRAIN</td>
</tr>
<tr>
<td>C71.9</td>
<td>MALIGNANT NEOPLASM OF BRAIN UNSPECIFIED SITE</td>
</tr>
</tbody>
</table>

The diagnoses or ICD-10 codes that support medical necessity are indicated above.

**DOCUMENTATION REQUIREMENTS**

For the purposes of this policy, it is expected that the medical record will support the need for the care provided. It is generally understood that the medical record includes the physician's office records, hospital records, nursing home records, home health agency records, records from other health care professionals and test reports.

This documentation must be available with precertification.

Medicare has made changes to its requirements for dispensing orders, detailed written orders, and proof of delivery. The Health Plan will require the following:
1. Physician detailed written order. Order must include the following:
   a. Member’s name
   b. Date
   c. Description of item. The medical record must contain the information that supports the request for the item requested. Information should include clinical documentation of the medical condition and surgical procedure performed, if any
   d. Order must include diagnosis code
   e. Physician signature with date. Date stamps are not appropriate
   f. Quantity of items required and duration. A new order is required if there is an increase in the quantity of the supply used per month and/or the type of supply used. If no precertification was required as within allowable quantities, the provider is to submit this information with the claim

2. There must be documentation in the supplier’s records to support the medical necessity of that item.

3. Proof of delivery to be kept on file by the provider of the item.

   **Note:** If templates or forms are submitted, (i.e., a Medicare Certificate of Medical Necessity, and/or a provider created form), The Health Plan reserves the right to request the medical record, that may include, but not limited to, the physician office notes, hospital and nursing facility records, and home health records.

   **Note:** Template provider forms, prescriptions, and attestation letters are not considered part of the medical record, even if signed by the ordering physician.

**OPTUNE (NOVOTTF™) PROVIDED WHILE A MEMBER IN PART A COVERED STAY**

Reimbursement for OPTUNE (NOVOTTF™) provided to a member while the member is covered in a Part A facility is based on specific contract information with the individual facility, and whether or not the device is intended for use while the member is in the facility.

**BILLING GUIDELINES**

The OPTUNE (NOVOTTF™) is categorized by Medicare as an item requiring frequent and substantial servicing. For items that are determined to require frequent and substantial service, rental payments include payment for supplies and accessories, unless specifically otherwise noted.

Therefore, electrodes/transducers, coded A4555, are not separately payable during the rental of the device, and all servicing, maintenance, and supplies are included in the monthly rental fee.

**KX, GA, and GZ MODIFIERS**

Suppliers may submit a claim with a KX modifier only if all the criteria for that item is met.

If coverage criteria are not met, the GA or GZ modifier must be used. When there is an expectation of a medical denial, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the GZ modifier, if they have not obtained a valid ABN.
ADVANCED BENEFICIARY NOTICE

The Health Plan expects providers to follow the Medicare policy on ABN across all Medicare, Medicaid, and Commercial plans.

NOTE: Providers may be held financially responsible if they furnish the above items without notifying the member, verbally and in writing, that the specific service being provided is not covered. This must be done prior to the dispensing of the device. The provider must submit the waiver or ABN to The Health Plan with the claim showing the member agreed to pay for the device. Generalized statements on waivers or ABN are not acceptable.

PRICING, DATA ANALYSIS, AND CODING (PDAC)

The Health Plan has implemented use of Medicare’s PDAC contractor for review of authorizations. Please refer to PDAC website for appropriate product classification list.
dmepdac.com/

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INTERNET LINKS AND SOURCES

Novocure Product Information
Retrieved from novocure.com/ttf_therapy.php?ID=16

National Government Services website. Medical Policy Center. Durable Medical Equipment. Tumor Treatment field Therapy. Local Coverage Determination L34738 and Article A52678. Jurisdiction B. Last accessed 10/1/14. Retrieved from http://www.ngsmedicare.com/ngs/portal/ngsmedicare/newngs/home-lob/lut/p/a1/04_Sj9CPykssy0xPLMnMz20vMAAfGj20JNHD1dDQ20Dbz20V0dDRxFz20M_BzdDP0NTIEKIIEU GPtbABW4Obm4BAYYuzsZEaffAADwNCckP1w_Ck0JpgvACvBYUZAbGmGQ6agIAL1i1Es/d/5/L2dBIFe vZ0FBIS9nQ5Eh/?LOB=DME&LOC=All%20States&ngsLOC=All%20States&ngsLOB=DME&jurisdiction=Jurisdiction%20B#

Local Coverage Determinations (LCD) for CGS Administrators, LLC (18003, DME MAC). Retrieved from cms.gov/medicare-coverage-database/indexes/lcd-list.aspx?Ctrctr=140&name=CGS%20Administrators.%20LLC%20(18003.%20DME%20MAC)&DocType=AllProposed&DocStatus=Draft&ContrVer=2&CntrctrSelected=140*2&LCntrctr=140*2&bc=AgACAAIAAA AAAA%3d%3d#ResultsAnchor

Hayes Technology Inc. NovoTTF-100A System (Novocure) for Treatment of Brain Tumors. 1/6/14. Retrieved from Hayesinc.com/subscribers/displaySubscriberArticle.do?articleId=13219&searchStore=%24search_type%24All%24icd%24keywords%2DTumor%2Cfield%2Ctherapy%2Dstatus%2Dall%24page%2D1%24from


Stupp et al. (2010). "A Prospective, Randomized, Open-Label, Phase III Clinical Trial of NovoTTF-100A Versus Best Standard of Care Chemotherapy in Patients With Recurrent Glioblastoma." Journal of Clinical Oncology 28 karger.com/Article/Abstract/140601


WEST VIRGINIA MEDICAID FEE SCHEDULE 2014 new codes

The Health Plan Provider Procedural Manual. Payment Voucher, Section 14, Page 11