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.

National Coverage Determination Policy	None
Local Coverage Determination Policy	Jurisdiction B. Local Coverage Determination L34738 and Article A52678
Effective Date	For service performed on or after 03/01/14
Review/Revision Date	01/19, 10/18, 05/2018, 04/01/2017, 02/01/16, 10/08/14
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.

novocure.com

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.

REPAIR, REPLACEMENT, AND REASONABLE USEFUL LIFETIME

The Optune (NOVOTTF™) is covered as a capped rental device and repair or replacement will be included in the monthly rental for the first 10 months.

CODING INFORMATION

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

HCPCS MODIFIERS

EY	NO PHYSICIAN OR OTHER LICENSED HEALTHCARE PROVIDER ORDER FOR THIS ITEM OR SERVICE
GA	WAIVER OF LIABILITY STATEMENT ISSUED AS REQUIRED BY PAYOR POLICY
GZ	ITEM OR SERVICE EXPECTED TO BE DENIED AS NOT REASONABLE AND NECESSARY
KX	REQUIREMENTS SPECIFIED IN THE MEDICAL POLICY HAVE BEEN MET

HCPCS CODES COVERED IF COVERAGE CRITERIA MET

E0766	ELECTRICAL STIMULATUION DEVICE USED FOR CANCER TREATMENT INLUDES ALL ACCESSORIES, ANY TYPE
A4555	ELECTRODE /TRANSDUCER FOR USE WITH ELECTRICAL STIMULATION DEVICE, USED FOR CANCER TREATMENT, REPLACEMENT ONLY

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.

C71.0	MALIGNANT NEOPLASM OF CEREBRUM EXCEPT LOBES AND VENTRICLES
C71.1	MALIGNANT NEOPLASM OF FRONTAL LOBE
C71.2	MALIGNANT NEOPLASM OF TEMPORAL LOBE
C71.3	MALIGNANT NEOPLASM OF PARIETAL LOBE
C71.4	MALIGNANT NEOPLASM OF OCCIPITAL LOBE
C71.5	MALIGNANT NEOPLASM OF VENTRICLES
C71.6	MALIGNANT NEOPLASM OF CEREBELLUM NOS
C71.7	MALIGNANT NEOPLASM OF BRAIN STEM
C71.8	MALIGNANT NEOPLASM OF OTHER PARTS OF BRAIN
C71.9	MALIGNANT NEOPLASM OF BRAIN UNSPECIFIED SITE

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 (NOVOTFF™) PROVIDED WHILE A MEMBER IN PART A FACILITY

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.

Payment for the device is included in the payment to a hospital if:

1. The device is provided to a patient during an inpatient hospital stay prior to the day of discharge; and
2. The patient uses the device for medically necessary inpatient treatment or rehabilitation.

A claim must not be submitted in this situation.

Reimbursement for electrical stimulation device used for cancer treatment provided while a member is in a SNF receiving Part A services, will be reimbursed according to individual facility contracts.

EQUIPMENT RETAINED FROM A PRIOR PAYOR

The Health Plan will not pay in excess of the contracted purchase price for any item in this policy. If the provider is seeking payment from The Health Plan, the item must be precerted and The Health Plan will pay the remaining rental months up to purchase price- if member meets guidelines above.

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/

AMA CPT/ADA CDT COPYRIGHT STATEMENT

indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

INTERNET LINKS AND SOURCES

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