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**CHANGE 111
6010.57-M
MAY 15, 2014**

**PUBLICATIONS SYSTEM CHANGE TRANSMITTAL
FOR
TRICARE POLICY MANUAL (TPM), FEBRUARY 2008**

The TRICARE Management Activity has authorized the following addition(s)/revision(s).

CHANGE TITLE: EVOLVING PRACTICES 14-003

CONREQ: 16971

PAGE CHANGE(S): See page 2.

SUMMARY OF CHANGE(S): See page 3.

EFFECTIVE DATE: See page 3.

IMPLEMENTATION DATE: Upon direction of the Contracting Officer.

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Date: 2014.05.12 14:45:09 -06'00'

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**ATTACHMENT(S): 6 PAGE(S)
DISTRIBUTION: 6010.57-M**

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CHAPTER 1

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SUMMARY OF CHANGES

CHAPTER 1

1. Section 3.1. This change allows coverage for the NovoTTF-100A device for treatment of recurrent glioblastoma as a rare disease. EFFECTIVE DATE: 09/01/2012.

CHAPTER 4

2. Section 22.2. This change removes the 12 month age limit for cochlear implantation. EFFECTIVE DATE: 07/27/2012.

Chapter 1

Section 3.1

Rare Diseases

Issue Date: May 18, 1994

Authority: [32 CFR 199.2\(b\)](#) and [32 CFR 199.4\(g\)\(15\)](#)

1.0 DESCRIPTION

TRICARE defines a rare disease as any disease or condition that affects less than 200,000 persons in the United States.

2.0 POLICY

2.1 Coverage for treatment of rare diseases may be considered on a case-by-case basis. Case-by-case review is not required for drugs, devices, medical treatments, and procedures that have already been established as safe and effective for treatment of rare diseases.

2.1.1 In reviewing the case, any or all of the following sources may be used to determine if the proposed benefit is considered safe and effective.

2.1.2 Trials published in refereed medical literature.

2.1.3 Formal technology assessments.

2.1.4 National medical policy organization positions.

2.1.5 National professional associations.

2.1.6 National expert opinion organizations.

2.2 If case review indicates that the proposed benefit for a rare disease is safe and effective for that disease, benefits may be allowed. If benefits are denied, an appropriate appealing party may request an appeal.

2.3 Off-label use of rituximab may be considered for cost-sharing for the treatment of recurrent nodular CD20 positive lymphocyte predominant Hodgkin's disease. The effective date is January 1, 2003.

2.4 Off-label use of rituximab may be considered for cost-sharing in reducing proteinuria for the treatment of Immunoglobulin A (IgA) nephropathy (proliferative glomerulonephritis). The effective date is May 1, 2007.

2.5 Effective May 13, 2009, Intraoperative Hyperthermic Chemotherapy (IPHC) (Current Procedural Terminology (CPT)¹ procedure codes 77600, 77605, and 96445) in conjunction with cytoreductive surgery or peritonectomy for treatment of pseudomyxoma peritonei resulting from appendiceal carcinoma may be covered on a case-by-case basis for adult patients when all of the following criteria are met:

- There is no evidence of distant metastasis.
- There is evidence of low histological aggressiveness of the disease.
- The patient has not undergone preoperative systemic chemotherapy.
- The patient's condition does not preclude major surgery.
- The chemotherapeutic agents used are Mitomycin C, Cisplatin (also known as Cisplatinum), or Fluorouracil.

2.6 External Infusion Pumps (EIPs) for insulin may be considered for cost-sharing when the diagnosis is Cystic Fibrosis-Related Diabetes (CFRD) with fasting hyperglycemia. See [Chapter 8, Section 2.3](#) for policy regarding EIPs. Effective January 21, 2009.

2.7 Post-operative proton beam radiosurgery/radiotherapy (CPT¹ procedure codes 77520, 77522, 77523, and 77525) may be considered for cost-sharing when the diagnosis is sacral chordoma. See [Chapter 5, Section 3.1](#) for policy regarding proton beam radiosurgery/radiotherapy.

2.8 Extracorporeal photopheresis (CPT¹ procedure code 36522) may be considered for cost-sharing when the diagnosis is Bronchiolitis Obliterans Syndrome (BOS) that is refractory to immunosuppressive drug treatment. See [Chapter 4, Section 9.2](#) for policy regarding photopheresis.

2.9 Off-label use of Selective Internal Radiation Therapy (SIRT) with yttrium-90 microspheres (resin or glass) may be considered for cost-sharing for the treatment of unresectable liver metastases from neuroendocrine tumors. The effective date is May 1, 2008. See [Chapter 5, Section 3.2](#) for policy regarding brachytherapy/radiation therapy.

2.10 Radiofrequency Ablation (RFA), when performed using an U.S. Food and Drug Administration (FDA) approved electrosurgical cutting and coagulation device, may be considered for cost-sharing for the treatment of liver metastases from gastric cancer. The effective date is June 1, 2010.

2.11 Effective September 1, 2012, the NovoTTF-100A system (HCPCS A4555 and E0766) may be cost-shared for treatment of adult patients (22 years of age or older) with recurrent glioblastoma after surgical and radiation options have been exhausted.

3.0 EXCLUSIONS

3.1 Intracranial angioplasty with stenting (CPT¹ procedure code 61635) of the venous sinuses for treatment of pseudotumor cerebri (also known as idiopathic intracranial hypertension and benign intracranial hypertension) is unproven.

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Chapter 1, Section 3.1

Rare Diseases

3.2 The off-label use of rituximab for the treatment of pediatric linear Immunoglobulin A (IgA) dermatosis is unproven.

3.3 Proton Beam Therapy (PBT)/radiosurgery/radiotherapy for the treatment of thymoma is unproven.

- END -

Cochlear Implantation

Issue Date: March 2, 1988

Authority: [32 CFR 199.4\(c\)\(2\)](#), [\(c\)\(3\)](#), [\(d\)\(3\)](#), and [32 CFR 199.5\(c\)\(2\)](#)

1.0 CPT¹ PROCEDURE CODES

69930, 90669, 90732, 92601 - 92604, 92626, 92627

2.0 HCPCS PROCEDURE CODES

Level II Codes L8614 - L8624

3.0 DESCRIPTION

A cochlear implant device is an electronic instrument, part of which is implanted surgically to stimulate auditory nerve fibers, and part of which is worn or carried by the individual to capture and amplify sound. Cochlear implant devices are available in single channel and multi-channel models. The purpose of implanting the device is to provide an awareness and identification of sounds and to facilitate communication for persons who are profoundly hearing impaired.

4.0 POLICY

4.1 Cochlear implantation using U.S. Food and Drug Administration (FDA) approved **single or multichannel** cochlear implants and when used according to approved **labeling** is a covered benefit.

4.2 Simultaneous or sequential bilateral cochlear implantation is a covered benefit for:

4.2.1 Adults aged 18 years and older with bilateral, pre or post-linguistic, sensorineural, moderate to profound hearing impairment who meet both of the following criteria:

4.2.1.1 Individual has bilateral severe to profound sensorineural hearing loss determined by a pure tone average of 70 dB or greater at 500 Hz, and 2000 Hz; and

4.2.1.2 Individual has limited benefit from appropriately fitted binaural hearing aids. Limited benefit from amplification is defined by test scores of 40% correct or less in best-aided listening condition on open-set sentence cognition (e.g., Central Institute for the Deaf (CID) sentences, Hearing in Noise Test (HINT) sentences).

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4.2.2 Children with bilateral sensorineural hearing impairment who meet all of the following criteria:

4.2.2.1 Child has profound, bilateral sensorineural hearing loss determined by a pure tone average of 90 dB or greater at 500, 1000 and 2000 Hz; and

4.2.2.2 Child has limited benefit from appropriately fitted binaural hearing aids. For children four years of age or younger, limited benefit is defined as failure to reach developmentally appropriate auditory milestones measured using the Infant-Toddler Meaningful Auditory Integration Scale, the Meaningful Auditory Integration Scale, or the Early Speech Perception test, or less than 20% correct on open-set word recognition test (Multisyllabic Lexical Neighborhood Test (MLNT)) in conjunction with appropriate amplification and participation in intensive aural habilitation over a three to six month period. For children older than four years of age, limited benefit is defined as less than 12% correct on the Phonetically Balanced-Kindergarten Test, or less than 30% correct on the Hearing in Noise Test for children, the open-set MLNT or Lexical Neighborhood Text (LNT), depending on the child's cognitive ability and linguistic skills; and

4.2.2.3 A three to six month hearing aid trial has been undertaken and failed by a child without previous experience with hearing aids.

4.2.3 The following additional criteria must also be met for unilateral (monaural) or bilateral (binaural) cochlear implantation in adults and children:

4.2.3.1 The individual must have had an assessment by an audiologist and from an otolaryngologist experienced in this procedure indicating the likelihood of success with this device; and

4.2.3.2 The individual must have the cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation. A post-cochlear implant rehabilitation program is necessary to achieve benefit from the cochlear implant. The rehabilitation program consists of six to ten sessions that last approximately 2.5 hours each. The rehabilitation program includes development of skills in understanding running speech, recognition of consonants and vowels, and tests of speech perception ability. See [Chapter 7, Sections 7.1 and 18.1](#); and

4.2.3.3 The individual should be up-to-date on age appropriate pneumococcal vaccination at least two weeks prior to the implant, in accordance with the Centers for Disease Control and Prevention (CDC).

4.3 Replacement of the cochlear implant external speech processor device is covered.

5.0 EXCLUSIONS

5.1 Cochlear implantation is contraindicated when preoperative radiographic evidence indicates an underdeveloped internal auditory canal, the absence of cochlear development or a physical condition which precludes placement of the electrode array or receiver-stimulator (e.g., cochlear ossification that prevents electrode insertion).

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Chapter 4, Section 22.2

Cochlear Implantation

5.2 Cochlear implantation is contraindicated when there is a middle ear infection, the cochlear lumen is structurally unsuited to implantation, or there is a lesion in the auditor nerve or acoustic area of the central nervous system.

5.3 Cochlear implantation may not be cost-shared when there is a contraindication to surgery and implantation, such as poor anesthetic risk, severe mental retardation, severe psychiatric disorders, and organic brain syndrome.

6.0 EFFECTIVE DATES

6.1 April 4, 2005.

6.2 July 27, 2012, for children under 12 months of age.

- END -

