OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
HEALTH AFFAIRS
16401 EAST CENTRETECH PARKWAY
AURORA, CO 80011-9066

DEFENSE
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MB&RS

CHANGE 146
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NOVEMBER 25, 2015

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 15-003**

CONREQ: 17674

PAGE CHANGE(S): See page 2.

SUMMARY OF CHANGE(S): This change adds coverage for transpupillary thermotherapy in conjunction with plaque radiotherapy for the treatment of choroidal melanoma, for image-guided robotic linear accelerator-based stereotactic body radiation therapy for the treatment of prostate cancer, and for Orthotopic Liver Transplantation for the Treatment of Acute Intermittent Porphyria.

EFFECTIVE DATE: See page 3.

IMPLEMENTATION DATE: December 28, 2015.

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Ann N. Fazzini
Team Chief, Medical Benefits & Reimbursement Section (MB&RS)
Defense Health Agency (DHA)

ATTACHMENT(S): **11 PAGE(S)**
DISTRIBUTION: **6010.57-M**

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CHANGE 146
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REMOVE PAGE(S)	INSERT PAGE(S)
CHAPTER 1	
Section 3.1, page 3	Section 3.1, page 3
CHAPTER 4	
Section 21.1, pages 1 and 2	Section 21.1, pages 1 and 2
Section 24.5, pages 3 and 4	Section 24.5, pages 3 - 5
CHAPTER 5	
Section 3.1, pages 1 - 4	Section 3.1, pages 1 - 5

SUMMARY OF CHANGES

CHAPTER 1

1. Section 3.1. This change adds coverage for Orthotopic Liver Transplantation for the Treatment of Acute Intermittent Porphyria. EFFECTIVE DATE: 02/01/2012.

CHAPTER 4

2. Section 21.1. This change adds coverage for transpupillary thermotherapy in conjunction with plaque radiotherapy for the treatment of choroidal melanoma. EFFECTIVE DATE: 01/01/2012.

3. Section 24.5. This change adds coverage for Orthotopic Liver Transplantation for the Treatment of Acute Intermittent Porphyria. EFFECTIVE DATE: 02/01/2012.

CHAPTER 5

4. Section 3.1. This change adds coverage for image-guided robotic linear accelerator-based stereotactic body radiation therapy (SBRT) for the treatment of prostate cancer. EFFECTIVE DATE: 10/24/2014.

2.13 Effective February 4, 2011, Radiesse® Voice laryngoplasty injections may be cost-shared for the treatment of type 1 laryngeal cleft (also described as supraglottic interarytenoid defects that extend no further than the true vocal folds).

2.14 Effective November 27, 1995, Orthotopic Liver Transplantation (OLT) may be cost-shared for the treatment of Crigler-Najjar Syndrome Type I. OLT may be performed both prior to the onset of neurological symptoms or after the onset of neurological symptoms.

2.15 Effective June 5, 2013, Off-label use of intravenous immune globulin (CPT[2] procedure code 90283) for the treatment of Hashimoto's Encephalopathy, may be considered in exceptional circumstances where there is progressive neurologic decline despite appropriate steroid therapy or where steroid therapy is contraindicated.

2.16 Effective January 4, 2013, allogeneic hematopoietic cell transplant (CPT[2] procedure code 38240) for the treatment of primary plasma cell leukemia.

2.17 Off-label use of Photodynamic Therapy (CPT[2] procedure code 67221) with Visudyne (HCPCS J3396) may be considered for cost-sharing for the treatment of retinal astrocytic hamartoma in Tuberous Sclerosis. The effective date is February 1, 2008.

2.18 Effective June 25, 2014, intracranial angioplasty with stenting (CPT[2] procedure code 61635) of the venous sinuses may be considered for cost-sharing for the treatment of pseudotumor cerebri (also known as idiopathic intracranial hypertension and benign intracranial hypertension).

2.19 Effective February 1, 2012, OLT (CPT[2] procedure code 47135) for the treatment of Acute Intermittent Porphyria.

3.0 EXCLUSIONS

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

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

- END -

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Chapter 4 Section 21.1

Eye And Ocular Adnexa

Issue Date: August 26, 1985
Authority: 32 CFR 199.4(c)(2), (c)(3) and (g)(46)

1.0 CPT[1] PROCEDURE CODES

0192T, 65091 - 65755, 65772 - 66172, 66180 - 68899, 77600 - 77615

2.0 DESCRIPTION

The eye is the organ of vision and the ocular adnexa are the appendages or adjunct parts; i.e., eyelids, lacrimal apparatus.

3.0 POLICY

3.1 Services and supplies required in the diagnosis and treatment of illness or injury involving the eye or ocular adnexa are covered.

3.2 Phototherapeutic Keratectomy (PTK) is covered for corneal dystrophies.

3.3 Strabismus. Surgical procedures and eye examinations to correct, treat, or diagnose strabismus are covered.

3.4 Corneal transplants. A corneal transplant (keratoplasty) is a covered surgical procedure. Relaxing keratotomy to relieve astigmatism following a corneal transplant is covered.

3.5 Transpupillary thermotherapy (laser hyperthermia, CPT[1] procedure codes 77600 - 77615), with chemotherapy, is covered for the treatment of retinoblastoma. See also Chapter 5, Section 5.1.

3.6 Intrastromal Corneal Ring Segments (Intacs®) is covered for U.S. Food and Drug Administration (FDA) approved indications for beneficiaries with keratoconus who meet all of the following criteria: (1) are unable to achieve adequate vision using lenses or spectacles; and (2) for whom corneal transplant is the only remaining option. Coverage allowed effective July 17, 2005.

3.7 Optonal ExPRESS Mini glaucoma Shunt (CPT[1] procedure code 0192T) to reduce Intraocular Pressure (IOP) in the treatment of glaucoma, that cannot be controlled effectively with medications.

3.8 Off-label use of Photodynamic Therapy (CPT[1] procedure code 67221) with Visudyne (HCPCS J3396) may be considered for cost-sharing for the treatment of retinal astrocytic hamartoma in Tuberous Sclerosis. The effective date is February 1, 2008.

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3.9 Transpupillary thermotherapy (CPT[2] procedure code 67299) with Plaque Radiotherapy (Brachytherapy) is covered for the treatment of choroidal melanoma. See also Chapter 5, Section 3.2.

4.0 EXCLUSIONS

4.1 Refractive corneal surgery except as noted in paragraph 3.4 (CPT[2] procedure codes 65760, 65765, 65767, 65770, 65771).

4.2 Eyeglasses, and contact lenses except as noted in Chapter 7, Section 6.2.

4.3 Orthokeratology.

4.4 Orthoptics, also known as visual training, vision therapy, eye exercises, eye therapy, is excluded by 32 CFR 199.4(g)(46) (CPT[2] procedure code 92065).

4.5 Epikeratophakia for treatment of aphakia and myopia is unproven.

4.6 Transpupillary thermotherapy (CPT[2] procedure code 67299) as primary treatment of choroidal melanoma is unproven.

4.7 Canaloplasty for the treatment of glaucoma (CPT[2] procedure codes 66174 and 66175).

4.8 Autologous serum eye drops for the treatment of dry eye syndrome, keratitis, or ocular hypertension is unproven.

4.9 Visudyne Photodynamic Therapy for Central Serous Retinopathy is considered unproven (CPT[2] procedure code 67221 and HCPCS J3396).

5.0 EFFECTIVE DATE

April 1, 2011, coverage for Optonal ExPRESS Mini Glaucoma Shunt.

- END -

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2.8 Orthotopic Liver Transplantation (OLT) (CPT[2] procedure code 47135) for the treatment of Acute Intermittent Porphyria in accordance with the TRICARE provisions for the treatment of rare diseases.

3.0 POLICY CONSIDERATIONS

3.1 For beneficiaries who reside in TRICARE regions but fail to obtain preauthorization for liver or LDLT, benefits may be extended if the services or supplies otherwise would qualify for benefits but for the failure to obtain preauthorization. If preauthorization is not received, the appropriate preauthorizing authority is responsible for reviewing the claims to determine whether the beneficiary's condition meets the clinical criteria for the transplantation. TRICARE Prime enrollees who failed to obtain preauthorization will be reimbursed only under POS rules.

3.2 Benefits will only be allowed for transplantations performed at a TRICARE or Medicare-certified liver transplantation center. Benefits are also allowed for transplants performed at a pediatric facility that is TRICARE-certified as a liver transplantation center on the basis that the center belongs to a pediatric consortium program whose combined experience and survival data meet the TRICARE criteria for certification. The contractor in whose jurisdiction the center is located is the certifying authority for TRICARE authorization as a liver transplantation center. Refer to Chapter 11, Section 7.1 for organ transplantation center certification requirements.

3.3 Liver transplantation will be paid under the Diagnosis Related Group (DRG).

3.4 Claims for transportation of the donor organ and transplantation team shall be adjudicated on the basis of billed charges, but not to exceed the transport service's published schedule of charges, and cost-shared on an inpatient basis. Scheduled or chartered transportation may be cost-shared.

3.5 Charges made by the donor hospital will be cost-shared on an inpatient basis and must be fully itemized and billed by the transplantation center in the name of the TRICARE patient.

3.6 Acquisition and donor costs are not considered to be components of the services covered under the DRG. These costs must be billed separately on a standard Centers for Medicare and Medicaid Services (CMS) 1450 UB-04 claim form in the name of the TRICARE patient.

3.7 When a properly preauthorized transplantation candidate is discharged less than 24 hours after admission because of extenuating circumstances, such as the available organ is found not suitable or other circumstances which prohibit the transplantation from being timely performed, all otherwise authorized services associated with the admission shall be cost-shared on an inpatient basis, since the expectation at admission was that the patient would remain more than 24 hours.

3.8 Liver or LDLT performed on an emergency basis in an unauthorized liver transplantation facility may be cost-shared <u>only</u> when the following conditions have been met:

3.8.1 The unauthorized center <u>must</u> consult with the nearest TRICARE or Medicare-certified liver transplantation center regarding the transplantation case;

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3.8.2 It must be determined and documented by the transplantation team physician(s) at the certified liver transplantation center that transfer of the patient (to the certified liver transplantation center) is not medically reasonable, even though transplantation is feasible and appropriate; and

3.8.3 All other TRICARE contractual requirements have been met.

4.0 EXCLUSIONS

4.1 Liver transplantation and LDLT is excluded when any of the following contraindications exist:

4.1.1 Significant systemic or multisystemic disease (other than hepatorenal failure) which limits the possibility of full recovery and may compromise the function of the newly transplanted organs.

4.1.2 Active alcohol or other substance abuse that interferes with compliance to strict treatment regimen.

4.1.3 Malignancies metastasized to or extending beyond the margins of the liver.

4.2 The following are also excluded:

4.2.1 Expenses waived by the transplantation center (e.g., beneficiary/sponsor not financially liable).

4.2.2 Services and supplies not provided in accordance with applicable program criteria (i.e., part of a grant or research program; unproven procedure).

4.2.3 Administration of an unproven immunosuppressant drug that is not FDA approved or has not received approval as an appropriate "off-label" drug indication.

4.2.4 Pre- or post-transplantation nonmedical expenses (e.g., out-of-hospital living expenses, to include hotel, meals, privately owned vehicle for the beneficiary or family members).

4.2.5 Transportation of an organ donor.

4.3 Artificial assist devices that are not FDA approved and that are not used in compliance with FDA approved indications.

5.0 EFFECTIVE DATES

5.1 November 1, 1994, for hepatitis C.

5.2 December 1, 1996, for hepatitis B.

5.3 April 5, 2010, for OTCD.

5.4 May 29, 2012, for CTLN1.

5.5 February 1, 2012, For Acute Intermittent Porphyria.

- END -

Chapter 5 Section 3.1

Radiation Oncology

Issue Date: March 27, 1991
Authority: 32 CFR 199.4(b)(2), (b)(2)(x), (c)(2)(viii), and (g)(15)

1.0 CPT[1] PROCEDURE CODES

61793, 61795, 77261 - 77421, 77427 - 77799, 0073T

2.0 HCPCS PROCEDURE CODES

G0339, G0340

3.0 DESCRIPTION

3.1 Radiation therapy is also known as radiotherapy, radiation treatment, x-ray therapy, cobalt therapy, and proton beam therapy. The primary purpose of radiation therapy is to eliminate or shrink localized cancers (as opposed to cancers that have spread to distant parts of the body).

3.2 Stereotactic radiosurgery/radiotherapy is a method of delivering ionizing radiation to small intracranial targets. Stereotactic radiosurgery entails delivering a high dose in a single session. Stereotactic radiotherapy entails fractionating the dose over a number of treatments.

3.2.1 There are three main variations of stereotactic radiosurgery/radiotherapy: gamma beam or gamma knife, linear accelerator (linac), and charged particle beam (proton or helium ion). The three radiation delivery devices differ technically in several ways: source of radiation, size and shape of the radiation field, and range of radiation dosages.

3.2.2 The radiosurgical/radiotherapy procedure is preceded by a process of localizing the target, which can be performed with one or more of the following techniques: skull x-ray, cerebral angiography, Computerized Tomography (CT), or Magnetic Resonance Imaging (MRI).

4.0 POLICY

4.1 Radiation therapy (fast neutron, hyperfractionated, and radioactive chromic phosphate synoviorthesis) is covered for those indications documented by reliable evidence as safe, effective and comparable or superior to standard care (proven). For coverage on brachytherapy/radiation therapy, see Section 3.2.

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4.2 Gamma knife radiosurgery/radiotherapy is covered for the following indications. This list of indications is not all inclusive. Other indications are covered when documented by reliable evidence as safe, effective, and comparable or superior to standard care (proven).

- Arteriovenous Malformations (AVMs).
- Benign brain tumors.
- Acoustic neuromas (vestibular Schwannomas).
- Pituitary adenomas.
- Craniopharyngiomas.
- Other tumors of the skull base.
- Pineal region tumors.
- Metastatic brain tumors.
- High grade gliomas (glioblastoma multiforme, anaplastic astrocytomas).

4.3 Linear accelerator radiosurgery/radiotherapy is covered for the following indications. This list of indications is not all inclusive. Other indications are covered when documented by reliable evidence as safe, effective, and comparable or superior to standard care (proven).

- AVMs.
- Acoustic neuromas (vestibular Schwannomas).
- Metastatic brain tumors.

4.4 Proton beam radiosurgery/radiotherapy is covered for the following indications. This list of indications is not all inclusive. Other indications are covered when documented by reliable evidence as safe, effective, and comparable or superior to standard care (proven).

- AVMs.
- Cushing's disease or acromegaly caused by pituitary microadenomas.
- As postoperative therapy in patients who have undergone biopsy or partial resection of the chordoma or low grade (I or II) chondrosarcoma of the basisphenoid region (skull-base chordoma or chondrosarcoma) or cervical spine.
- As primary therapy for patients with uveal melanoma, with no evidence of metastasis or extrascleral extension, and with tumors up to 22 mm in largest diameter and 14 mm in height.
- Prostate cancer.
- Meningioma.
- Low grade glioma (astrocytoma, grade I-II).
- Glioblastoma multiforme.
- Soft tissue sarcoma (liposarcoma).
- Hodgkin's disease when conventional radiotherapy is contraindicated.
- Acoustic neuromas.
- As post-operative therapy for sacral chordoma under the rare disease policy as described in Chapter 1, Section 3.1.

4.5 Helium ion beam radiosurgery/radiotherapy is covered for the following indications. This list of indications is not all inclusive. Other indications are covered when documented by reliable evidence as safe, effective, and comparable or superior to standard care (proven).

4.5.1 As primary therapy for patients with melanoma of the uveal tract, with no evidence of metastasis or extrascleral extension, and with tumors up to 24 mm in largest diameter and 14 mm in height.

4.5.2 As postoperative therapy in patients who have undergone biopsy or partial resection of the chordoma or low grade (I or II) chondrosarcoma of the basisphenoid region (skull-base chordoma or chondrosarcoma) or cervical spine.

4.6 Extracranial stereotactic radiosurgery/radiotherapy including image-guided robotic linear accelerator-based stereotactic body radiotherapy (SBRT) (CPT[2] procedure codes 77435, 77373 and HCPCS codes G0339, G0340) and all related medically necessary services and supplies (CPT[2] procedure code 55876) are covered for the following indications.

- Primary and metastatic lung carcinoma.
- Prostate cancer.

4.7 Frameless stereotaxy (neuronavigation) is covered for the following indications. This list of indications is not all inclusive. Other indications are covered when documented by reliable evidence as safe, effective, and comparable or superior to standard care (proven).

- Localization, surgical planning and guidance for intracranial tumors, skull base tumors, metastatic brain tumors, AVMs, cavernomas, chordomas, and pituitary adenomas.
- Biopsy guidance.
- Cerebrospinal fluid shunt placement.
- Surgery for intractable epilepsy.
- Spinal surgery.

4.8 The frameless stereotaxy device must be U.S. Food and Drug Administration (FDA) approved. The following devices are FDA approved: StealthStation System, The Operating Arm, ISG Viewing Wand, MKM System, and Philips Easyguide. Other systems which are FDA approved are also covered.

4.9 High energy neutron radiation treatment (CPT[2] procedure codes 77422 and 77423) is covered for adenoid cystic carcinoma for the following indications:

- Unresectable, inoperable or recurrent tumors.
- Locally advanced disease.
- In situations where surgical extirpation would cause considerable morbidity.

5.0 EXCLUSIONS

5.1 Helium ion beam radiosurgery/radiotherapy for AVMs and ependymoma is unproven.

5.2 Intra-Operative Radiation Therapy (IORT) is unproven.

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5.3 High energy neutron radiation treatment delivery, single treatment area using a single port or parallel-opposed ports with no blocks or simple blocking (CPT[3] procedure code 77422) is unproven (except for treatment of adenoid cystic carcinoma, see paragraph 4.9).

5.4 High energy neutron radiation treatment delivery, single treatment area using a single port or parallel-opposed ports with no blocks or simple blocking one or more isocenter(s) with coplanar or non-coplanar geometry with blocking and/or wedge, and/or compensator(s) (CPT[3] procedure code 77423) is unproven (except for treatment of adenoid cystic carcinoma, see paragraph 4.9).

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

5.6 The off-label use of Selective Internal Radiation Therapy (SIRT), also known as radioembolization, with yttrium-90 microspheres (resin or glass) for the treatment of unresectable liver tumors from metastatic breast cancer is unproven and excluded from TRICARE coverage.

6.0 EFFECTIVE DATES

6.1 February 26, 1986, for proton beam radiosurgery/radiotherapy for AVMs.

6.2 March 1, 1988, for proton beam radiosurgery/radiotherapy for patients with Cushing's disease or acromegaly caused by pituitary microadenoma.

6.3 October 6, 1988, for gamma beam (gamma knife) radiosurgery/radiotherapy for treatment of AVM, benign brain tumors, acoustic neuromas, pituitary adenomas, craniopharyngiomas, other tumors of the posterior fossa and pineal region tumors.

6.4 January 1, 1990, for proton beam radiosurgery/radiotherapy for soft tissue sarcoma (liposarcoma).

6.5 June 18, 1990, for proton beam radiosurgery/radiotherapy for chordomas or chondrosarcomas.

6.6 January 1, 1994, for gamma beam (gamma knife) and linear accelerator radiosurgery/radiotherapy for metastatic brain tumors.

6.7 January 1, 1996, for proton beam radiosurgery/radiotherapy for uveal melanoma.

6.8 January 1, 1996, for helium ion beam radiosurgery/radiotherapy for uveal melanoma and chordomas or chondrosarcomas.

6.9 April 1, 1996, for linear accelerator radiosurgery/radiotherapy for AVMs and acoustic neuromas.

6.10 April 26, 1996, for proton beam radiosurgery/radiotherapy for prostate cancer.

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6.11 October 1, 1997, for gamma knife radiosurgery/radiotherapy for high grade gliomas (glioblastoma multiforme, anaplastic astrocytomas).

6.12 January 1, 1998, for extracranial stereotactic radiosurgery/radiotherapy for lung carcinoma.

6.13 The date of FDA approval for frameless stereotaxy.

6.14 October 24, 2014, for image-guided robotic linear accelerator-based stereotactic body radiation therapy (SBRT) and all related medically necessary services and supplies for the treatment of prostate cancer.

- END -