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SUMMARY OF CHANGE(S): See page 3.

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CHANGE 142
6010.57-M
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REMOVE PAGE(S)

CHAPTER 1

Section 3.1, pages 1 - 3

CHAPTER 4

Section 6.1, pages 3 and 4

Section 9.1, pages 5 and 6

Section 20.1, pages 3 and 4

Section 21.1, pages 1 and 2

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Section 20.1, pages 3 and 4

Section 21.1, pages 1 and 2

SUMMARY OF CHANGES

CHAPTER 1

1. Section 3.1.
 - a. This change adds coverage for the off-label use of rituximab for the treatment of neuromyelitis optica (NMO). EFFECTIVE DATE: 03/26/2010.
 - b. This change confirms that photodynamic therapy with the off-label use of Visudyne may be used in the treatment of Retinal Astrocytic Hamartoma in Tuberous Sclerosis. EFFECTIVE DATE: 02/01/2008.
 - c. This change allows, and removes the exclusion of, intracranial angioplasty with stenting (CPT procedure code 61635) of the venous sinuses to be considered for cost-sharing for the treatment of pseudotumor cerebri (also known as idiopathic intracranial hypertension and benign intracranial hypertension). EFFECTIVE DATE: 06/25/2014.

CHAPTER 4

2. Section 6.1. This change confirms that athletic pubalgia surgery is unproven. EFFECTIVE DATE: As stated in the issuance.
3. Section 9.1. This change allows, and removes the exclusion of, intracranial angioplasty with stenting (CPT procedure code 61635) of the venous sinuses to be considered for cost-sharing for the treatment of pseudotumor cerebri (also known as idiopathic intracranial hypertension and benign intracranial hypertension). EFFECTIVE DATE: 06/25/2014.
4. Section 20.1. This change adds a reference for coverage policy regarding treatment of pseudotumor cerebri. EFFECTIVE DATE: 06/25/2014.
5. Section 21.1. This change confirms that photodynamic therapy with the off-label use of Visudyne may be used in the treatment of Retinal Astrocytic Hamartoma in Tuberous Sclerosis. EFFECTIVE DATE: 02/01/2008.

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 Off-label use of rituximab (HCPCS J9310) may be considered for cost-sharing for the treatment of neuromyelitis optica. The effective date is March 26, 2010.

2.6 Effective May 13, 2009, Intraperitoneal 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.

2.7 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.

2.8 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.

2.9 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.

2.10 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.

2.11 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.

2.12 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.

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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 (CPT² 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 (CPT² procedure code 38240) for the treatment of primary plasma cell leukemia.

2.17 Off-label use of Photodynamic Therapy (CPT² 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 (CPT² 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).

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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5.10 Femoroacetabular Impingement (FAI) open surgery, surgical dislocation (CPT³ procedure codes 27140 and 27179), for the treatment of hip impingement syndrome or labral tear is unproven.

5.11 Hip arthroscopy with debridement of articular cartilage (CPT³ procedure code 29862) for the treatment of FAI is unproven.

5.12 Femoroplasty (CPT³ procedure code 29999) for the treatment of FAI syndrome is unproven.

5.13 Osteochondral allograft of the humeral head with meniscal transplant and glenoid microfracture in the treatment of shoulder pain and instability is unproven.

5.14 Thermal Intradiscal Procedures (TIPs) (CPT³ procedure codes 22526, 22527, 62287, and Healthcare Common Procedure Coding System (HCPCS) code S2348) are unproven. TIPs are also known as: Intradiscal Electrothermal Annuloplasty (IEA), Intradiscal Electrothermal Therapy (IDET), Intradiscal Thermal Annuloplasty (IDTA), Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT), Coblation Percutaneous Disc Decompression, Nucleoplasty (also known as Percutaneous Radiofrequency (RF) Thermomodulation or Percutaneous Plasma Dissection), Radiofrequency Annuloplasty (RA), Intradiscal Biacuplasty (IDB), Percutaneous (or Plasma) Disc Decompression (PDD), Targeted Disc Decompression (TDD), Cervical Intradiscal RF Lesioning.

5.15 Total hip resurfacing (HCPCS code S2118) for treatment of degenerative hip disease is unproven.

5.16 Spinal manipulation under anesthesia (CPT³ procedure codes 00640 and 22505) for the treatment of back pain is unproven.

5.17 Minimally Invasive Lumbar Decompression (mild®) for the treatment of Degenerative Disc Disease (DDD) and/or spinal stenosis is unproven.

5.18 ACI surgery for the repair of patellar cartilage lesions is unproven.

5.19 iFuse Implant System (CPT³ procedure code 27279) for treatment of sacroiliac joint pain is unproven.

5.20 Athletic pubalgia surgery is unproven.

6.0 EFFECTIVE DATES

6.1 February 6, 2006, for percutaneous vertebroplasty and balloon kyphoplasty.

6.2 May 1, 2008, for TAR.

6.3 May 1, 2008, for core decompression of the femoral head.

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TRICARE Policy Manual 6010.57-M, February 1, 2008

Chapter 4, Section 6.1

Musculoskeletal System

6.4 December 24, 2012, for single-level, cervical TDR using an FDA approved cervical artificial intervertebral disc.

6.5 December 2, 2013, for HE ESWT for plantar fasciitis.

- END -

3.11.7 All procedures are performed in a Centers for Medicare and Medicaid Services (CMS) approved facility that has been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes.

3.12 Transcatheter Aortic Valve Replacement (TAVR) for the treatment of severe symptomatic aortic stenosis is proven safe and effective for patients who are not candidates for Surgical Aortic Valve Replacement (SAVR).

3.13 TAVR for the treatment of severe symptomatic aortic stenosis in high-risk operative patients is considered proven safe and effective.

3.14 Intracranial angioplasty with stenting (CPT⁴ 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).

4.0 EXCLUSIONS

4.1 Thermogram; cephalic (CPT⁴ procedure code 93760); peripheral (CPT⁴ procedure code 93762) are unproven.

4.2 Percutaneous Myocardial Laser Revascularization (PMR) is unproven.

4.3 Cardiomyoplasty (Cardiac Wrap) for treatment of heart failure is unproven.

4.4 Minimally Invasive CABG surgery to include Minimally Invasive Direct Coronary Artery Bypass (MIDCAB) and Port Access Coronary Artery Bypass (PACAB) are unproven.

4.5 Percutaneous Transluminal Angioplasty (PTA) in the treatment of obstructive lesions of the vertebral and cerebral arteries is unproven. PTA of the carotid artery without stenting is unproven. PTA of the carotid artery with stenting but without embolic protection (CPT⁴ procedure code 37216) is unproven.

4.6 Signal-Average Electrocardiography (CPT⁴ procedure code 93278) is unproven.

4.7 Percutaneous transluminal mechanical thrombectomy vein(s) including intraprocedural pharmacological thrombolytic injections and fluroscopic guidance (CPT⁴ procedure code 37187) is unproven.

4.8 Percutaneous transluminal mechanical thrombectomy, vein(s) including intraprocedural pharmacological thrombolytic injections and fluroscopic guidance, repeat treatment on subsequent day during course of thrombolytic therapy (CPT⁴ procedure code 37188) is unproven.

5.0 EFFECTIVE DATES

5.1 March 1, 2001, for gamma and beta intracoronary radiotherapy (brachytherapy).

5.2 January 1, 2002, for TMR.

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TRICARE Policy Manual 6010.57-M, February 1, 2008

Chapter 4, Section 9.1

Cardiovascular System

- 5.3** October 1, 2003, for VADs as destination therapy.
- 5.4** December 1, 2003, for endovenous RFA/obliteration.
- 5.5** January 1, 2005, for ABPM.
- 5.6** March 17, 2005, for PTA of the carotid artery with stenting in beneficiaries at high risk for CEA.
- 5.7** March 21, 2006, for percutaneous transluminal mechanical thrombectomy for acute limb ischemia.
- 5.8** January 1, 2007, for pulmonary vein isolation/ablation.
- 5.9** January 1, 2009, for endovenous laser ablation/therapy.
- 5.10** May 1, 2011, for endovenous RFA/obliteration for the treatment of incompetent perforator veins.
- 5.11** July 27, 2012, for endovenous laser ablation/therapy for the treatment of incompetent perforator veins.
- 5.12** February 8, 2012, for TAVR for the treatment of severe symptomatic aortic stenosis in patients who are not candidates for SAVR.
- 5.13** July 27, 2012, for TAVR, for the treatment of severe symptomatic aortic stenosis in high-risk operative patients.
- 5.14** June 25, 2014, for intracranial angioplasty with stenting of the venous sinuses for the treatment of pseudotumor cerebri.

- END -

2.8 Endoscopic laminotomy (CPT³ procedure code 63030) is covered for the treatment of lumbar spinal stenosis. The endoscopic spinal system used in the procedure must be FDA approved.

2.9 Sacral Nerve Stimulation (SNS) for the treatment of chronic fecal incontinence is covered for patients who have failed or are not candidates for more conservative treatment, and who have a weak but structurally intact anal sphincter refractory to conservative measures. See [Section 14.1](#) for coverage policy for the urinary system and the Sacral Nerve Root Stimulation (SNS).

3.0 EXCLUSIONS

3.1 N-butyl-2-cyanoacrylate (Histacryl Bleu®), iodinated poppy seed oils (e.g., Ethiodol®), and absorbable gelatin sponges are not FDA approved.

3.2 Transcutaneous, percutaneous, functional dorsal column electrical stimulation in the treatment of multiple sclerosis or other motor function disorders is unproven.

3.3 Deep brain neurostimulation in the treatment of insomnia, depression, anxiety, and substance abuse is unproven.

3.4 Psychosurgery is not in accordance with accepted professional medical standards and is not covered.

3.5 Endovascular GDC treatment of wide-necked aneurysms and rupture is unproven.

3.6 Cerebellar stimulators/pacemakers for the treatment of neurological disorders are unproven.

3.7 Dorsal Root Entry Zone (DREZ) thermocoagulation or microcoagulation neurosurgical procedure is unproven.

3.8 Extraoperative electrocortigraphy for stimulation and recording in order to determine electrical thresholds of neurons as an indicator of seizure focus is unproven.

3.9 Neuromuscular Electrical Stimulation (NMES) for the treatment of denervated muscles is unproven.

3.10 Stereotactic cingulotomy is unproven.

3.11 Laminoplasty, cervical with decompression of the spinal cord, two or more vertebral segments with reconstruction of the posterior bony elements (CPT³ procedure codes 63050 and 63051).

3.12 Balloon angioplasty, intracranial, percutaneous (CPT³ procedure code 61630) is unproven.

3.13 Transcatheter placement of intravascular stent(s) intracranial (e.g., atherosclerotic or venous sinus stenosis) including angioplasty, if performed (CPT³ procedure code 61635) is unproven. See [Chapter 1, Section 3.1](#) for coverage policy regarding treatment of pseudotumor cerebri.

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3.14 Balloon dilation of intracranial vasospasm, initial vessel (CPT⁴ procedure code 61640) each additional vessel in same family (CPT⁴ procedure code 61641) or different vascular family (CPT⁴ procedure code 61642) is unproven.

3.15 Endoscopic thoracic sympathectomy.

3.16 Trigger point injection for migraine headaches.

3.17 Sphenopalatine ganglion block (CPT⁴ procedure code 64505) for the treatment of chronic migraine headaches and neck pain is unproven.

3.18 RF denervation (CPT⁴ procedure codes 64626, 64627) for the treatment of thoracic facet pain is unproven. Pulsed Radiofrequency Ablation (RFA) for spinal pain is unproven.

3.19 Implantation of Occipital Nerve Stimulator for the treatment of chronic intractable migraine headache is unproven.

3.20 Cryoablation of Occipital Nerve (CPT⁴ procedure code 64640) for the treatment of chronic intractable headache is unproven.

3.21 Spinal cord and deep brain neurostimulation in the treatment of chronic intractable headache or migraine pain is unproven.

3.22 Thermal Intradiscal Procedures (TIPs) (CPT⁴ procedure codes 22526, 22527, 62287, and Healthcare Common Procedure Coding System (HCPCS) code S2348) are unproven. TIPs are also known as: Intradiscal Electrothermal Annuloplasty (IEA), Intradiscal Electrothermal Therapy (IDET), Intradiscal Thermal Annuloplasty (IDTA), Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT), Coblation Percutaneous Disc Decompression, Nucleoplasty (also known as Percutaneous RF thermomodulation or Percutaneous Plasma Diskectomy), Radiofrequency Annuloplasty (RA), Intradiscal Biacuplasty (IDB), Percutaneous (or Plasma) Disc Decompression (PDD), Targeted Disc Decompression (TDD), Cervical Intradiscal RF Lesioning.

3.23 Laser ablation of paravertebral facet joint nerves (CPT⁴ procedure codes 64622 and 64623) is unproven. **(This applies only to laser ablation and should not be applied to RFA.)**

3.24 Minimally Invasive Lumbar Decompression (mild®) for the treatment of Degenerative Disc Disease (DDD) and/or spinal stenosis is unproven.

4.0 EFFECTIVE DATES

4.1 January 1, 1989, for PAVM.

4.2 April 1, 1994, for therapeutic embolization for treatment of meningioma.

4.3 July 14, 1997, for GDC.

4.4 The date of FDA approval of the embolization device for all other embolization procedures.

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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 CPT¹ 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, CPT¹ 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 (CPT¹ 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 (CPT¹ 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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4.0 EXCLUSIONS

4.1 Refractive corneal surgery except as noted in [paragraph 3.4](#) (CPT² 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\(g\)\(46\)](#) (CPT² procedure code 92065).

4.5 Epikeratophakia for treatment of aphakia and myopia is unproven.

4.6 Transpupillary thermotherapy (CPT² procedure code 67299) for treatment of choroidal melanoma is unproven.

4.7 Canaloplasty for the treatment of glaucoma (CPT² 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 (CPT² procedure code 67221 and HCPCS J3396).

5.0 EFFECTIVE DATE

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

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