

## Sources of Information

### CPT 0078T-0081T:

Reconsideration request received November 09, 2012:

Amiot S, Haulon S, Becquemin JP, et al. Fenestrated endovascular grafting: the French multicentre experience. *Eur J Vasc Endovasc Surg.* 2010;39:537-544.

Bicknell CD, Cheshire NJW, Riga CV, et al. Treatment of complex aneurysmal disease with fenestrated and branched stent grafts. *Eur J Vasc Endovasc Surg.* 2009;37:175-181.

Canavati R, Millen A, Brennan J, et al. Comparison of fenestrated endovascular and open repair of abdominal aortic aneurysms not suitable for standard endovascular repair.

Copyright © 2012 by the Society for Vascular Surgery.<http://dx.doi.org/10.1016/j.jvs.2012.08.040>.

Chisci E, Kristmundsson T, de Donato G, et al. The AAA With a challenging neck: outcome of open versus endovascular repair with standard and fenestrated stent-grafts. *J Endovasc Ther.* 2009;16:137-146.

Early results of fenestrated endovascular repair of juxtarenal aortic aneurysms in the United Kingdom. *Circulation.* 2012;125:2707-2715.

FDA letter premarket approval Zenith Fenestrated AAA Endovascular Graft (with the adjunctive Zenith Alignment Stent) April 4, 2012.

Greenberg RK, Sternbergh III WC, Makaroun M, et al. Intermediate results of a United States multicenter trial of fenestrated endograft repair for juxtarenal abdominal aortic aneurysms. *J Vas Surg.* 2009;50(4):730-737.

Haulon S, Amiot S, Magnan PE, et al. An analysis of the French multicentre experience of fenestrated aortic endografts. Medium-term outcomes. *Annals of Surgery.* 2010;251(2):357-362.

Kristmundsson T, Sonesson B, Malina M, Björsses K, Dias N, Resch T. Fenestrated endovascular repair for juxtarenal aortic pathology. *J Vasc Surg.* 2009;49:568-575.

Nordon IM, Hinchliffe RJ, Holt PJ, Loftus IM, Thompson MM. Modern treatment of Juxtarenal abdominal aortic aneurysms with fenestrated endografting and open repair: a systematic review. *Eur J Vasc Endovasc Surg.* 2009;38:35-41.

O'Neill S, Greenberg RK, Haddad F, Resch T, Sereika J, Katz E. A prospective analysis of fenestrated endovascular grafting: intermediate-term outcomes. *Eur J Vasc Endovasc Surg.* 2006;32:115-123.

Scurr JRH, Brennan JA, Gilling-Smith GL, Harris PL, Vallabhaneni SR, McWilliams RG. Fenestrated endovascular repair for juxtarenal aortic aneurysm. *British Journal of Surgery*. 2008;95:326–332.

Sun Z, Mwipatayi BP, Semmens JB, Lawrence-Brown M. Short to midterm outcomes of fenestrated endovascular grafts in the treatment of abdominal aortic aneurysms: a systematic review. *J Endovasc Ther*. 2006;13:747–753.

Tambyraja AL, Fishwick NG, Bown MJ, Nasim A, McCarthy MJ, Sayers RD. Fenestrated aortic endografts for juxtarenal aortic aneurysm: medium term outcomes. *Eur J Vasc Endovasc Surg*. 2011;42:54–58.

Verhoeven ELG, Vourliotakis G, Bos WTGJ, et al. Fenestrated stent grafting for short-necked and juxtarenal abdominal aortic aneurysm: an 8-year single-centre experience. *Eur J Vasc Endovasc Surg*. 2010;39: 529–536.

Wilderman M, Sanchez LA. Fenestrated grafts or debranching procedures for complex abdominal aortic aneurysms. *Perspectives in Vascular Surgery and Endovascular Therapy*. 2009;21(1):13–18.

#### CPT 0183T:

Reconsideration request received October 18, 2013:

Driver VR, Yao M, Miller CJ. Noncontact low-frequency ultrasound therapy in the treatment of chronic wounds: a meta-analysis. *Wound Repair Regen*. 2011;19(4):475–480.

Ennis WJ, Foremann P, Mozen N, Massey J, Conner-Kerr T, Meneses P. Ultrasound therapy for recalcitrant diabetic foot ulcers: results of a randomized, double-blind, controlled, multicenter study. *Ostomy Wound Manage*. 2005;51(8):24–39.

IN-BALANCE VLU Inflammation, Bacteria, & Angiogenesis Effects in Launching Venous Leg Ulcer Healing; ClinicalTrials.gov identifier: [NCT01549860]  
<http://clinicaltrials.gov/show/NCT01549860>

Kavros SJ, Miller JL, Hanna SW. Treatment of ischemic wounds with noncontact, lowfrequency ultrasound: the Mayo Clinic experience, 2004–2006. *Adv Skin Wound Care*. 2007;20(4):221–226.

Olyae M, Rad FS, Elahifar MA, Garkaz A, Mahsa G. High-frequency and noncontact low-frequency ultrasound therapy for venous leg ulcer treatment: a randomized, controlled study. *Ostomy Wound Manage*. 2013 Aug;59(8):14–20.

Pragmatic Randomised Controlled Trial of MIST Ultrasound Therapy Compared to UK Standard Care for the Treatment of Non-healing Venous Leg Ulcers; ClinicalTrials.gov identifier: [NCT01671748] <http://clinicaltrials.gov/show/NCT01671748>

The MIST Therapy system for the promotion of wound healing. National Institute for Health and Clinical Excellence (NICE) medical technology guidance 5, Issued July 2011: [guidance.nice.org.uk/mtg5](http://guidance.nice.org.uk/mtg5).

Voigt J, Wendelken M, Driver V, Alvarez OM. Low-frequency ultrasound (20–40 kHz) as an adjunctive therapy for chronic wound healing: a systematic review of the literature and meta-analysis of eight randomized controlled trials. *Int J Low Extrem Wounds.* 2011 Dec;10(4):190–9.

Yao M, Hasturk H, Kantarci A, Gu G, Garcia-Lavin S, Fabbi M, Park N, Hayashi H, Attala K, French MA, Driver VR. A pilot study evaluating noncontact low frequency ultrasound and underlying molecular mechanism on diabetic foot ulcers. *Int Wound J.* 2012 Nov 19. doi: 10.1111/iwj.12005. [Epub ahead of print]

#### CPT 0184T:

Reconsideration request: February 2014

Araki Y, Isomoto H, Shirouzu K. Video-assisted gasless transanal endoscopic microsurgery: A review of 217 cases of rectal tumors over the past 10 years. *Dig Surg.* 2003; 20(1):48– 52.

Medical Services Advisory Committee (MSAC). Transanal endoscopic microsurgery. MSAC Assessment Report. MSAC Reference 15. Canberra, ACT: MSAC; March 2003.

Middleton PF, Sutherland LM, Maddern GJ. Transanal endoscopic microsurgery: A systematic review. *Dis Colon Rectum.* 2005; 48(2):270-284.

Burghardt J, Buess G. Transanal endoscopic microsurgery (TEM): A new technique and development during a time period of 20 years. *Surg Technol Int.* 2005; 14:131-137.

Tjandra JJ, Kilkenny JW, Buie WD, et al. Practice parameters for the management of rectal cancer (revised). *Dis Colon Rectum* 2005;48(3):411-323.

Floyd ND, Saclarides TJ. Transanal endoscopic microsurgical resection of pT1 rectal tumors. *Dis Colon Rectum.* 2006; 49 (2):164-168.

Lin GL, Meng WC, Lau PY, et al. Local resection for early rectal tumours: Comparative study of transanal endoscopic microsurgery (TEM) versus posterior trans-sphincteric approach (Mason's operation). *Asian J Surg.* 2006;29(4):227-232.

Borschitz T, Heintz A, Junginger T. The influence of histopathologic criteria on the long-term prognosis of locally excised pT1 rectal carcinomas: Results of local excision (transanal endoscopic microsurgery) and immediate reoperation. *Dis Colon Rectum.* 2006;49(10):1492-1506; discussion 1500-1505.

Serra Aracil X, Bombardó Junca J, Mora López L, et al. Transanal endoscopic microsurgery (TEM). Current situation and future expectations. *Cir Esp.* 2006; 80(3):123-132.

Papagrigoriadis S. Transanal endoscopic micro-surgery (TEM) for the management of large or sessile rectal adenomas: A review of the technique and indications. *Int Semin Surg Oncol.* 2006; 3:13.

Rajput A, Bullard Dunn K. Surgical management of rectal cancer. *Semin Oncol.* 2007; 34 (3):241-249.

Cirincione E, Cagir B. Rectal cancer. eMedicine Medicine Topic 1994. Omaha, NE: eMedicine.com; 2007. Available at: <http://www.emedicine.com/med/topic1994.htm>. Accessed November 26, 2007.

National Cancer Institute (NCI). Stages of rectal cancer. Rectal Cancer Treatment (PDQ). Patient Version. Bethesda, MD: NCI; updated June 18, 2008. Available at: <http://www.cancer.gov/cancertopics/pdq/treatment/rectal/Patient/page2>. Accessed October 24, 2008.

Whiteford MH. Transanal endoscopic microsurgery (TEM) resection of rectal tumors. *J Gastrointest Surg.* 2007; 11(2):155-157.

National Cancer Institute (NCI). Treatment option overview. Rectal Cancer Treatment (PDQ). Patient Version. Bethesda, MD: NCI; updated June 18, 2008. Available at: <http://www.cancer.gov/cancertopics/pdq/treatment/rectal/Patient/page4>. Accessed October 24, 2008.

Bretagnol F, Rullier E, George B, et al. Local therapy for rectal cancer: Still controversial? *Dis Colon Rectum.* 2007a;50(4):523-533.

Bretagnol F, Merrie A, George B, et al. Local excision of rectal tumours by transanal endoscopic microsurgery. *Br J Surg.* 2007b; 94(5):627-633.

Maslekar S, Pillinger SH, Monson JR. Transanal endoscopic microsurgery for carcinoma of the rectum. *Surg Endosc.* 2007; 21(1):97-102.

Zacharakis E, Freilich S, Rekhraj S, et al. Transanal endoscopic microsurgery for rectal tumors: The St. Mary's experience. *Am J Surg.* 2007; 194(5):694-698.

Borschitz T, Heintz A, Junginger T. Transanal endoscopic microsurgical excision of pT2 rectal cancer: Results and possible indications. *Dis Colon Rectum.* 2007; 50(3):292-301.

Helgstrand F, Iversen E, Bech K. Transanal endoscopic microsurgery. The latest 5 years' experience in Roskilde County. *Ugeskr Laeger.* 2007;169(19):1784-1788.

Røkke O, Færden AE, Øvrebø K. Transanal endoscopic microsurgery for tumours in rectum. *Tidsskr Nor Laegeforen.* 2007; 127(22):2954-2958.

Borschitz T, Junginger T. Progress report about the 1st Workshop on Local Excision of Rectal Cancer. *Zentralbl Chir.* 2007;132(2):99-105.

National Comprehensive Cancer Network (NCCN). Rectal cancer. Clinical

Practice Guidelines in Oncology v.1.2008. Jenkintown, PA: NCCN; September 2007. Available at: [http://www.nccn.org/professionals/physician\\_gls/PDF/rectal.pdf](http://www.nccn.org/professionals/physician_gls/PDF/rectal.pdf). Accessed November 26, 2007.

Vallejo Godoy S, Marquez Calderon S. Outcomes of transanal endoscopic surgery in patients with rectal tumours. Report. Sevilla, Spain: Andalusian Agency for Health Technology Assessment (AETSA); 2007.

Guerrieri M, Baldarelli M, Organetti L, et al. Transanal endoscopic microsurgery for the treatment of selected patients with distal rectal cancer: 15 years' experience. *Surg Endosc.* 2008; 22(9):2030-2035.

Serra-Aracil X, Vallverdú H, Bombardó-Junca J, et al. Long-term follow-up of local rectal cancer surgery by transanal endoscopic microsurgery. *World J Surg.* 2008; 32(6):1162- 1167.

Baatrup G, Breum B, Qvist N, et al. Transanal endoscopic microsurgery in 143 consecutive patients with rectal adenocarcinoma. Results from a Danish multicenter study. *Colorectal Dis.* 2009; 11(3):270-275.

Southern Health Technology/Clinical Practice Committee. Transanal endoscopic microsurgery (TEM). Application No. 09003N. Clayton, VIC: Centre for Clinical Effectiveness, Monash University Institute for Health Services Research; March 27, 2009.

Palma P, Horisberger K, Joos A, et al. Local excision of early rectal cancer: Is transanal endoscopic microsurgery an alternative to radical surgery? *Rev Esp Enferm Dig.* 2009; 101(3):172-178.

Bach SP, Hill J, Monson JR, et al; Association of Coloproctology of Great Britain and Ireland Transanal Endoscopic Microsurgery (TEM) Collaboration. A predictive model for local recurrence after transanal endoscopic microsurgery for rectal cancer. *Br J Surg.* 2009; 96(3):280-290.

Keay E, Farrah K. Transanal endoscopic microsurgery for rectal cancer: A clinical and cost effectiveness review. Health Technology Inquiry Service (HTIS). Ottawa, ON: Canadian Agency for Drugs and Technologies in Health (CADTH); April 3, 2008.

National Working Group on Gastrointestinal Cancers. Rectal cancer. Cancer Clinical Practice Guidelines Version 2.0. Amsterdam, The Netherlands: Association of Comprehensive Cancer Centres (ACCC); October 14, 2008.

Dias AR, Nahas CS, Marques CF, et al. Transanal endoscopic microsurgery: Indications, results and controversies. *Tech Coloproctol.* 2009; 13(2):105-111.

Casadesus D. Surgical resection of rectal adenoma: A rapid review. *World J Gastroenterol.* 2009;15(31):3851-3854.

De Graaf EJ, Doornbosch PG, Tollenaar RA, et al. Transanal endoscopic microsurgery versus total mesorectal excision of T1 rectal adenocarcinomas with curative intention. *Eur J Surg Oncol.* 2009; 35(12):1280-1285.

Baatrup G, Svensen R, Ellensen VS. Benign rectal strictures managed with transanal resection a novel application for transanal endoscopic microsurgery. *Colorectal Dis.* 2010;12(2):144-146.

Kinoshita T, Kanehira E, Omura K, et al. Transanal endoscopic microsurgery in the treatment of rectal carcinoid tumor. *Surg Endosc.* 2007; 21(6):970-974.

Tsai BM, Finne CO, Nordenstam JF, et al. Transanal endoscopic microsurgery resection of rectal tumors: Outcomes and recommendations. *Dis Colon Rectum.* 2010; 53(1):16-23.

Shields CJ, Tiret E, Winter DC; International Rectal Carcinoid Study Group. Carcinoid tumors of the rectum: A multi-institutional international collaboration. *Ann Surg.* 2010; 252(5):750- 755.

Steinhagen E, Chang G, Guillem JG. Initial experience with transanal endoscopic microsurgery: The need for understanding the limitations. *J Gastrointest Surg.* 2011; 15(6):958-962.

Kumar AS, Sidani SM, Kolli K, et al. Transanal endoscopic microsurgery for rectal carcinoids: The largest reported U.S. experience. *Colorectal Dis.* 2012;14(5):562-566

Gracia JA, Ramirez JM, Callejo D, et al. Efficiency and outcomes of harmonic device in transanal endoscopic microsurgery compared with monopolar scalpel. *Surg Endosc.* 2011;25(10):3209-3213.

Ashraf S, Hompes R, Slater A, et al; Association of Coloproctology of Great Britain and Ireland Transanal Endoscopic Microsurgery (TEM) Collaboration. A critical appraisal of

endorectal ultrasound and transanal endoscopic microsurgery and decision-making in early rectal cancer. *Colorectal Dis.* 2012; 14(7):821-826.

Aetna, Clinical Policy Bulletin, Number: 0747: Transanal Endoscopic Microsurgery for Rectal Cancer

National Comprehensive Cancer Network (NCCN). Rectal cancer. Clinical Practice Guidelines in Oncology v.2.2014. [http://www.nccn.org/professionals/physician\\_gls/PDF/rectal.pdf](http://www.nccn.org/professionals/physician_gls/PDF/rectal.pdf). Accessed January 4, 2014.

Lezoche, G et al "A prospective randomized study with a 5-year minimum follow-up evaluation of transanal endoscopic microsurgery versus laparoscopic total mesorectal excision after neoadjuvant therapy", *Surgical Endoscopy*(2008) 22:352–358

Kunitake, H; Abbas, M, "Transanal Endoscopic Microsurgery for Rectal Tumors: A Review",

*The Permanente Journal* / Spring 2012 / Volume 16 (2): 45-50

Wellpoint, Medical Policy, SURG 00110, Transanal Endoscopic Microsurgical (TEM) Excision of Rectal Lesions, 07/09/2013.

**CPT 0191T:**

Reconsideration request received July 19, 2012:

Arriola-Villalobos P, Martinez-de-la-Casa JM, Diaz-Valle D, Fernández-Pérez C, García-Sánchez J, García-Feijoó J. Combined iStent trabecular micro-bypass stent implantation and phacoemulsification for coexistent open-angle glaucoma and cataract: a long-term study. *Br J Ophthalmol*. 2012. doi:10.1136/bjophthalmol-2011-300218.

Craven ER, Katz LJ, Wells JM, Giamporcaro JE. Cataract surgery with trabecular micro-bypass stent implantation in patients with mild-to-moderate open-angle glaucoma and cataract: Two-year follow-up. *J Cataract Refract Surg*. 2012;38:1339–1345.

FDA letter for premarket approval for Glaukos iStent® Trabecular Micro-Bypass Stent (Models: GTS-100R, GTS-100L) and insterter (GTS-100i). June 25, 2012.

Fea A. Phacoemulsification versus phacoemulsification with micro-bypass stent implantation in primary open-angle glaucoma. Randomized double-masked clinical trial. *J Cataract Refract Surg*. 2010;36:407-412.

Fernández-Barrientos Y, García-Feijoó J, Martinez-de-la-Casa JM, Pablo LE, Fernández-Pérez C, García Sánchez J. Fluorophotometric study of the effect of the glaukos trabecular microbypass stent on aqueous humor dynamics. *Investigative Ophthalmology & Visual Science*. 2010;51(7):3327-3332.

Samuelson TW, Katz LJ, Wells JM, Duh YJ, Giamporcaro JE. Randomized evaluation of the trabecular micro-bypass stent with phacoemulsification with glaucoma and cataract. *American Academy of Ophthalmology*. 2010 doi:10.1016/j.optha.2010.07.007.

**CPT 0197T:**

11/01/2011 is the original effective date of article A51543  
Original determination references: November 2011

Brabbins D, Martinez A, Yan D, et al. A dose-escalation trial with the adaptive radiotherapy process as a delivery system in localized prostate cancer: analysis of chronic toxicity. *Int J Radiation Oncology Biol Phys*. 2005;61(2):400-408.

Cheung MR, Tucker SL, Dong L, et al. Investigation of bladder dose and volume factors influencing late urinary toxicity after external beam radiotherapy for prostate cancer. *Int J Radiation Oncology Biol Phys*. 2007;67(4):2059-1065.

Jackson A, Skwarchuk MW, Zelefsky MJ, et al. Late rectal bleeding after conformal radiotherapy of prostate cancer (ii): volume effects and dose-volume histograms. *Int J Radiation Oncology Biol Phys.* 2001;49(3):685-698.

Kupelian P, Willoughby T, Mahadevan A, et al. Multi-institutional clinical experience with the calypso system in localization and continuous real-time monitoring of the prostate gland during external radiotherapy. *Int J Radiation Oncology Biol Phys.* 2007;67(4):1088-1098.

Langen KM, Willoughby TR, Meeks SL, et al. Observations of real-time prostate gland motion using electromagnetic tracking. *Int J Radiation Oncology Biol Phys.* 2008;71(4):1084-1090.

Leibel SA, Fuks Z, Zelefsky MJ, et al. Intensity-modulated radiotherapy. *Cancer J.* 2002;8:164-176.

Noel C, Parikh PJ, Roy M, et al. Prediction of intrafraction prostate motion: accuracy of pre- and post-treatment imaging and intermittent imaging. *Int J Radiation Oncology Biol Phys.* 2008;1-7.

Sandler HM, Yu Liu P, Dunn RL, et al. Reduction in patient-reported acute morbidity in prostate cancer patients treated with 81-GY intensity-modulated radiotherapy using reduced planning target volume margins and electromagnetic tracking: assessing the impact of margin reduction study. *Urology* 2010;75(5):1004-1008.

## **CPT 0206T:**

Reconsideration request for 0206T received January 27, 2012:

AHRQ Technology Assessment, ECG-based signal analysis technologies (2010).

Elhendy A, Bax JJ, Poldermans D. Dobutamine stress myocardial perfusion imaging in coronary artery disease\*. <i>J Nucl Med.</i> 2002;43(12):1634-1646.

FDA 510(k) summary K992703 for Cardiotron EKG mult-phase information analysis system March 21, 2000.

Geleijnse ML, Krenning BJ, Soliman SII, Nemes A, Galema TW, ten Cate FJ. Dobutamine stress echocardiography for the detection of coronary artery disease in women. <i>Am J Cardiol.</i> 2007;99:714-717. © 2007 Elsevier Inc.

Grube E, Bootsma A, Buellesfeld L, Yuecel S, Shen JT, Imhoff M. Computerized two-lead resting ECG analysis for the detection of coronary

artery stenosis after coronary revascularization. <i>Int. J. Med. Sci.</i> 2008;5(2):50-61.

Grube E, Bootsvelt A, Yuecel S, Shen JT, Imhoff, M. Computerized two-lead resting ECG analysis for the detection of coronary artery stenosis. *< i>Int. J. Med. Sci.* 2007;4(5):249-263.

Hosokawa J, Shen JT, Imhoff M. Computerized 2-lead resting ECG analysis for the detection of relevant coronary artery stenosis in comparison with angiographic findings. *< i>Congest Heart Fail.* 2008;14:251-260.

Marwick TH, Leano RL, Brown J, et al. Myocardial strain measurement with 2-dimensional speckle-tracking echocardiography. *< i>JACC: Cardiovascular Imaging.* 2009;2(1):80- 84.

Patel MR, Peterson ED, Dai D, et al. Low diagnostic yield of elective coronary angiography. *< i>N Engl J Med.* 2010;362:886-895.

Smart SC, Bhatia A, Hellman R, et al. Dobutamine-atropine stress echocardiography and dipyridamole sestamibi scintigraphy for the detection of coronary artery disease: limitations and concordance. *< i>Journal of the American College of Cardiology.* 2000;36(4):1265- 1273.

Strobeck JE, Mangieri A, Rainford N, A paired-comparison of the MultiFunction CardioGramsm (MCG) and sesta-mibi SPECT myocardial perfusion imaging (MPI) to quantitative coronary angiography for the detection of relevant coronary artery obstruction (&#8805;70%) - a single-center study of 116 consecutive patients referred for coronary angiography. *< i>Int. J. Med. Sci.* 2011;8(8):717-724.

Strobeck JE, Rainford N, Arkus B, Imhoff M. Comparing MultiFunction-CardioGram™ and coronary angiography for detection of hemodynamically relevant coronary artery stenosis (>70%) in women. *< i>Cardiology.* 2009;3(1):82-91.

Strobeck JE, Shen JT, Singh B, et al. Comparison of a two-lead, computerized, resting ECG signal analysis device, the multifunction-cardiogramsm or MCG (a.k.a. 3DMP), to quantitative coronary angiography for the detection of relevant coronary artery stenosis (>70%) - a meta-analysis of all published trials performed and analyzed in the US. *< i>Int. J. Med. Sci.* 2009;6(4):143-155.

Weiss MB, Narasimhadvara SM, Feng GQ, Shen JT. Computer-enhanced frequency-domain and 12-lead electrocardiography accurately detect abnormalities consistent with obstructive and nonobstructive coronary artery disease. *< i>Heart Disease.* 2002;4:2-12. Lippincott Williams & Wilkens, Inc.

Reconsideration request received August 19, 2015 :

Amano T, Shinoda N, Kunimura A, Harada K, Uetani T, Takashima H, et al. Non-invasive assessment of functionally significant coronary stenoses through mathematical analysis of spectral ECG components. *Open Heart.* 2014;1(1):e000144.

Gould KL, Johnson NP, Bateman TM, Beanlands RS, Bengel FM, Bober R, et al. Anatomic versus physiologic assessment of coronary artery disease. Role of coronary flow reserve, fractional flow reserve, and positron emission tomography imaging in revascularization decision-making. *J Am Coll Cardiol.* 2013;62(18):1639-53.

Takeshita, M. et al , "Noninvasive Mathematical Analysis of Spectral Electrocardiographic Components for Coronary Lesions of Intermediate to Obstructive Stenosis Severity–Relationship with Classic and Functional SYNTAX Score". , *Catheterization and Cardiovascular Interventions* 00:00–00 (2015)

## **CPT 0245T-0248T:**

Reconsideration request received November 01, 2011:

Ahmed Z, Mohyuddin Z. Management of flail chest injury: internal fixation versus endotracheal intubation and ventilation. *J Thorac Cardiovasc Surg.* 1995;110:1676-1680.

Alexander JQ, Gutierrez CJ, Mariano MC, et al. Blunt chest trauma in the elderly patient: how cardiopulmonary disease affects outcome. *The American Surgeon.* 2000;66(9):855- 857.

Chest Trauma Rib fractures & Flail Chest

<http://www.trauma.org/archive/thoracic/CHESTflail.html> 10/

501k Summary Synthes MatrixRIB Fixation System. September 08, 2008.

FDA letter premarket approval Synthes MatrixRIB Fixation System. September 08, 2008.

Lotfipour S, Kaku SK, Vaca FE, et al. Factors associated with complications in older adults with isolated blunt chest trauma. *WestJEM.* 2009;10:79-84.

Mayberry JC, Ham LB, Schipper PH, Ellis TJ, Mullins RJ. Surveyed opinion of American trauma, orthopedic, and thoracic surgeons on rib and sternal fracture repair. *The Journal of TRAUMA® Injury, Infection, and Critical Care.* 2009;6(3):875-879.

Mayberry JC, Kroeker AD, Ham LB, Mullins RJ, Trunkey DD. Long-term morbidity, pain, and disability after repair of severe chest wall injuries. *The American Surgeon.* 2009;75(5):389- 394.

Nirula R, Allen B, Layman R, Falimirski ME, Somberg LB. Rib fracture stabilization in patients sustaining blunt chest injury. *The America Surgeon.* 2006;72:307-309.

Shorr RM, Rodriguez A, Indeck MC, Crittenden MD, Hartunian S, Cowley RA. Blunt chest trauma in the elderly. *The Journal of Trauma*. 1989;29(2):234-237.

Tanaka H, Yukioka T, Yamaguti Y, et al. Surgical stabilization of internal pneumatic stabilization? A prospective randomized study of management of severe flail chest patients. *J Trauma*. 2002;52(4):727-732.

#### CPT 0249T:

Reconsideration request received April, 14, 2014:

De Nardi P, Capretti G, Corsaro A, Staudacher C. A prospective, randomized trial comparing the short- and long-term results of doppler-guided transanal hemorrhoid dearterialization with mucopexy versus excision hemorrhoidectomy for grade III hemorrhoids. *Dis Colon Rectum*;57:348-53.

Denoya PI, Fakhoury M, Chang K, Fakhoury J, Bergamaschi R. Dearterialization with mucopexy versus haemorrhoidectomy for grade III or IV haemorrhoids: short-term results of a double-blind randomized controlled trial. *Colorectal Dis* 2013;15:1281-8.

Elmer SE, Nygren JO, Lenander CE. A randomized trial of transanal hemorrhoidal dearterialization with anopexy compared with open hemorrhoidectomy in the treatment of hemorrhoids. *Dis Colon Rectum* 2013;56:484-90.

Infantino A, Altomare DF, Bottini C, et al. Prospective randomized multicentre study comparing stapler haemorrhoidopexy with Doppler-guided transanal haemorrhoid dearterialization for third-degree haemorrhoids. *Colorectal Dis* 2011;14:205-11.

Festen S, van Hoogstraten MJ, van Geloven AA, Gerhards MF. Treatment of grade III and IV haemorrhoidal disease with PPH or THD. A randomized trial on postoperative complications and short-term results. *Int J Colorectal Dis* 2009;24:1401-5.

Bursics A, Morvay K, Kupcsulik P, Flautner L. Comparison of early and 1-year follow-up results of conventional hemorrhoidectomy and hemorrhoid artery ligation: a randomized study. *Int J Colorectal Dis* 2004;19:176-80.

#### CPT 0256T-0259T:

Reconsideration request received December 21, 2011:

FDA letter approval for Edwards SAPIEN™ Transcatheter heart Valve, model 9000TFX, sized 23mm and 26mm and accessories (RetroFlex3™ Delivery System, models 9120FS23 and 9120FS26; RetroFlex™ Balloon catheter, models 9120BC20 and 9120BC23; and Crimper, models 9100CR23 and 9100CR26).

Leon MB, Smith CR, Mack M, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *NEJM*. 2010;363(17):1597-1607.

Reynolds MR, Magnuson EA, Lei Y, et al. Health-related quality of life after transcatheter aortic valve replacement in inoperable patients with severe aortic stenosis. *Circulation*. 2011;124(18):1964-1972.

### **CPT 0291T:**

Reconsideration request received July 10, 2012:

Alfonso F, Paulo M, Gonzalo N, et al. Diagnosis of spontaneous coronary artery dissection by optical coherence tomography. *JACC*. 2012;59(12):1073-1079.

Ben-Dor I, Mahmoudi M, Pichard AD, Satler LF, Waksman R. Optical coherence tomography: a new imaging modality for plaque characterization and stent implantation. *J Interven Cardiol*. 2011;24(2):184-192.

Capodanno D, Prati F, Pawlowsky T, et al. Comparison of optical coherence tomography and intravascular ultrasound for the assessment of in-stent tissue coverage after stent implantation. *EuroIntervention*. 2009;5:538-543.

501k Summary – Optical Coherence Tomography Imaging System. April 2011.

Gonzalo N, Escaned J, Alfonso F, et al. Morphometric assessment of coronary stenosis relevance with optical coherence tomography. *JACC*. 2012;59(12):1080-1089.

Herrero-Garibi J, Cruz-Gonzalez I, Parejo-Diaz P, Jang IK. Optical coherence tomography: its value in intravascular diagnosis today. *Rev Esp Cardiol*. 2010;63(8):951-962.

Parkiah SA, Costa MA. High-resolution lesion assessment with OCT. *Cardiac Interventions Today*. 2010;28-34.

Prati F, Di Vito L, Biondi-Zocca G, et al. Angiography alone versus angiography plus optical coherence tomography to guide decision making during percutaneous coronary intervention: the CLL-OPCI study. *OCT Consensus Document*. *JACC*. 2011.

Prati F, Regar E, Mintz GS. Expert review document on methodology, terminology, and clinical applications of optical coherence tomography: physical principals, methodology of image acquisition, and clinical application for assessment of coronary arteries and atherosclerosis. *European Heart Journal*. 2010;31:401-415.  
doi:10.1093/eurheartj/ehp433.

Tearney GJ, Regar E, Adriaenssens T, et al. Consensus standards for acquisition, measurement, and reporting of intravascular optical coherence tomography studies.  
<i>JACC.</i>2012;59(12):1058-1072.

Tsimikas S, DeMaria AN. The clinical emergence of optical coherence tomography.  
<i>JACC.</i>2012;59(12):1090-1092.

Viceconte N, Chan PH, Barrero EA, et al. Frequency domain optical coherence tomography for guidance of coronary stenting. <i>Int J Cardiol.</i> (2011), doi 10.1016/j.ijcard.2011;11.090.

#### CPT 0295T-0298T:

##### Sources added for CPT codes 0295T-0298T:

Balmelli N, Naegeli B, Bertel O. Diagnostic yield of automatic and patient-triggered ambulatory cardiac event recording in the evaluation of patients palpitations, dizziness, or syncope. *Clin Cardiol.* 2003;26:173-176.

Dagres N, Kottkamp H, Piorkowski C, et al. Influence of the duration of Holter monitoring on the detection of arrhythmia recurrences after catheter ablation of atrial fibrillation: implications for patient follow-up. *Int J Cardiol.* 2010;139:305-306.

Edgerton JR, Mahoney C, Mack MJ, Roper K, Herbert MA. Long-term monitoring after surgical ablation for atrial fibrillation: how much is enough? *J thorac Cardiovas Surg.* 2011;142(1):162-165.

Eggen T. Feasibility and diagnostic yield of using a novel, single-use outpatient cardiac event monitor initiated in the emergency department. *Heart Rhythm.* 2010;7(55):s118. Abstract po1-78.

Hoefman E, van Weert HC, Boer KR, Reitsma J, Koster RW, Bindels PJ. Optimal duration of event recording for diagnosis of arrhythmias in patients with palpitations and light-headedness in the general practice. *Fam Pract.* 2007;24:11-13.

Jabaudon D. Usefulness of ambulatory 7-day ECG monitoring for the detection of atrial fibrillation and flutter after acute stroke and transient ischemic attack. *Stroke*. 2004;34:1647-1651.

Kinlay S, Leitch JW, Neil A, Chapman BL, Hardy DB, Fletcher PJ. Cardiac event recorders yield more diagnoses and are more cost-effective than 48-hour Holter monitoring in patients with palpitations. *Ann Intern Med*. 1996;124:16-20.

Martinez T, Sztajzel J. Utility of event loop recorders for the management of arrhythmias in young ambulatory patients. *Int J Cardiol*. 2004;97:495-498.

Pastor-Pérez FJ, Manzano-Fernández S, Goya-Esteban R, et al. Comparison of detection of arrhythmias in patients with chronic heart failure secondary to non-ischemic versus ischemic cardiomyopathy by 1 versus 7-day Holder monitoring. *Am J Cardiol*. 2010;106:677-681.

Reiffel JA, Schwarzberg R, Murry M. Comparison of autotriggered memory loop recorders versus standard loop recorders versus 24-hour Holter monitors for arrhythmia detection. *Am J Cardiol*. 2005;95:1055-1059.

Scirica BM, Braunwald E, Belardinelli L, et al. Relationship between nonsustained ventricular tachycardia after non-ST-elevation acute coronary syndrome and sudden cardiac death. *Circulation*. 2010;122:455-462.

Windfelder JM, et al. Extended Holter monitoring improves detection of recurrence compared to 48 hour Holter monitoring following atrial fibrillation ablation. *Heart Rhythm*. 2010;7(55):S3. Abstract AB02-2.

Zimetbaum P, Goldman A. Ambulatory arrhythmia monitoring? Choosing the right device. *Circulation*. 2010;122:1629-1636.

Zimetbaum PJ, Kim KY, Josephson ME, Golberger AL, Cohen DJ. Diagnostic yield and optimal duration of continuous-loop event monitoring for the diagnosis of palpitations. *Ann Intern Med*. 1998;128:890-895.

#### **CPT 0331T-0332T:**

Reconsideration request received June 19, 2014:

AdreView [prescribing information]. Arlington Heights, IL: GE Healthcare; 2013.

Agostini D, Belin A, Amar MH, et al. Improvement of cardiac neuronal function after carvedilol treatment in dilated cardiomyopathy: a <sup>123</sup>I-MIBG scintigraphic study. *J Nucl Med*. 2000 May;41(5):845-51.

Bax , J. et al. <sup>123</sup>I-mIBG Scintigraphy to Predict Inducibility of Ventricular Arrhythmias on Cardiac Electrophysiology Testing: A Prospective Multicenter Pilot Study *Circulation*:

*Cardiovascular Imaging Circ Cardiovasc Imaging.* 2008;1:131-140; originally published online July 30, 2008

Chirumamilla, A. MD, and Mark I. Travin, MD, Cardiac Applications of 123I-mIBG Imaging, Seminars in Nuclear Medicine, Department of Nuclear Medicine and Division of Cardiology/Department of Medicine, Montefiore Medical Center, Albert Einstein College of Medicine, Bronx, NY.

Data on file. Submission of clinical and economic data supporting formulary consideration of AdreView (Iobenguane I 123 Injection). GE Healthcare; March 2014.

Dewland TA, et al. Dual-Chamber Implantable Cardioverter-Defibrillator Selection Is Associated With Increased Complication Rates and Mortality Among Patients Enrolled in the NCDR Implantable Cardioverter-Defibrillator Registry. *JACC.* 2011;58:1007-13.

Epstein AE, DiMarco JP, Ellenbogen KA, et al. ACC/AHA/HRS 2008 Guidelines for device-based therapy of cardiac rhythm abnormalities: executive summary. *J Am Coll Cardiol.* 2008;51:2085-2105.

Jacobson AF, Senior R, Cerqueira MD, et al. Myocardial iodine-123 meta-iodobenzylguanidine imaging and cardiac events in heart failure: results of the prospective ADMIRE-HF (AdreView Myocardial Imaging for Risk Evaluation in Heart Failure) Study. *J Am Coll Cardiol.* 2010;55:2212-2212.

Kasama S. et al. Prognostic Value of Serial Cardiac 123I-MIBG Imaging in Patients with Stabilized Chronic Heart Failure and Reduced Left Ventricular Ejection Fraction, *J Nucl Med.* 2008;49: 907-914.

Ketchum ES, Jacobson AF, Caldwell JH, et al. Selective improvement in Seattle heart failure model risk stratification using iodine-123 meta-iodobenzylguanidine imaging. *J Nucl Cardiol,* 2012;19:1007-1016.

O'Day K, Levy W, Johnson M, Jacobson AF, et al. Screening Implantable Cardioverter Defibrillators Eligible Heart Failure Patients with I-123 Metaiodobenzyl Guanidine Imaging versus No Screening: An Economic Model Comparing Costs and Outcome; March 2014.

Sanders GD, Hlatky MA, Owens DK, et al. Cost-effectiveness of implantable cardioverter-defibrillators. *N Engl J Med.* 2005; 353:1471-80.

Strauss W.H., et al., Metaiodobenzylguanidine Imaging Comes of Age A New Arrow in the Prognostic Quiver for Heart Failure Patients\*, *Journal of the American College of Cardiology* Vol. 55, No. 20, 2010

Tamaki S., MD, et al. Cardiac Iodine-123 Metaiodobenzylguanidine Imaging Predicts Sudden Cardiac Death Independently of Left Ventricular Ejection Fraction in Patients With Chronic Heart Failure and Left Ventricular Systolic Dysfunction Results From a Comparative Study With Signal-Averaged Electrocardiogram, Heart Rate Variability, and QT Dispersion, *Journal of the American College of Cardiology*, Vol. 53, No. 5, 2009.

Yancy CQ, Jessup M, Bozkurt B, et al. 2013 ACCF/AHA guideline for the management of heart failure. *J Am Coll Cardiol.* 2013;62(16):e147-e239.

Zheng ZJ, Croft JB, Giles WH, et al. Sudden Cardiac Death in the United States, 1989 to 1998. *Circulation.* 2001; 104:2158-2163.

**CPT 0334T:**

Reconsideration request received June 21, 2013:

Cummings J Jr, Capobianco RA: Minimally invasive sacroiliac joint fusion: one-year outcomes in 18 patients. *Ann Surg Innov Res* 2013, 7(1):12.

Duhon, et al, "Safety and Midterm Effectiveness of Minimally Invasive Sacroiliac Joint Fusion: A Prospective Study." *Medical Devices: Evidence and Research* 2013.

Graham Smith, et al, "Open versus minimally invasive sacroiliac joint fusion: A multi-center comparison of perioperative measures and clinical outcomes." *Annals of Surgical Innovation and Research* 2013, 7:14.

Investigation of Sacroiliac Fusion Treatment (INSITE); ClinicalTrials.gov identifier: [NCT01681004]

<http://www.clinicaltrials.gov/ct2/show/NCT01681004?term=NCT01681004&rank=1>

Miller et al, "Analysis of postmarket complaints database for the iFuse SI Joint Fusion System: a minimally invasive treatment for degenerative sacroiliitis and sacroiliac joint disruption." *Medical Devices: Evidence and Research* 2013:6 77–84.

Rudolf, L. Sacroiliac Joint Arthrodesis-MIS Technique with Titanium Implants: Report of the First 50 Patients and Outcomes. *Open Orthop. J.* 6, 495–502 (2012).

Sachs D, Capobianco R. One year successful outcomes for novel sacroiliac joint arthrodesis system. *Ann Surg Innov Res.* 2012;6(1):13.

Sachs D, Capobianco R: Minimally invasive sacroiliac joint fusion: one-year outcomes in 40 patients. *Adv Orthop* 2013, 2013:536128.

Sachs, D. Minimally Invasive versus Open Sacroiliac Joint Fusion: A Comparison of Process Measures and Description of Technique. *Int. Soc. Adv. Spine Surg.* 187 (2013).

Smith, AG, et. al. Open versus minimally invasive sacroiliac joint fusion: a multi-center comparison. *Annals of Surgical Innovation and Research* 2013, 7:14.

**CPT 0336T:**

Reconsideration request received June 24, 2015:

American College of Obstetricians and Gynecologists (ACOG). Alternatives to hysterectomy in the management of leiomyomas. ACOG practice bulletin number 96; 2008. Available at: [http://www.guideline.gov/summary/summary.aspx?ss=15&doc\\_id=13318&string](http://www.guideline.gov/summary/summary.aspx?ss=15&doc_id=13318&string). Accessed September 15, 2015.

ANTHEM Medical Policy # SURG.00077: Uterine Fibroid Ablation: Laparoscopic or Percutaneous Image Guided Techniques. Accessed October 5, 2015.

[https://www.anthem.com/medicalpolicies/policies/mp\\_pw\\_a053391.htm](https://www.anthem.com/medicalpolicies/policies/mp_pw_a053391.htm)

Berman JM, Bolnick, JM, Pemueller RR et al. Reproductive outcomes in women following radiofrequency volumetric thermal ablation of symptomatic fibroids. *The Journal of Reproductive Medicine*. 2015; 4 (5-6):194-198.

Berman JM, Guido RS, Garza Leal JG, Pemueller RR, Whaley FS, Chudnoff SG; Halt Study Group. Three-Year outcome of the Halt trial: a prospective analysis of radiofrequency volumetric thermal ablation of myomas. *J Minim Invasive Gynecol*. 2014; 21(5):767-774.

Chudnoff SG, Berman JM, Levine DJ, et al. Outpatient procedure for the treatment and relief of symptomatic uterine myomas. *Obstet Gynecol*. 2013; 121(5):1075-1082.

Cigna Medical Coverage Policy #0504: Radiofrequency Ablation (RFA) of Uterine Fibroids (CPT® Code 0336T). Accessed October 5, 2015.

[https://cignaforhcp.cigna.com/public/content/pdf/coveragePolicies/medical/mm\\_0504\\_coverage\\_positioncr\\_iteria\\_omnibus\\_codes.pdf](https://cignaforhcp.cigna.com/public/content/pdf/coveragePolicies/medical/mm_0504_coverage_positioncr_iteria_omnibus_codes.pdf)

Galen DI, Pemeuller RR, Leal JG, Abbott KR, Falls JL, Macer J. Laparoscopic radiofrequency fibroid ablation: phase II and phase III results. *JSLS*. 2014; 18(2):182-190.

Guido RS, Macer JA, Abbott K, Falls, JL, Tilley IB, Chudnoff SG. Radiofrequency volumetric thermal ablation of fibroids: a prospective, clinical analysis of two years' outcome from the Halt trial. *Health Qual Outcomes*. 2013; 11(1):139.

Hahn M, Brucker S, Kraemer D, et al. Radiofrequency volumetric thermal ablation of fibroids and laparoscopic myomectomy: long-term follow-up from a randomized trial. *Geburtsh Frauenheilk*. 2015; 75:442-449.

Reconsideration request received April 5, 2016

Krämer B et al. Interim analysis of a randomized controlled trial comparing laparoscopic radiofrequency volumetric thermal ablation of uterine fibroids, *Int J Gynecol Obstet* (2015). <http://dx.doi.org/10.1016/j.ijgo.2015.10.008>

Stewart EA. Uterine fibroids. *New England Journal of Medicine*. 2015; 372:1646-55, DOI: 10.1056/NEJMcp1411029

Thompson MJ, Carr BR. Intramural myomas: to treat or not to treat, *International Journal of Women's Health*; 2016:8 145–149

American College of Obstetricians and Gynecologists (ACOG). Alternatives to hysterectomy in the management of leiomyomas. ACOG practice bulletin number 96; 2008. Available at: [http://www.guideline.gov/summary/summary.aspx?ss=15&doc\\_id=13318&string](http://www.guideline.gov/summary/summary.aspx?ss=15&doc_id=13318&string). Accessed September 15, 2015.

**CPT 0337T:**

Reconsideration request received January 2, 2014:

Akiyama E, Sugiyama S, Matsuzawa Y, et al. Incremental prognostic significance of peripheral endothelial dysfunction in patients with heart failure with normal left ventricular ejection fraction. *J Am Coll Cardiol* 2012;60:1778-86.

Bonetti PO, Barsness GW, Keelan PC, et al. Enhanced external counterpulsation improves endothelial function in patients with symptomatic coronary artery disease. *J Am Coll Cardiol* 2003;41:1761-68.

Bonetti, P. et al., Noninvasive Identification of Patients With Early Coronary Atherosclerosis by Assessment of Digital Reactive Hyperemia, *Journal of the American College of Cardiology*, Vol. 44, No. 11, 2004: 2137-41.

Dangardt F, Osika W, Chen Y, et al. Omega-3 fatty acid supplementation improves vascular function and reduces inflammation in obese adolescents. *Atherosclerosis* 2010; 212:580-5.

Deshmunkh SH, Patel SR, Pinassi E, et al. Ranolazine improves endothelial function in patients with stable coronary artery disease. *Coron Artery Dis* 2009;20:343-7.

Fisher NDL, Hughes M, Gerhard-Herman M, Hollenberg NK. Flavenol-rich cocoa induces nitric-oxide-dependent vasodilation in healthy humans. *J Hypertens* 2003;21:2281-6.

Heffernan KS, Karas RH, Patvardhan EA, et al. Peripheral arterial tonometry for risk stratification in men with coronary artery disease. *Clin Cardiol* 2010; 33:94-8.

Kim JY, Paik JK, Kim OY, et al. Effects of lycopene supplementation on oxidative stress and markers of endothelial function in healthy men. *Atherosclerosis* 2011; 215:189-95.

Matsue, Y, et al. Peripheral microvascular dysfunction predicts residual risk in coronary artery disease patients on statin therapy, *Atherosclerosis*, 2014

Matsue Y, Suzuki M, Nagahori W, et al. Endothelial dysfunction measured by peripheral arterial tonometry predicts prognosis in patients with heart failure and preserved ejection fraction. *Internat J Cardiol* 2012, <http://dx.doi.org/10.1016/j.ijcard.2012.09.021>

Matsuzawa, Y, et al. Digital Assessment of Endothelial Function and Ischemic Heart Disease in Women, *Journal of the American College of Cardiology* Vol. 55, No. 16, 2010

Matsuzawa Y, Sugiyama S, Sumida H, et al. Peripheral endothelial function and cardiovascular events in high-risk patients. *J Am Heart Assoc* 2013;2:e000426. doi: 10.1161/JAHA.113.000426.

Rubinshtein R, Kuvvin JT, Soffler M, et al. Assessment of endothelial function by non-invasive peripheral arterial tonometry predicts late cardiovascular adverse events. *Eur Heart J* 2010;31:1142-8.

Schoenenberger AW, Urbanek N, Bergner M, et al. Associations of reactive hyperemia index and intravascular ultrasound-assessed coronary plaque morphology in patients with coronary artery disease. *Am J Cardiol* 2012;109:1711-6.

Toggweiler,S. et al: Prevalence of endothelial dysfunction, *Clin. Cardiol.* 33, 12, 746–752 (2010), Published online in Wiley Online Library ([wileyonlinelibrary.com](http://wileyonlinelibrary.com))DOI:10.1002/clc.20836 , 2010 Wiley Periodicals, Inc.

Yamaoka-Tojo M, Tojo T, Kosugi R, et al. Effects of ezetimibi add-on therapy for high-risk patients with dyslipidemia. 2009;8:41-9.

Current Procedural Terminology (CPT®), American Medical Association (2010)

Galiano K, Obwegeser AA, Bodner G, et al. Ultrasound guidance for facet joint injections in the lumbar spine: a computed tomography-controlled feasibility study. <i>Anesth Analg.</i> 2005;101(2):579-583.

Galiano K, Obwegeser AA, Bodner G, et al. Ultrasound-guided facet joint injections in the middle to lower cervical spine: a CT-controlled sonoanatomic study. <i>Clin J Pain.</i> 2006;22(6):538-543.

Galiano K, Obwegeser AA, Walch C, Schatzer R, Ploner F, Gruber H. Ultrasound-guided versus computed tomography-controlled facet joint injections in the lumbar spine: a prospective randomized clinical trial. *<u>Reg Anesth Pain Med</u>* 2007;32(4):317-322.

Greher M, Kirchmair L, Enna B, et al. Ultrasound-guided lumbar facet nerve block: accuracy of a new technique confirmed by computed tomography. *<u>Anesthesiology</u>* 2004;101(5):1195-2000.

Greher M, Scharbert G, Kamolz LP, et al. Ultrasound-guided lumbar facet nerve block: a sonoanatomic study of a new methodologic approach. *<u>Anesthesiology</u>* 2004;100(5):1242-1248.

#### **CPT 0378T-0379T:**

Reconsideration request received April 1, 2015 :

Age-Related Eye Disease Study Research Group. A Simplified Severity Scale for Age-Related Macular Degeneration: AREDS Report No. 18 *Arch Ophthalmol*. 2005 November ; 123(11): 1570-1574

AREDS Group A randomized, placebo-controlled, clinical trial of high-dose supplementation with vitamins C and E, beta carotene, and zinc for age-related macular degeneration and vision loss. AREDS report no 8. Age-related Eye Disease Study Research Group. *Arch Ophthalmol* 2001; 119:1417-36.

Boyer D et al Subgroup Analysis of the MARINA Study of Ranibizumab in Neovascular Age-Related Macular Degeneration *Ophthalmology* 2007;114:246-252

Bressler NM, Bressler SB, Congdon NG, Ferris FL, Friedman DS, Klein R, Linbald AS, Milton RC Seddon JM Age-Related Eye Disease Study Research Group Potential public health impact of Age- Related Study results: AREDS report no 11 *Arch Ophthalmol*. 2003 Nov;121(11):1621-4

Chew, Emily Y., et al. Randomized Trial of a Home Monitoring System for Early Detection of Choroidal Neovascularization Home Monitoring of the Eye (HOME) Study. *Ophthalmology* 2014; 121: 535-544.

Effect of Lesion Size, Visual Acuity, and Lesion Composition on Visual Acuity Change With and Without Verteporfin Therapy for Choroidal Neovascularization Secondary to Age-related Macular Degeneration: TAP and VIP Report *Am J Ophthalmol* 2003;136:407-418

Ferris FL III, Fine SL, Hyman L. Age-related macular degeneration and blindness due to neovascular maculopathy. *Arch Ophthalmol* 1984; 102:1640-2.

Jager R, Mieler W, and Miller J. Age-Related Macular Degeneration. *N Engl J Med* 2008;358:2606-17.

Loewenstein A, Malach M, Goldstein M, et al. Replacing the Amsler grid: a new method for monitoring patients with age-related macular degeneration. *Ophthalmology* 2003; 110:966-970. See also Goldstein M, Loewenstein A, Barak A, et al. Results of a multicenter clinical trial to evaluate the preferential hyperacuity perimeter for detection of age-related macular degeneration. *Retina* 2005; 25:296-303.

Olsen T, et al American Academy of Ophthalmology Retinal Panel Preferred Practice Pattern Age Related Macular Degeneration. *American Academy of Ophthalmology* 2014

Rosenfeld PJ, Brown DM, Heier JS et al MARINA Study Group Ranibizumab for Neovascular Age- Related Macular Degeneration. *N Engl J Med* 2006; 355:1419-31.

Kaiser P et al Ranibizumab for Predominantly Classic Neovascular Age-related Macular Degeneration: Subgroup Analysis of First-year ANCHOR Results. *Am J Ophthalmol* 2007; 144:850-857.

Olsen T et al Fluorescein Angiographic Lesion Type Frequency in Neovascular Age-Related Macular Degeneration. *Ophthalmology* 2004;111:250-255

Parkes L, Lund J, Anelucci A, et al. Compulsory averaging of crowded orientation signals in human vision. *Nat Neurosci*. 2001; 4:739-744.

Fine AM, Elman MJ, Ebert EM, et al. Earliest symptoms caused by neovascular membranes in the macula. *Arch Ophthalmol* 1986;104:513-514

Shona et al Visual acuity outcomes in ranibizumab-treated neovascular age-related macular degeneration stratified by baseline vision. *Clinical & Experimental Ophthalmology* 2010

Loewenstein A, Malach M, Goldstein M, et al. Replacing the Amsler grid: a new method for monitoring patients with age-related macular degeneration. *Ophthalmology* 2003; 110:966-970.

Goldstein M, Loewenstein A, Barak A, et al. Results of a multicenter clinical trial to evaluate the preferential hyperacuity perimeter for detection of age-related macular degeneration. *Retina* 2005; 25:296- 303

Alster Y, Bressler NM, Bressler SB et al Preferential Hyperacuity Perimeter (PreView PHP) for Detecting Choroidal Neovascularization Study. *Ophthalmology* 2005;112:1758-1765

Loewenstein A, Ferencz J, Lang Y et al Toward earlier detection of choroidal neovascularization secondary to age-related macular degeneration. Multicenter evaluation of preferential hyperacuity perimeter designed as a home device

Chakravarthy U et al Functional and morphological benefits in early detection of neovascular age-related macular degeneration using the Preferential Hyperacuity Perimeter In press, *Retina* 2011

Stur M and Manor Y Long-Term Monitoring of Age-Related Macular Degeneration With Preferential Hyperacuity Perimetry *Ophthalmic Surg Lasers Imaging* 2010;41:598-606

Schmidt-Erfurth U, et al. Br J Ophthalmol 2014;98:1144–1167. doi:10.1136/bjophthalmol-2014-305702

#### CPT 0392T-0393T:

Reconsideration request received July 21, 2015:

American Society of General Surgeons (ASGS) Board of Trustees. LINX Statement of Support from ASGS. [www.theasgs.org](http://www.theasgs.org)

ANTHEM Medical Policy # SURG 00131: Lower Esophageal Sphincter Augmentation Devices for the Treatment of Gastroesophageal Reflux Disease (GERD) Accessed October 5, 2015.

[https://www.anthem.com/medicalpolicies/policies/mp\\_pw\\_c151320.htm](https://www.anthem.com/medicalpolicies/policies/mp_pw_c151320.htm)

Bonavina L, Saino G, Bona D, Sironi A, Lazzari V. One Hundred Consecutive Patients Treated with Magnetic Sphincter Augmentation for Gastroesophageal Reflux Disease: 6 Years of Clinical Experience from a Single Center. *J Am Coll Surg* 2013 July; epub

Cigna Medical Coverage Policy #0019: Endoscopic Antireflux Procedures. Accessed October 5, 2015.

[https://cignaforhcp.cigna.com/public/content/pdf/coveragePolicies/medical/mm\\_0019\\_coverage\\_criteria\\_endoscopic\\_treatment\\_for\\_gerd.pdf](https://cignaforhcp.cigna.com/public/content/pdf/coveragePolicies/medical/mm_0019_coverage_criteria_endoscopic_treatment_for_gerd.pdf)

Ganz, Robert A. Long-Term Outcomes of Patients Receiving a Magnetic Sphincter Augmentation Device for Gastroesophageal Reflux. *Clinical Gastroenterology and Hepatology*, May 2015

Gould J, Oleynikov D, Rattner D, Soper N, Velanovich V. TAVAC Safety and Effectiveness Analysis: LINX® Reflux Management System. Society of American Gastrointestinal and Endoscopic Surgeons; [www.sages.org](http://www.sages.org)

Humana Coverage Policy #0019: Endoscopic Antireflux Procedures. Accessed October 5, 2015.[http://apps.humana.com/tad/tad\\_new/Search.aspx?searchtype=beginswith&docbegin=G&policyType=medical](http://apps.humana.com/tad/tad_new/Search.aspx?searchtype=beginswith&docbegin=G&policyType=medical)

Katz P, Gerson L, Vela M. Guidelines for the Diagnosis and Management of Gastroesophageal Reflux Disease. Am J Gastroenterol advance online publication, 19 February 2013; doi: 10.1038/ajg.2012.444

Lipham JC, Taiganides P, Louie B, Ganz R, DeMeester T. Safety Analysis of First 1000 Patients Treated with Magnetic Sphincter Augmentation for Gastroesophageal Reflux Disease. Diseases of the Esophagus, March 2014

Louie B, Farivar A, Shultz D, Brennan C, Vallieres E, Aye R. Short-Term Outcomes Using Magnetic Sphincter Augmentation Versus Nissen Fundoplication for Medically Resistant Gastroesophageal Reflux Disease. Annals of Thoracic Surgery , June 2014; epub

Reynolds J, Zehetner J, Wu P, Shah S, Bildzukewicz N, Lipham J. Laparoscopic Magnetic Sphincter Augmentation vs Laparoscopic Nissen Fundoplication: A Matched-Pair Analysis of 100 Patients. J Am Coll Surg 2015 February; epub

Reconsideration request received July 1, 2015 :

Saino G, Bonavina L, Lipham, JC et al. Magnetic sphincter augmentation for gastroesophageal reflux at 5 years: final results of a pilot study show long-term acid reduction and symptom improvement. *Journal of Laparoendoscopic & Advanced Surgical Techniques* 2015;25(10): 1-8. DOI:10.1089/lap.2015.0394.

Ganz RA, Edmundowicz SA, Taiganides PA, et al. Long-term outcomes of patients receiving a magnetic sphincter augmentation device for gastroesophageal reflux.

*Clinical Gastroenterology and Hepatology*. 2015; Article in press. <http://dx.doi.org/10.1016/j.cgh.2015.05.028>.

Warren HF, Reynolds J, Lipham JC et al. Multi-institutional outcomes using magnetic sphincter augmentation versus Nissen fundoplication for chronic gastroesophageal reflux disease. *Surg Endosc*. DOI 10.1007/s00565-015-4659-y.

Reynolds JL, Zehetner J, Nich A, et al. Charges, outcomes, and complications: a comparison of magnetic sphincter augmentation versus laparoscopic Nissen fundoplication for the treatment of GERD. *Surg Endos*.

DOI 10.1007/s00464-015-5635-6.

**CPT 0394T:**

Reconsideration request received March 10, 2016:

Halpern N. Radiation therapy in skin cancer. A historical perspective and current applications. *Dermatol Surg*. 1997;23:1089-1093.

Bhatnagar A. Nonmelanoma skin cancer treated with electronic brachytherapy: results at 1 year. *Brachytherapy*. 2013;March-April; 12 (2):134-140.

Green WH and Cognetta A. Efficacy of superficial radiation therapy. In: CognettaA and Mendenhall WM, eds. *Radiation Therapy for Skin Cancer*. Springer, NY: Springer Science; 2013:71-81.

Garcia-Martinez T, Chan JP, Perez-Calatayud J, Ballester F. Dosimetric characteristics of a new unit for electronic skin brachytherapy. *J Contemp Brachytherapy*. 2014; 6(1).

Tormo A, Celada F, Rodriguez S, Botella R, Ballesta A, Kasper M, Ouhib Z, Santos M, Perez-Calatayud

J. Nonmelanoma skin cancer treated with HDR Valencia applicator: clinical outcomes. *J Contemp Brachytherapy*. 2014;6:167-172.

Doggett S, Willoughby M, Willoughby C, Mafong E, Han A. Incorporation of electronic brachytherapy for skin cancer into a community dermatology practice. *J Clinical and Aesthetic Derm*. November 2015; 8(11):28-32.

Strom T, Harrison LB. Radiotherapy for management of basal and squamous cell carcinoma. *Curr Probl Cancer*. 2015; 39:237 – 247.

**CPT 0394T-0395T:**

Reconsideration request received March 9, 2016:

Bhatnagar A, Loper A , The initial experience of electronic brachytherapy for the treatment of non- melanoma skin cancer. *Radiat Oncol.* 2010 Sep 28;5:87. doi: 10.1186/1748-717X-5-87.

Bhatnagar A. Nonmelanoma skin cancer treated with electronic brachytherapy: results at 1 year. *Brachytherapy.* 2013;March-April; 12 (2):134-140.

Gauden R, Pracy M, Avery A-M et al. HDR brachytherapy for superficial non-melanoma skin cancers.

*Journal of Medical Imaging and Radiation Oncology.* 2013;57:212-217.

Ouhib Z, Kasper M, Perez Calatayud J, Rodriguez S, Bhatnagar A, Pai S, Strasswimmer J. Aspects of dosimetry and clinical practice of skin brachytherapy: The American Brachytherapy Society working group report. *Brachytherapy.* 2015; 14(6):840-858.

Rong Y, Zuo L, Shang L, Bazan JG Radiotherapy treatment for nonmelanoma skin cancer. *Expert Rev Anticancer Ther.* Early online, 1-12 (2015) 10.1586/140.2015.1042865.

Sayler E, Eldredge-Hindy H, Dinome J et al. Clinical implementation and failure mode and effects analysis of HDR skin brachytherapy using Valencia and Leipzig surface applicators. *Brachytherapy.* 2015;14:293-299.

Lukens JN, Gamez M, Hu K, Harrison LB. Modern brachytherapy. *Seminars in Oncology* 2014;41:831- 847.

National Comprehensive Cancer Network®. (NCCN). Clinical Practice Guidelines in Oncology™ © 2015 National Comprehensive Cancer Network, Inc. For additional information: <http://www.nccn.org>. Accessed June 3, 2016.

- Basal Cell Skin Cancer. Version 1.2015.
- Squamous Cell Skin Cancer. Version 1.2015

American Association of Physicists in Medicine. The 2007 response to the CRCPD request for recommendations for the CRCPD's model regulations for electronic brachytherapy .AAPM Report No.

152. Available at <http://www.aapm.org/pubs/reports/>. Accessed June 4, 2016.

American College of Radiology (ACR) and the American Society for Therapeutic Radiation and Oncology (ASTRO) Practice Guidelines & Technical Standards. ACR-ASTRO Practice Parameter for the Performance of High-Dose-Rate Brachytherapy. Available at:

<http://www.acr.org/Quality-Safety/Standards-Guidelines/Practice-Guidelines-by-Modality/Radiation-Oncology>. Accessed June 4, 2016.

Park CC, Yom SS, Podgorsak MB, et al. American Society for Therapeutic Radiology and Oncology (ASTRO) Emerging Technology Committee report on electronic brachytherapy. *Int J Radiat Oncol Biol Phys.* 2010; 76:963-972.

Patel RR, Beitsch PD, Nichols TD, et al. Postsurgical treatment of early-stage breast cancer with electronic brachytherapy: outcomes and health-related quality of life at 1 year. *Am J Clin Oncol;* 2012;36(5):430-435.

Dooley WC, Wurzer JC, Megahy M, et al. Electronic brachytherapy as adjuvant therapy for early stage breast cancer: a retrospective analysis. *Onco Targets Ther.* 2011;4:13-20.

Mehta VK, Algan O, Greim K, et al. Experience with an electronic brachytherapy technique for intracavitary accelerated partial breast irradiation. *Am J Clin Oncol* 2010;33:327-335.

Kamrava M, Chung MP, DeMarco J, et al. Electronic brachytherapy for postsurgical adjuvant vaginal cuff irradiation therapy in endometrial and cervical cancer: a retrospective study. *Brachytherapy* 2013;12:141-147.

Dooley WC, Thropay JP, Schreiber GJ, et al. Use of electronic brachytherapy to deliver postsurgical adjuvant radiation therapy for endometrial cancer: a retrospective multicenter study. *Onco Targets Ther.* 2010;3:197-203.

Dickler A, Puthawala MY, Thropay JP, et al. Prospective multi-Center trial utilizing electronic brachytherapy for the treatment of endometrial cancer. *Radiation Oncology.* 2010;5:67.

#### **CPT Code 0406T, 0407T**

Reconsideration request received April 27, 2016:

Forwith et al (2011). ADVANCE: A multisite trial of bioabsorbable steroid-eluting sinus implants. *Laryngoscope.* 121:2473-2480.

Han et al. (2012). Effect of steroid releasing sinus implants on postoperative medical and surgical interventions: an efficacy meta-analysis. *Int Forum Allergy Rhinology.* 2:271-279.

Marple et al. (2012). Advance II: A prospective, randomized study assessing safety and efficacy of bioabsorbable steroid-releasing sinus implants, otolaryngology–head and neck surgery. *Otolaryngology–Head and Neck Surgery*. 146(6):1004–1011.

Matheny et al. (2014). Safety, feasibility, and efficacy of placement of steroid-eluting bioabsorbable sinus implants in the office setting: a prospective case series. *Int Forum Allergy Rhinology*. 2014;4:808–815.

Murr et al. (2011). Safety and efficacy of a novel bioabsorbable, steroideluting sinus stent. *Int Forum Allergy Rhinology*. 2011;1(1):23-32.