

4. Ultrasound Ablation of Uterine Fibroids with Magnetic Resonance Guidance (MRgFUS) (APCs 0195 and 0202)

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Magnetic resonance guided focused ultrasound (MRgFUS) is a noninvasive surgical procedure that uses high intensity focused ultrasound waves to destroy tissue in combination with magnetic resonance imaging (MRI). Currently, the two Category III CPT codes for this procedure are 0071T (Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume less than 200 cc of tissue) and 0072T (Focused ultrasound ablation of uterine leiomyomata, including MR guidance; total leiomyomata volume greater or equal to 200 cc of tissue), which were implemented on January 1, 2005.

In the CY 2006 OPSS proposed rule, we proposed to continue to assign both codes to APC 0193 (Level V Female Reproductive Proc). However, at the August 2005 APC Panel meeting, the APC Panel recommended that CMS work with stakeholders to assign CPT codes 0071T and 0072T to appropriate New Technology APCs. Based on our review of several factors, which included information presented at the August 2005 APC Panel meeting, the comments received on the CY 2006 OPSS proposed rule, and our analysis of OPSS claims data for different procedures, we reassigned CPT code 0071T from APC 0193 to APC 0195 (Level IX Female Reproductive Proc) and CPT code 0072T from APC 0193 to APC 0202 (Level X Female Reproductive Proc) effective January 1, 2006, to reflect the higher level of resources we estimated were required when performing the MRgFUS procedures.

In the CY 2007 OPSS/ASC proposed rule, we proposed to continue to assign CPT code 0071T to APC 0195 and CPT code 0072T to APC 0202. We received comments on the CY 2007 proposed APC assignments recommending that we revise the APC assignments for CPT codes 0071T and 0072T. The commenters indicated that, while MRgFUS treats anatomical sites that are similar to other procedures assigned to APCs 0195 and 0202, the resources utilized differ dramatically. Several commenters recommended that the most appropriate APC assignment for the MRgFUS procedures would be APC 0127 (Level IV Stereotactic Radiosurgery), based on their analyses of the procedures' resource use and clinical characteristics.

As we stated in both the CY 2006 OPSS final rule with comment period and the CY 2007 OPSS/ASC final rule with comment period, we believe that MRgFUS treatment bears a significant relationship to technologies already in use in hospital outpatient departments (70 FR 68600 and 71 FR 68050, respectively). The use of focused ultrasound for thermal tissue ablation has been in development for decades, and the recent application of MRI to

focused ultrasound therapy provides monitoring capabilities that may make the therapy more clinically useful. We continue to believe that, although MRgFUS therapy is relatively new, it is an integrated application of existing technologies (MRI and ultrasound), and its technology resembles other OPPS services that are assigned to clinical APCs for which we have significant OPPS claims data. In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68050), we explained our belief that retaining MRgFUS procedures in clinical APCs with other female reproductive procedures would enable us both to set accurate payment rates and to maintain appropriate clinical homogeneity of the APCs. Furthermore, we did not agree with commenters that MRgFUS procedures shared sufficient clinical and resource characteristics with cobalt-based stereotactic radiosurgery (SRS) to reassign them to that particular clinical APC 0127, where only the single specific SRS procedure was assigned for CY 2007 and which had a CY 2007 APC median cost of \$8,460.53. Consequently, in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68051), we finalized payment for these procedures in APCs 0195 and 0202 as proposed.

Analysis of our hospital outpatient data for claims submitted for CY 2006 indicates that MRgFUS procedures are rarely performed on Medicare patients. As we stated in the CY 2006 OPPS final rule with comment period and CY 2007 OPPS/ASC final rule with comment period, because treatment of uterine fibroids is most common among women younger than 65 years of age, we do not expect that there ever will be many Medicare claims for the MRgFUS procedures (70 FR 68600 and 71 FR 68050, respectively). For OPPS claims submitted from CY 2005 through CY 2006, our claims data show that there were only two claims submitted for CPT code 0071T in CY 2005 and one in CY 2006. We have no hospital claims for CPT code 0072T from either of those years.

At its March 2007 meeting, the APC Panel recommended that, for CY 2008, CMS reassign CPT codes 0071T and 0072T from APCs 0195 and 0202 to APC 0067 (Level III Stereotactic Radiosurgery, MRgFUS, and MEG), which has a proposed APC median cost of \$3,869.96 for CY 2008. The APC Panel discussed its general belief that while the MRgFUS procedures may not be performed frequently on Medicare patients, CMS should pay appropriately for the procedures to ensure access for Medicare beneficiaries.

In addition, following discussion of the potential for reassignment of the CPT codes to New Technology APCs, the APC Panel specifically recommended that the procedures be assigned to a clinical APC at this point in their adoption into clinical practice, instead of a New Technology APC. Furthermore, since publication of the CY 2007 OPPS/ASC final rule with comment period, we have received input from interested individuals and organizations regarding the clinical and resource characteristics of MRgFUS procedures.

Based on our consideration of all information available to us regarding the necessary hospital resources for the MRgFUS procedures in comparison with other procedures for which we have historical hospital claims data, for CY 2008 we are proposing to accept the APC Panel's recommendation to reassign these services to clinical APC 0067, an APC that currently contains two linear accelerator-based stereotactic radiosurgery (SRS) procedures that are conducted in a single or first session, rather than procedures for

subsequent SRS treatment fractions. We agree with the APC Panel that these SRS procedures share sufficient clinical and resource similarity with the MRgFUS services, including reliance on image guidance in a single treatment session to ablate abnormal tissue, to justify their assignment to the same clinical APC. Unlike the cobalt-based SRS service that we concluded in the CY 2007 OP/ASC final rule with comment period was not similar to MRgFUS procedures based on clinical and resource considerations, these linear accelerator-based SRS procedures are not performed solely on intracranial lesions and generally do not require immobilization of the patient's head in a frame that is screwed into the skull, thereby exhibiting characteristics more consistent with MRgFUS treatments. In addition, based on our understanding of the MRgFUS procedures described by the two CPT codes which differ only in the volume of uterine leiomyomata treated, we believe it would be most appropriate to assign both of these procedures to the same clinical APC, as recommended by the APC Panel. Therefore, for CY 2008 we are proposing to reassign CPT codes 0071T and 0072T to APC 0067, with a proposed APC median cost of \$3,869.96, as reflected in Table 32.

Table 32.--Proposed CY 2008 APC Assignments of MRgFUS Procedures

HCPCS Code	Short Descriptor	CY 2007 SI	CY 2007 APC	CY 2007 APC Median Cost	Proposed CY 2008 SI	Proposed CY 2008 APC	Proposed CY 2008 APC Median Cost
0071T	U/s leiomyomata ablate <200	T	0195	\$ 1,742.20	S	0067	\$3,869.96
0072T	U/s leiomyomata ablate >200	T	0202	\$ 2,534.46	S	0067	\$3,869.96