

Case Number:	CM14-0160672		
Date Assigned:	10/06/2014	Date of Injury:	05/17/2000
Decision Date:	11/03/2014	UR Denial Date:	08/30/2014
Priority:	Standard	Application Received:	09/30/2014

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The expert reviewer is Board Certified in Internal Medicine and is licensed to practice in California. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The patient is an injured worker with the diagnoses of right vocal cord paralysis secondary to cervical surgery, dysphonia secondary to cervical surgery, and dysphagia secondary to cervical surgery. Mechanism of injury was slip and fall accident. Date of injury was 5/17/2000. Otorhinolaryngology evaluation report dated February 4, 2014 documented that the patient was eight months status post Radiesse vocal fold injection. She states her cough and aspiration are basically resolved. Her voice is about 75% better. She indicates that people are not aware that she has a voice issue, and she can speak for 40 minutes before it gets weak. Overall, she is extremely pleased. Physical examination was documented. She is alert and in no acute distress. Her skin turgor is excellent, and her general demeanor appears to be good. Fiberoptic laryngoscopy revealed that her vocal cords are meeting in the midline without ulceration or masses. The patient tolerated this procedure well. Diagnosis were right vocal cord paralysis, secondary to necessary cervical surgery; dysphonia hoarseness, secondary to necessary cervical surgery; dysphagia swallowing difficulties, secondary to necessary cervical surgery; and deviated nasal septum. Primary treating physician's progress report dated 3/5/14 documented the diagnoses of cervical post laminotomy pain syndrome, history of anterior discectomy and cervical fusion in 2002 with pseudoarthrosis and hardware loosening, revision C4-7 anterior discectomy cervical fusion in 2010, and right vocal cord paralysis with dysphonia. Otorhinolaryngology evaluation report dated August 11, 2014 documented that the patient was 14 months post vocal cord injection and will require another injection to keep her condition from deteriorating. Otorhinolaryngology evaluation report dated October 3, 2014 documented that the patient has weak vocal folds secondary to a May 17, 2000, slip-and-fall accident at work. Her resulting injuries necessitated two cervical spine surgeries. Those surgeries resulted in voice loss and difficulties swallowing certain foods. On June 4, 2013, a Radiesse Voice Gel injection to the

right true vocal fold was administered. She subsequently showed the expected improvement. The patient is approximately 16 months post injection, and its effects are beginning to fade. Pain management report dated August 20, 2014 documented that the patient has recurrent dysphonia and will require repeat right vocal cord injections for the paralysis, and documented objective finding of dysphonia. Utilization review determination date was 8/30/1414.

IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

1 Radiesse Injection: Overturned

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Vocal Fold Injection: Review of Indications, Techniques, and Materials for Augmentation. Pavan S. Mallur, MD and Clark A. Rosen, MD. Clin Exp Otorhinolaryngol. 2010 Dec;3(4):177-82. doi: 10.3342/ceo.2010.3.4.177. Epub 2010 Dec 22. PMID: 21217957 <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3010535/> Radiesse-voice.com http://www.radiesse-voice.com/docs/RADIESSE_Voice_Instructions_for_Use.pdf <http://www.radiesse-voice.com/pages.php?id=8&type=1> FDA 510(k)

Decision rationale: Medical Treatment Utilization Schedule (MTUS) does not address RADIESSE. FDA 510(k) Summary of Safety and Effectiveness (2007) documented that Radiesse is indicated for vocal fold medialization and vocal fold insufficiency that may be improved by injection of a soft tissue bulking agent. Radiesse injection augments the size of the displaced or deformed vocal fold so that it may meet the opposing fold at the midline for improved phonation. Vocal fold insufficiency associated with serious aspiration difficulties may be an urgent indication. Corporate communications document that Radiesse is FDA-cleared for vocal fold augmentation and vocal fold insufficiency. Medical literature review published in the journal Clinical and Experimental Otolaryngology (2010) documented that vocal fold injection plays a major role in the treatment of many patients with dysphonia, and Radiesse Voice Gel provides the best treatment option. Calcium hydroxylapatite (CaHA), known by the trade name Radiesse Voice, is currently a FDA approved substance for potentially long-term vocal fold injection. Medical records document the diagnoses of right vocal cord paralysis secondary to cervical surgery, dysphonia secondary to cervical surgery, and dysphagia secondary to cervical surgery. Otorhinolaryngology reports documented benefit from the Radiesse Voice Gel injection to the right true vocal fold that was administered on June 4, 2013. Otorhinolaryngology evaluation report dated February 4, 2014 documented improvement of the patient's voice, cough, and aspiration. Fiberoptic laryngoscopy revealed that her vocal cords are meeting in the midline without ulceration or masses. Otorhinolaryngology evaluation report dated August 11, 2014 documented that the patient was 14 months post vocal cord injection and will require another injection to keep her condition from deteriorating. Otorhinolaryngology evaluation report dated October 3, 2014 documented that past cervical spine surgeries resulted in voice loss and difficulties swallowing certain foods. On June 4, 2013, a Radiesse Voice Gel injection to the right true vocal fold was administered. She subsequently showed the expected improvement. The

patient is approximately 16 months post injection, and its effects are beginning to fade. Pain management report dated August 20, 2014 documented that the patient has recurrent dysphonia and will require repeat right vocal cord injections for the paralysis, and documented the objective finding of dysphonia. Medical records documented evidence supporting the medical necessity of RADIESSE injection for right vocal cord paralysis, dysphonia, and dysphagia secondary to cervical surgery. Therefore, the request for 1 Radiesse Injection is medically necessary.