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November 3, 2016

Novitas Solutions
Medical Policy Department
Union Trust Building
Suite 600
501 Grant Street
Pittsburgh, PA 15219-4407

RE: Comments to draft LCD DL35130 – Vertebroplasty, Vertebral Augmentation (Kyphoplasty) Percutaneous

Dear Medical Director:

On behalf of the International Society for the Advancement of Spine Surgery (ISASS), I am writing to submit comments to draft LCD DL35130 - Vertebroplasty, Vertebral Augmentation (Kyphoplasty) Percutaneous.

ISASS is a global, scientific and educational society organized to provide an independent venue to discuss and address the issues involved with all aspects of basic and clinical science of motion preservation, stabilization, innovative technologies, MIS procedures, biologics and other fundamental topics to restore and improve motion and function of the spine.

Specifically, ISASS has concerns with three parts of the draft LCD:

1. ***Limitations*** – "*Neither vertebroplasty nor percutaneous vertebral augmentation is indicated for treatment of lesions of the sacrum or coccyx. Therefore, HCPCS codes 0200T and 0201T are non-covered services. Please refer to LCD L35094 Services That Are Not Reasonable and Necessary for additional information regarding Category III codes.*"

While we recognize that percutaneous sacral augmentation is reported using Category III (T) codes, which are typically non-covered services, there is precedent for Medicare coverage of these procedures. The Medicare Administrative Contractor (MAC), Cahaba, provides coverage for 0200T and 0201T, and First Coast Service Options reviews coverage for 0200T and 0201T on a case-by-case basis. ISASS supports coverage of 0200T and 0201T based on the literature (Attachment 1) and requests Novitas review the current literature on percutaneous sacroplasty and update the LCD accordingly.

2. ***Limitations*** – *"These procedures are not to be considered prophylactic for osteoporosis of the spine or for chronic back pain unrelated to acute or subacute compression fracture."*

There are select cases in which prophylactic use of percutaneous vertebroplasty for some osteoporotic vertebrae is clinically necessary to either improve, maintain or salvage fixation of spinal instrumentation by providing anterior/middle column support immediately adjacent to a fusion construct in an osteoporotic patient to avoid catastrophic failure from proximal junctional kyphosis (PJK) induced burst fracture. Percutaneous vertebroplasty should be covered these select cases. Currently, three MACs do not limit coverage of prophylactic use of percutaneous vertebroplasty for osteoporosis.

3. ***Utilization Guidelines*** – *"The use of this procedure in more than two vertebral levels is rarely justified. Should denials occur related to number of levels treated, documentation of the necessity for use in more than two levels should be maintained in the patient's medical record and made available to Medicare upon request."*

Novitas should not restrict coverage to treatment of vertebral fractures for more than two levels. Three level fracture involvement is not that rare. The following Level I studies have protocols with stated inclusion criteria of 1-3 vertebral compression fractures:

- Cancer Patient Fracture Evaluation (CAFE) - A Multicenter, Prospective, Randomized, Controlled Study to Compare Balloon Kyphoplasty to Non-surgical Fracture Management in the Treatment of Painful, Acute Vertebral Body Compression Fractures in Cancer Patients
    - In this trial, 35% of treated patients had one fracture, 26% of treated patients had two fractures and 38% of treated patients had 3 fractures.

- Kyphoplasty And Vertebroplasty In the Augmentation and Restoration of Vertebral Body Compression Fractures (KAVIAR) - A Multicenter, Randomized, Prospective Clinical Trial to Compare the Short- and Long-term Safety and Effectiveness of Balloon Kyphoplasty to Vertebroplasty in the Treatment of Painful, Acute Osteoporosis-related Vertebral Body Compression Fractures (VCFs)
    - In this trial, 78% of patients had one fracture, 17% had two fractures, and 4% had three fractures.

- Fracture Reduction Evaluation (FREE) - An International Multicentric, Multidisciplinary Prospective and Randomized Study to Compare Minimally Invasive Reduction and Fixation Using the KyphX System and Radiopaque PMMA Cement to Medical Therapy Alone for the Treatment of Painful, Acute Osteopenic Vertebral Body Compression Fractures
    - In this trial, 67% of patients had one fracture, 23% of patients had two fractures and 10% of patients had three fractures.

- Evaluation of Outcomes for Quality of Life and Activities of Daily Living for BKP in the Treatment of VCFs (EVOLVE) - A Prospective and Multicenter Evaluation of Outcomes for Quality of Life and Activities of Daily Living for Balloon Kyphoplasty in the Treatment of Vertebral Compression Fractures

- Investigational Vertebroplasty Efficacy and Safety Trial (INVEST) – A randomized controlled trial of percutaneous vertebroplasty
    - In this trial, 71% of treated patients had one fracture, 19% of treated patients had two fractures and 10% of treated patients had three fractures.

- Vertebroplasty versus conservative treatment in acute osteoporotic vertebral compression fractures (Vertos II): An open-label randomized trial
    - In this trial, patients had an average of 2.4 fractures.

- Clinical Evaluation of the Crosstrees Pod™ in the Treatment of Pathologic Fracture of the Vertebral Body (Levels T4 - L5) in Adult Patients (CROSSTREES)

Additionally, there is precedent for Medicare coverage of more than two vertebral levels. The MAC, Noridian Healthcare Solutions, makes a reasonable allowance for coverage of more than two vertebral levels in its LCD for Percutaneous Vertebral Augmentation (L24228), "*While treatment of only one to two levels would be anticipated, treatment of no more than three (3) vertebral levels within the range of T1-L5 may be covered and reimbursed during the entire episode of pain caused by or related to an acute compression fracture(s), regardless of the number of fractures. Hence, if more than three acute fractures are present, alternative therapies must be employed. Treatment of three levels may be subject to pre-or post-pay review*."

ISASS recommends Novitas review the current literature on the number of levels treated and update the LCD accordingly.

Thank you for your time and consideration of our comments. Please do not hesitate to contact Liz Vogt, Director of Health Policy & Advocacy by email at liz@isass.org or by phone at (630) 375-1432 with questions or requests for additional information. We look forward to establishing a continued partnership with Novitas, so together we can advocate for quality patient care and superior patient outcomes.

Sincerely,

Morgan P. Lorio, MD, FACS
Chair, Coding and Reimbursement Task Force
International Society for the Advancement of Spine Surgery

Attachment 1 – Sacroplasty Literature Review

The treatment of sacral fractures has occurred for over 30 years and has evolved since its first description in 1982 (1). Several techniques for sacral augmentation and sacral fracture treatment have been published. The first large study that was performed demonstrated that sacroplasty was a safe and effective treatment for painful sacral insufficiency fractures (SIFs). The rate of improvement is rapid with over 50% reduction in pain achieved prior to post-procedure discharge of the patient. Pain reduction occurs primarily within the first three months but is sustained at 12 months following the treatment (2). Sacral fractures are common, especially for high-risk groups such as those suffering from rheumatoid arthritis, diabetes, renal failure, or long-term corticosteroid use, all of which contribute to decreased osseous elasticity and demineralization. Recent literature has suggested that in these at-risk groups, insufficiency fracture prevalence is somewhere between 9.5% and 11.4% (3). Sacral fractures are also associated with a high rate of morbidity and mortality.

The sacroplasty procedure involves injecting stabilizing material (usually PMMA) into the cancellous portion of the sacrum at the S1 and S2 levels. These levels are the most commonly fractured portions of the sacrum and are also the largest sacral vertebral levels that provide the greatest amount of structural support. Sacroplasty is similar to a vertebroplasty procedure and may be performed under fluoroscopy, CT, or a combination of both modalities. Sacroplasty was first reported in 2001 with the treatment of symptomatic metastatic sacral lesions (4, 5) and subsequent contributions to the literature have documented its safety and efficacy (6, 7).

In 2007, a prospective multi-center study assessing the safety and effectiveness of sacroplasty was published by Frey, DePalma et al., which better outlined the clinical utility of sacroplasty in the treatment of osteoporotic SIFs along with accurately categorizing the incidence of procedural complications (2). The authors reported a mean patient age of 76.6 years and stipulated that patients must have tried and failed non-surgical management (NSM). The mean baseline VAS was 7.7, which decreased to 3.2 immediately following the procedure, and was 0.7 at one year. There were no persistent complications resulting from the procedure and the patients' opioid use dropped substantially.

In 2008, Frey, DePalma et al. published another study with similar outcomes of patients treated with percutaneous sacroplasty. This manuscript reported that greater than 75% of the patients had their pain decreased by more than half within 30 minutes following the procedure (8). The authors also reported follow-up information from some of their former patients.

In 2009, a meta-analysis by E Bailey, et al. on sacroplasty literature between 2002 and 2008 was published, including a total of 15 publications (9). The criteria for inclusion in this study were manuscripts published in the English language evaluating osteoporotic SIFs. Analysis of the literature included information regarding patient numbers, surgical technique, and procedural outcomes. Cumulatively, the 15 studies amounted to data on 108 patients, with the largest single study including 52 patients. The average patient age was 75.5 years and had a minimum follow up time of 2.5 months and a mean follow up time of 9.1 months. While Gjertsen et al. suggested that infection, pulmonary emboli, and nerve damage are all potential complications of sacroplasty (10), no patients experienced these complications.

In a search of more recent sacroplasty literature (published between 2009 and 2016), a total of 488 patients were included in the ten publications identified. Four of the ten studies had follow ups of up to one year, including data for 236 patients (11, 12, 13, 14). Shorter follow-ups were conducted for 182 patients. In the remaining 70 patients, either no follow-ups were conducted or no data was recorded at the follow-ups. Talmadge et al. followed their 18 patients through 48 weeks (15). Gupta et al. followed 53 patients at an average of 27 +/- 3.7 days (16). Dougherty et al. conducted follow ups at a median of 2.5 weeks for 45 of the total 57 patients (17). Pereria et al. conducted, on the average, a one-month follow up for all of the 58 patients (18). Kang & Lee et al. were able to follow all of their eight patients in the short term, which they defined as "less than 1 month", and five of their patients for longer, which they defined as "more than 1 month" (19). Lastly, Hassan, Naderi et al., Cho et al., and Trouvin et al. failed to include any information on their follow-ups (20, 21, 22, 23).

With regard to pain relief, seven of the ten publications used VAS scores to measure pain relief. Studies by Kortman et al., Eichler et al., Pereira et al., Hassan, and Naderi et al. examined VAS scores from cohorts ranging between 3 and 243 patients. The decreases in short-term mean VAS scores for these studies ranged from 61.7% to 75.27% (11, 12, 18, 20, 21). Gupta et al. compiled VAS scores for only 27 of 53 patients, with a mean decrease of 67.67% in those 27 patients' scores (16). Kamel et al. had a lower level of mean pain relief, finding only a 50% post-op pain decrease in their 19 patients. However, this moderate decrease in pain improved to 80% over the course of a year (14). The Eichler et al. study also suggests that pain relief increases as time elapses, finding that a mean VAS decrease of 61.7% post-procedure increased to 74.1% over the course of a year (12). While Kang & Lee et al. and Kang & Kim et al. did not note VAS scores, they found that cumulatively, seven of their nine total patients (77.78%) experienced significant pain relief postoperatively (19).

Another factor analyzed when considering the clinical outcome of sacroplasty is patient mobility. Gupta et al. used the Functional Mobility Scale (FMS) to determine procedural effect on mobility and ambulation. The average pre-procedure score of 3.0 (2.0 – 3.0) fell to 1.0 (0.25 – 2.8) ($p<.001$) (16). Talmadge et al. utilized the Clinical Mobility Scale (CMS) to shed light on the effectiveness of sacroplasty on mobility. They reported that mean CMS scores significantly improved over the course of 48 weeks, indicating that patient mobility scores continue to improve even beyond four weeks post-procedure (15). While exact score measurements were not specified, other studies noted that their patients experienced improved mobility and/or ability to ambulate (14, 18, 19, 20).

The final factor used to determine clinical outcomes for sacral augmentation was effect on analgesic use. Kamel et al., Gupta et al., and Pereira et al. all noted significant reductions in analgesic and opioid use (14, 16, 18). Kortman et al. suggested that their patients exhibited a decrease in analgesic use as well, but provided no statistical analysis of this decrease (11).

In an effort to expand the body of literature on the long-term effects of sacroplasty, Beall et al. recently completed 10-year prospective study of patients with SIF's treated with sacral augmentation and review of the literature on the treatment of sacral fractures. The first procedure was performed in January of 2004 and subsequently all patients were observed over the course of their treatment. The results and those reported in previous studies establish that

sacroplasty allows for decreased use of medications, and results in pain relief, greater patient mobility and improved patient satisfaction. In addition to the published body of literature, these results show strong evidence in support of sacroplasty as a safe and efficacious treatment of sacral insufficiency fractures. SIFs are indeed a source of significant pain and discomfort for patients, and though several treatment options exist (NSM, surgery, as well as sacroplasty), this study finds that sacroplasty is a viable and durable option for treating patients with persistently painful SIF's.

The Visual Analog Scale (VAS) was analyzed in the experimental and control groups (210 participants and 34 participants, respectively) in the post-procedure follow-up visits and in a 10-years post-procedure follow-up. According to the Wilcoxon Rank Sum Test, the difference between the pre-treatment VAS averages for the experimental (8.29) and control (7.47) groups was not statistically significant. The experimental group's average pre-procedure VAS of 8.29 dropped to 3.63 post-procedure, (a 56.2% decrease). The control group, however, achieved a 27.2% decrease after two weeks. A two-year follow-up showed a 92% decrease in pain in the experimental group and an 85% decrease for the control group. Patients followed from two to ten years exhibited a drop in pain from 92% to 94% as compared with their pre-procedure pain level. While the decreases in pain from year one to year two, and year two to year ten were found to be statistically insignificant, they were significant relative to all other time points and demonstrate that the pain relief produced by sacroplasty is not only significant, but is maintained up to a decade after the procedure. Experimental group results demonstrate a greater decrease in VAS scores as compared to the control group, indicating lower pain levels and higher positive affect following sacroplasty treatment.

Pain reduction is substantial in patients treated with sacroplasty and is consistently reported in the sacroplasty literature. This study demonstrated the control group's only significant decrease in mean VAS was between pre-treatment and 2 weeks ($p=0.002$), whereas the experimental group had significant decreases over the periods pre-op through post-op ($p<0.001$), post-op through 2 weeks ($p<0.001$), 12 weeks through 24 weeks ($p=0.014$), and 24 weeks through one year ($p=0.002$). Not only was the overall pain relief greater in magnitude for the experimental cohort, but patients also experienced statistically significant drops in mean VAS scores between follow ups for a longer period of time. Despite the significant reduction in patient pain in the control group out to year two, the difference between patient satisfaction was statistically significant between the sacroplasty and control groups at this point in time ($p<0.001$).

In conclusion, the sacroplasty literature strongly indicates the safety and efficacy of this procedure in treating patients with sacral insufficiency fractures. The long-term study by Beall et al. of patients treated with sacroplasty supports previously reported data that shows statistically significant reduction of pain and analgesic use and demonstrates that these results are durable for up to at least ten years. Compared to a control group, the degree of pain relief for sacroplasty patients was greater and they had statistically significant decreases in pain scores at more time intervals for a longer time than did the patients in the NSM group. Unfortunately, due to the fragility of this patient population, morbidity and mortality related to the SIF's are common and based on the vertebral augmentation literature; this can be mitigated with the use of osseous augmentation. These results in addition to the published body of

literature show strong evidence in support of sacroplasty as a safe and efficacious treatment of sacral insufficiency fractures and worthy of coverage.

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