



BENCHMARK MEDICAL
BETTER HEALTHCARE THROUGH BETTER DATA

Vertebral Compression Fracture Registry

Services to meet Noridian Administrative Service,
LLC Local Coverage Determination #L32032



Services Summary

Vertebral compression fracture (VCF), the collapse of the spinal bones most often related to osteoporosis, occurs in over 700,000 Americans each year. VCFs often cause debilitating pain and are commonly treated with narcotics, analgesics, rehabilitation, and sometimes interventional procedures such as cement augmentation (e.g. kyphoplasty, vertebroplasty, and other approaches). There has been much debate about the effectiveness of these interventions and as a result, in 2012 Noridian Administrative Services, LLC (NAS), the Medicare administrator for Jurisdiction F (covering 10 Western states) and Minnesota, issued a local coverage decision (LCD). This LCD requires detailed information about pre-procedure management, intra-operative details, and long term, post-operative functional outcomes as a condition of payment for patients undergoing VCF procedures.

The LCD for Vertebroplasty, Vertebral Augmentation; Percutaneous (L32032) with an effective date of 2/27/2012 states that:

- *All the documentation requirements described in the Indications section of the LCD must be met.*
- *Documentation must validate the medical reasonableness and necessity of the procedure.*
- *Documentation must be made available to NAS upon request. Lack of appropriate documentation will result in non-coverage of this procedure.*
- *When the documentation does not meet the criteria for the service rendered or the documentation does not establish the medical necessity for the services, such services will be denied as not reasonable and necessary under Section 1862(a)(1) of the Social Security Act.*

REGISTRY SERVICES

To support clinicians and clinical centers involved in the interventional management of VCFs, BenchMarket Medical worked with NAS to create a simplified approach for providers to submit patient and procedure information to meet LCD requirements. The BenchMarket Medical VCF Registry checklists each of the LCD requirements to make data submission easy. The VCF Registry is coupled with a state-of-the-art patient survey center to collect important post-operative functional outcomes after VCF procedures. Participation in the registry and completion of all the data elements is a pathway to reimbursement.

“Noridian supports the use of the BenchMarket registry for establishing the required follow-up and as a primary means for reporting outcomes.”

**Bernice Hecker, MD, MHA, FACC
Medicare Contractor Medical Director
Noridian Administrative Services, LLC**

HOW IT WORKS

At the patient pre-operative appointment, clinicians or staff collect baseline functional outcomes and patient preferences for post-discharge survey contacts by following instructions provided in the BenchMarket Medical VCF patient packet. On the day of the VCF procedure, clinicians or staff enter this information along with clinical and procedural data into the web-based, HIPAA-compliant, and secure VCF Registry database. BenchMarket Medical will enroll the patient into a survey protocol initiating post-discharge data collection at three time points after the procedure, per LCD requirements: 7, 30, and 90 days. At these time points, the survey center will attempt to contact the patient to assess functional status, pain, and report of any readmissions to an acute care hospital. Follow-up information received from the patient will be entered into the VCF Registry and linked to the initial patient clinical and procedural data. BenchMarket Medical will submit both the initial patient clinical and procedural data along with all post-discharge data to NAS on behalf of the facility. If patient contact is not completed, a report of “attempts to contact” will be delivered to NAS. NAS has agreed that completing 4 attempts to contact, even if the patient does not respond, will meet LCD requirements.

The BenchMarket VCF registry includes an additional and optional time point for tracking functional outcomes at 12 months. The LCD requires that at the 12 month follow-up the provider ...*“must document that reasonable follow-up of the patient is arranged for by the operating provider for at least one year... The name and contact information of the following provider must be present in the patient’s medical record”*. This data point is provided for in the registry.

NAS also has stated that, “We wanted one year follow-up but needed to compromise with our providers –for payment and review purposes...our decision to continue coverage would be easier to make if we had one year follow-up.”

BenchMarket has added the provision for including 12 month functional outcomes for those hospitals or clinicians who would like to provide this data to NAS.

Healthcare providers and facilities will have 24-hour online access to patient records and reports about their own patients entered into the VCF Registry to facilitate internal data review or quality improvement activities.

BENEFIT TO PROVIDERS

The LCD requires that over 20 specific conditions are met and that specific documentation is made available to NAS as a condition of reimbursement. Included within the conditions are pre-procedure and post-procedure patient reported functional outcomes. By working directly with NAS in the development of the registry, the BenchMarket Medical VCF Registry provides a structured, easy-to-use format for medical providers to accurately submit required information and a solution to capturing patient report of outcomes. BenchMarket Medical offers medical providers with an approved and standardized approach to collecting these patient reports – including offering medical providers instructions and materials for collecting patient functional outcomes prior to procedure as required by the LCD. Moreover, capturing

post-discharge functional outcomes is both burdensome and expensive for individual providers; BenchMarket Medical offers an inexpensive, convenient method to systematically contact patients on schedule with LCD requirements. As an added benefit, BenchMarket Medical returns to providers their own patient data so clinicians and staff can track patient care and drive local quality improvement activities.

HOW THE VCF REGISTRY MEETS THE LCD REQUIREMENTS

The table below maps the LCD requirements to the VCF Registry:

LCD Requirement	BenchMarket VCF Registry Data Point
Coverage for any procedure limited to no more than 3 vertebral level; Payable levels are T5-L5 (L4/L5, not L5/S1).	16
Will not allow payment on procedures performed immediately following acute compression fractures or diagnosis of them; Will not pay for procedures performed in ER or immediately following presentation to ER.	12, 13, 14, 15
Non-specific documentation of “lower back pain” or similar language will not support payment; Documented comprehensive pain evaluation and examination; Any patient currently significantly symptomatic from other spinal pathology requires treatment prior.	12, 13, 14, 15
Medical Record Documentation, clearly noted and documented: Medical record documentation support that the procedure is conducted in accordance with the clinical and procedural criteria established in the literature produced in recent years.	20, 21
One or more vertebral compression fractures are present, confirmed by x-ray or MRI; Clearly demonstrated vertebral compression fracture.	16, 18, 20
Patient’s pain is related to the demonstrated fracture.	20
Medical record must contain a detailed operative procedure narrative report. Boilerplate or other non-specific report will not meet requirement. <i>A descriptive, non-“boilerplate” Operative Report is still required in medical record.</i>	21
Document patient is neurologically intact relative to the vertebral levels of proposed treatment.	19

LCD Requirement	BenchMarket VCF Registry Data Point
<p>H&P must be present in the medical record; Complete assessment of the patient by the provider who performs procedure is an absolute requirement (or provider group with interval assessment by the proceduralist).</p> <p><i>A descriptive, History & Physical is still required in medical record.</i></p>	21
<p>Age of fracture must be less than four months (if age of fracture is not clearly documented; MRI may be useful if vertebral augmentation is considered).</p>	15
<p>Severity of pain.</p>	10 <i>Numeric Rating Scale for Pain</i>
<p>Non-invasive pain interventions applied for reasonable time period; If prolonging treatment pending response to medical management is not an option, it must be documented in the rationale. Example: adequate pain control impairs basic ADLs or is associated with respiratory compromise. <i>Must be clearly documented in medical record.</i></p>	10, 11, 13
<p>Must begin with least invasive approaches (options: bed rest, bracing, local or systemic analgesics – narcotic or non-narcotic); Includes appropriate dosage of appropriate analgesic medication.</p>	10, 11, 13, 14, 15
<p>Interference to activities of daily life (ADLs) is documented.</p>	11 & 13 <i>Roland Morris Disability Questionnaire</i>
<p>Procedure must be performed with CT or fluoroscopy (real-time imaging); Must retain images of final trocar placement; Must retain images of vertebral body at end of procedure. <i>Must keep copies of images in medical record.</i></p>	28
<p>Follow-up of patient is arranged for by the operating provider for at least one year if operating provider is not anticipating personally providing this follow-up. Name and contact information of the following provider must be present in the patient's medical record; telephone follow-up with documentation of outcomes is acceptable; must contain patient comfort/activity/pain scores at each follow-up.</p>	34-49



How to Get Started

ONE-TIME REGISTRATION FEE

Administrative enrollment per facility **\$1,000**
Includes the first five patients enrolled

PATIENT ENROLLMENT FEE

Not including 12 month PRO **\$125 per patient**
Patient enrollment includes facility access to submit cases
and post-discharge follow-up by patient survey

Including 12 month PRO **\$150 per patient**

PAYMENT FOR SERVICES

Registration fee is due upon contract execution and includes enrollment of the first 5 patients. Thereafter, hospitals will be billed on a quarterly basis for each patient enrolled into the registry. Interested providers and facilities must sign a VCF Registry services agreement and also enter into a Business Associate Agreement with BenchMarket Medical. Visit the BenchMarket Medical website to download these documents and access the User Registration Form, or email us at vcfregistry@benchmarkmedical.com.



The BenchMarket Story

BETTER HEALTHCARE THROUGH BETTER DATA

Today's hospitals need more than great clinicians and great facilities. They need great data, with clear insight on how to use that data to drive change. BenchMarket Medical has developed a new way for healthcare organizations to build a successful, data-driven future.

Founded by a proven IT innovator and practicing clinicians who are recognized experts in outcomes research, BenchMarket has created a proprietary platform to extract and analyze data from across clinical care information systems.

BenchMarket's combination of technical savvy and clinical expertise helps hospitals and clinicians actively address real-world issues such as assessing the efficacy of surgical procedures, post-operative infection rates, readmissions, and length of stay.

In addition to meeting payer interests through its registries, BenchMarket harnesses hospital data to measure meaningful clinical process of care and outcome measures from established quality improvement programs. This gives hospital administrators and clinicians actionable guidance they can reliably use to improve quality, reduce variation in care, control costs, and much more.

BenchMarket's performance dashboards analyze costs and outcomes and provide information that is customized for clinicians and hospitals. BenchMarket data leads to productive conversations between clinicians and administrators about resource use because it links quality-of-care measures to resource expenditures.

BenchMarket drives efficiency while optimizing quality.
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