



**SANDHILLS
CENTER**



Rib fixation

Clinical Policy ID: CCP.1395

Recent review date: 9/2021

Next review date: 1/2023

Policy contains: Flail chest; open reduction and internal fixation of the ribs; rib fixation.

This policy is a Sandhills Center Clinical Coverage Policy adopted from AmeriHealth Caritas of North Carolina. These clinical policies are used to assist with making coverage determinations. Sandhills Center's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Sandhills Center when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Sandhills Center clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Sandhills Center's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Sandhills Center will update its clinical policies as necessary. Sandhills Center clinical policies are not guarantees of payment.

Coverage policy

Internal rib fixation (also called open reduction and internal fixation or surgical stabilization of the ribs) (CPT codes 21811 - 21813) is clinically proven and, therefore, medically necessary for the treatment of flail chest injury in members who are skeletally mature and either (Kasotakis, 2017; Pieracci, 2017):

- Fail to wean from a ventilator due to mechanical instability or pain.
- Require thoracotomy for additional thoracic procedures.
- Have chronic impaired pulmonary mechanics at least three to six months following a non-union associated with multiple (at least three), severe (bi-cortical) displaced fractures.
- Have chronic, disabling pain refractory to medical management at least three to six months following a non-union.

Note: Flail chest is defined as fracture of three or more sequential ribs at multiple sites, resulting in paradoxical chest wall movement (Kasotakis, 2017).

Limitations

Other indications, including non-flail chest injury, are not medically necessary due to insufficient empirical research (Choi, 2021; Kasotakis, 2017; Wijffels, 2020).

Rib fixation surgery is generally medically necessary for repair of ribs 3 to 10, because ribs 1, 2, 11, and 12 are not considered major contributors to chest wall stability and pulmonary mechanics and they are technically

challenging to access. In select cases, repair of ribs 1, 2, 11, and 12 may be medically necessary for marked displacement, vascular impingement, or localized refractory pain (Pieracci, 2017).

Contraindications to rib fixation generally include (Cataneo, 2015; Kasotakis, 2017; Pieracci, 2017; Schuurmans, 2017; Swart, 2017):

- Severe pulmonary contusion.
- Severe traumatic brain injury (e.g., Glasgow coma scale < 10).
- Spinal injury that precludes lateral decubitus positioning.
- Open rib fractures with soiling or infection.
- Anatomic location of rib fractures not amenable to surgical fixation.
- Myocardial contusion.
- Other injuries that could be adversely affected by general anesthesia.

Chest computed tomography is medically necessary for members being considered for rib fixation; however, routine three-dimensional reconstruction of chest computed tomography is not medically necessary (Pieracci, 2017).

For Medicare members only

Internal fixation (CPT 21812 and 21813) is medically necessary to stabilize and provide fixation for fractures, fusions, and osteotomies of the ribs. In most instances, internal fixation of fractures involving one to three ribs (CPT 21811) is not required and is not considered reasonable and necessary (Centers for Medicare & Medicaid Services, 2018).

Alternative covered services

- Trauma/intensive care.
- Standard medical management (e.g., pain control, pulmonary hygiene, positive pressure ventilation).

Background

Rib fractures are common in patients with blunt chest trauma, and for the vast majority, the treatment of choice is medical management, consisting of respiratory assistance and pain control (Mitchell, 2017). Patients with substantial chest wall trauma, particularly involving a flail chest pattern, often face considerable morbidity and mortality. Among survivors, chronic chest wall pain, deformity, longstanding disability, and poor quality of life are common.

For more than 40 years, surgical stabilization of rib fractures (rib fixation) has been performed with the goal of restoring the mechanical integrity of the chest wall (Bottlang, 2010). Early surgical approaches used metal plates, bio-absorbable plates, intramedullary hardware, and suturing and bridging techniques, and achieved mixed results. Several techniques are now obsolete, and, in many cases, rib fixation continues to require open thoracotomy with considerable surgical insult (Bemelman, 2016).

The physical and anatomical properties of the rib cage lend complexity, the potential for persistent complications, and limitations to rib fixation. Less-invasive posterolateral approaches, muscle-sparing techniques, improved hardware, and video-assisted thoracic surgery may improve procedural morbidity (Bottlang, 2010). In the United States, surgical expertise in rib fixation techniques is generally confined to levels I and II trauma centers (Witt, 2017). Various surgeons (trauma, orthopedic, thoracic) may perform the procedure, but there is no consensus on the indications, technique, or timing (Mayberry, 2009).

The U.S. Food and Drug Administration (2018) issued 510(k) market approval to several bone fixation appliances designed for rib fixation. These devices are classified as class II prosthetic, orthopedic single or multiple component metallic bone fixation appliances and accessories (21CFR888.3030). Predicate devices are indicated for use in patients who are skeletally mature with normal or osteoporotic bone for chest wall fixation.

Findings

For this policy, we included one Cochrane review (Cataneo, 2015), one recent systematic review (Schuurmans, 2017), one meta-analysis with a cost-effectiveness analysis (Swart, 2017), and two evidence-based guidelines (Kasotakis, 2017; Pieracci, 2017). The benefits of rib fixation have been best described in low-quality evidence from three small, randomized controlled trials, which compared rib fixation to non-operative management, and several cohort studies of persons with flail chest (generally confined to ribs 3 through 10) during the acute injury stage (Cataneo, 2015; Kasotakis, 2017; Schuurmans, 2017). Rib fixation had positive effects on pain, duration of mechanical ventilation, incidence of pneumonia, likelihood of tracheostomy, and lengths of stay in both the intensive care unit and hospital. There is insufficient evidence to recommend any one particular technique, approach, or appliance over another.

Patients enrolled in the randomized controlled trials were age 18 or older, ventilator-dependent, and either unable to wean by post-injury day 5 or had no prospect of weaning after 48 hours (Granetzny, 2005; Marasco, 2013; Tanaka, 2002). Surgery took place early after the injury (e.g., within 24 to 72 hours), thereby avoiding inflammation, severe hematoma, and early callous formation that can complicate operative outcomes. Surgery targeted ribs 3 to 10 because ribs 1, 2, 11, and 12 were not considered major contributors to chest wall stability and pulmonary mechanics, and they were technically challenging to access.

Criteria for selecting patients who are most likely to benefit from the surgery in addition to the study inclusion criteria have not been established, but exclusion criteria from the randomized controlled trials provide some additional insight (Granetzny, 2005; Marasco, 2013; Tanaka, 2002):

- Fewer than three adjacent rib fractures.
- Severe pulmonary contusion.
- Anatomic location of rib fractures not amenable to surgical fixation (e.g., fractures directly adjacent to spinal column).
- Injuries that would likely prolong tracheal intubation and mechanical ventilation (e.g., moderate-to-severe traumatic brain injury [Glasgow coma score < 10]).
- Spinal cord injury precluding lateral decubitus positioning.

Both guidelines acknowledge that the clinical indications are expanding despite a lack of supportive evidence (Kasotakis, 2017; Pieracci, 2017). An international colloquium of surgeons with expertise in the procedure identified additional indications based on expert opinion or very-low-quality evidence (Pieracci, 2017):

- Anticipated chronic pain or impaired pulmonary mechanics associated with multiple (at least three), severe (bi-cortical) displaced fractures.
- Acute respiratory failure attributable to fractures (irrespective of radiographic fracture pattern) and refractory to medical management.
- Chronic non-unions for persistent, disabling pain refractory to medical management.
- In select cases, repair of ribs 1, 2, 11, and 12 for marked displacement, vascular impingement, or localized refractory pain.
- Additional thoracic procedures when thoracotomy is required.

For now, evidence-based indications remain confined to the most severely injured patients with flail chest. The benefit of surgical rib fixation to a non-flail chest injury or non-trauma conditions (e.g., congenital rib deformity) is not supported by available, empirical research.

Policy updates

In 2019, we identified no newly published, relevant literature to add to the policy.

In 2020, we added two systematic reviews to the policy (Beks, 2019; Peek, 2020). The synthesized results from randomized controlled trials and observational studies included in these reviews confirm prior findings that rib fixation is a safe procedure with a relatively low complication risk and results in improved short-term mortality outcomes, inpatient stays, and long-term outcomes. No policy changes are warranted.

In 2021, we added two systematic reviews and meta-analyses comparing surgical and nonoperative treatment for rib fractures with primarily flail chest injuries (Long, 2020) and nonflail chest injuries (Wijffels, 2020), and we added one cost-effectiveness analysis of surgical stabilization of rib fractures by flail chest status and age groups (Choi, 2021). The new information continues to support a beneficial but still controversial role for rib fixation procedures for treating select patients with flail chest injury in terms of faster recovery, lower risk of complications, and overall prognosis. More robust data are needed to confirm the effectiveness and cost-effectiveness of rib fixation procedures for nonflail chest injuries. No policy changes are warranted.

References

On June 25, 2021, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “rib fracture surgery,” “rib fixation,” “operative reduction and internal fixation,” “ORIF,” “Thoracic Injuries/surgery” (MeSH), “Fracture Fixation” (MeSH), and “Rib Fractures/surgery” (MeSH). We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

21CFR888.3030.

Beks RB, Peek J, de Jong MB, et al. Fixation of flail chest or multiple rib fractures: Current evidence and how to proceed. A systematic review and meta-analysis. *Eur J Trauma Emerg Surg.* 2019;45(4):631-644. Doi: 10.1007/s00068-018-1020-x.

Bemelman M, van Baal M, Yuan JZ, Leenen L. The role of minimally invasive plate osteosynthesis in rib fixation: A review. *Korean J Thorac Cardiovasc Surg.* 2016;49(1):1-8. Doi: 10.5090/kjtcs.2016.49.1.1.

Bottlang M, Walleser S, Noll M, et al. Biomechanical rationale and evaluation of an implant system for rib fracture fixation. *Eur J Trauma Emerg Surg.* 2010;36(5):417-426. Doi: 10.1007/s00068-010-0047-4.

Cataneo AJ, Cataneo DC, de Oliveira FH, et al. Surgical versus nonsurgical interventions for flail chest. *Cochrane Database Syst Rev.* 2015;(7):Cd009919. Doi: 10.1002/14651858.CD009919.pub2.

Centers for Medicare & Medicaid Services. Local Coverage Article. A53931 Fracture of ribs with internal fixation. <https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleid=53931&ver=5&bc=CAAAAAAAAAAAAA>. Effective February 26, 2018.

Choi J, Mulaney B, Laohavinij W, et al. Nationwide cost-effectiveness analysis of surgical stabilization of rib fractures by flail chest status and age groups. *J Trauma Acute Care Surg.* 2021;90(3):451-458. Doi: 10.1097/ta.0000000000003021.

- Granetzny A, Abd El-Aal M, Emam E, Shalaby A, Boseila A. Surgical versus conservative treatment of flail chest. Evaluation of the pulmonary status. *Interact Cardiovasc Thorac Surg*. 2005;4(6):583-587. Doi: 10.1510/icvts.2005.111807.
- Kasotakis G, Hasenboehler EA, Streib EW, et al. Operative fixation of rib fractures after blunt trauma: A practice management guideline from the Eastern Association for the Surgery of Trauma. *J Trauma Acute Care Surg*. 2017;82(3):618-626. Doi: 10.1097/ta.0000000000001350.
- Long R, Tian J, Wu S, et al. Clinical efficacy of surgical versus conservative treatment for multiple rib fractures: A meta-analysis of randomized controlled trials. *Int J Surg*. 2020;83:79-88. Doi: 10.1016/j.ijso.2020.09.010.
- Marasco SF, Davies AR, Cooper J, et al. Prospective randomized controlled trial of operative rib fixation in traumatic flail chest. *J Am Coll Surg*. 2013;216(5):924-932. Doi: 10.1016/j.jamcollsurg.2012.12.024.
- 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. *J Trauma*. 2009;66(3):875-879. Doi: 10.1097/TA.0b013e318190c3d3.
- Mitchell JD. Blunt chest trauma: is there a place for rib stabilization? *J Thorac Dis*. 2017;9(Suppl 3):S211-s217. Doi: 10.21037/jtd.2017.04.05.
- Peek J, Beks RB, Hietbrink F, et al. Complications and outcome after rib fracture fixation: A systematic review. *J Trauma Acute Care Surg*. 2020;89(2):411-418. Doi: 10.1097/ta.0000000000002716.
- Pieracci FM, Majercik S, Ali-Osman F, et al. Consensus statement: Surgical stabilization of rib fractures rib fracture colloquium clinical practice guidelines. *Injury*. 2017;48(2):307-321. Doi: 10.1016/j.injury.2016.11.026.
- Schuermans J, Goslings JC, Schepers T. Operative management versus non-operative management of rib fractures in flail chest injuries: a systematic review. *Eur J Trauma Emerg Surg*. 2017;43(2):163-168. Doi: 10.1007/s00068-016-0721-2.
- Swart E, Laratta J, Slobogean G, Mehta S. Operative treatment of rib fractures in flail chest injuries: A meta-analysis and cost-effectiveness analysis. *J Orthop Trauma*. 2017;31(2):64-70. Doi: 10.1097/bot.0000000000000750.
- 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; discussion 732.
<https://journals.lww.com/jtrauma/pages/articleviewer.aspx?year=2002&issue=04000&article=00020&type=abstract>.
- U.S. Food and Drug Administration. 510(k) Premarket Notification database searched using product codes HRS and HWC. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>.
- Wijffels MME, Prins JTH, Perpetua Alvino EJ, Van Lieshout EMM. Operative versus nonoperative treatment of multiple simple rib fractures: A systematic review and meta-analysis. *Injury*. 2020;51(11):2368-2378. Doi: 10.1016/j.injury.2020.07.009.
- Witt CE, Bulger EM. Comprehensive approach to the management of the patient with multiple rib fractures: A review and introduction of a bundled rib fracture management protocol. *Trauma Surg Acute Care Open*. 2017;2(1):e000064. Doi: 10.1136/tsaco-2016-000064.

Policy updates

7/2018: initial review date and clinical policy effective date: 9/2018

9/2019: Policy references updated.

9/2020: Policy references updated.

9/2021: Policy references updated.