

Subject:	Internal Rib Fixation Systems	Publish Date:	06/28/2024
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Description/Scope

This document addresses the treatment of rib fracture(s) using an open approach and an internal fixation system. Operative reduction and internal fixation with the use of simple pins, wires or plates, *without* use of specially designed internal rib fixation devices, is not addressed in this document.

Position Statement

Medically Necessary:

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Additional required information

- C. Submit the rationale used to preliminarily indicate the service is experimental/investigational**
 - 1. Include peer-reviewed journal articles in PDF format with links to the online articles**
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Internal Rib Fixation Systems

The use of an internal rib fixation system is considered **medically necessary** for the open treatment of flail chest in individuals dependent (require > 4 hours per day of positive pressure ventilation) on mechanical ventilation in the absence of other causes of ventilator dependency such as severe brain injury.

Investigational and Not Medically Necessary:

The use of an internal rib fixation system is considered **investigational and not medically necessary** for all other indications.

Rationale

Rib fractures are one of the most common injuries of the chest. Ribs usually fracture at the point of impact or where they are the weakest (at the posterior angle). Typically, the fifth through ninth ribs are affected. Simple rib fractures can be treated with analgesia and respiratory care (to prevent complications such as pneumonia or atelectasis). Complex rib fractures or multiple rib fractures may require a more aggressive treatment plan. Pain with inspiration and expiration, along with inability to properly inflate and deflate the lungs, may require mechanical ventilation to assist with respiratory effort. With multiple rib fractures, flail chest can occur, causing a paradoxical movement of the chest wall that may alter respiratory effort and hinder breathing.

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There are a small number of randomized clinical trials available evaluating the use of surgical fixation vs. non-surgical management for flail chest. Tanaka and colleagues (2002) reported on a randomized controlled trial of the management of individuals with a diagnosis of severe flail chest. Their study randomly assigned 37 individuals with flail chest and acute respiratory failure to either surgery or internal pneumatic stabilization at 5 days after injury. A total of 18 individuals underwent surgical fixation and 19 individuals had respiratory management of positive end expiratory pressure (PEEP) ventilation with spontaneous intermittent mandatory ventilation mode with pressure support ventilation until they reached extubation criteria. In the surgical group, 5/18 individuals had pneumonia, length of mechanical ventilation was 10.8 days, length of intensive care unit (ICU) stay was 16.5 days, and 3 individuals required tracheostomy. In the medical group, 17/19 individuals had pneumonia, length of mechanical ventilation was 18.3 days, length of ICU stay was 26.8 days, and 15 individuals required tracheostomy. While the study has limitations including a small group size, it found that surgical fixation was associated with decreased time in the ICU and decreased length of mechanical ventilation.

Another randomized controlled trial was conducted by Granetzny and colleagues (2005). This study involved 40 individuals prospectively assigned to either surgical treatment or non-surgical care (packing and strapping). The surgical intervention group had significantly better results in terms of mean days of mechanical ventilation (2 vs. 12, $p=0.001$), shorter ICU stay (15.6 days vs. 9.6 days, $p=0.001$), and mean hospital stay (23.00 days vs. 11.7 days, $p=0.001$). Additionally, at 2 months follow-up, individuals in the surgical group demonstrated significantly better

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pulmonary function test results, including % forced vital capacity (FVC) ($p=0.001$), total lung capacity (TLC) ($p=0.001$), and forced midexpiratory flow rate (FEF) 75 ($p=0.001$).

In a 2011 retrospective review, Althausen and colleagues reported on 22 participants with flail chest who received open reduction internal fixation compared to 28 matched controls. The surgical group had shorter ICU days when compared to the matched controls (7.59 days vs. 9.68 days), decreased days on the ventilator (4.14 days versus 9.68 days), shorter overall hospital length of stay (11.9 days versus 19 days), fewer tracheostomies (4.55% versus 39.29%), less pneumonia (4.55% versus 25%), and a decreased requirement for oxygen at home (4.55% versus 17.86%). In the surgical group, there were no reported cases of hardware failure, hardware prominence, wound infection or nonunion.

Marasco and others (2013) described a small randomized controlled trial involving 46 individuals with traumatic flail chest. Participants were assigned to receive surgical treatment ($n=22$) or standard of care with pulmonary support ($n=23$). While the two groups were not significantly different for most factors, the control group did undergo a higher number of orthopedic and other general surgical procedures. This, difference, however, was not statistically significant (74% vs. 48%; $p=0.07$). In a multivariate analysis of immediate post-operative outcomes, the control group had a higher rate on non-invasive ventilation ($p=0.01$), longer ICU stay ($p=0.03$), and higher rate of tracheostomy ($p=0.04$). At 3 months follow-up, 2 individuals in the operative group had persistent flail chest symptoms. This study identifies several significant benefits of surgical fixation for flail chest, including shorter ICU

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and non-invasive ventilation times and a lower tracheostomy rate. However, the small subject pool and single center design of this study limits generalization of these findings.

Bottlang and others (2013) reported results of a prospective single center case series study involving 19 individuals with flail chest. They report that mean duration of mechanical ventilation was 6.4 days (range 0-37 days). Epidural analgesia was used for 15 individuals with a mean duration of 6.6 days (range 2-18 days). The mean duration of ICU stay was 7.9 days (range 1-34 days), and mean duration of hospitalization was 18.4 days (range 4-68 days). Postoperative complications included pneumonia (n=6), atelectasis (n=2), and wound infection (n=1). Three- and 6-month follow-up were obtained from 16 (84.2%) and 15 (78.9%) participants, respectively. At 3 months, participants were reported to have a % FVC of 84% and a % forced expiratory volume (FEV1) of 77%. These measures improved to 85% and 79% at 6 months. Return to pre-injury activities was reported for 5 participants at 3 months and 7 participants at 6 months. At 6 months, there were no reported hardware failures or migration. Complete healing of treated ribs was noted as well.

In a 2015 retrospective analysis by Zhang and colleagues, 24 individuals received open fixation surgery of the fractured ribs for their flail chest compared to 15 individuals who received conservative treatment only. In the non-surgical group, 2 individuals died, but there was no significant difference in mortality. Those in the surgical group had a hospital stay of 38 days compared to 60 days for the non-surgical group. This study is limited by its small size, retrospective design, lack of post-discharge follow-up, and reporting of results from only one treating center.

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The authors conclude that additional larger, multicenter, prospective randomized controlled studies are required to determine the ideal management for flail chest and pulmonary contusion.

Slobogean and colleagues (2013) conducted a meta-analysis of studies comparing surgical fixation vs. non-operative management of flail chest. They identified 11 publications involving 753 individuals, but only 2 randomized controlled trials. They reported that surgical fixation resulted in better outcomes for all pooled analyses, including substantial decreases in ventilator days (mean 8 days; 95% confidence interval [CI], 5 to 10 days) and the odds of developing pneumonia (odds ratio [OR] 0.2; 95% CI, 0.11 to 0.32). Additional benefits included decreased ICU days (mean 5 days; 95% CI, 2 to 8 days), mortality (OR 0.31; 95% CI, 0.20 to 0.48), septicemia (OR 0.36; 95% CI, 0.19 to 0.71), tracheostomy (OR 0.06; 95% CI, 0.02 to 0.20), and chest deformity (OR 0.11; 95% CI, 0.02 to 0.60). All results were stable to basic sensitivity analysis. The authors noted that the results should be viewed in the context of the pooled studies, which were mostly retrospective in nature. The authors note that additional prospective randomized trials are still necessary.

Another meta-analysis by Leinicke and colleagues (2013) reported on nine studies which compared operative management to non-operative management in adults with flail chest. The outcomes included duration of mechanical ventilation, length of stay in the intensive care unit, length of stay in the hospital, mortality, pneumonia, and tracheostomy. While the studies overall showed reduction in the above mentioned outcomes, the surgical technique used varied among the studies and included the use of metal plates, absorbable plates, intramedullary fixation, Judet

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struts, and U-plates. Different surgical techniques may vary in terms of their safety and efficacy. Currently there is no standard approach to operative fixation for those individuals with flail chest. Further studies are necessary to help standardize other aspects of care that can also impact outcomes (for example, protocols which guide weaning from mechanical ventilation and sedation).

A 2017 meta-analysis by Swart and colleagues reported on 20 studies which compared nonoperative treatment to operative treatment for diagnosis of flail chest. The analysis concluded that operative management was associated with a decrease in mortality, pneumonia, and tracheostomy requirements when compared to non-operative management. They note the retrospective comparative nature of most studies used in the analysis is a major limitation.

In 2019 the results of two large retrospective nonrandomized controlled trials were published. The first (Beks, 2019a), involved 332 participants with flail chest or multiple rib fractures admitted to one of the two hospitals. One hospital treated all participants nonoperatively and the other hospital with rib fixation with the MatrixRIB® device. There were 92 participants with a flail chest, 37 (40%) undergoing rib fixation and 55 (60%) having non-operative treatment. The remaining 240 participants had multiple rib fractures, 28 (12%) underwent rib fixation and 212 (88%) had non-operative treatment. After propensity score matching for both groups, rib fixation was reported to not be associated with intensive care unit length of stay (for flail chest participants) or with hospital length of stay

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(for multiple rib fracture participants). Since the operative and non-operative study groups were cared for by different teams in different hospitals, it is possible that variations in care may have confounded the results.

A second study by the same group (Beks 2019b), involved 166 participants who underwent rib fixation with the MatrixRIB device, 66 with flail chest and 99 with multiple rib fractures with an Injury Severity Score (ISS) of 24 and 21, respectively. Overall, the most common complication reported by the authors was pneumonia (n=58, 35%). A sample of 103 participants (62%) were followed for an average of 3.9 years. For this population it was reported that 48% experienced implant-related irritation and 9 had implant removal. Significant variation in the treated injuries, method of rib fixation and duration of follow-up, as well as a significant loss of follow-up, all limit the strength of this study's conclusions.

Wu and colleagues (2020) published the results of a prospective nonrandomized trial involving 61 participants with multiple bicortical rib fractures with hemothorax caused by severe blunt chest trauma. All participants were ventilator dependent. A total of 21 participants agreed to treatment with the MatrixRIB device and 40 underwent standard non-operative care. The authors reported that the length of ventilator use and hospital stay were significantly shorter in the MatrixRIB group (p=0.002, p=0.011, respectively). There was significant overlap in the confidence limits for these variables. The rate of pneumonia was higher in the non-operative group (p=0.005). This study's lack of randomization reduces the strength of its findings. The use of individuals whose families refused consent for rib fixation as a control group raises concern over possible selection bias.

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Niziolek and colleagues (2022) hypothesized that implementation of a surgical stabilization of rib fracture program resulted in improved short-term outcomes for those individuals with severe chest wall injuries. The study compared outcomes of those who had surgical stabilization versus those with non-operative management. For those who underwent surgical stabilization, all were plated using an internal rib fixation system. There were 22 individuals who initially underwent surgical stabilization (the early surgical group). Using those 22 individuals, the authors used a propensity score match to define a non-operative cohort (n=36) which resulted in an approximate 1:1 match. There were 40% of individuals who had early surgical stabilization with requirement for mechanical ventilation compared to 47% of individuals who were treated non-operatively requiring mechanical ventilation. Of those who required mechanical ventilation, those who had early surgical stabilization had a median of 6 days on the ventilator compared to 16 days in the non-operative group. Over a 12-month period, the authors then recruited another 23 participants who received surgical stabilization. When these additional 23 surgical participants were included in the analysis versus the non-operative group, the risk for acute respiratory distress syndrome was 2% versus 14% respectively. The need for tracheostomy was also reduced for the surgical group compared to the non-operative group (9% versus 33%). There were three incidents of surgical site infections in the surgical group. Other complications including pulmonary, cardiac and infections, as well as readmissions were unchanged between the surgical and non-surgical groups.

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Previously, if rib fractures required surgical intervention, the most used method was a formal thoracotomy. The addition of intraoperative thoracoscopy and computed tomography have allowed for less invasive approaches with smaller incisions and muscle-sparing techniques.

While much of the current literature is limited to retrospective studies and small sample sizes, the preponderance of evidence shows benefits from internal rib fixation for individuals with flail chest. These benefits include decreased hospital days, decreased ICU days, and decreased days of mechanical ventilation.

The United States Food and Drug Administration has granted 510(k) clearance to several devices for the fixation and stabilization of rib fractures including those that use an open approach or those that use approaches other than open.

Background/Overview

The purpose of the ribs is to protect the internal organs such as the heart and lungs. The chest wall consists of 12 pairs of ribs. Ribs one to seven connect to both the sternum in the front (anteriorly) and the spine in the back (posteriorly). Ribs 8 to 10 attach to the costal cartilage anteriorly. The lowest two ribs are “floating” and do not connect anteriorly. The first three ribs are relatively protected by the scapula, clavicle, and soft tissue. The middle ribs (numbers 4 to 10) are the most vulnerable and susceptible to injury from blunt trauma. Direct trauma to the

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Medical Policy

Internal Rib Fixation Systems

chest wall causes most rib fractures. This can be blunt trauma such as a motor vehicle crash or penetrating trauma such as a gunshot.

Rib fractures can be associated with internal injury such as to the abdominal organs, aorta, spleen, liver or lungs. Rib fractures can be painful which can hinder breathing. Once significant accompanying injuries have been ruled out, the cornerstone of rib fracture management is pain control. Pain relief is essential to avoid complications such as pneumonia. Severe injuries can lead to mechanical ventilatory support to assist the individual in breathing.

Definitions

Atelectasis: A collapse of all or part of the lung.

Flail chest: Paradoxical movement of the chest wall, visible with respiration, caused by contiguous rib fractures (generally three or more ribs are fractured with two or more fractures in each rib).

Internal fixation device: A specialized device specifically designed and intended to be used for the repair of rib fractures. Simple pins, wires or plates are not considered devices for the purposes of this document.

Pneumonia: An infection of the lungs which can be caused by a virus or bacteria.

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Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT

	For the following codes when specified as a specialized internal fixation device:
21811	Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 1-3 ribs
21812	Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 4-6 ribs
21813	Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 7 or more ribs

ICD-10 Procedure

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OPH104Z-OPH144Z	Insertion of internal fixation device into 1 to 2 ribs [by approach; includes codes OPH104Z, OPH134Z, OPH144Z]
OPH204Z-OPH244Z	Insertion of internal fixation device into 3 or more ribs [by approach; includes codes OPH204Z, OPH234Z, OPH244Z]
OPS104Z-OPS144Z	Reposition 1 to 2 ribs with internal fixation device [by approach; includes codes OPS104Z, OPS134Z, OPS144Z]
OPS204Z-OPS244Z	Reposition 3 or more ribs with internal fixation device [by approach; includes codes OPS204Z, OPS234Z, OPS244Z]

ICD-10 Diagnosis

M96.A2	Fracture of one rib associated with chest compression and cardiopulmonary resuscitation
M96.A3	Multiple fractures of ribs associated with chest compression and cardiopulmonary resuscitation
M96.A4	Flail chest associated with chest compression and cardiopulmonary resuscitation
S22.31XA-S22.39XS	Fracture of one rib
S22.41XA-S22.49XS	Multiple fractures of ribs
S22.5XXA-S22.5XXS	Flail chest

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Internal Rib Fixation Systems

When services are Investigational and Not Medically Necessary:

For the procedure and diagnosis codes listed above when criteria are not met or for all other diagnoses not listed; or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

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Peer Reviewed Publications:

1. Althausen PL, Shannon S, Watts C, et al. Early surgical stabilization of flail chest with locked plate fixation. J Orthop Trauma. 2011; 25(11):641-648.
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Internal Rib Fixation Systems

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Government Agency, Medical Society, and Other Authoritative Publications:

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AdvantageRib
MatrixRIB Fixation System
RibFix Advantage™
RibFix Blu® Thoracic Fixation System
RibLoc System®
Rib fracture

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
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Reviewed	05/09/2024	MPTAC review. Revised Rationale and References sections.
Reviewed	05/11/2023	MPTAC review. Updated Rationale and References sections.
	09/28/2022	Updated Coding section with 10/01/2022 ICD-10-CM changes; added M96.A2, M96.A3, M96.A4.
Reviewed	05/12/2022	MPTAC review. Updated Rationale and References sections.
Reviewed	05/13/2021	MPTAC review. Updated References and Index sections.
Reviewed	05/14/2020	MPTAC review. Updated Description/Scope, Definitions, References and Index sections.
Revised	06/06/2019	MPTAC review. Clarified MN statement regarding open approach and dependency of mechanical ventilation. Updated Rationale, Background/Overview, Index, and References sections.
Revised	11/08/2018	MPTAC review. Added MN indications to include flail chest. Updated Rationale, Definitions, Coding and References sections.
Reviewed	07/26/2018	MPTAC review. Updated Rationale section.
Revised	11/02/2017	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Title change. Updated Description/Scope section.
	10/01/2017	Updated Coding section with 10/01/2017 ICD-10-PCS procedure code descriptor changes.
Reviewed	11/03/2016	MPTAC review. Updated Rationale and References sections.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

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The requirements below are specific to the Florida Medicaid Managed Care Plan and are not a part of the Medical Policy or Clinical UM guideline approved by Elevance Health's Medical Policy and Technology Assessment Committee.

If the Florida Medicaid Managed Care Plan intends to deny coverage on the basis that a diagnostic test, therapeutic procedure, or medical device or technology is experimental or investigational, the Managed Care Plan shall submit a request for coverage determination to the Agency in accordance with rule 59G-1.035, F.A.C and Core SMMC Contract, Attachment II, Section VI.G.4.d.

Below is a list of the materials the plans are required to submit when they deny coverage as experimental/investigational:

- A. Include the CPT or HCPCS code(s)
- B. Include a list of other state Medicaid agencies and private insurers who cover the service
- C. Include information about the health service from the U.S. Food and Drug Administration
- D. Include known risks of the service and health outcomes of others who have received it
- E. Include a list of covered alternative services, if any, that could be used to treat the condition
- F. Identify a specific recipient needing the service
- G. Include the recipient's health history
- H. Include the disease information necessitating the requested service
- I. Include a rationale for the immediacy of the review

Additional required information

- A. Submit the rationale used to preliminarily indicate the service is experimental/investigational
 1. Include peer-reviewed journal articles in PDF format with links to the online articles
 2. Include evidence-based clinical guidelines reviewed by the plan
- B. Submit direct contact information (name, phone number, & email address) for the Medical Director

Medical Policy

Internal Rib Fixation Systems

Reviewed	11/05/2015	MPTAC review. Updated Rationale and References sections. Removed ICD-9 codes from Coding section.
Reviewed	11/13/2014	MPTAC review. Updated Rationale and References. Updated Coding section with 01/01/2015 CPT changes; removed 0245T, 0246T, 0247T, 0248T deleted 12/31/2014.
Reviewed	11/14/2013	MPTAC review. Updated Rationale and References.
Reviewed	11/08/2012	MPTAC review. Updated Description/Scope, Rationale, Background/Overview, References and Index.
Reviewed	11/17/2011	MPTAC review. Updated Rationale and References.
	02/17/2011	Updated Rationale and References.
New	11/18/2010	MPTAC review. Initial document development.

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