Clinical Policy Title: Rib fixation

Clinical Policy Number: CCP.1395

Effective Date: September 1, 2018
Initial Review Date: July 3, 2018
Most Recent Review Date: August 1, 2018
Next Review Date: August 2019

Related policies:
None.

ABOUT THIS POLICY: AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas’ 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 AmeriHealth Caritas 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. AmeriHealth Caritas’ 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. AmeriHealth Caritas’ clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas’ clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas considers the use of internal rib fixation (also called open reduction and internal fixation or surgical stabilization of the ribs) (CPT codes 21811 – 21813) to be 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 (Kasotakis, 2017).

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 (Kasotakis, 2017; Pieracci, 2017; Schuurmans, 2017; Swart, 2017; Cataneo, 2015):

- 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:

AmeriHealth Caritas considers internal fixation (CPT 21812 and 21813) to be 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 (A53931, L36954).

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.

**Searches**

AmeriHealth Caritas searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services.

We conducted searches on May 22, 2018. Search terms were: “intramedullary rib fixation,” “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:
- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
• **Guidelines based on systematic reviews.**

• **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

For this policy, we included one Cochrane review (Cataneo, 2015), one recent systematic review (Schuirmans, 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. 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 (Marasco, 2013; Granetzny, 2005; 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 (Marasco, 2013; Granetzny, 2005; 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:**

None.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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| Kasotakis (2017) for the Eastern Association for the Surgery of Trauma Guideline: operative fixation of rib fractures after blunt trauma | **Key points:**  
- Available evidence consists of 19 retrospective studies and three poor-quality randomized controlled trials of adult patients with flail chest who underwent internal fixation. Overall quality of studies was low.  
- Despite the variability in surgical technique and conservative management options, surgical rib stabilization consistently demonstrated a positive effect across studies conducted in a variety of settings, regarding duration of mechanical ventilation, hospital length of stay, intensive care length of stay, incidence of pneumonia, and need for tracheostomy. The effect on mortality was greater in studies conducted before 2000.  
- They conditionally recommend rib open reduction and internal fixation for adults with flail chest injury.  
- They do not recommend internal fixation for pain control or any of the outcomes in patients with non-flail chest based on currently available data. |
| Pieracci (2017) Consensus statement: Surgical stabilization of rib fractures rib fracture colloquium clinical practice guidelines | **Key points:**  
- Levels of Evidence are adapted from the Oxford Centre for Evidence-based Medicine (1a – 5). Grades of recommendation adapted from the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system (A - D).  
- Consider surgical stabilization of rib fracture for:  
  - Flail chest (level 2b, grade B).  
  - Multiple, severe (bi-cortical) displaced fractures (level 4, grade C).  
  - Failure of early, optimal non-operative management, regardless of radiographic fracture pattern (level 5, grade D).  
  - Chronic non-unions for persistent disabling pain refractory to conservative |


In select cases, repair of ribs 1, 2, 11, and 12 for marked displacement, vascular impingement, or localized refractory pain.

- Pulmonary contusion and traumatic brain injury should not be considered absolute contraindications, but require evaluation on a case-by-case basis (level 5, grade D).
- Surgical stabilization of rib fracture is technically easier and preferred within 72 hours of injury.
- Patients considered for the procedure should undergo chest computed tomography (level 2C, grade B), but not routine three-dimensional reconstructions of chest computed tomography (level 2B, grade B).
- Whenever possible, muscle-sparring techniques should be used (level 5, grade D).
- There is insufficient evidence to recommend a percutaneous approach over any other approach (level 5, grade D).
- Thoracoscopic approaches should not be performed outside of the context of a research study (level 5, grade D).
- Rib fractures may be fixed using either plates or intra-medullary struts.

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<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>Schuurmans (2017)</td>
<td><strong>Key points:</strong></td>
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<td>Operative management versus non-operative management of rib fractures in flail chest injuries: a systematic review</td>
<td>- Systematic review of three randomized controlled trials (123 total adults patients) comparing operative management versus non-operative management of flail chest.</td>
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<td></td>
<td>- Overall quality: poor with high risk of bias, small number of patients included, different methodologies and differences in presentation of outcomes.</td>
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<td>- Evidence suggests a positive effect of surgical rib fracture fixation for pneumonia rate (effect size [ES] 0.5; 95% confidence interval [CI] 0.3 to 0.7), duration of mechanical ventilation (ES -6.5 days; 95% CI -11.9 to -1.2), duration of intensive care unit stay (ES -5.2 days; 95% CI -6.2 to -4.2), duration of hospital stay (ES -11.4 days; 95% CI -12.4 to -10.4), tracheotomy rate (ES 0.4; 95% CI 0.2 to 0.7), and treatment costs (saving $9,968 to $14,443 per patient).</td>
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<td>- No significant between-group difference in mortality rate (ES 0.6; 95% CI 0.1 to 2.4).</td>
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<td>Swart (2017)</td>
<td><strong>Key points:</strong></td>
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<td>- Operative treatment decreased mortality, pneumonia, and tracheotomy (risk ratios of 0.44, 0.59, and 0.52, respectively), as well as time in intensive care and total length of stay (3.3 and 4.8 days, respectively).</td>
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<td>- Operative fixation was associated with higher costs than non-operative treatment ($23,682 versus $8,629 per case, respectively) and superior outcomes (32.60 quality-adjusted life year [QALY] versus 30.84 QALY), giving it an incremental cost-effectiveness ratio of $8,577/QALY.</td>
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<td>Cataneo (2015)</td>
<td><strong>Key points:</strong></td>
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<tr>
<td>Cochrane review</td>
<td>- Systematic review of three randomized controlled trials (123 total patients) of surgical versus nonsurgical treatment for flail chest.</td>
</tr>
<tr>
<td>Surgical versus nonsurgical interventions for flail chest</td>
<td>- Overall quality: poor with high risk of bias and underpowered.</td>
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Inconclusive evidence of a difference in mortality between treatment groups (risk ratio [RR] 0.56; 95% CI 0.13 to 2.42). Six reported deaths were due to pneumonia, pulmonary embolism, mediastinitis, and septic shock.

Compared with nonsurgical treatment, surgery reduced the frequency of pneumonia (RR 0.36; 95% CI 0.15 to 0.85), chest deformity (RR 0.13; 95% CI 0.03 to 0.67), and tracheostomy (RR 0.38; 95% CI 0.14 to 1.02). Due to differences in reporting, duration of mechanical ventilation, length of intensive care unit stay, and length of hospital stay could not be combined, but results suggest improvement in these measures.

References

Professional society guidelines/other:


Peer-reviewed references:

21CFR888.3030.


**Centers for Medicare & Medicaid Services National Coverage Determinations:**

No National Coverage Determinations were identified as of the writing of this policy.

**Local Coverage Determinations:**

A53931 Fracture of Ribs with Internal Fixation.

L36954 Noncovered Services other than CPT® Category III Noncovered Services.

**Commonly submitted codes**
Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
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<tr>
<td>21812</td>
<td>Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 4-6 Ribs</td>
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<tr>
<td>21813</td>
<td>Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 7 or more Ribs</td>
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<tr>
<th>ICD-10 Code</th>
<th>Description</th>
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<tr>
<td>S22.5xx+</td>
<td>Flail chest</td>
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<tr>
<th>HCPCS Level II Code</th>
<th>Description</th>
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