

Anthem, Inc.
Medical Policy Questionnaire

July 27, 2018

Policy Number: SURG.00120

Policy Title: Internal Rib Fixation Systems

This questionnaire and draft policy as part of a clinical vetting process for Anthem, are Confidential and Proprietary. These documents are for use only by the organization and its physician members or physician faculty. Their contents should not be disclosed to any other parties without advanced written consent of Anthem.

Anthem, Inc. incorporates input from physicians practicing in relevant clinical areas along with other sources such as the peer-reviewed published medical literature, technology assessments, evidence-based consensus statements, and evidence-based guidelines from nationally recognized professional medical specialty societies as part of our process for developing and maintaining medical policies and clinical UM guidelines.

We are currently reviewing our medical policy on the topic of Internal Rib Fixation Systems. We are requesting your expert opinion regarding this topic and have developed a series of relevant questions presented in the table below.

- We are sending the draft policy and questionnaire for input regarding medical necessity of the use of an internal rib fixation system.

Your feedback and the feedback we receive from others on this topic may be shared with non-Anthem entities, including in instances where you are reviewing an Anthem vendor's guideline, the vendor. Your input will be considered as Anthem, Inc. formulates its medical policy positions, which affect the more than 40 million medical members enrolled in our plans.

Attached is the *draft version* of the medical policy.

We will carefully review your responses to the questions below and we welcome additional insights you provide on this topic. Please be sure to:

- **Answer all questions**
- **Complete the conflict of interest**
- **Complete the demographic information and release statement on the following page**
- **Provide peer-reviewed literature citations when you disagree with a policy position or recommend changes to criteria**

Thank you for supporting our process to maintain medical necessity determinations consistent with the principles of evidence-based medicine by providing your expertise, guidance and input.

Please complete the information on the following page.

Please return your comments to: Barbara Brown at Technology.Compendium@Anthem.com on or before August 24, 2018.

The following information is needed for this review.

Individual vs Society (or Committee) Response		Please check ONE of the following:		
Does this review reflect the opinion of the individual reviewer OR does this review represent the opinion of the Society (or a committee of the Society) as a whole?		<input type="checkbox"/> This review reflects the opinion of the individual reviewer OR <input checked="" type="checkbox"/> This review represents the opinion of the Society (or a committee of the Society) as a whole. <u>If a committee of the Society, please provide the name of the committee here:</u> CHEST WALL INJURY SOCIETY		
Reviewer Information				
Name		CHEST WALL INJURY SOCIETY, Fredric Pieracci, MD, MPH, FACS		
Board Certification in: <i>(Note: BC is required)</i>		General Surgery, Surgical Critical Care, General Preventive Medicine		
Academic/Hospital Affiliation(s):		Denver Health Medical Center		
Address:		777 Bannock Street, MC0206		
State(s) of Medical Licensure:		CO		
Phone:	303-436-4029			
Fax:	303-436-6572			
Date:	08/08/2018			
Conflict of Interest		Yes	No	Comments
Do you have now, or have you had previously, any commercial or research relationship (e.g., served as a consultant, advisor, speaker, or researcher) with any company (e.g., biotechnology, device, medical product, pharmaceutical) or program which provides or markets products associated with or related to the focus of this questionnaire (e.g., within the therapeutic category or general area)? - If yes, please disclose that relationship.		X		Members of the Chest Wall Injury Society Executive Committee and board of directors have served as consultants to DePuy Synthes, Zimmer Biolet, Acute Innovations, and KLS Martin, as well as received research support from these entities.
Your input will be shared with the applicable medical policy committee(s) when this topic is presented. Please indicate if Anthem, Inc. may release the following points of information to the committee(s) and non-Anthem entities, including in instances where you are reviewing an Anthem vendor's guideline, the vendor.				
		Yes	No	Comments
Name of your Academic/Hospital Affiliation(s)		X		Chest Wall Injury Society
Your Name		X		Fredric M. Pieracci

ACS

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Definitions of Medically Necessary and Investigational included in Exhibit I				
		Yes	No	Comments
General questions:				
1	Is the POLICY POSITION clear and supported by the medical evidence in the peer reviewed medical literature? If no, please comment.		X	The policy position is clear but unsupported by both the medical evidence cites, as well as additional medical evidence omitted from it. Please see attached response letter.
2	Is the RATIONALE section clear and does it accurately reflect the currently available medical evidence? If no, please comment.		X	Main issues with the rational section are 1) omission of several studies, 2) omission of outpatient and quality of life outcomes and 3) omission of cost-effectiveness data.
3	Is the DESCRIPTION section clear and accurate? If no, please comment.	X		
Specific questions regarding the Policy determination:				
4	<ul style="list-style-type: none"> The policy indicates the use of an internal rib fixation system is considered investigational and not medically necessary for all indications. <ul style="list-style-type: none"> Do you agree? 		X	Please see attached response letter
5	<ul style="list-style-type: none"> Do you consider internal rib fixation systems medically necessary for the treatment of flail chest? <ul style="list-style-type: none"> If yes, please comment on specific criteria (or conditions) which would be useful in selecting appropriate patient populations and cite literature to support. 	X		Please see attached response letter. Relevant variables include 1) radiographic diagnosis of flail chest 2) pulmonary derangements attributable to the flail chest 3) pain attributable to the flail chest and despite medical therapy and 4) the absence of contra-indications such as severe traumatic brain injury, severe pulmonary contusion, and persistent shock.
6	<ul style="list-style-type: none"> Do you consider internal rib fixation systems medically necessary for the treatment of non-union? <ul style="list-style-type: none"> If yes, please comment on specific criteria (or conditions) which would be useful in selecting appropriate patient populations and cite literature to support. 	X		Please see attached response letter. Relevant variables include 1) the diagnosis of non union by CT scan at least 3-6 after injury 2) pain attributable to the fracture and despite medical management and 3) thoughtful management of patient expectations.
7	<ul style="list-style-type: none"> Are there any specific clinical or patient characteristics for when internal rib fixation systems are not appropriate? <ul style="list-style-type: none"> If yes, please comment and cite literature to support. 	X		Contra-indications to rib fixation may be grouped broadly into 1) respiratory failure not due to rib fractures (e.g., severe pulmonary contusion or congestive heart failure, severe traumatic brain injury) and 2) instability for the OR due to persistent shock.
8	<ul style="list-style-type: none"> Is there evidence to support one type of internal rib fixation system over another? <ul style="list-style-type: none"> If yes, please comment and cite literature to support. 		X	There are no studies comparing one system to another.
9	<p>Improved Patient Outcomes:</p> <ul style="list-style-type: none"> Is there adequate evidence to demonstrate that the use of internal rib fixation systems as a treatment of flail chest or non-union provides significant improvements in clinical outcomes <i>compared to the available alternatives</i>? 	X		Please see attached response letter. The alternative of non operative management has been consistently found to be inferior to rib fixation. Additional, narcotic dependence is a rising concern, specifically in patients with severe chest wall injuries.

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		Yes	No	Comments
10	<ul style="list-style-type: none"> Compared to the available alternatives, is there adequate evidence to demonstrate that the use of internal rib fixation systems as a treatment of flail chest or non-union in individuals with respiratory failure can shorten the duration of mechanical ventilation when there is an inability to discontinue mechanical ventilation? 	X		Please see attached response letter. Duration of mechanical ventilation is one of the most common outcomes in the literature cited and the vast majority of studies have found an improvement with rib fixation as compared to non-operative management.
11	<ul style="list-style-type: none"> Is there additional <i>peer-reviewed literature</i>, other than that cited in the policy, to demonstrate improved patient outcomes due to the use of internal rib fixation systems as a treatment of flail chest or non-union? <ul style="list-style-type: none"> If yes, please comment and cite literature to support. 	X		Please see attached response letter.
12	<ul style="list-style-type: none"> Is there <i>other information</i> you feel is relevant regarding the <i>medical necessity</i> of this technology? <ul style="list-style-type: none"> If yes, please comment. 	X		Please see attached response letter.

EXHIBIT I

Medically Necessary Definition

"Medically Necessary" services are procedures, treatments, supplies, devices, equipment, facilities or drugs (all services) that a medical practitioner, exercising prudent clinical judgment, would provide to a covered individual for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

- in accordance with generally accepted standards of medical practice; and
- clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the covered individual's illness, injury or disease; and
- not primarily for the convenience of the covered individual, physician or other health care provider; and
- not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that covered individual's illness, injury or disease.

For these purposes, "generally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, national physician specialty society recommendations and the views of medical practitioners practicing in relevant clinical areas and any other relevant factors.

Investigational Definition

"Investigational" means that the procedure, treatment, supply, device, equipment, facility or drug (all services) does not meet the Anthem Technology Evaluation Criteria because it does not meet **one or more** of the following criteria:

- have final approval from the appropriate government regulatory body; or
- have the credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community which permits reasonable conclusions concerning the effect of the procedure, treatment, supply, device, equipment, facility or drug (all services) on health outcomes; or
- be proven materially to improve the net health outcome; or
- be as beneficial as any established alternative; or
- show improvement outside the investigational settings.