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Friday, August 10, 2018

Dear Ms. Sennette,

The Chest Wall Injury Society strongly disagrees with the proposed Anthem position statement: *the use of an internal rib fixation system is considered **investigational and not medically necessary** for all indications*. This letter provides background on the Chest Wall Injury Society, followed by the rationale for our disagreement with the aforementioned position statement.

The Chest Wall Injury Society ([www.cwisociety.org](http://www.cwisociety.org)) represents an international group of trauma, orthopedic, and thoracic surgeons with a mission of optimizing the operative and non-operative care of the patient with chest wall injury. Our society was founded in 2016 and currently rests at 129 members from 13 countries, spread across 5 continents. Many of the seminal publications related to rib fixation, including those referenced in your position statement, were authored by one or more of our members.

The literature review provided in the position statement is comprised of a selective sample of studies published on rib fixation. For example, the studies of Richardson et al.<sup>1</sup> and Bottlang et al.<sup>2</sup> represent case series of 7 and 19 subjects, respectively. These particular studies, in our opinion, offer limited insight into the efficacy of the operation. In the following paragraphs, we offer an organized summary of literature not cited within the position statement, beginning with consensus statements, followed by meta-analyses, prospective trials, and, finally, retrospective studies. Our literature review includes two salient outcomes that were not addressed in the Anthem position statement: cost-effectiveness comparisons and outpatient quality of life.

Two consensus statements regarding the efficacy of rib fixation were published in 2017, one by the Chest Wall Injury Society<sup>3</sup> and the other by the Eastern Association for the Surgery of Trauma<sup>4</sup>. Both documents employed the Grade methodology<sup>5</sup> to weigh evidence and render recommendations. Both documents conditionally recommended rib fixation in patients with flail chest, as well as recognized the need for additional data to support rib fixation in patients without flail chest. These documents currently represent the most exhaustive analyses of the literature, and were subjected to peer review.

The three randomized controlled trials of Tanaka et al.<sup>6</sup>, Granetzny et al.<sup>7</sup>, and Marasco et al.<sup>8</sup> were appropriately described in the Anthem review. It should be noted that all three trials found significant benefit to rib fixation for flail chest. The Anthem review notes the relatively small sample sizes in each trial (n = 37, 40, and 46, respectively). It should also be noted that many other orthopedic therapies not

considered investigational, such as open reduction and internal fixation of long bones and pelvis, do not have a similar number of randomized trials assessing their effectiveness. One validated methodology for overcoming small samples sizes from single-institution studies is meta-analysis<sup>9</sup>. The meta-analyses of Slobogean<sup>10</sup> and Leinicke<sup>11</sup>, both published in 2013, were mentioned in the Anthem review. Both analyses concluded that rib fixation was associated with favorable outcomes. We would add two more recent meta-analyses, by Coughlin et al. in 2016<sup>12</sup> and Swart et al. in 2017<sup>13</sup>. The former was a more rigorous analyses of the three RCT, which concluded that rib fixation in patients with flail chest was associated with significant clinical benefit. The latter included 20 studies (the largest to date) and was the most statistically robust of the four, involving both cost-effectiveness and sensitivity analyses. The study concluded that rib fixation for flail chest was both clinically and economically favorable. Finally, the study of Pieracci et al.<sup>14</sup>, though not randomized, was prospective. The Anthem review states that the surgical techniques to stabilize the rib fractures were not provided for the operative group. However, the technique was described in detail in the methods section, and the authors' technique paper on which the trial was based<sup>15</sup> was also referenced. To this extent, although there will be subtle variations in surgical technique for any operation, we believe that a generic approach to rib fixation has been well described by this group and others<sup>16 17</sup>, at least to an extent equal to that of additional orthopedic approaches and operations.

Three additional retrospective studies are cited in the Anthem review; those of Nirula et al<sup>18</sup>, de Moya et al.<sup>19</sup>, and Khandelwald et al<sup>20</sup>. However, there are several additional studies, both prospective and retrospective, that were omitted<sup>21 22 23 24 25 26 27</sup>. Particularly concerning to us is the absence of literature pertaining to rib fixation that has been published this year. Specifically, Pieracci et al. published a multicenter evaluation of the optimal timing of rib fixation, involving 551 patients from 4 centers. The authors found that patients who had early rib fixation fared better than those who underwent delayed repair, suggesting that the operation is most beneficial when performed early after injury. This finding was reproduced in a more recent retrospective analysis<sup>28</sup>. Furthermore, both Kane et al. and Ali-Osman et al. published case control series this year; each study concluded that rib repair was beneficial, particularly in geriatric patients. Importantly, each of these studies included patients with non-flail chest injury patterns.

It is also important to consider that there have been negative studies of rib fixation. Both DeFrest et al. and Farquhar et al. recently published single institution, retrospective studies comprised of relatively low sample sizes (n= 41 and 19, respectively), and reported no benefit to rib fixation. However, the findings of these two studies have not been reproducible in subsequent efforts, and their methodologic limitations have been recognized<sup>29</sup>.

Finally, the Anthem review does not address either cost-effectiveness or long-term quality of life improvements associated with rib fixation. The former has been evaluated by Tanaka et al., Bhatnagar et al.<sup>30</sup>, and Leinicke et al.. Tanaka et al. evaluated cost related to care while in the intensive care unit. The study found an approximately \$10,000 lower total cost in the rib fixation group. Bhatnagar used Markov transition state analysis to model the cost savings associated with rib fixation based on outcomes published in the aforementioned studies using Medicare 2010 reimbursement rates. They found that rib

fixation saved \$1,500 if the model assumed no quality of life improvement. The cost savings increased as the assumed quality of life variable increased. When the risk for ventilator associated pneumonia was set to 22%, the cost savings with SSRF was estimated to be \$8,400 per patient. In summary, rib fixation was found in all of these analyses to decrease both direct and indirect costs. Moreover, although long term quality of life data are relatively sparse, there is some evidence to support lasting improvements following rib fixation<sup>31 32</sup>.

In conclusion, the Chest Wall Injury Society, which represents a multidisciplinary group of experts in the field of rib fracture management, disagrees with the Anthem position statement. Specifically, the statement that rib fixation is investigational for all indications is both too broad and not supported by current evidence. At a minimum, the procedure is indicated selectively in patients with flail chest, respiratory compromise due to the flail chest, and no other contra-indications (e.g., severe traumatic brain injury). Beyond this indication, we believe that there exists adequate literature, cited herein, to support the operation selectively for patients with severe chest wall injury in the absence of flail chest (e.g., multiple severely displaced rib fractures), provided that there is pulmonary compromise and/or pain secondary to the chest wall injury. Our recommendation is to provide coverage for the operation in all patients with a diagnosis of flail chest, as well as those patients with  $\geq 3$  bicortical fractures with either pulmonary physiologic derangement or pain refractory to medical management. Finally, coverage should be provided for the indication of non-union, provided that there is

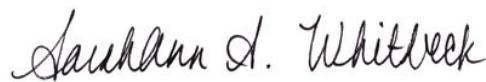
- 1) radiographic evidence of non-union at least 3 months after injury;
- 2) persistent disabling pain refractory to non-operative management;
- 3) thoughtful management of patient expectations.

Rib fixation is a well-studied operation that, when applied appropriately, saves lives, decreases complications, and decreases costs. To deny this operation to all patients would be both shortsighted and inconsistent with available evidence. Please do not hesitate to contact us if we may be of further assistance.

Best regards,



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