

# HERC Coverage Guidance – Disposition of Public Comments

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## Commenters

Identification	Stakeholder
A	Society of Interventional Radiology, Fairfax, VA [ <i>Submitted December 10, 2014</i> ]

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### Public Comments

Ident.	#	Comment	Disposition
A	1	The Society of Interventional Radiology (SIR) is a professional medical association that represents approximately 5,400 members who are practicing in the specialty of vascular and interventional radiology. The society and its membership are dedicated to improving public health through pioneering advances in minimally invasive, image-guided therapy. Our members are at the forefront of innovative and minimally invasive therapies to treat an array of diseases and conditions without surgery. Interventional radiology treatments have become first-line care for many conditions, including inferior vena cava (IVC) filter placements (and retrieval) for patients at risk of pulmonary embolisms.	Thank you for taking the time to comment.
	2	SIR has been at the forefront of advancing the science around IVC filters, even prior to the U.S. Food and Drug Administration’s (FDA’s) August 2010 safety communication. We realized several years ago that a rigorous research trial would be the only way to come to any conclusions about IVC filter procedures. Accordingly, SIR and the Society for Vascular Surgery, in partnership, have launched a national large-scale, multispecialty prospective clinical research trial to evaluate the use of IVC filters (IVCFs) and related follow-up treatment in the United States. This collaboration between SIR and the SVS is set to enroll the first patient in spring 2015, with participation from seven IVCF manufacturers. The Predicting the Safety and Effectiveness of Inferior Vena Cava Filters (PRESERVE) trial will directly address the August 2010 FDA medical alert detailing the possibility that retrievable IVC filters could move or fracture, potentially causing significant health risks for patients. SIR and the SVS collaboratively formed the IVC Filter Study Group Foundation, a 501(c)(3) not-for-profit entity that sponsors and will oversee the PRESERVE trial. The study will have the goal of obtaining a real-world view of the safety and efficacy of most filters placed in the United States.	Thank you for Informing EbGS about the PRESERVE trial.
	3	With respect to the draft Oregon report, we offer several overall comments and suggestions that the commission may want to consider:  The draft report’s recommendations and reasons for those recommendations are clear and, in general, well-supported. Overall, relative to the primary question raised in the report, SIR asserts that the medical community is in concurrence that <b>IVC filters prevent pulmonary emboli (PE)</b> . It is clear from all available literature that IVCFs reduce PE rates (see the 1998 randomized, prospective, PREPIC study by Decousus et al., which demonstrated a clear reduction in PE incidence in the IVCF group).	Thank you for your comment.
	4	SIR agrees with the draft’s recommendation that IVCFs are not appropriate in people who can be anticoagulated but are appropriate for people who cannot be.	Thank you for your comment.
	5	The draft makes a “weak recommendation” for use of IVCFs for trauma patients . Filters are not indicated for the vast majority of patients with trauma, but the draft fails to note that in its recommendation, implying that the decision about whether or not to place an IVCF in a trauma patient is up to the treating physician. SIR agrees with that implication but suggests that the authors consider providing more specifics about which trauma patients may benefit from placement of an IVCF—e.g., pelvic trauma, trauma with venous injury, expected prolonged immobilization or mechanical ventilation, and injuries that will obviate use of anticoagulation. However, since the precise patient populations that will 100 percent benefit from an IVCF is uncertain, SIR asserts that patients will benefit the most when that decision is left to the treatment team when all factors can be used in the medical decision process.	Additional box language has been added to address this concern. A weak recommendation for coverage of IVC filters in <u>some</u> patients with trauma is made, with the clarification that “Examples of trauma for which IVC filters may

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			be indicated include patients with severe trauma and prolonged hospitalization.”
	6	SIR is uncertain about the draft’s recommendation that IVCFs are not appropriate for patients who are to undergo bariatric surgery. In general, this recommendation is true. However, there are several studies (admittedly small and/or retrospective) that suggest that patients with a body-mass index (BMI) > 60 or a history of venous thromboembolic (VTE) disease might benefit from the use of an IVCF. The SIR is concerned that the draft’s recommendation against IVCFs for all bariatric surgery patients might result in payment policies that deny reimbursement for use of an IVCF in a patient with a BMI > 60 or a history of VTE disease. Preventing a fatal PE is paramount, and SIR asserts that each patient’s situation needs to be carefully evaluated and that a blanket statement may be problematic.	No citations provided. The evidence source identified no RCTs in this population; conclusions were based on 2 prospective cohort studies, 8 retrospective cohort studies and 2 case reports. BMI ranged from 45 to 74 kg/m <sup>2</sup> .
	7	Furthermore, developers of the draft may want to delve further into other potential scenarios in which an IVCF might be appropriately placed. For example, what if an IVCF is requested for a patient who is undergoing resection of a large pelvic tumor with thrombus likely present in the iliac veins inferior to the tumor?	If high risk, pharmacologic anticoagulation may be indicated.
	8	<p>SIR would advise caution on using language in the draft that states “whenever possible, the IVC filter should be retrieved.” Retrievable filters are approved for permanent use and many are used with the intention that they will be permanent. As stated in the draft policy (without a listed strength of recommendation), those filters should be removed without consideration of the clinical scenario. We encourage the HERC to closely follow the latest FDA guidance. In its May 2014 Update, the FDA stated:</p> <p><i>“The FDA encourages all physicians involved in the treatment and follow-up of patients receiving IVC filters to consider the risks and benefits of filter removal for each patient. A patient should be referred for IVC filter removal when the risk/benefit profile favors removal and the procedure is feasible given the patient’s health status.”</i></p> <p>SIR suggests a change in wording of the draft report to be more consistent with the FDA statement: “The implanting physicians and clinicians responsible for the ongoing care of patients with retrievable IVC filters should consider removing the filter as soon as protection from PE by the IVC filter is no longer needed.”</p>	Box language has been modified, and a weak recommendation (expert opinion) added.
	9	Thank you for the opportunity to submit these comments. If we can provide any additional information or if the Health Evidence Commission wishes further discussion on this topic with SIR members who frequently perform IVC filter procedures, please do not hesitate to contact Susan E. Sedory Holzer, MA, CAE, SIR’s executive director, at (703) 691-1805, or <a href="mailto:sholzer@sirweb.org">sholzer@sirweb.org</a> .	Thank you providing this information.

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Commenter	References
A2	Decousus H, Leizorovicz A, Parent F, Page Y, Tardy B, Girard P, et al. A clinical trial of vena caval filters in the prevention of pulmonary embolism in patients with proximal deep-vein thrombosis. N Engl J Med 1998;338(7):409-15.

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