April 4, 2017

Blue Shield of California
Attn: Medical Policy Committee and Prior Authorization Department
50 Beale Street
San Francisco CA 94105

Re: Epidural Spine Injections Medical Policy

To Whom It May Concern:

The Spine Intervention Society (SIS), a multi-specialty association of more than 2,600 physicians dedicated to the development and promotion of the highest standards for the practice of interventional procedures in the diagnosis and treatment of spine pain, would like to take this opportunity to comment on the Blue Shield’s coverage policy for epidural spine injections.

The Society's membership includes many of the clinicians and academicians whose published literature provides the seminal references upon which the practice of evidence-informed interventional spine care is based. Our organization has a strong record of working to eliminate fraudulent, unproven, and inappropriate procedures. At the same time, we are equally committed to assuring that appropriate, effective, and responsible treatments are preserved so that patients do not have to suffer or undergo more invasive and often unnecessary surgical procedures.

We would specifically like to comment on the current policy’s classification of full anticoagulation as a contraindication for epidural injections. While evidence has demonstrated a risk of hemorrhagic complications in anticoagulated patients undergoing interlaminar epidural steroid injections (1-7), the same cannot be said for lumbar transforaminal epidural steroid injections (LTFESI). There may actually be more risk in discontinuing anticoagulants, increasing the risk for vascular or cerebrovascular events.

Studies have attempted to estimate the prevalence of bleeding complications amongst patients who underwent lumbar transforaminal injections, while continuing anticoagulant and antiplatelet medications. One study found no bleeding complications in 90 cases in which anticoagulant and antiplatelet drugs were continued [8]. Another larger study reported no complications in 955 patients who continued anticoagulants, and none in 663 patients who continued antiplatelet medications [9]. These figures indicate that the 95% confidence interval for hemorrhagic complications is 0.0 - 0.4% when continuing anticoagulants and is 0.0 - 0.6% when continuing antiplatelet medications.
In that same large, prospective study, anticoagulants were ceased in 1,626 patients [9]. Nine patients suffered thrombo-embolic complications. One died from a stroke. Another died from a myocardial infarction. Five suffered non-fatal strokes, one suffered a myocardial infarction, and one suffered a pulmonary embolism. The prevalence of these complications was 9 in 1,626 (0.4%; 95% CI: 0.2% - 0.7%).

Although small (0.4%; 0.2% - 0.7%), the risk of vascular and cerebrovascular complications is not negligible, and the nature of the complications is severe and potentially life-threatening. Moreover, in patients taking warfarin, the risk of vascular and cerebrovascular medical complications (0.6%; 0.32 – 1.15%) is almost significantly greater statistically than the risk of hemorrhagic complications in like patients undergoing lumbar transforaminal injections (0.00 – 0.38%). These figures warn that guidelines and policies concerning the cessation of anticoagulants need to balance the risk of hemorrhagic complications against a potentially greater risk of medical complications.

**Because no serious hemorrhagic complications have been reported following LTFESI in anticoagulated patients, ceasing anticoagulants may pose a greater risk to patients than continuing anticoagulants.**

We hope that this information, as well as any dialogue and collaboration between Blue Shield of California and the Spine Intervention Society, will lead to the establishment of a reasonable coverage policy that will eliminate inappropriate utilization while preserving access in appropriately selected patients. We offer our ongoing input and expertise in this matter. If we may answer any questions or provide any assistance, please feel free to contact Belinda Duszynski, Senior Director of Policy and Practice at bduszynski@spinalinjection.org.

Sincerely,

John MacVicar, MB ChB
President
Spine Intervention Society

**References:**