SI-BONE, Inc. Announces Blue Cross Blue Shield Association Raises Clinical Evidence Rating for MIS SI Joint Fusion

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Upgraded Rating Applies Only to Triangular Implants, Clearing the Way for Positive Coverage Policies Specific to the Patented iFuse Implant System® for Blue Cross Blue Shield Member Plans

SAN JOSE, Calif., January 2, 2018 -- SI-BONE, Inc., a medical device company that pioneered the use of the iFuse Implant System®("iFuse"), a minimally invasive surgical (MIS) device indicated for fusion for certain disorders of the sacroiliac (SI) joint, announced that Blue Cross Blue Shield Association (BCBSA), after an extensive review of all existing peer-reviewed published clinical safety and effectiveness data, has assigned triangular implants for SI joint fusion a "Moderate" quality evidence recommendation. The BCBSA rating system encompasses a four-level rating scale of Substantial, Moderate, Low to None and Uncertain. In order for a technology to receive a moderate or substantial rating, the clinical evidence must be sufficient to determine the effects of the technology on health outcomes with confidence. The BCBSA updated technology assessment states that for individuals with common disorders affecting the sacroiliac joint who are treated with sacroiliac fusion/fixation with a triangular implant, the evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome. The evidence used to develop the upgraded assessment was developed exclusively using the patented triangular iFuse Implants, which have been commercially available since 2009. The updated assessment further states that for patients with SI joint pain, the evidence is insufficient for treatment with therapeutic corticosteroid injections, radiofrequency ablation or cylindrical threaded implants.

The evidence required to establish a sufficient effect on health outcomes typically includes:

1. Consistent results from well-designed, well-conducted studies in clearly-defined populations.
2. Well designed and conducted studies generally controlled for bias through random allocation of participants; blinded assessment of outcomes; minimizing loss to follow-up; and complete reporting of results. Study populations are representative of the population of clinical interest. Study size is adequate to test the hypothesis and assumptions for calculating study power are clearly reported.
3. Studies assessing the effects of the technology on health outcomes, including both the beneficial and harmful effects on length of life, quality of life and ability to function.
4. Evidence from effectiveness studies or post-marketing studies that confirm that the observed effects of the intervention are generalizable outside the research setting.
5. Evidence from effectiveness studies or post-marketing studies to assess long term effects of the technology on health outcomes.
6. Clinical study data available through a curated open data access source.

The Blue Cross and Blue Shield Association is a national federation of 36 independent, community-based and locally-operated Blue Cross and Blue Shield companies that collectively provide healthcare coverage for more than 106 million members across all 50 states, the District of Columbia and Puerto Rico.

Daniel Cher, MD, Vice President of Clinical Affairs at SI-BONE commented, "there is abundant evidence showing that the sacroiliac joint is a significant contributor to lower back pain and that common types of SI joint dysfunction can be effectively treated with a minimally invasive surgical procedure using the triangular iFuse Implant, which we brought to market in 2009. That said, the SI joint has been under-diagnosed and under-treated for decades and our philosophy has been to take a high level scientific approach, including well-designed and well-executed clinical studies so that the data from these studies could stand on their own for educational, clinical and patient purposes."

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About SI joint dysfunction

The SI joint has been attributed as a source of pain in 15-30 percent of patients with chronic low back pain[1-4], and in up to 43 percent of patients with new onset or persistent low back pain after lumbar fusion.[5] SI joint dysfunction is often misdiagnosed and the resulting pain can be incorrectly attributed to other causes. SI joint dysfunction can be identified when a patient points to their source of pain directly over the posterior superior iliac spine (PSIS), known as the Fortin Finger Test, combined with a number of positive provocative maneuvers to stress the SI joint and elicit the pain, followed by image-guided diagnostic injections to confirm the diagnosis. The SI joint is the largest of the eight major joints in the human body and the last to have a proven surgical treatment. The iFuse Implant, first FDA-cleared in 2009, is the only device for treatment of SI joint dysfunction supported by significant published clinical evidence, including level 1 trials, showing safety and durable effectiveness, including providing lasting pain relief. The iFuse Implant was designed specifically to withstand the extreme forces resulting from load-bearing and the unique rotational and translational motion of the SI joint referred to as nutation, and is supported by more than 50 peer-reviewed publications including two Level 1 randomized controlled trials (www.si-bone.com/results).

About SI-BONE, Inc.

SI-BONE, Inc. (San Jose, California) is a leading medical device company that has developed the iFuse Implant System, a proprietary minimally invasive surgical implant system to fuse the sacroiliac joint to treat common disorders of the joint that can cause lower back pain. Patients with certain types of sacroiliac joint dysfunction experience pain that can be debilitating.

The iFuse Implant System is intended for sacroiliac fusion for conditions including sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months. There are potential risks associated with the iFuse Implant System. It may not be appropriate for all patients and all patients may not benefit. For information about the risks, visit: www.si-bone.com/risks

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