**Sample Template Letter for an Appeal Request**

**This template is designed to assist providers in appealing a preauthorization request denial for the Vertiflex™ Procedure†. This template is not intended to replace any medical judgment; it is merely to assist with the structure of a coverage request. There are several places in red within this template that encourage patient-specific information. Please review this letter once you have personalized it to the specific patient and eliminate all red fonts and template-related directions, including this document title and section.**

(Insert Physician Letterhead)

DATE

Insurance Name:

Attn: Appeals Department
Street Address

City, State, Zip

Fax Number:

Patient Name:

ID Number:

Group Number:

Date of Birth:

Case Reference Number:

**Procedure Code**: 22869, +22870 (if two-level procedure) Insertion of a lumbar interspinous process stabilization device without decompression or fusion

**Principal Diagnosis**: Enter patient’s principal diagnosis

To Whom It May Concern:

I am writing on behalf of, Patient Name, to appeal the decision to deny the preauthorization request regarding coverage for the posterior interspinous decompression spacer procedure to treat lumbar spinal stenosis. (Enter the denial rationale per the denial letter i.e., The request was denied as a non-covered benefit due to experimental/investigational rationale).

Patient Name has been suffering from this lumbar spinal stenosis (Insert length of time patient has been experiencing symptoms of lumbar spinal stenosis). With spinal stenosis comes moderate to severe leg, buttock, groin and/or back pain, including numbness and weakness in the lower extremities and associated with the pain, numbness, and/or cramping of neurogenic intermittent claudication. This condition is a major contributor of disability and lost productivity. (Include specific impact to patient including impact to quality of life and ADLs)

The appropriate treatment options currently available to this patient are: (Enter treatment options available to patient, which may include continued conservative treatment, minimally invasive placement of a posterior interspinous process space or decompressive surgery (lumbar laminectomy and/or fusion).

As this patient’s treating physician, I believe that (Enter most appropriate treatment for patient) and that this choice does indeed meet the requirements as being reasonable and medically necessary for the following reasons:

* Describe the patient’s medical condition and past treatment experiences:
	+ Patient medical history
	+ Patient pain level and how long they have suffered
	+ Prior attempts/failures utilizing conservative therapies over the past X months (e.g., medications (such as non-steroidal anti-inflammatory medication, opiates, etc.) epidural steroid injections, physical therapy, back brace/corset, modification of activity level, etc.)
	+ Provide information regarding the patient’s condition (ability/inability to work, sleep, participate in physical therapy/activities of daily life, etc.).
	+ Stress again why this is the best treatment for your patient.

Although surgical decompression is the other treatment option, the patient is not a good candidate for such an invasive surgical procedure (Please provide any concurrent co-morbidities the patient may have and the correlation with the patient’s age.) and/or the patient does not want to have such a significant surgical procedure at this time when an FDA-approved minimally invasive treatment option is available.

According to a recent study specific to treating LSS patients with concurrent medical comorbidities, “similar to other minimally invasive techniques it has specific advantages over more open spinal surgical procedures, including shorter procedure time, the possibility to be performed under local anesthesia, minimal or no muscle disruption or blood loss and less risks of nerve damage or cerebrospinal fluid leaks.” (Hartman 2019).

Interspinous process distraction (IPD) devices (aka. “spacers”) provides an alternative treatment to address a distinct gap in the continuum of care of lumbar spinal stenosis. Interspinous spacers effectively bridge the often-lengthy interval between failed conservative care and the point where surgical decompression becomes necessary to manage intractable symptoms of neurogenic intermittent claudication secondary to a confirmed diagnosis of LSS at one or two adjacent levels from L1-L5. These devices are inserted posteriorly via a minimally invasive procedure without disruption of osseous or ligamentous tissues. Spacers provide immediate symptom relief by acting as spinal extension blocker to prevent the repetitive compression of neural elements during back extension that is the primary source of claudicant symptoms.

The interspinous spacer device which I have recommended to my patient is the Superion® Indirect Decompression System. This FDA-approved device is a non-fusion, spinal column load-sharing device used to stabilize the spine at the implanted level. The procedure is performed utilizing a minimally invasive, percutaneous approach through the vertebrae in the posterior spine under local anesthesia. The implant is inserted through a cannula about the size of a dime and does not require surgical dissection. This procedure is performed either a hospital or ambulatory surgical center (ASC) on an outpatient basis.

It is important to state clearly that this device/procedure is not experimental nor investigational, based primarily on the substantial body of published clinical literature to support the safety, efficacy, and durability of the Vertiflex Procedure. In further support of the evidence, ECRI, a Health Technology Assessment, issued a Product Brief indicating that the evidence is somewhat favorable.

There are many clinical benefits associated with the placement of the device for patients suffering from lumbar spinal stenosis including the following results of durable clinical outcomes throughout and after 5 years of clinical follow-up:

* The device/procedure received PMA approval from the FDA in 2015. This PMA approval was based upon a randomized controlled trial which was the largest FDA IDE medical device trial for lumbar spinal stenosis
* The clinical results from the use of the Superion device are durable. Patients in the Superion IDE trial have been followed for 60 months which has resulted in the publication of 2-year, 3-year,

4-year, and 5-yearclinical outcomes data.

* The Vertiflex™ Procedure† has been reported to reduce leg pain at 5-years post-surgery. 84% of patients surveyed at 60-months post-treatment reported immediate and durable clinically significant improvement, exhibiting a mean of 75% reduction in leg pain vs. baseline.
* High levels of patient satisfaction have been reported among patients who had the Superion Indirect Decompression System implanted. 90% of patients reported they were “satisfied” or “somewhat satisfied” at 5-year follow up.
* The same 5-year follow up study reported 75% of patients reported a clinically significant improvement in symptom severity. 81% reported a clinically significant improvement in physical function.
* Significant positive and durable longitudinal changes in SF-12 PCS and MCS scores were reported through 5 years of follow-up.
* A significant reduction in opiate use among Superion patients between the preoperative baseline period of the IDE trial through five years of clinical follow-uphas been shown in a recent 2018 publication. Between baseline and 5 years of follow-up, there was an 85% decrease in the proportion of subjects using opioids. A similar pattern was also observed among subjects with a history of opiates before entering the trial.
* Regarding the current coverage and reimbursement landscape, the Vertiflex Procedure is being reimbursed by all Medicare Administrative Contractors (MACs), including various commercial payers when medically necessary for patients meeting the approved indications for use and clinical criteria.

To date, widespread adoption and utilization by the medical community continues with over 21,000 procedures and over 1,200 trained physicians, nationwide. It is my professional opinion that the insertion of a lumbar interspinous spacer would provide significant clinical and quality of life benefits

for my patient. This treatment is medically necessary and appropriate for this stage of the disease progression.

I respectfully request that upon a re-review of the patient’s clinical notes demonstrating medical necessity and the clinical evidence presented, the initial denial be overturned to enable my patient access to treatment.

Please contact me directly if you require additional information or if you would like to discuss the specifics of this case. I can be reached at Phone # or by email at E-Mail Address.

Thank you in advance for your consideration of this request.

Sincerely,

Physician Signature

Physician Name

Facility Name

Full Address

Phone

†Superion® Indirect Decompression System

**REFERENCES**

Centers for Disease Control and Prevention. [*2018 Annual Surveillance Report of Drug-Related Risks and Outcomes - United States.*](https://www.cdc.gov/drugoverdose/pdf/pubs/2018-cdc-drug-surveillance-report.pdf?s_cid=cs_828) *Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. Published August 31, 2018.*

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