Letter of Medical Necessity for the Carevix® Suction Cervical Stabilizer

Patient Information

Date: _____

Patient Name: _____

Patient Date of Birth: _____

Health Insurance Member ID # (if applicable): _____

To Whom It May Concern:

This letter serves to document the medical necessity for the use of the Carevix® Suction Cervical Stabilizer during a transcervical gynecological procedure for the above-listed patient. The Carevix® is a Class II, FDA-cleared (510(k) K223866), single-use device that stabilizes the cervix atraumatically via suction during intrauterine device (IUD) placement, hysteroscopy, endometrial biopsy, and other office-based gynecological procedures.

Traditional cervical tenacula pierce cervical tissue and are associated with increased risks of pain, trauma, vasovagal episodes, and bleeding. For this patient, such risks are elevated due to one or more of the following:

- ☐ **Nulliparous status or small cervical dimensions**
- ☐ **Prior cervical procedures (e.g., LEEP, cone biopsy) or known cervical fragility**
- ☐ **Documented anxiety or low pain tolerance**
- ☐ **Use of anticoagulant medications or bleeding disorder**
- ☐ **Anatomical or positional cervical challenges requiring non-traumatic traction**
- ☐ **Other:** _____

Therefore, use of Carevix® is medically necessary to reduce procedural complications and ensure patient safety.

A randomized controlled trial[1] comparing Carevix® to a traditional tenaculum during IUD placement demonstrated an up to 73% average reduction in pain scores, particularly during cervical traction, and 83% fewer bleeding events compared to procedures without Carevix®. A majority of patients preferred Carevix® for future procedures.

Based on this patient's individual clinical needs and the demonstrated safety, efficacy, and patient experience improvements associated with Carevix®, I attest to its use as medically necessary.

Sincerely,

_____

Signature

_____

Print Name, Credential(s)

[1] Yaron M, Legardeur H, Barcellini B, Akhoundova F, and Mathevet P (2023), Safety and efficacy of a suction cervical stabilizer for intrauterine contraceptive device insertion: Results from a randomized, controlled study, Contraception, Volume 123, 2023, 110004, ISSN 0010-7824, doi: 10.1016/j.contraception.2023.110004.