

Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.



**BlueCross BlueShield
of Alabama**

Name of Blue Advantage Policy:

Surgical Interruption of Pelvic Nerve Pathways for Primary and Secondary Dysmenorrhea

Policy #: 210

Latest Review Date: September 2023

Category: OB/GYN Reproductive

ARCHIVED EFFECTIVE 11/1/2023

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

- 1. Safe and effective;*
- 2. Not experimental or investigational*;*
- 3. Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
 - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
 - Furnished in a setting appropriate to the patient's medical needs and condition;*
 - Ordered and furnished by qualified personnel;*
 - One that meets, but does not exceed, the patient's medical need; and*
 - At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **laparoscopic uterine nerve ablation (LUNA) or presacral neurectomy (LPSN)** as a **non-covered** benefit and is considered **investigational** as a technique to treat primary or secondary dysmenorrhea.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Two laparoscopic surgical approaches are proposed as adjuncts to conservative surgical therapy for the treatment of primary and secondary dysmenorrhea. These approaches are laparoscopic uterine nerve ablation (LUNA) and presacral neurectomy (PSN).

Dysmenorrhea is defined as the occurrence of painful menstrual cramps. Primary dysmenorrhea occurs in the absence of an identifiable cause, while secondary dysmenorrhea is related to an identifiable pathologic condition, such as endometriosis, adenomyosis, or pelvic adhesions. First-line pharmacologic therapy typically includes non-steroidal anti-inflammatory drugs (NSAIDs), which reduce prostaglandin production, or oral contraceptives. Patients with endometriosis frequently undergo surgery to ablate, excise, or enucleate endometrial deposits or lyse pelvic adhesion. Collectively, these surgical procedures may be referred to as “conservative surgical therapy.”

Laparoscopic uterine nerve ablation (LUNA) and presacral neurectomy (PSN) are two laparoscopic surgical approaches that have been investigated as techniques to interrupt the majority of the cervical sensory nerve fibers in patients with dysmenorrhea. Uterine nerve ablation involves the transection of the uterosacral ligaments at their insertion into the cervix, while presacral neurectomy involves the removal of the presacral nerves lying within the interiliac triangle. Presacral neurectomy (PSN) interrupts a greater number of nerve pathways compared to laparoscopic uterine nerve ablation (LUNA), and is technically more demanding. There are concerns regarding the efficacy and safety of these procedures.

KEY POINTS:

The literature was reviewed through September 15, 2023.

Summary of Evidence

For individuals who have primary or secondary dysmenorrhea who receive LUNA, the evidence includes RCTs and a systematic review. Relevant outcomes are symptoms and treatment-related

morbidity. RCTs comparing LUNA plus conventional treatment to conventional treatment alone, and meta-analyses of these trials, have not found a consistent benefit for the addition of LUNA. In addition, sample sizes tended to be small, and there are few studies with follow-up of 12 months or longer. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have primary or secondary dysmenorrhea who receive PSN, the evidence includes RCTs and a systematic review. Relevant outcomes are symptoms and treatment-related morbidity. No trials on primary dysmenorrhea were available and there are only several trials on secondary dysmenorrhea. A pooled analysis of 2 trials with a total of 197 women with secondary dysmenorrhea associated with endometriosis found significantly greater symptom relief with PSN plus surgery versus surgery alone at 12 months. The largest and most recent trial found improvement in pain outcomes but also higher complication rates with PSN, and had some methodologic limitations which limit its interpretation. The net health benefit remains unclear and needs to be further assessed in additional trials. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements

National Institute for Health and Clinical Excellence (NICE)

In 2007, NICE issued interventional procedure guidance number 234 on LUNA for chronic pelvic pain. The guidance states “The evidence on laparoscopic uterine ablation (LUNA) for chronic pelvic pain suggests that it is not efficacious and therefore should not be used.”

U.S. Preventive Services Task Force Recommendations

Not Applicable

KEY WORDS:

Dysmenorrhea, LUNA, presacral neurectomy, laparoscopic uterine nerve ablation, uterine nerve ablation, PSN, LPSN, laparoscopic presacral neurectomy, UNA

APPROVED BY GOVERNING BODIES:

LUNA and LPSN are surgical procedures and, as such are not subject to regulation by the U.S. Food and Drug Administration (FDA).

BENEFIT APPLICATION:

Coverage is subject to member’s specific benefits. Group-specific policy will supersede this policy when applicable. The use of this device for contraceptive management is a group-specific benefit.

CURRENT CODING:

CPT codes:

There is no specific CPT code for laparoscopic uterine nerve ablation or presacral neurectomy. CPT code 58578 (unlisted laparoscopy procedure, uterus) may be used. For secondary dysmenorrhea, presacral neurectomy may be performed in conjunction with either of the following procedures:

58578	Unlisted laparoscopy procedure, uterus
58660	Laparoscopy, surgical; with lysis of adhesions (salpingolysis, ovariocyesis) (separate procedure)
58662	Laparoscopy, surgical; with fulguration or excision of lesions of the ovary, pelvic viscera, or peritoneal surface by any method

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POLICY HISTORY:

Adopted for Blue Advantage, March 2005

Available for comment May 12-June 27, 2005

Medical Policy Group, December 2006

Medical Policy Group, December 2008

Medical Policy Group, March 2010

Medical Policy Group, August 2011

Medical Policy Group, March 2012

Medical Policy Group, April 2013

Medical Policy Group, October 2013

Medical Policy Group, April 2014

Medical Policy Group, April 2015

Medical Policy Group, October 2016

Medical Policy Group, September 2019

Medical Policy Group, December 2020

Medical Policy Group, December 2021

Medical Policy Group, September 2022: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.

Medical Policy Group, September 2023: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.

Medical Policy Group, November 2023: Archived effective 11/1/2023.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.