



An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 12/05/23
LAST REVIEW DATE: 11/19/24
CURRENT EFFECTIVE DATE: 11/19/24
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

NEXT ANNUAL REVIEW DATE: 4TH QTR 2025

PERCUTANEOUS ELECTRICAL NERVE FIELD STIMULATION FOR IRRITABLE BOWEL SYNDROME

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Irritable Bowel Syndrome:

Irritable bowel syndrome (IBS) is estimated to affect 5% to 10% of the population globally, and accounts for between 2.4 and 3.5 million physician visits in the United States each year. Up to two-thirds of individuals with IBS are female, and it is most common in individuals less than 50 years of age. The cause of IBS remains unknown but is believed to be due to a dysfunction in gut-brain interaction. Symptoms of IBS can include diarrhea, constipation, or both. Abdominal pain and bloating are also common IBS symptoms. These symptoms decrease quality of life and create a significant healthcare burden.

Percutaneous Electrical Nerve Field Stimulation:

Because there are few pharmacologic treatments for children and adolescents with IBS, nonpharmacologic options are commonly explored. Percutaneous electrical nerve field stimulation (PENFS) is a potential treatment option for these individuals. PENFS involves a non-implantable device which stimulates nerves remotely from the site of pain and has been studied for a variety of musculoskeletal or neuropathic pain conditions or for individuals with opioid withdrawal. Electrical impulses are transmitted to cranial nerve bundles in the ear targeting brain areas involved in processing pain. In the case of individuals with irritable bowel syndrome, nerves processing pain for the abdominal region are targeted.

FDA cleared percutaneous electrical nerve stimulation devices for irritable bowel syndrome include the IB-Stim™ and the First Relief® v1.

Criteria:

- Percutaneous electrical nerve field stimulation for abdominal pain in individuals with irritable bowel syndrome is considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
 1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes;
 3. Insufficient evidence to support improvement of the net health outcome; or
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
 5. Insufficient evidence to support improvement outside the investigational setting.

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Resources:

Literature reviewed 11/19/24. We do not include marketing materials, poster boards and non-published literature in our review

Resources prior to 10/01/24 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. Babygirija R, Sood M, Kannampalli P, Sengupta JN, Miranda A. Percutaneous electrical nerve field stimulation modulates central pain pathways and attenuates post-inflammatory visceral and somatic hyperalgesia in rats. *Neuroscience*. Jul 25 2017;356:11-21. doi:10.1016/j.neuroscience.2017.05.012
2. Bora G, Atkinson SN, Pan A, Sood M, Salzman N, Karrento K. Impact of auricular percutaneous electrical nerve field stimulation on gut microbiome in adolescents with irritable bowel syndrome: A pilot study. *J Dig Dis*. May 2023;24(5):348-358. doi:10.1111/1751-2980.13203
3. Castillo DF, Denson LA, Haslam DB, et al. The microbiome in adolescents with irritable bowel syndrome and changes with percutaneous electrical nerve field stimulation. *Neurogastroenterol Motil*. Jul 2023;35(7):e14573. doi:10.1111/nmo.14573
4. Chang L, Sultan S, Lembo A, Verne GN, Smalley W, Heidelbaugh JJ. AGA Clinical Practice Guideline on the Pharmacological Management of Irritable Bowel Syndrome With Constipation. *Gastroenterology*. Jul 2022;163(1):118-136. doi:10.1053/j.gastro.2022.04.016
5. Chogle A, El-Chammas K, Santucci N, et al. A multicenter registry study on percutaneous electrical nerve field stimulation for pediatric disorders of gut-brain interaction. *J Pediatr Gastroenterol Nutr*. Apr 2024;78(4):817-826. doi:10.1002/jpn3.12174
6. Chogle A, Visnagra K, Janchoi J, et al. Prospective study of the effect of auricular percutaneous electrical nerve field stimulation on quality of life in children with pain related disorders of gut-brain interaction. *Front Pain Res (Lausanne)*. 2023;4:1223932. doi:10.3389/fpain.2023.1223932
7. IB-Stim. Accessed June 26, 2024. <https://ibstim.com/research/#FDA-Classification>
8. International Foundation for Gastrointestinal Disorders. IBS Facts and Statistics. Accessed June 26, 2024. <https://aboutibs.org/what-is-ibs/facts-about-ibs/>
9. Karrento K, Zhang L, Conley W, et al. Percutaneous electrical nerve field stimulation improves comorbidities in children with cyclic vomiting syndrome. *Front Pain Res (Lausanne)*. 2023;4:1203541. doi:10.3389/fpain.2023.1203541
10. Kovacic K, Hainsworth K, Sood M, et al. Neurostimulation for abdominal pain-related functional gastrointestinal disorders in adolescents: a randomised, double-blind, sham-controlled trial. *Lancet Gastroenterol Hepatol*. Oct 2017;2(10):727-737. doi:10.1016/S2468-1253(17)30253-4

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11. Kovacic K, Kolacz J, Lewis GF, Porges SW. Impaired vagal efficiency predicts auricular neurostimulation response in adolescent functional abdominal pain disorders. *Am J Gastroenterol*. Sep 2020;115(9):1534-1538. doi:10.14309/ajg.0000000000000753
12. Krasaelap A, Sood MR, Li BUK, et al. Efficacy of Auricular Neurostimulation in Adolescents With Irritable Bowel Syndrome in a Randomized, Double-Blind Trial. *Clin Gastroenterol Hepatol*. Aug 2020;18(9):1987-1994 e2. doi:10.1016/j.cgh.2019.10.012
13. Lacy BE, Pimentel M, Brenner DM, et al. ACG Clinical Guideline: Management of Irritable Bowel Syndrome. *Am J Gastroenterol*. Jan 1 2021;116(1):17-44. doi:10.14309/ajg.0000000000001036
14. Lembo A, Sultan S, Chang L, Heidelbaugh JJ, Smalley W, Verne GN. AGA Clinical Practice Guideline on the Pharmacological Management of Irritable Bowel Syndrome With Diarrhea. *Gastroenterology*. Jul 2022;163(1):137-151. doi:10.1053/j.gastro.2022.04.017
15. Miranda A. Opinion: Percutaneous electrical nerve field stimulation compared to standard medical therapy in adolescents with functional abdominal pain disorders. *Front Pain Res (Lausanne)*. 2024;5:1279946. doi:10.3389/fpain.2024.1279946
16. National Institute of Diabetes and Digestive and Kidney Diseases. Definition & Facts for Irritable Bowel Syndrome. Updated November 2017. Accessed June 26, 2024. <https://www.niddk.nih.gov/health-information/digestive-diseases/irritable-bowel-syndrome/definition-facts>
17. Roberts A, Sithole A, Sedghi M, Walker CA, Quinn TM. Minimal adverse effects profile following implantation of periauricular percutaneous electrical nerve field stimulators: a retrospective cohort study. *Med Devices (Auckl)*. 2016;9:389-393. doi:10.2147/MDER.S107426
18. Santucci NR, Beigarten AJ, Khalid F, et al. Percutaneous electrical nerve field stimulation in children and adolescents with functional dyspepsia-integrating a behavioral intervention. *Neuromodulation*. Aug 16 2023;doi:10.1016/j.neurom.2023.07.005
19. Santucci NR, King C, El-Chammas KI, et al. Effect of percutaneous electrical nerve field stimulation on mechanosensitivity, sleep, and psychological comorbidities in adolescents with functional abdominal pain disorders. *Neurogastroenterol Motil*. Aug 2022;34(8):e14358. doi:10.1111/nmo.14358
20. Santucci NR, Sahay R, El-Chammas KI, et al. Percutaneous electrical nerve field stimulation compared to standard medical therapy in adolescents with functional abdominal pain disorders. *Front Pain Res (Lausanne)*. 2023;4:1251932. doi:10.3389/fpain.2023.1251932
21. Shah E, Eswaran S, Harer K, et al. Percutaneous electrical nerve field stimulation for adolescents with irritable bowel syndrome: Cost-benefit and cost-minimization analysis. *J Pediatr Gastroenterol Nutr*. Mar 2024;78(3):608-613. doi:10.1002/jpn3.12118



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Coding:

CPT: 0720T

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<u>History:</u>	<u>Date:</u>	<u>Activity:</u>
Medical Policy Panel (ad hoc)	11/19/24	Review with revisions
Medical Policy Panel	10/01/24	Review with revisions
Medical Policy Panel	12/05/23	Approved guideline
Medical Director (Dr. Raja)	11/30/23	Development

Policy Revisions:

11/19/24 Updated: Resources section
10/01/24 Updated: Resources section



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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idilkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idilkidgo beehaz'áanii hólo díí t'áá hazaadk'ehjí háká a'doowotgo bee haz'á doo baqah ilinígóó. Ata' halne'ígíí kojí' bich'í' hodilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

