

Electrical Stimulation and Electromagnetic Therapy for Wounds (for Indiana Only)

Policy Number: CS035IN.04 Effective Date: April 1, 2023

☐ Instructions for Use

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Related Policy

<u>Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation (for Indiana Only)</u>

Application

This Medical Policy only applies to the state of Indiana.

Coverage Rationale

Electrical Stimulation and Electromagnetic Therapy for wounds is medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® Medicare: Procedures, Wound Care.

Click here to view the InterQual® criteria.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
*E0769	Electrical stimulation or electromagnetic wound treatment device, not otherwise classified
G0281	Electrical stimulation, (unattended), to one or more areas, for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care, as part of a therapy plan of care
G0282	Electrical stimulation, (unattended), to one or more areas, for wound care other than described in G0281
*G0295	Electromagnetic therapy, to one or more areas, for wound care other than described in G0329 or for other uses

HCPCS Code	Description
*G0329	Electromagnetic therapy, to one or more areas for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care as part of a therapy plan of care

Note: Codes labeled with an asterisk (*) are not managed for medical necessity review for the state of Indiana at the time this policy became effective. Refer to the most up to date prior authorization list for Indiana at Prior Authorization and Notification: UnitedHealthcare Community Plan of Indiana.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

The FDA has not approved any electrical stimulation or electromagnetic devices specifically for the treatment of chronic wounds. Use of these devices for wound healing is an off-label indication.

The FDA regulates electrical stimulation devices as Class II devices, and more than 500 of these devices have been cleared by the FDA 510(k) process. To locate marketing clearance information for a specific device or manufacturer, search the following Center for Devices and Radiological Health (CDRH) 510(k) database or the Premarket Approval (PMA) database by product and/or manufacturer name:

- http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
- http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm

(Accessed October 17, 2022)

Electromagnetic Therapy Devices

The Diapulse® device is classified by the FDA as "diathermy, shortwave, for use other than applying therapeutic deep heat" and received a device class 3 license in 1987. In 1991, the FDA notified the Diapulse Corporation that their device may only be marketed as adjunctive therapy in the palliative treatment of postoperative edema and pain in superficial soft tissue. It has not been approved by the FDA for the treatment of chronic wounds. This means the manufacturer may not market the device for wound healing although this does not prohibit physicians and other healthcare providers from providing this therapy for unapproved uses. The SofPulse™ device is also classified under "diathermy, shortwave, for use other than applying therapeutic deep heat" and received a device class 3 license in 1996.

The Provant® Wound Closure System utilizes the Regenesis Model 42, classified by the FDA as a short-wave diathermy device. It received 510(k) clearance in October 1997 for use in the palliative treatment of postoperative pain and edema in superficial soft tissue. According to the FDA, this device applies electromagnetic energy to the body and is substantially equivalent to the SofPulse device.

Policy History/Revision Information

Date	Summary of Changes
04/01/2023	 Coverage Rationale Revised language to indicate electrical stimulation and electromagnetic therapy for wounds are medically necessary in certain circumstances; for medical necessity clinical coverage criteria, refer to the InterQual® Medicare: Procedures, Wound Care Applicable Codes Added notation to indicate HCPCS codes E0769, G0295, and G0329 are not managed for medical necessity review for the state of Indiana at this time; refer to the most current <i>Prior Authorization and Notification List</i> for UnitedHealthcare Community Plan of Indiana
	 Supporting Information Removed <i>Definitions</i>, <i>Description of Services</i>, <i>Clinical Evidence</i>, and <i>References</i> sections Archived previous policy version CS035IN.03

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.