



MEDICAL COVERAGE GUIDELINES
SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE: 08/09/11
LAST REVIEW DATE: 01/22/19
LAST CRITERIA REVISION DATE: 02/04/14
ARCHIVE DATE:

NEGATIVE PRESSURE WOUND THERAPY

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 Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline 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.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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NEGATIVE PRESSURE WOUND THERAPY (cont.)

Description:

Negative pressure wound therapy (NPWT) uses negative pressure therapy or suction devices to aspirate and remove fluids, debris and infectious materials and debris from wound beds to promote the formation of granulation tissue. It is believed that NPWT contributes to wound healing by removing excess interstitial fluid, increasing the vascularity of the wound and/or creating beneficial mechanical forces that draw the edges of the wound closer together. NPWT may be used as an adjunct to surgical therapy or as an alternative to surgery in a debilitated individual.

NPWT devices may be powered (battery and/or electrically operated) or non-powered (mechanically or spring operated).

- Powered devices include:
 - extriCARE® 2400 NPWT System
 - Foryou NPWT NP 32 Device
 - Kalypto®
 - PICO™ Single Use Negative Pressure Wound Therapy System
 - Prevena™ Incision Management System
 - RENASYS™ EZ PLUS
 - RENASYS™ GO
 - Vacuum Assisted Closure® (V.A.C.)
 - V.A.C. Via™
 - Versatile 1™ Wound Negative Pressure Therapy System
 - XLR8 PLUS

- Non-powered devices include:
 - Smart Negative Pressure (SNaP)™ Wound Care System

Definitions:

Chronic Wound:

Chronic wound is present for at least 30 days despite standard medical and surgical management.

Progressive Improvement of Healing:

Improvement of wound closure as documented by quantitative measurements of wound length, depth and width over a specified time period.

Healed Wound:

Healed wound has attained complete closure.

NEGATIVE PRESSURE WOUND THERAPY (cont.)

Criteria:

Powered Negative Pressure Wound Therapy:

- Powered negative pressure wound therapy (device and associated supplies) is considered **medically necessary** for the treatment of acute and chronic wounds unless otherwise contraindicated
- Powered negative pressure wound therapy is considered contraindicated or **not medically necessary** with documentation of **ANY** of the following:
 1. Failure of progressive improvement of healing over the past 30 days
 2. Necrotic tissue with eschar
 3. Untreated osteomyelitis
 4. Cancer in the wound
 5. Fistula within the vicinity of the wound
 6. Nutritionally compromised individual without nutritional supplementation
 7. Adequate wound healing has occurred or depth of wound is less than 0.5 cm
- Powered negative pressure wound therapy for all other indications not previously listed or if above criteria not met is considered **experimental or investigational** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

Non-Powered Negative Pressure Wound Therapy:

- Non-powered negative pressure wound therapy is considered **experimental or investigational** based upon:
 1. Insufficient evidence to support improvement of the net health outcome, and
 2. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.



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Resources:

Literature reviewed 02/20/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

1. 1.01.16 Blue Cross Blue Shield Association Medical Policy Reference Manual. Negative Pressure Wound Therapy in the Outpatient Setting. Re-issue date 01/11/2018, issue date 01/30/1998.
2. Armstrong DG, Marston WA, Reyzelman AM, Kirsner RS. Comparative effectiveness of mechanically and electrically powered negative pressure wound therapy devices: A multicenter randomized controlled trial. *Wound Repair Regen.* May-Jun 2012;20(3):332-341.
3. Hutton DW, Sheehan P. Comparative effectiveness of the SNaP Wound Care System. *Int Wound J.* Apr 2011;8(2):196-205.



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NEGATIVE PRESSURE WOUND THERAPY (cont.)

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'idííkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idííkidgo beehaz'áanii hólg díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilínígóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 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.

