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#### **Medicare Advantage Medical Coverage Policy**

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#### **Disclaimer**

**Change Summary** 

The Coverage Summaries are reviewed by the iCare Medicare Utilization Management Committee. Clinical policy is not intended to preempt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test, or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. References to CPT® codes or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee of claims payment. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from iCare

### **Related Medicare Advantage Medical/Pharmacy Coverage Policies**

None

#### **Related Documents**

Please refer to <a href="CMS website">CMS website</a> for the most current applicable National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

Туре	Title	ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories
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			J5 - Wisconsin	
			Physicians Service	
			Insurance	
			Corporation	IA, KS, MO, NE
LCD	Wound Care	<u>L37228</u>	Corporation	
LCA	Dilling and Cadings Wayned Care		J8 - Wisconsin	IN, MI
	Billing and Coding: Wound Care	<u>A55909</u>	Physicians Service	
			Insurance	
			Corporation	
	Wound and Ulcer Care	L38902	JE - Noridian	CA, HI, NV, American
LCD			Healthcare	Samoa, Guam,
LCA	Billing and Coding: Wound and	<u>A58565</u>	Solutions, LLC	Northern Mariana
	Ulcer Care		Solutions, LLC	Islands
	Wound and Ulcer Care	<u>L38904</u>	JF - Noridian	AK, AZ, ID, MT, ND,
LCD			Healthcare	OR, SD, UT, WA, WY
LCA	Billing and Coding: Wound and	<u>A58567</u>	Solutions, LLC	
	Ulcer Care		III No Star	
			JH - Novitas	AD CO NIM OV TV
	Wound Care	125125	Solutions, Inc. (Part A/B MAC)	AR, CO, NM, OK, TX, LA, MS
LCD	Woulld Care	<u>L35125</u>	A/ B IVIAC)	LA, IVIS
LCA	Billing and Coding: Wound Care	A53001	JL - Novitas	DE, D.C., MD, NJ, PA
	bining and county. Wound care	<u> </u>	Solutions, Inc. (Part	DE, D.C., 141D, 143, 174
			A/B MAC)	
1.00	Wound Care	L37166	JN - First Coast	
LCD			Service Options, Inc.	FL, PR, U.S. VI
LCA	Billing and Coding: Wound Care	<u>A55818</u>	(Part A/B MAC)	
			DME A - Noridian	CT, DE, DC, ME, MD,
			Healthcare	MA, NH, NJ, NY, PA,
			Solutions, LLC (DME	RI, VT
			MAC)	
				IL, IN, KY, MI, MN,
	Negative Pressure Mound		DME B - CGS	OH, WI
	Negative Pressure Wound	<u>L33821</u>	Administrators, LLC	
LCD	Therapy Pumps		(DME MAC)	AL, AR, CO, FL, GA,
LCA	Negative Pressure Wound	A F 2 F 4 4	DN4E C CCC	LA, MS, NM, NC, OK,
	Therapy Pumps - Policy Article	<u>A52511</u>	DME C - CGS	SC, TN, TX, VA, WV,
	crapy ramps roney Article		Administrators, LLC (DME MAC)	PR, U.S. VI
			(DIVIE IVIAC)	AK, AZ, CA, HI, ID, IA,
			DME D - Noridian	KS, MO, MT, NE, NV,
			Healthcare	ND, OR, SD, UT, WA,
			Solutions, LLC (DME	WY, American
			MAC)	Samoa, Guam,
	1	I	1	

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	Northern Mariana
	Islands

#### **Description**

Negative pressure wound therapy (NPWT), also called vacuum assisted wound closure, refers to wound dressing systems that continuously or intermittently apply subatmospheric pressure to the surface of a wound. NPWT is most commonly used in the treatment of acute and chronic wounds such as surgical wounds, various soft tissue injuries or ulcers (eg, diabetic foot, pressure and venous leg). This technique may also be prescribed to promote healing prior to using a flap or skin graft by advancing early healing of the site, thereby preparing the wound bed for surgical reconstruction. NPWT involves the application of a localized vacuum to the wound surface to draw the edges of the wound together. NPWT devices are available as rental (portable) or disposable (single-use) units.

The NPWT device consists of a dressing of gauze and/or open-celled reticulated foam that is placed in the wound. A tube is embedded into the dressing and sealed with an adhesive transparent dressing. Attached to the tube is a vacuum pump which applies negative pressure to the wound. This pressure drains fluid and exudates from the wound to a disposable canister. The intent of this treatment is to help reduce edema, improve vascularity and oxygenation of the wound bed, provide a moist environment and help stimulate healthy granulation tissue conducive to rapid wound healing.

Negative pressure wound therapy placement over surgically closed incisions is an alternative to absorbent dressings, gauze and adhesive medical tape (eg, npSIMS, Prevena, Prevena Duo and Prevena Restor Incision Management System). Purportedly intended to promote healing by holding incision sides closed, removing fluid and reducing the incidence of seromas and surgical site infections.

Negative pressure wound therapy with instillation (NPWTi) is the combination of NPWT with timed, intermittent delivery of a topical solution. The fluid reportedly helps to remove wound exudate, slough and bacteria to purportedly promote more rapid healing of the wound. The solution is delivered and remains in the wound for a set amount of time and subsequently removed via NPWT.

## **Coverage Determination**

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

Please refer to the above Medicare guidance for **negative pressure wound therapy (NPWT) device**.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the following criteria:

**Negative pressure wound therapy, or NPWT, (codes 97605-97608)** will be considered medically reasonable and necessary when one of the following indications is met<sup>12,13</sup>:

- Chronic, non-healing ulcer with lack of improvement despite standard wound therapy which includes: applications of dressings, adequate blood glucose control, debridement of necrotic tissue (if present), maintenance of an adequate nutritional status, offloading, and weekly evaluations with documentation of wound measurements (i.e. length, width, and depth) in one of the following clinical situations:
  - Acute wounds; OR
  - Subacute and dehisced wounds; OR
  - Traumatic wounds; OR
  - Ulcers (such as diabetic or pressure); OR
  - Chronic <u>Stage III or IV pressure ulcers</u>; **OR**
  - Chronic diabetic neuropathic ulcer; OR
  - o Chronic venous ulcer; OR
  - Flaps and grafts; OR
- Complications of a surgically created wound (e.g., dehiscence, post sternotomy disunion with exposed sternal bone, post sternotomy mediastinitis, or postoperative disunion of the abdominal wall); **OR**
- Traumatic wound (preoperative flap or graft, exposed bones, tendons, or vessels) and a need for
  accelerated formation of granulation tissue not achievable by other topical wound treatments (the
  individual has comorbidities that will not allow for healing times usually achievable with other available
  topic wound treatments).

**Continuation of NPWT** treatment for an additional 30 days for the treatment of wounds will be considered medically reasonable and necessary when documentation is provided by an appropriate licensed medical professional and **ALL** of the following criteria are met:

• There is improvement in the wound measurements (volume or surface dimension) with NPWT treatment

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

#### **Coverage Limitations**

<u>US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage</u>

**NPWT** devices will not be considered medically reasonable and necessary for wounds that have responded to standard therapeutic measures **OR** for individuals with the following contraindications<sup>12,13,54</sup>:

- Exposed vital organs; OR
- Fistulas to organs or body cavities; OR

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- Malignancy in the wound; **OR**
- Necrotic tissue with eschar; **OR**
- Placement over exposed arteries or veins; OR
- Placement over exposed nerves; OR
- Presence of exposed anastomotic sites (located at the site of the surgical connection of two tubular structures); OR
- Untreated osteomyelitis

# **Coding Information**

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
97605	Negative pressure wound therapy (eg, vacuum assisted drainage collection), utilizing durable medical equipment (DME), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters	
97606	Negative pressure wound therapy (eg, vacuum assisted drainage collection), utilizing durable medical equipment (DME), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters	
97607	Negative pressure wound therapy, (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters	
97608	Negative pressure wound therapy, (eg, vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters	
CPT®		
Category III Code(s)	Description	Comments
No code(s) ide	entified	

HCPCS Code(s)	Description	Comments
A6550	Wound care set, for negative pressure wound therapy electrical pump, includes all supplies and accessories	
A7000	Canister, disposable, used with suction pump, each	
A9272	Wound suction, disposable, includes dressing, all accessories and components, any type, each	
E2402	Negative pressure wound therapy electrical pump, stationary or portable	
K0743	Suction pump, home model, portable, for use on wounds	
K0744	Absorptive wound dressing for use with suction pump, home model, portable, pad size 16 sq in or less	
K0745	Absorptive wound dressing for use with suction pump, home model, portable, pad size more than 16 sq in but less than or equal to 48 sq in	
K0746	Absorptive wound dressing for use with suction pump, home model, portable, pad size greater than 48 sq in	

#### References

- Agency for Healthcare Research and Quality (AHRQ). Technology Assessment. Negative pressure wound therapy technologies for chronic wound care in the home setting. <a href="https://www.ahrq.gov">https://www.ahrq.gov</a>. Published September 15, 2014. Accessed February 7, 2023.
- American Academy of Orthopaedic Surgeons (AAOS). Prevention of surgical site infections after major extremity trauma evidence based clinical practice guideline. <a href="https://www.aaos.org">https://www.aaos.org</a>. Published March 21, 2022. Accessed February 15, 2023.
- 3. American Diabetes Association (ADA). Standards of medical care in diabetes 2023. <a href="https://www.diabetes.org">https://www.diabetes.org</a>. Published January 2023. Accessed February 14, 2023.
- 4. Centers for Medicare & Medicaid Services (CMS). Local Coverage Article (LCA). Billing and Coding: Wound and Ulcer Care (A58565). <a href="https://www.cms.gov">https://www.cms.gov</a>. Published November 28, 2021. Updated February 3, 2022. Accessed August 29, 2023.
- 5. Centers for Medicare & Medicaid Services (CMS). Local Coverage Article (LCA). Billing and Coding: Wound and Ulcer Care (A58567). <a href="https://www.cms.gov">https://www.cms.gov</a>. Published November 28, 2021. Updated February 3, 2022. Accessed August 29, 2023.
- Centers for Medicare & Medicaid Services (CMS). Local Coverage Article (LCA). Billing and Coding: Wound Care (A53001). <a href="https://www.cms.gov">https://www.cms.gov</a>. Published October 1, 2015. Updated February 10, 2022. Accessed August 29, 2023.

- 7. Centers for Medicare & Medicaid Services (CMS). Local Coverage Article (LCA). Billing and Coding: Wound Care (A55818). <a href="https://www.cms.gov">https://www.cms.gov</a>. Published December 7, 2017. Updated February 10, 2022. Accessed August 29, 2023.
- 8. Centers for Medicare & Medicaid Services (CMS). Local Coverage Article (LCA). Billing and Coding: Wound Care (A55909). <a href="https://www.cms.gov">https://www.cms.gov</a>. Published April 16, 2018. Updated April 27, 2023. Accessed August 29, 2023.
- 9. Centers for Medicare & Medicaid Services (CMS). Local Coverage Article (LCA). Negative Pressure Wound Therapy Pumps (A52511). <a href="https://www.cms.gov">https://www.cms.gov</a>. Published October 1, 2015. Updated August 15, 2021. Accessed August 29, 2023.
- 10. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Wound and Ulcer Care (L38902). https://www.cms.gov. Published November 28, 2021. Accessed August 29, 2023.
- 11. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Wound and Ulcer Care (L38904). <a href="https://www.cms.gov">https://www.cms.gov</a>. Published November 28, 2021. Accessed August 29, 2023.
- 12. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Wound Care (L35125). <a href="https://www.cms.gov">https://www.cms.gov</a>. Published October 1, 2015. Updated July 23, 2020. Accessed August 29, 2023.
- 13. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Wound Care (L37166). <a href="https://www.cms.gov">https://www.cms.gov</a>. Published December 7, 2017. Updated July 23, 2020. Accessed August 29, 2023.
- 14. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Wound Care (L37228). <a href="https://www.cms.gov">https://www.cms.gov</a>. Published April 16, 2018. Updated April 27, 2023. Accessed August 29, 2023.
- 15. Centers for Medicare & Medicaid Services (CMS). Local Coverage Determination (LCD). Negative Pressure Wound Therapy Pumps (L33821). <a href="https://www.cms.gov">https://www.cms.gov</a>. Published October 1, 2015. Updated May 1, 2021. Accessed August 29, 2023.
- 16. ECRI Institute. Clinical Evidence Assessment. ActiV.A.C. negative pressure wound therapy (3M KCI, Inc.) for treating chronic wounds. <a href="https://www.ecri.org">https://www.ecri.org</a>. Published March 9, 2023. Accessed March 17, 2023.
- 17. ECRI Institute. Clinical Evidence Assessment. Avelle negative pressure wound therapy system (ConvaTec, Inc.) for surgical wound healing. <a href="https://www.ecri.org">https://www.ecri.org</a>. Published August 1, 2020. Accessed February 6, 2023.
- 18. ECRI Institute. Clinical Evidence Assessment. PICO single-use negative pressure wound therapy system (Smith & Nephew, Inc.) for treating surgical wounds. <a href="https://www.ecri.org">https://www.ecri.org</a>. Published October 14, 2015. Updated January 18, 2023. Accessed February 6, 2023.

- 19. ECRI Institute. Clinical Evidence Assessment. Prevena incision management system (KCI USA, Inc., a 3M Company) for delivering negative pressure wound therapy. <a href="https://www.ecri.org">https://www.ecri.org</a>. Published February 1, 2012. Updated August 14, 2020. Accessed February 6, 2023.
- 20. ECRI Institute. Clinical Evidence Assessment. Standard-of-care practices for managing diabetic foot ulcers. <a href="https://www.ecri.org">https://www.ecri.org</a>. Published January 28, 2020. Updated December 31, 2021. Accessed February 6, 2023.
- 21. ECRI Institute. Clinical Evidence Assessment. V.A.C.Ulta with instillation and dwell therapy (3M KCI, Inc.) for negative pressure wound therapy. <a href="https://www.ecri.org">https://www.ecri.org</a>. Published September 1, 2018. Updated May 1, 2021. Accessed February 6, 2023.
- 22. ECRI Institute. Hotline Response (ARCHIVED). Vacuum-assisted and negative pressure wound therapies for reducing surgical site infections. <a href="https://www.ecri.org">https://www.ecri.org</a>. Published June 30, 2015. Accessed February 6, 2023.
- 23. ECRI Institute. Product Brief. Prevena incision management systems (3M + KCI USA, Inc.) for post-mastectomy and breast reconstruction wound healing. <a href="https://www.ecri.org">https://www.ecri.org</a>. Published March 27, 2020. Accessed February 6, 2023.
- 24. ECRI Institute. Product Brief (ARCHIVED). Renasys system (Smith and Nephew plc.) for performing negative pressure wound therapy. <a href="https://www.ecri.org">https://www.ecri.org</a>. Published March 15, 2016. Updated September 18, 2018. Accessed February 6, 2023.
- 25. ECRI Institute. Product Brief (ARCHIVED). SNaP wound care system (Spiracur, Inc.) for delivering negative pressure wound therapy. <a href="https://www.ecri.org">https://www.ecri.org</a>. Published September 3, 2014. Accessed February 6, 2023.
- 26. ECRI Institute. Product Brief (ARCHIVED). SVED system (Cardinal Health) for performing negative pressure wound therapy. <a href="https://www.ecri.org">https://www.ecri.org</a>. Published March 30, 2017. Updated September 18, 2018. Accessed February 6, 2023.
- Hayes, Inc. Clinical Research Response (ARCHIVED). Negative pressure wound therapy (NPWT) for clean, closed, orthopedic incisions of the ankle and lower leg.
   <a href="https://evidence.hayesinc.com/https://evidence.hayesinc.com">https://evidence.hayesinc.com</a>. Published July 26, 2021. Accessed February 6, 2023.
- 28. Hayes, Inc. Clinical Research Response (ARCHIVED). Negative pressure wound therapy (NPWT) for primary arthroplasty of the hip or knee. <a href="https://evidence.hayesinc.com">https://evidence.hayesinc.com</a>. Published July 26, 2021. Accessed February 6, 2023.
- 29. Hayes, Inc. Clinical Research Response (ARCHIVED). Negative pressure wound therapy (NPWT) for revision arthroplasty of the hip or knee. <a href="https://evidence.hayesinc.com">https://evidence.hayesinc.com</a>. Published July 26, 2021. Accessed February 6, 2023.

- 30. Hayes, Inc. Evidence Analysis Research Brief. Negative pressure wound therapy for closed surgical incisions following total joint arthroplasty. <a href="https://evidence.hayesinc.com">https://evidence.hayesinc.com</a>. Published October 18, 2022. Accessed February 6, 2023.
- 31. Hayes, Inc. Evidence Analysis Research Brief. Outpatient negative pressure wound therapy for treatment of chronic wounds. <a href="https://evidence.hayesinc.com">https://evidence.hayesinc.com</a>. Published March 31, 2022. Accessed February 6, 2023.
- 32. Hayes, Inc. Evidence Analysis Research Brief (ARCHIVED). PICO single use negative pressure wound therapy system (Smith & Nephew) for clean surgical incisions. <a href="https://evidence.hayesinc.com">https://evidence.hayesinc.com</a>. Published May 5, 2020. Accessed February 6, 2023.
- 33. Hayes, Inc. Evolving Evidence Review. PICO single use negative pressure wound therapy system (Smith & Nephew) for cesarean birth wound care. <a href="https://evidence.hayesinc.com">https://evidence.hayesinc.com</a>. Published June 30, 2022. Accessed February 6, 2023.
- 34. Hayes, Inc. Health Technology Assessment. Negative pressure wound therapy after surgery for pilonidal disease. <a href="https://evidence.hayesinc.com">https://evidence.hayesinc.com</a>. Published February 26, 2020. Updated March 13, 2023. Accessed March 17, 2023.
- 35. Hayes, Inc. Health Technology Assessment. Prophylactic negative pressure wound therapy in elective open abdominal surgeries. <a href="https://evidence.hayesinc.com">https://evidence.hayesinc.com</a>. Published February 4, 2021. Updated February 17, 2023. Accessed March 9, 2023.
- 36. Hayes, Inc. Health Technology Brief (ARCHIVED). Negative pressure wound therapy after fasciotomy. <a href="https://evidence.hayesinc.com">https://evidence.hayesinc.com</a>. Published February 26, 2014. Updated January 25, 2016. Accessed February 6, 2023.
- 37. Hayes, Inc. Health Technology Brief (ARCHIVED). Negative pressure wound therapy with instillation. <a href="https://evidence.hayesinc.com">https://evidence.hayesinc.com</a>. Published December 1, 2016. Updated November 28, 2018. Accessed February 6, 2023.
- 38. Hayes, Inc. Health Technology Brief (ARCHIVED). SNaP wound care system (Spiracur Inc.) for treatment of lower extremity ulcers. <a href="https://evidence.hayesinc.com">https://evidence.hayesinc.com</a>. Published December 27, 2012. Updated December 30, 2014. Accessed February 6, 2023.
- 39. Hayes, Inc. Medical Technology Directory (ARCHIVED). Negative pressure wound therapy (NPWT) in the adjunct treatment of skin grafts. <a href="https://evidence.hayesinc.com">https://evidence.hayesinc.com</a>. Published June 25, 2015. Updated July 25, 2019. Accessed February 6, 2023.
- 40. Hayes, Inc. Medical Technology Directory (ARCHIVED). Negative pressure wound therapy for chronic wounds: home use. <a href="https://evidence.hayesinc.com">https://evidence.hayesinc.com</a>. Published December 15, 2016. Updated May 10, 2021. Accessed February 6, 2023.

- 41. Hayes, Inc. Medical Technology Directory (ARCHIVED). Negative pressure wound therapy for postsurgical mediastinitis. <a href="https://evidence.hayesinc.com">https://evidence.hayesinc.com</a>. Published March 12, 2015. Updated February 26, 2019. Accessed February 6, 2023.
- 42. Hayes, Inc. Medical Technology Directory (ARCHIVED). Negative pressure wound therapy for wounds other than sternal wounds and skin grafts. <a href="https://evidence.hayesinc.com">https://evidence.hayesinc.com</a>. Published July 17, 2012. Updated May 26, 2016. Accessed February 6, 2023.
- 43. MCG Health. Negative pressure wound therapy (vacuum-assisted wound closure). 26<sup>th</sup> edition. <a href="https://www.mcg.com">https://www.mcg.com</a>. Accessed February 8, 2023.
- 44. National Pressure Injury Advisory Panel (NPIAP). Clinical Practice Guideline. Prevention and treatment of pressure ulcers/injuries: quick reference guide. <a href="https://www.npiap.com">https://www.npiap.com</a>. Published 2019. Accessed February 15, 2023.
- 45. National Pressure Injury Advisory Panel (NPIAP). NPIAP pressure injury stages. <a href="https://www.npiap.com">https://www.npiap.com</a>. Published 2016. Accessed February 15, 2023.
- 46. National Pressure Injury Advisory Panel (NPIAP). NPUAP position statement on staging 2017 clarifications. https://www.npiap.com. Published January 24, 2017. Accessed February 15, 2023.
- 47. Society for Vascular Surgery (SVS). Management of venous leg ulcers: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum (ARCHIVED). <a href="https://www.veinforum.org">https://www.veinforum.org</a>. Published August 2014. Accessed February 15, 2023.
- 48. Society for Vascular Surgery (SVS). The management of diabetic foot: a clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine. <a href="https://www.vascular.org">https://www.vascular.org</a>. Published February 2016. Accessed February 15, 2023.
- 49. UpToDate, Inc. Basic principles of wound management. <a href="https://www.uptodate.com">https://www.uptodate.com</a>. Updated January 2023. Accessed February 7, 2023.
- 50. UpToDate, Inc. Enterocutaneous and enteroatmospheric fistulas. <a href="https://www.uptodate.com">https://www.uptodate.com</a>. Updated January 2023. Accessed February 7, 2023.
- 51. UpToDate, Inc. Management of diabetic foot ulcers. <a href="https://www.uptodate.com">https://www.uptodate.com</a>. Updated January 2023. Accessed February 7, 2023.
- 52. UpToDate, Inc. Management of perineal complications following an abdominal perineal resection. <a href="https://www.uptodate.com">https://www.uptodate.com</a>. Updated January 2023. Accessed February 7, 2023.
- 53. UpToDate, Inc. Management of the open abdomen in adults. <a href="https://www.uptodate.com">https://www.uptodate.com</a>. Updated January 2023. Accessed February 7, 2023.

- 54. UpToDate, Inc. Negative pressure wound therapy. <a href="https://www.uptodate.com">https://www.uptodate.com</a>. Updated January 2023. Accessed February 7, 2023.
- 55. UpToDate, Inc. Overview of control measures for prevention of surgical site infection in adults. <a href="https://www.uptodate.com">https://www.uptodate.com</a>. Updated January 2023. Accessed February 7, 2023.
- 56. UpToDate, Inc. Overview of the evaluation and management of surgical site infection. <a href="https://www.uptodate.com">https://www.uptodate.com</a>. Updated January 2023. Accessed February 7, 2023.
- 57. UpToDate, Inc. Overview of treatment of chronic wounds. <a href="https://www.uptodate.com">https://www.uptodate.com</a>. Updated January 2023. Accessed February 7, 2023.
- 58. UpToDate, Inc. Patient management following extremity fasciotomy. <a href="https://www.uptodate.com">https://www.uptodate.com</a>. Updated January 30, 2023. Accessed February 7, 2023.
- 59. UpToDate, Inc. Primary operative management of hand burns. <a href="https://www.uptodate.com">https://www.uptodate.com</a>. Updated January 2023. Accessed February 7, 2023.
- 60. UpToDate, Inc. Skin autografting. <a href="https://www.uptodate.com">https://www.uptodate.com</a>. Updated January 2023. Accessed February 7, 2023.
- 61. UpToDate, Inc. Surgical management of hidradenitis suppurativa. <a href="https://www.uptodate.com">https://www.uptodate.com</a>. Updated January 2023. Accessed February 7, 2023.
- 62. UpToDate, Inc. Surgical management of necrotizing soft tissue infections. <a href="https://www.uptodate.com">https://www.uptodate.com</a>. Updated January 2023. Accessed February 7, 2023.
- 63. UpToDate, Inc. Surgical management of pressure-induced skin and soft tissue injuries. <a href="https://www.uptodate.com">https://www.uptodate.com</a>. Updated January 2023. Accessed February 7, 2023.
- 64. UpToDate, Inc. Surgical management of sternal wound complications. <a href="https://www.uptodate.com">https://www.uptodate.com</a>. Updated January 2023. Accessed February 7, 2023.
- 65. UpToDate, Inc. Surgical resection of primary and soft tissue sarcoma of the extremities. <a href="https://www.uptodate.com">https://www.uptodate.com</a>. Updated January 2023. Accessed February 7, 2023.
- 66. UpToDate, Inc. Treatment of deep burns. <a href="https://www.uptodate.com">https://www.uptodate.com</a>. Updated January 2023. Accessed February 7, 2023.
- 67. US Food & Drug Administration (FDA). 510(k) summary: Avelle negative pressure wound therapy system. <a href="https://www.fda.gov">https://www.fda.gov</a>. Published October 19, 2018. Accessed January 24, 2019.
- 68. US Food & Drug Administration (FDA). 510(k) summary: Invia Motion negative pressure wound therapy system. <a href="https://www.fda.gov">https://www.fda.gov</a>. Published December 1, 2016. Accessed November 7, 2019.

- 69. US Food & Drug Administration (FDA). 510(k) summary: MyNeWT negative pressure wound therapy system. https://www.fda.gov. Published February 8, 2017. Accessed February 12, 2018.
- 70. US Food & Drug Administration (FDA). 510(k) summary: Nexa negative pressure wound therapy system. <a href="https://www.fda.gov">https://www.fda.gov</a>. Published June 8, 2017. Accessed January 24, 2019.
- 71. US Food & Drug Administration (FDA). 510(k) summary: npSIMS negative pressure surgical incision management system (npSIMS). <a href="https://www.fda.gov">https://www.fda.gov</a>. Published August 23, 2021. Accessed January 21, 2022.
- 72. US Food & Drug Administration (FDA). 510(k) summary: Occlusion detection dressing kit. <a href="https://www.fda.gov">https://www.fda.gov</a>. Published September 22, 2017. Accessed February 19, 2021.
- 73. US Food & Drug Administration (FDA). 510(k) summary: PICO 7Y single use negative pressure wound therapy system. <a href="https://www.fda.gov">https://www.fda.gov</a>. Published January 18, 2019. Accessed January 21, 2020.
- 74. US Food & Drug Administration (FDA). 510(k) summary: PICO single use negative pressure wound therapy system. https://www.fda.gov. Published January 28, 2016. Accessed January 31, 2017.
- 75. US Food & Drug Administration (FDA). 510(k) summary: Prevena incision management system. <a href="https://www.fda.gov">https://www.fda.gov</a>. Published November 6, 2015. Accessed January 31, 2017.
- 76. US Food & Drug Administration (FDA). 510(k) summary: Prevena Restor Incision management system. https://www.fda.gov. Published February 15, 2019. Accessed January 29, 2021.
- 77. US Food & Drug Administration (FDA). 510(k) summary: PWD negative pressure wound therapy system. https://www.fda.gov. Published September 21, 2022. Accessed February 7, 2023.
- 78. US Food & Drug Administration (FDA). 510(k) summary: SNaP wound care system. <a href="https://www.fda.gov">https://www.fda.gov</a>. Published November 19, 2015. Accessed February 1, 2017.
- 79. US Food & Drug Administration (FDA). 510(k) summary: SVED wound treatment system. <a href="https://www.fda.gov">https://www.fda.gov</a>. Published March 4, 2015. Accessed January 28, 2021.
- 80. US Food & Drug Administration (FDA). 510(k) summary: UNO negative pressure wound therapy system. <a href="https://www.fda.gov">https://www.fda.gov</a>. Published April 6, 2017. Accessed February 12, 2018.
- 81. US Food & Drug Administration (FDA). 510(k) summary: V.A.C. Via negative pressure wound therapy system. <a href="https://www.fda.gov">https://www.fda.gov</a>. Published November 15, 2013. Accessed February 1, 2017.
- 82. US Food & Drug Administration (FDA). 510(k) summary: V.A.C.Ulta negative pressure wound therapy system. https://www.fda.gov. Published January 26, 2017. Accessed February 13, 2018.
- 83. US Food & Drug Administration (FDA). FDA safety communication: update on serious complications associated with negative pressure wound therapy systems. <a href="https://www.fda.gov">https://www.fda.gov</a>. Published February 24, 2011. Accessed February 17, 2015.

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# Appendix

# Appendix A Pressure injury/wound staging classifications:

Stage 1	Nonblanchable erythema of intact skin — Intact skin with a localized area of		
Pressure Injury	nonblanchable erythema which may appear differently in darkly pigmented skin.		
i ressure injury	Presence of blanchable erythema or changes in sensation, temperature or firmness		
	may precede visual changes. Color changes do not include purple or maroon		
	discoloration; these may indicate deep tissue pressure injury.		
Stage 2	Partial thickness skin loss with exposed dermis – The wound bed is viable, pink or		
Pressure Injury	red, moist and may also present as an intact or ruptured serum filled blister.		
riessure injury	•		
	Adipose (fat) is not visible and deeper tissues are not visible. Granulation tissue, slough and eschar are not present. These injuries commonly result from adverse		
	microclimate and shear in the skin over the pelvis and shear in the heel. This stage		
	should not be used to describe moisture associated skin damage (MASD) including		
	incontinence associated dermatitis (IAD), intertriginous dermatitis (ITD), medical		
	adhesive related skin injury (MARSI) or traumatic wounds (skin tears, burns,		
	abrasions).		
Stage 3	Full thickness skin loss – Adipose (fat) is visible in the ulcer and granulation tissue		
Pressure Injury	and epibole (rolled wound edges) are often present. Slough and/or eschar may be		
i ressure injury	visible. The depth of tissue damage varies by anatomical location; areas of		
	significant adiposity can develop deep wounds. Undermining and tunneling may		
	occur. Fascia, muscle, tendon, ligament, cartilage and/or bone are not exposed.		
Stage 4	Full-thickness skin and tissue loss – Full-thickness skin and tissue loss with exposed		
Pressure Injury	or directly palpable bone, cartilage, fascia, ligament, muscle or tendon in the ulcer.		
i ressure injury	Slough and/or eschar may be visible. Epibole (rolled edges), undermining and/or		
	tunneling often occur. Depth varies by anatomical location.		
Unstageable	Obscured full-thickness skin and tissue loss – The extent of tissue damage within		
Pressure Injury	the ulcer cannot be confirmed because it is obscured by slough or eschar. If slough		
i ressure injury	or eschar is removed, a Stage 3 or Stage 4 pressure injury will be revealed. Stable		
	eschar (dry, adherent and intact without erythema or fluctuance) on the heel or		
	ischemic limb should not be softened or removed.		
Deep Tissue	Persistent nonblanchable deep red, maroon or purple discoloration – Intact or		
Pressure Injury	nonintact skin with localized area of persistent nonblanchable deep red, maroon,		
(DTPI)	purple discoloration or epidermal separation revealing a dark wound bed or blood		
	filled blister. Pain and temperature change often precede skin color changes.		
	Discoloration may appear differently in darkly pigmented skin. This injury results		
	from intense and/or prolonged pressure and shear forces at the bone-muscle		
	interface. The wound may evolve rapidly to reveal the actual extent of tissue injury		
	or may resolve without tissue loss. If fascia, granulation tissues, muscle, necrotic		
	tissues, subcutaneous tissues or other underlying structures are visible, this		
	indicates a full thickness pressure injury (Unstageable, Stage 3 or Stage 4). Do not		
	use DTPI to describe vascular, traumatic, neuropathic or dermatologic conditions.		

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Medical Device	Injury resulting from the use of devices designed and applied for diagnostic or
Related	therapeutic purposes. The resultant pressure injury generally conforms to the
Pressure Injury	pattern or shape of the device. The injury should be staged using the staging
	system.
Mucosal	Injury is found on mucous membranes with a history of a medical device in use at
Membrane	the location of the injury. Due to the anatomy of the tissue these injuries cannot be
Pressure Injury	staged.

# **Change Summary**

-	01/01/2024 New Policy.	