

Palmetto Medicare Policy Primer

Medicare Jurisdiction (JM) & (JJ) NC, SC, WV, VA, AL, GA & TN Application of Skin Substitutes LCD #L36466

Indications

Presence of neuropathic diabetic foot ulcer(s) having failed to respond to documented conservative wound-care measures of greater than four weeks, during which the patient is compliant with recommendations, and without evidence of underlying osteomyelitis or nidus of infection.

- Presence of a venous stasis ulcer that is unresponsive to documented appropriate therapy for greater than 4 weeks with documented compliance.
- Presence of a full-thickness skin loss ulcer that is the result of abscess, injury, or trauma that has failed to respond to appropriate control of infection, foreign body, tumor resection, or other disease process for a period of 4 weeks or longer.

All listed products, unless they are specifically FDA-labeled or cleared for use in the types of wounds being treated, will be considered to be biologic dressings and part of the relevant Evaluation and Management (E/M) service provided and not separately reimbursed.

Limitations

- One specific skin substitute graft per wound, per treatment will be allowed for wound care in compliance with FDA guidelines for that specific product not to exceed 10 applications or treatments.
- Repeat treatment with the same skin substitute graft is not considered medically reasonable and necessary when a previous full course of applications was unsuccessful.
- Unsuccessful treatment is defined as increase in size or depth of an ulcer or no change in baseline size or depth and no sign of improvement or indication that improvement is likely (such as granulation, epithelialization, or progress towards closing) for a period of 4 weeks past start of therapy.
- Retreatment of healed ulcers, those showing greater than 75% size reduction and smaller than 0.5 sq.cm, is not considered medically reasonable and necessary.













It is the expectation that a specific skin substitute product will be used for the episode
of each documented wound, and in compliance with FDA assessments and submitted
guidelines for the specific product. Greater than ten (10) applications for treatment of a
single wound within a 12 week period of time will be considered not reasonable and
necessary and will be subject to review.

Documentation

- Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service(s)). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
- The submitted medical record must support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code must describe the service performed.
- Medical record documentation must support the medical necessity of the services as directed in this policy.
- The documentation must support that the service was performed and must be included in the patient's medical record. This information is normally found in the history and physical, office/progress notes, hospital notes, and/or procedure report.
- The medical record must clearly show that the criteria listed under the "Indications and Limitations of Coverage and/or Medical Necessity" section has been met, as well as, the appropriate diagnosis and response to treatment.
- The documentation must support the need for skin substitute application and the product used.
- A description of the wound(s) must be documented at baseline (prior to beginning conservative treatment) relative to size, location, stage, duration, and presence of infection, in addition to type of treatment given and response.
- If obvious signs of worsening or lack of treatment response is noted, continuing treatment with the skin substitute would not be considered medically reasonable and necessary without documentation of a reasonable rationale for doing so.
- Documentation of smoking history, and that the patient has received counseling on the
 effects of smoking on surgical outcomes and treatment for smoking cessation (if applicable)
 as well as outcome of a reasonable rationale for doing so.
- Patient is a nonsmoker, or has refrained from smoking for at least 4 weeks prior to planned skin replacement surgery, or has received counseling on the effects of smoking on surgical outcome especially wound healing and treatment for smoking cessation.

- The amount of utilized and wasted skin substitute must be clearly documented in the procedure note with the following minimum information:
 - Date, time and location of ulcer treated;
 - Name of skin substitute and how the product is supplied;
 - Amount of product unit used;
 - Amount of product unit discarded;
 - Reason for the wastage;
 - Manufacturer's serial/lot/batch or other unit identification number of graft material.
 When the manufacturer does not supply the unit identification, the record must document such.

Coding

HCPCS Codes:

- Q4101: Apligraf, per square centimeter
- Q4106: Dermagraft, per square centimeter
- Q4172: PuraPly, PuraPly Antimicrobial per square centimeter
- Q4159: Affinity, per square centimeter
- Q4160: NuShield, per square centimeter

JW Modifier:

Effective January 1, 2017 in Physician Office Setting (Place of service 11): Claims for discarded drug or biological amount not administered to any patient shall be submitted using the JW modifier. This modifier, billed on a separate line, will provide payment for the amount of discarded drug or biological. Providers must document the discarded drugs or biologicals in patient's medical record.

CPT Codes:

Application Codes for Leg, Arm or Trunk:

- 15271: Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
- 15272: Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)
- 15273: Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area
- 15274: Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)

Application Codes for Foot, Face, Scalp, etc.:

- 15275: Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
- 15276: Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)
- 15277: Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area
- 15278: Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; each additional 100 sq cm wound surface area, or part thereof (List separately in addition to code for primary procedure)

ICD 10 Codes

- E10.52 Type 1 diabetes mellitus with diabetic peripheral angiopathy with gangrene
- E10.621 Type 1 diabetes mellitus with foot ulcer
- E10.622 Type 1 diabetes mellitus with other skin ulcer
- E11.52 Type 2 diabetes mellitus with diabetic peripheral angiopathy with gangrene
- E11.621 Type 2 diabetes mellitus with foot ulcer
- E11.622 Type 2 diabetes mellitus with other skin ulcer
- E13.52 Other specified diabetes mellitus with diabetic peripheral angiopathy with gangrene
- E13.621 Other specified diabetes mellitus with foot ulcer
- E13.622 Other specified diabetes mellitus with other skin ulcer
- 170.231 Atherosclerosis of native arteries of right leg with ulceration of thigh
- 170.232 Atherosclerosis of native arteries of right leg with ulceration of calf
- 170.233 Atherosclerosis of native arteries of right leg with ulceration of ankle
- 170.234 Atherosclerosis of native arteries of right leg with ulceration of heel and midfoot
- 170.235 Atherosclerosis of native arteries of right leg with ulceration of other part of foot
- 170.238 Atherosclerosis of native arteries of right leg with ulceration of other part of lower right leg
- 170.241 Atherosclerosis of native arteries of left leg with ulceration of thigh
- 170.242 Atherosclerosis of native arteries of left leg with ulceration of calf
- 170.243 Atherosclerosis of native arteries of left leg with ulceration of ankle
- 170.244 Atherosclerosis of native arteries of left leg with ulceration of heel and midfoot
- 170.245 Atherosclerosis of native arteries of left leg with ulceration of other part of foot

170.248	Atherosclerosis of	f native arteries	of left lea	with ulcera	tion of other	part of low	er left led

- 170.261 Atherosclerosis of native arteries of extremities with gangrene, right leg
- 170.262 Atherosclerosis of native arteries of extremities with gangrene, left leg
- 170.263 Atherosclerosis of native arteries of extremities with gangrene, bilateral legs
- 170.291 Other atherosclerosis of native arteries of extremities, right leg
- 170.292 Other atherosclerosis of native arteries of extremities, left leg
- 170.293 Other atherosclerosis of native arteries of extremities, bilateral legs
- 170.331 Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of thigh
- 170.332 Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of calf
- 170.333 Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of ankle
- 170.334 Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of heel and midfoot
- 170.335 Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of other part of foot
- 170.338 Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of other part of lower leg
- 170.341 Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of thigh
- 170.342 Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of calf
- 170.343 Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of ankle
- 170.344 Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of heel and midfoot
- 170.345 Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of other part of foot
- 170.348 Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of other part of lower leg
- 170.361 Atherosclerosis of unspecified type of bypass graft(s) of the extremities with gangrene, right leg
- 170.362 Atherosclerosis of unspecified type of bypass graft(s) of the extremities with gangrene, left leg
- 170.363 Atherosclerosis of unspecified type of bypass graft(s) of the extremities with gangrene, bilateral legs
- 183.011 Varicose veins of right lower extremity with ulcer of thigh
- 183.012 Varicose veins of right lower extremity with ulcer of calf
- 183.013 Varicose veins of right lower extremity with ulcer of ankle
- 183.014 Varicose veins of right lower extremity with ulcer of heel and midfoot
- 183.015 Varicose veins of right lower extremity with ulcer other part of foot

183.018	Varicose veins of right lower extremity with ulcer other part of lower leg
183.021	Varicose veins of left lower extremity with ulcer of thigh
183.022	Varicose veins of left lower extremity with ulcer of calf
183.023	Varicose veins of left lower extremity with ulcer of ankle
183.024	Varicose veins of left lower extremity with ulcer of heel and midfoot
183.025	Varicose veins of left lower extremity with ulcer other part of foot
183.028	Varicose veins of left lower extremity with ulcer other part of lower leg
I83.211	Varicose veins of right lower extremity with both ulcer of thigh and inflammation
183.212	Varicose veins of right lower extremity with both ulcer of calf and inflammation
183.213	Varicose veins of right lower extremity with both ulcer of ankle and inflammation
183.214	Varicose veins of right lower extremity with both ulcer of heel and midfoot and inflammation
183.215	Varicose veins of right lower extremity with both ulcer other part of foot and inflammation
183.218	Varicose veins of right lower extremity with both ulcer of other part of lower extremity and inflammation
183.221	Varicose veins of left lower extremity with both ulcer of thigh and inflammation
183.222	Varicose veins of left lower extremity with both ulcer of calf and inflammation
183.223	Varicose veins of left lower extremity with both ulcer of ankle and inflammation
183.224	Varicose veins of left lower extremity with both ulcer of heel and midfoot and inflammation
183.225	Varicose veins of left lower extremity with both ulcer other part of foot and inflammation
183.228	Varicose veins of left lower extremity with both ulcer of other part of lower extremity and inflammation
187.011	Postthrombotic syndrome with ulcer of right lower extremity
187.012	Postthrombotic syndrome with ulcer of left lower extremity
187.013	Postthrombotic syndrome with ulcer of bilateral lower extremity
187.031	Postthrombotic syndrome with ulcer and inflammation of right lower extremity
187.032	Postthrombotic syndrome with ulcer and inflammation of left lower extremity
187.033	Postthrombotic syndrome with ulcer and inflammation of bilateral lower extremity
187.311	Chronic venous hypertension (idiopathic) with ulcer of right lower extremity
187.312	Chronic venous hypertension (idiopathic) with ulcer of left lower extremity
187.313	Chronic venous hypertension (idiopathic) with ulcer of bilateral lower extremity
187.331	Chronic venous hypertension (idiopathic) with ulcer and inflammation of right lower extremity
187.332	Chronic venous hypertension (idiopathic) with ulcer and inflammation of left lower extremity
187.333	Chronic venous hypertension (idiopathic) with ulcer and inflammation of bilateral lower extremity

L89.152	Pressure ulcer of sacral region, stage 2
L89.153	Pressure ulcer of sacral region, stage 3
L89.154	Pressure ulcer of sacral region, stage 4
L89.212	Pressure ulcer of right hip, stage 2
L89.213	Pressure ulcer of right hip, stage 3
L89.214	Pressure ulcer of right hip, stage 4
L89.222	Pressure ulcer of left hip, stage 2
L89.223	Pressure ulcer of left hip, stage 3
L89.224	Pressure ulcer of left hip, stage 4
L89.312	Pressure ulcer of right buttock, stage 2
L89.313	Pressure ulcer of right buttock, stage 3
L89.314	Pressure ulcer of right buttock, stage 4
L89.322	Pressure ulcer of left buttock, stage 2
L89.323	Pressure ulcer of left buttock, stage 3
L89.324	Pressure ulcer of left buttock, stage 4
L89.42	Pressure ulcer of contiguous site of back, buttock and hip, stage 2
L89.43	Pressure ulcer of contiguous site of back, buttock and hip, stage 3
L89.44	Pressure ulcer of contiguous site of back, buttock and hip, stage 4
L89.512	Pressure ulcer of right ankle, stage 2
L89.513	Pressure ulcer of right ankle, stage 3
L89.514	Pressure ulcer of right ankle, stage 4
L89.522	Pressure ulcer of left ankle, stage 2
L89.523	Pressure ulcer of left ankle, stage 3
L89.524	Pressure ulcer of left ankle, stage 4
L89.612	Pressure ulcer of right heel, stage 2
L89.613	Pressure ulcer of right heel, stage 3
L89.614	Pressure ulcer of right heel, stage 4
L89.622	Pressure ulcer of left heel, stage 2
L89.623	Pressure ulcer of left heel, stage 3
L89.624	Pressure ulcer of left heel, stage 4
L89.892	Pressure ulcer of other site, stage 2
L89.893	Pressure ulcer of other site, stage 3
L89.894	Pressure ulcer of other site, stage 4
L97.111	Non-pressure chronic ulcer of right thigh limited to breakdown of skin
L97.112	Non-pressure chronic ulcer of right thigh with fat layer exposed
L97.113	Non-pressure chronic ulcer of right thigh with necrosis of muscle
L97.114	Non-pressure chronic ulcer of right thigh with necrosis of bone
L97.115	Non-pressure chronic ulcer of right thigh with muscle involvement without

evidence of necrosis

L97.116	Non-pressure chronic ulcer of right thigh with bone involvement without evidence of necrosis
L97.118	Non-pressure chronic ulcer of right thigh with other specified severity
L97.121	Non-pressure chronic ulcer of left thigh limited to breakdown of skin
L97.122	Non-pressure chronic ulcer of left thigh with fat layer exposed
L97.123	Non-pressure chronic ulcer of left thigh with necrosis of muscle
L97.124	Non-pressure chronic ulcer of left thigh with necrosis of bone
L97.125	Non-pressure chronic ulcer of left thigh with muscle involvement without evidence of necrosis
L97.126	Non-pressure chronic ulcer of left thigh with bone involvement without evidence of necrosis
L97.128	Non-pressure chronic ulcer of left thigh with other specified severity
L97.211	Non-pressure chronic ulcer of right calf limited to breakdown of skin
L97.212	Non-pressure chronic ulcer of right calf with fat layer exposed
L97.213	Non-pressure chronic ulcer of right calf with necrosis of muscle
L97.214	Non-pressure chronic ulcer of right calf with necrosis of bone
L97.215	Non-pressure chronic ulcer of right calf with muscle involvement without evidence of necrosis
L97.216	Non-pressure chronic ulcer of right calf with bone involvement without evidence of necrosis
L97.218	Non-pressure chronic ulcer of right calf with other specified severity
L97.221	Non-pressure chronic ulcer of left calf limited to breakdown of skin
L97.222	Non-pressure chronic ulcer of left calf with fat layer exposed
L97.223	Non-pressure chronic ulcer of left calf with necrosis of muscle
L97.224	Non-pressure chronic ulcer of left calf with necrosis of bone
L97.225	Non-pressure chronic ulcer of left calf with muscle involvement without evidence of necrosis
L97.226	Non-pressure chronic ulcer of left calf with bone involvement without evidence of necrosis
L97.228	Non-pressure chronic ulcer of left calf with other specified severity
L97.311	Non-pressure chronic ulcer of right ankle limited to breakdown of skin
L97.312	Non-pressure chronic ulcer of right ankle with fat layer exposed
L97.313	Non-pressure chronic ulcer of right ankle with necrosis of muscle
L97.314	Non-pressure chronic ulcer of right ankle with necrosis of bone
L97.315	Non-pressure chronic ulcer of right ankle with muscle involvement without evidence of necrosis
L97.316	Non-pressure chronic ulcer of right ankle with bone involvement without evidence of necrosis
L97.318	Non-pressure chronic ulcer of right ankle with other specified severity

L97.321	Non-pressure chronic ulcer of left ankle limited to breakdown of skin
L97.322	Non-pressure chronic ulcer of left ankle with fat layer exposed
L97.323	Non-pressure chronic ulcer of left ankle with necrosis of muscle
L97.324	Non-pressure chronic ulcer of left ankle with necrosis of bone
L97.325	Non-pressure chronic ulcer of left ankle with muscle involvement without evidence of necrosis
L97.326	Non-pressure chronic ulcer of left ankle with bone involvement without evidence of necrosis
L97.328	Non-pressure chronic ulcer of left ankle with other specified severity
L97.411	Non-pressure chronic ulcer of right heel and midfoot limited to breakdown of skin
L97.412	Non-pressure chronic ulcer of right heel and midfoot with fat layer exposed
L97.413	Non-pressure chronic ulcer of right heel and midfoot with necrosis of muscle
L97.414	Non-pressure chronic ulcer of right heel and midfoot with necrosis of bone
L97.415	Non-pressure chronic ulcer of right heel and midfoot with muscle involvement without evidence of necrosis
L97.416	Non-pressure chronic ulcer of right heel and midfoot with bone involvement without evidence of necrosis
L97.418	Non-pressure chronic ulcer of right heel and midfoot with other specified severity
L97.421	Non-pressure chronic ulcer of left heel and midfoot limited to breakdown of skin
L97.422	Non-pressure chronic ulcer of left heel and midfoot with fat layer exposed
L97.423	Non-pressure chronic ulcer of left heel and midfoot with necrosis of muscle
L97.424	Non-pressure chronic ulcer of left heel and midfoot with necrosis of bone
L97.425	Non-pressure chronic ulcer of left heel and midfoot with muscle involvement without evidence of necrosis
L97.426	Non-pressure chronic ulcer of left heel and midfoot with bone involvement without evidence of necrosis
L97.428	Non-pressure chronic ulcer of left heel and midfoot with other specified severity
L97.511	Non-pressure chronic ulcer of other part of right foot limited to breakdown of skin
L97.512	Non-pressure chronic ulcer of other part of right foot with fat layer exposed
L97.513	Non-pressure chronic ulcer of other part of right foot with necrosis of muscle
L97.514	Non-pressure chronic ulcer of other part of right foot with necrosis of bone
L97.515	Non-pressure chronic ulcer of other part of right foot with muscle involvement without evidence of necrosis
L97.516	Non-pressure chronic ulcer of other part of right foot with bone involvement without evidence of necrosis
L97.518	Non-pressure chronic ulcer of other part of right foot with other specified

	severity
L97.521	Non-pressure chronic ulcer of other part of left foot limited to breakdown of skin
L97.522	Non-pressure chronic ulcer of other part of left foot with fat layer exposed
L97.523	Non-pressure chronic ulcer of other part of left foot with necrosis of muscle
L97.524	Non-pressure chronic ulcer of other part of left foot with necrosis of bone
L97.525	Non-pressure chronic ulcer of other part of left foot with muscle involvement without evidence of necrosis
L97.526	Non-pressure chronic ulcer of other part of left foot with bone involvement without evidence of necrosis
L97.528	Non-pressure chronic ulcer of other part of left foot with other specified severity
L97.811	Non-pressure chronic ulcer of other part of right lower leg limited to breakdown of skin
L97.812	Non-pressure chronic ulcer of other part of right lower leg with fat layer exposed
L97.813	Non-pressure chronic ulcer of other part of right lower leg with necrosis of muscle
L97.814	Non-pressure chronic ulcer of other part of right lower leg with necrosis of bone
L97.815	Non-pressure chronic ulcer of other part of right lower leg with muscle involvement without evidence of necrosis
L97.816	Non-pressure chronic ulcer of other part of right lower leg with bone involvement without evidence of necrosis
L97.818	Non-pressure chronic ulcer of other part of right lower leg with other specified severity
L97.821	Non-pressure chronic ulcer of other part of left lower leg limited to breakdown of skin
L97.822	Non-pressure chronic ulcer of other part of left lower leg with fat layer exposed
L97.823	Non-pressure chronic ulcer of other part of left lower leg with necrosis of muscle
L97.824	Non-pressure chronic ulcer of other part of left lower leg with necrosis of bone
L97.825	Non-pressure chronic ulcer of other part of left lower leg with muscle involvement without evidence of necrosis
L97.826	Non-pressure chronic ulcer of other part of left lower leg with bone involvement without evidence of necrosis

L97.828

L97.912

L97.913

severity

Non-pressure chronic ulcer of other part of left lower leg with other specified

Non-pressure chronic ulcer of unspecified part of right lower leg with fat layer

Non-pressure chronic ulcer of unspecified part of right lower leg with necrosis

of muscle Non-pressure chronic ulcer of unspecified part of right lower leg with necrosis L97.914 of bone Non-pressure chronic ulcer of unspecified part of right lower leg with muscle L97.915 involvement without evidence of necrosis Non-pressure chronic ulcer of unspecified part of right lower leg with bone L97.916 involvement without evidence of necrosis Non-pressure chronic ulcer of unspecified part of right lower leg with other L97.918 specified severity Non-pressure chronic ulcer of unspecified part of left lower leg with fat layer L97.922 exposed Non-pressure chronic ulcer of unspecified part of left lower leg with necrosis L97.923 of muscle Non-pressure chronic ulcer of unspecified part of left lower leg with necrosis 197.924 of bone Non-pressure chronic ulcer of unspecified part of left lower leg with muscle L97.925 involvement without evidence of necrosis Non-pressure chronic ulcer of unspecified part of left lower leg with bone L97.926 involvement without evidence of necrosis Non-pressure chronic ulcer of unspecified part of left lower leg with other L97.928 specified severity Non-pressure chronic ulcer of buttock with muscle involvement without L98.415 evidence of necrosis

Non-pressure chronic ulcer of buttock with bone involvement without

Non-pressure chronic ulcer of buttock with other specified severity

L98.416

L98.418

evidence of necrosis

Palmetto Medicare Sample Model Documentation

Medicare Jurisdiction (JM) & (JJ) NC, SC, WV, VA, AL, GA & TN Pre-Treatment

1.	Duration	of	ulcer:	weeks

- 2. Documentation (in the pre-service record) specifically addressing circumstances as to why the wound has failed to respond to standard wound care treatment of greater than 4 weeks and must reference specific interventions that have failed. Such record should include updated medication history, review of pertinent medical problems that may have occurred since the previous wound evaluation, and explanation of the planned skin replacement surgery with choice of CTP graft product. The procedure risks and complications should also be reviewed and documented. Documentation of smoking cessation counseling and cessation measures prescribed, if applicable, must also be documented in the patient's record.
- 3. Exact location of ulcer
- 4. Describe adequate treatment of the underlying disease process contributing to the ulcer.
- **5.** Diagnosis of patient

Treatment

- **6.** Document measurement of ulcer (width and length or circumference and depth) immediately prior to application of the skin substitute sq cm
- 7. Document whether this is an initial application of skin substitute or a reapplication.
- **8.** For skin substitute reapplications, document that applications have been successful (e.g. decrease in size or depth, increase in granulation tissue).
- **9.** Document the wound dressing changes and the standard conservative measures accompanying the wound treatment with the skin substitute.
- **10.** Document how the wound site was prepared, and how the skin substitute was fixated on the wound.
- 11. Product Wastage Documentation Requirements:
 - Date and time
 - Location of ulcer
 - Approximate amount of product unit used
 - · Approximate amount of product unit discarded
 - Reason for the wastage
 - Manufacture's serial/lot/batch number

Modifiers

JW: Skin substitute not applied to wound, wastage