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**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>E10.52</td>
<td>Type 1 diabetes mellitus with diabetic peripheral angiopathy with gangrene</td>
</tr>
<tr>
<td>E10.621</td>
<td>Type 1 diabetes mellitus with foot ulcer</td>
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<tr>
<td>E10.622</td>
<td>Type 1 diabetes mellitus with other skin ulcer</td>
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<td>E11.52</td>
<td>Type 2 diabetes mellitus with diabetic peripheral angiopathy with gangrene</td>
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<tr>
<td>E11.621</td>
<td>Type 2 diabetes mellitus with foot ulcer</td>
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<td>E11.622</td>
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<td>E13.52</td>
<td>Other specified diabetes mellitus with diabetic peripheral angiopathy with gangrene</td>
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<tr>
<td>E13.621</td>
<td>Other specified diabetes mellitus with foot ulcer</td>
</tr>
<tr>
<td>E13.622</td>
<td>Other specified diabetes mellitus with other skin ulcer</td>
</tr>
<tr>
<td>I70.231</td>
<td>Atherosclerosis of native arteries of right leg with ulceration of thigh</td>
</tr>
<tr>
<td>I70.232</td>
<td>Atherosclerosis of native arteries of right leg with ulceration of calf</td>
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<tr>
<td>I70.233</td>
<td>Atherosclerosis of native arteries of right leg with ulceration of ankle</td>
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<td>Atherosclerosis of native arteries of right leg with ulceration of heel and midfoot</td>
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<td>I70.235</td>
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<td>I70.238</td>
<td>Atherosclerosis of native arteries of right leg with ulceration of other part of lower right leg</td>
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<tr>
<td>I70.241</td>
<td>Atherosclerosis of native arteries of left leg with ulceration of thigh</td>
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<td>I70.242</td>
<td>Atherosclerosis of native arteries of left leg with ulceration of calf</td>
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<td>I70.244</td>
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<tr>
<td>I70.245</td>
<td>Atherosclerosis of native arteries of left leg with ulceration of other part of foot</td>
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</table>

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I70.248  Atherosclerosis of native arteries of left leg with ulceration of other part of lower left leg
I70.261  Atherosclerosis of native arteries of extremities with gangrene, right leg
I70.262  Atherosclerosis of native arteries of extremities with gangrene, left leg
I70.263  Atherosclerosis of native arteries of extremities with gangrene, bilateral legs
I70.291  Other atherosclerosis of native arteries of extremities, right leg
I70.292  Other atherosclerosis of native arteries of extremities, left leg
I70.293  Other atherosclerosis of native arteries of extremities, bilateral legs
I70.331  Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of thigh
I70.332  Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of calf
I70.333  Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of ankle
I70.334  Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of heel and midfoot
I70.335  Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of other part of foot
I70.338  Atherosclerosis of unspecified type of bypass graft(s) of the right leg with ulceration of other part of lower leg
I70.341  Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of thigh
I70.342  Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of calf
I70.343  Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of ankle
I70.344  Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of heel and midfoot
I70.345  Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of other part of foot
I70.348  Atherosclerosis of unspecified type of bypass graft(s) of the left leg with ulceration of other part of lower leg
I70.361  Atherosclerosis of unspecified type of bypass graft(s) of the extremities with gangrene, right leg
I70.362  Atherosclerosis of unspecified type of bypass graft(s) of the extremities with gangrene, left leg
I70.363  Atherosclerosis of unspecified type of bypass graft(s) of the extremities with gangrene, bilateral legs
I83.011  Varicose veins of right lower extremity with ulcer of thigh
I83.012  Varicose veins of right lower extremity with ulcer of calf
I83.013  Varicose veins of right lower extremity with ulcer of ankle
I83.014  Varicose veins of right lower extremity with ulcer of heel and midfoot
I83.015  Varicose veins of right lower extremity with ulcer other part of foot

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I83.018 Varicose veins of right lower extremity with ulcer other part of lower leg
I83.021 Varicose veins of left lower extremity with ulcer of thigh
I83.022 Varicose veins of left lower extremity with ulcer of calf
I83.023 Varicose veins of left lower extremity with ulcer of ankle
I83.024 Varicose veins of left lower extremity with ulcer of heel and midfoot
I83.025 Varicose veins of left lower extremity with ulcer other part of foot
I83.028 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
I83.212 Varicose veins of right lower extremity with both ulcer of calf and inflammation
I83.213 Varicose veins of right lower extremity with both ulcer of ankle and inflammation
I83.214 Varicose veins of right lower extremity with both ulcer of heel and midfoot and inflammation
I83.215 Varicose veins of right lower extremity with both ulcer other part of foot and inflammation
I83.218 Varicose veins of right lower extremity with both ulcer of other part of lower extremity and inflammation
I83.221 Varicose veins of left lower extremity with both ulcer of thigh and inflammation
I83.222 Varicose veins of left lower extremity with both ulcer of calf and inflammation
I83.223 Varicose veins of left lower extremity with both ulcer of ankle and inflammation
I83.224 Varicose veins of left lower extremity with both ulcer of heel and midfoot and inflammation
I83.225 Varicose veins of left lower extremity with both ulcer other part of foot and inflammation
I83.228 Varicose veins of left lower extremity with both ulcer of other part of lower extremity and inflammation
I87.011 Postthrombotic syndrome with ulcer of right lower extremity
I87.012 Postthrombotic syndrome with ulcer of left lower extremity
I87.013 Postthrombotic syndrome with ulcer of bilateral lower extremity
I87.031 Postthrombotic syndrome with ulcer and inflammation of right lower extremity
I87.032 Postthrombotic syndrome with ulcer and inflammation of left lower extremity
I87.033 Postthrombotic syndrome with ulcer and inflammation of bilateral lower extremity
I87.311 Chronic venous hypertension (idiopathic) with ulcer of right lower extremity
I87.312 Chronic venous hypertension (idiopathic) with ulcer of left lower extremity
I87.313 Chronic venous hypertension (idiopathic) with ulcer of bilateral lower extremity
I87.331 Chronic venous hypertension (idiopathic) with ulcer and inflammation of right lower extremity
I87.332 Chronic venous hypertension (idiopathic) with ulcer and inflammation of left lower extremity
I87.333 Chronic venous hypertension (idiopathic) with ulcer and inflammation of bilateral lower extremity

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<th>Code</th>
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<td>L97.112</td>
<td>Non-pressure chronic ulcer of right thigh with fat layer exposed</td>
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<tr>
<td>L97.113</td>
<td>Non-pressure chronic ulcer of right thigh with necrosis of muscle</td>
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<tr>
<td>L97.114</td>
<td>Non-pressure chronic ulcer of right thigh with necrosis of bone</td>
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<tr>
<td>L97.115</td>
<td>Non-pressure chronic ulcer of right thigh with muscle involvement without</td>
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Non-pressure chronic ulcer of right thigh with bone involvement without evidence of necrosis
L97.116
Non-pressure chronic ulcer of right thigh with other specified severity
L97.118
Non-pressure chronic ulcer of left thigh limited to breakdown of skin
L97.121
Non-pressure chronic ulcer of left thigh with fat layer exposed
L97.122
Non-pressure chronic ulcer of left thigh with necrosis of muscle
L97.123
Non-pressure chronic ulcer of left thigh with necrosis of bone
L97.124
Non-pressure chronic ulcer of left thigh with muscle involvement without evidence of necrosis
L97.125
Non-pressure chronic ulcer of left thigh with bone involvement without evidence of necrosis
L97.126
Non-pressure chronic ulcer of left thigh with other specified severity
L97.128
Non-pressure chronic ulcer of right calf limited to breakdown of skin
L97.211
Non-pressure chronic ulcer of right calf with fat layer exposed
L97.212
Non-pressure chronic ulcer of right calf with necrosis of muscle
L97.213
Non-pressure chronic ulcer of right calf with necrosis of bone
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Non-pressure chronic ulcer of right calf with muscle involvement without evidence of necrosis
L97.215
Non-pressure chronic ulcer of right calf with bone involvement without evidence of necrosis
L97.216
Non-pressure chronic ulcer of right calf with other specified severity
L97.218
Non-pressure chronic ulcer of left calf limited to breakdown of skin
L97.221
Non-pressure chronic ulcer of left calf with fat layer exposed
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Non-pressure chronic ulcer of left calf with necrosis of muscle
L97.223
Non-pressure chronic ulcer of left calf with necrosis of bone
L97.224
Non-pressure chronic ulcer of left calf with muscle involvement without evidence of necrosis
L97.225
Non-pressure chronic ulcer of left calf with bone involvement without evidence of necrosis
L97.226
Non-pressure chronic ulcer of left calf with other specified severity
L97.228
Non-pressure chronic ulcer of right ankle limited to breakdown of skin
L97.311
Non-pressure chronic ulcer of right ankle with fat layer exposed
L97.312
Non-pressure chronic ulcer of right ankle with necrosis of muscle
L97.313
Non-pressure chronic ulcer of right ankle with necrosis of bone
L97.314
Non-pressure chronic ulcer of right ankle with muscle involvement without evidence of necrosis
L97.315
Non-pressure chronic ulcer of right ankle with bone involvement without evidence of necrosis
L97.316
Non-pressure chronic ulcer of right ankle with other specified severity
L97.318

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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

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<tr>
<th>Code</th>
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<tbody>
<tr>
<td>L97.521</td>
<td>Non-pressure chronic ulcer of other part of left foot limited to breakdown of skin</td>
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<tr>
<td>L97.522</td>
<td>Non-pressure chronic ulcer of other part of left foot with fat layer exposed</td>
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<tr>
<td>L97.523</td>
<td>Non-pressure chronic ulcer of other part of left foot with necrosis of muscle</td>
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<td>L97.525</td>
<td>Non-pressure chronic ulcer of other part of left foot with muscle involvement without evidence of necrosis</td>
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<td>L97.526</td>
<td>Non-pressure chronic ulcer of other part of left foot with bone involvement without evidence of necrosis</td>
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<td>L97.528</td>
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<td>L97.813</td>
<td>Non-pressure chronic ulcer of other part of right lower leg with necrosis of muscle</td>
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<td>L97.814</td>
<td>Non-pressure chronic ulcer of other part of right lower leg with necrosis of bone</td>
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<td>Non-pressure chronic ulcer of other part of left lower leg with necrosis of bone</td>
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</tr>
<tr>
<td>L97.912</td>
<td>Non-pressure chronic ulcer of unspecified part of right lower leg with fat layer exposed</td>
</tr>
<tr>
<td>L97.913</td>
<td>Non-pressure chronic ulcer of unspecified part of right lower leg with necrosis</td>
</tr>
</tbody>
</table>

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Non-pressure chronic ulcer of unspecified part of right lower leg with necrosis of bone
Non-pressure chronic ulcer of unspecified part of right lower leg with muscle involvement without evidence of necrosis
Non-pressure chronic ulcer of unspecified part of right lower leg with bone involvement without evidence of necrosis
Non-pressure chronic ulcer of unspecified part of right lower leg with other specified severity
Non-pressure chronic ulcer of unspecified part of left lower leg with fat layer exposed
Non-pressure chronic ulcer of unspecified part of left lower leg with necrosis of muscle
Non-pressure chronic ulcer of unspecified part of left lower leg with necrosis of bone
Non-pressure chronic ulcer of unspecified part of left lower leg with muscle involvement without evidence of necrosis
Non-pressure chronic ulcer of unspecified part of left lower leg with bone involvement without evidence of necrosis
Non-pressure chronic ulcer of unspecified part of left lower leg with other specified severity
Non-pressure chronic ulcer of buttock with muscle involvement without evidence of necrosis
Non-pressure chronic ulcer of buttock with bone involvement without evidence of necrosis
Non-pressure chronic ulcer of buttock with other specified severity
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

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