Wound Care Documentation Requirements

2/22/21
How many elements (regulatory requirements) must be properly documented by the supplier and physician in order to qualify for coverage when ordering for a new patient or existing patient refill?

1/1/2019 - 1/1/2020

• **New Patient—25 elements**
  - 14 Supplier Documentation Requirements
  - 11 Medical Record Documentation Requirements

• **Existing/Refill Patient—29 elements**
  - 18 Supplier Documentation Requirements
  - 11 Medical Record Documentation Requirements

1/1/2020 - Present

• **New Patient—19 elements**
  - 6 Supplier Documentation Requirements
  - 13 Medical Record Documentation Requirements

• **Existing/Refill Patient—23 elements**
  - 10 Supplier Documentation Requirements
  - 13 Medical Record Documentation Requirements

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New Patient – Supplier Documentation (Prior to 1/1/2020)

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**Dispensing Order**

1. Detailed Description of the item (i.e., type of dressing/brand name of dressing)
2. Beneficiary’s name
3. Prescribing physician/practitioner’s name
4. Date of the order
5. Prescribing physician/practitioner’s signature (if a written order) or supplier signature (if verbal order) and date

**Detailed Written Order (General)**

1. Beneficiary’s name
2. Date of the order
3. A description of all items (i.e., type of dressing/brand name of dressing)
4. Date of the order
5. Prescribing physician/practitioner’s name
6. Physician/practitioner’s signature and date

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**Detailed Written Order (Surgical Dressing Specific)**

1. The size of the dressing (if applicable),
2. The number/amount to be used at one time (if more than one), and
3. The frequency of dressing change
New Patient – Supplier Documentation  (As of 1/1/2020)

*NEW* Standard Written Order replaces Dispensing Order, Written Order, and Detailed Written Order

**Standard Written Order (SWO):**
1. Beneficiary's name or Medicare Beneficiary Identifier (MBI)
2. Order Date
3. General description of the item
   - The description can either be a general description, a HCPCS code, a HCPCS code narrative, or a brand name/model number
4. Quantity to be dispensed, if applicable
5. Treating practitioner's name or National Provider Identifier (NPI)
6. Treating practitioner's signature

DME MACs will consider the totality of the medical records.

New Patient – Physician/Practitioner’s Medical Record
(Prior to 1/1/2020)

**Qualifying Wound Requirements**
1. Debridement/Surgically created wound, without exclusions

**Qualifying Dressing**
1. Type(s) of Dressing, per wound
2. Frequency of Change, per dressing (i.e. treatment protocols)
3. Documentation defining which dressings are Primary/Secondary dressings
4. Information defining the number of surgical/debrided wounds being treated with a dressing (i.e. linking dressing use to specific wound(s))
5. Wound size (length x width) and depth
6. Amount of drainage
7. Staging/Grading/Status of the wound, establishing "full or partial thickness"

**Additional Requirements**
1. The type of each wound (e.g., surgical wound, pressure ulcer, burn, etc.)
2. Wound(s) location
3. Adhere to Medical Record/Documentation Signature Requirements

Expected Duration of need-not required. If listed, MACS may audit based on the medical record duration.
New Patient – Physician/Practitioner’s Medical Record, Nursing Home, or Home Care Nursing Records

(As of 1/1/2020)

Qualifying Wound Requirements
1. Debridement/Surgically created wound, without exclusions

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1. Type(s) of Dressing, per wound
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1. The type of each wound (e.g., surgical wound, pressure ulcer, burn, etc.)
2. Wound(s) location
3. Adhere to Medical Record/Documentation Signature Requirements

Additional Qualifying Dressing Requirements as of 1/1/20:
4. Dressing size, if applicable
5. The number amount to be used at one time, per wound, per dressing.

Expected Duration of need-not required. If listed, MACS may audit based on the medical record duration.

Existing Patient Reorder/Refill

Note: All of the previous elements for a new patient, plus:

Supplier Documentation
Continued Need
1. Patient’s wound is still active/open
2. Patient is still treating with prescribing physician (seen in last 30 days)

Continued Use
1. Patient is still using the products prescribed on the underlying dispensing/detailed written order
2. Quantity of product the patient currently has on hand

Physician/Practitioner’s Medical Record
1. All of the 12 MR elements must be documented and updated by the treating physician (or their designee) on a monthly basis in order for the medical record to establish continued need and use
2. Evaluation is expected on a weekly basis for beneficiaries in a nursing facility or for beneficiaries with heavily draining or infected wounds.
Qualifying Wound and Thickness

**Qualifying Wound**: Caused or treated by surgical procedure; or, after debridement of the wound regardless of debridement technique
- Surgical (e.g., sharp instrument or laser);
- Mechanical (e.g., irrigation or wet-to-dry dressings);
- Chemical (e.g., topical application of enzymes); or
- Autolytic (e.g., application of occlusive dressings to an open wound)

**Partial Thickness**: Associated with Stage 1 and 2 wounds. Loss of skin with exposed dermis. Wound bed is viable, pink or red, moist, and may also present as an intact or ruptured serum-filled blister. Adipose (fat) is not visible and deeper tissues are not visible. Granulation tissue, slough, and eschar are not present.

**Full Thickness**: Associated with Stage 3 and 4 wounds. Loss of skin and/or tissue, in which adipose (fat) is visible and granulation tissue and epibole (rolled wound edges) are often present with exposed or directly palpable fascia, muscle, tendon, ligament, cartilage, or bone in the ulcer. Slough and/or eschar may be visible. Depth varies by anatomical location; undermining and/or tunneling may occur.

*Note: The LCD only includes NPIAP Staging definitions; however, there are several crosswalks available for Wagoner Scale Grading.*
Clinical Situations Where Dressings are Not Covered Under the Surgical Dressings Benefit

- Drainage from a cutaneous fistula which has not been caused by or treated by a surgical procedure
- A Stage 1 pressure ulcer
- Grade 0 Diabetic Foot Ulcers
- A first-degree burn
- Wounds caused by trauma which to not require surgical closure or debridement – e.g., skin tear or abrasion
- A venipuncture or arterial puncture site (e.g., blood sample) other than the site of an indwelling catheter or needle
- Unstageable is considered a “missing element” and is often associated with a wound that has not been debrided by CMS

Clinical Situations Where Dressings are Covered Under the Surgical Dressings Benefit

<table>
<thead>
<tr>
<th>Dressing Category</th>
<th>Exudate</th>
<th>Thickness</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>None</td>
<td>Low</td>
</tr>
<tr>
<td>Hydrogel (Gel, Sheets, Impregnated Gauze)</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Collagen (Gel, Sheets, Powder)*</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Alginate or Other Fiber Gelling Dressing</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Transparent Film</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Hydrocolloid Dressings</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Composite Dressings</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Specialty Absorptive</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Foam</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

* Collagen may also be used for wounds that have stalled or have not progress towards a healing goal.
Sizing

- Dressing size for a primary dressing/filler must be based on and appropriate to the size of the wound. For secondary dressings/wound covers, the pad size is usually about 2 inches greater than the dimensions of the wound. For example, a 2 in. x 2 in. wound requires a 4 in. x 4 in. pad size.

- Alginate Dressings must be approximate to the size of the wound, when a traditional alginate dressing.

- CMS will consider an Alginate HCPC secondary/cover as reasonable and necessary, when the product is a super absorber dressing. Super Absorber Alginate dressings may go beyond the wound margins. Additional product information may need to be provided to the DME MAC medical review team, e.g., composition, bordered or non-bordered, etc.

Reasonable Frequency of Use

- For purposes of this policy, the product in contact with the wound determines the change frequency. It is not reasonable and necessary to use a combination of products with differing change intervals.

- For example, it is not reasonable and necessary to use a secondary dressing with a weekly change frequency over a primary dressing with a daily change interval. Such claims will be denied as not reasonable and necessary.
Additional Guidance

- When a wound cover with an adhesive border is being used, no other dressing is needed on top of it and additional tape is not required. Reasons for use of additional tape must be well documented.
  
  Example: Bordered foam, Bordered Gauze, or a Composite dressing is ordered with tape. The tape will not be covered. Even in a location that is difficult to maintain adhesion due to movement, e.g., the foot, ankle, knee, Medicare does not view additional dressings, such as a conforming gauze and/or tape as reasonable and necessary.

- Use of more than one type of wound filler or more than one type of wound cover in a single wound is not reasonable and necessary. The exception is a primary dressing composed of (1) an alginate or other fiber gelling dressing; or, (2) a saline, water, or hydrogel impregnated gauze dressing. Either of these might need an additional wound cover.
  
  Example: 1. A collagen and alginate requested for the same wound to be used at the same time. Only the item viewed by DME MACs as the “Primary Dressing” (the dressing in contact with the wound) will be viewed as medically necessary. The other dressing, usually the alginate, will be an out-of-pocket expense for the patient. Alginate dressings have a shared primary function of exudate management, so it is not unusual for ordering providers to feel an alginate is necessary as a secondary “primary” dressing, especially when used with a wound filler for wounds that tunnel or have cavities.

- It is not appropriate to use combinations of a hydrating dressing on the same wound at the same time as an absorptive dressing, e.g., hydrogel and alginate/foam.
  
  A DWO may request a bordered foam as the primary dressing, but medical records may indicate the patient is instructed to use a hydrogel as the primary dressing. Regardless of what the DWO states, DME MACs deny the dressings providers actually supply, based on what is indicated in the medical record. Even when the rendering provider did not supply the conflicting dressing noted in the medical record.

- For purposes of this policy, the product in contact with the wound determines the change frequency. It is not reasonable and necessary to use a combination of products with differing change intervals. For example, it is not reasonable and necessary to use a secondary dressing with a weekly change frequency over a primary dressing with a daily change interval. Such claims will be denied as not reasonable and necessary.
  
  Requests for collagen pad, daily, with a bordered foam wound cover, 3x per week, is not reasonable and necessary. The rendering supplier must acknowledge the difference in change intervals and supply the collagen dressing for a 3x per week dressing change interval.

- It is not reasonable and necessary to use a secondary dressing with primary dressings that contain an impervious backing layer with or without and adhesive border.
  
  Most bordered foam dressings have an impervious backing; therefore, wrapping gauze and tape would not be viewed as medically necessary.

- Dressings containing multiple components are classified based upon the clinically predominant component. (e.g., Calcium Alginate and Calcium Alginate with silver are covered under the same HCPCs: A6196-A6199).
  
  Medicare does not reimburse separately for products that contain certain materials, e.g., silver, copper, charcoal, honey, etc.
Regulatory Documents

Current Medicare Guidelines to Qualify Surgical Dressings for Coverage
- Local Coverage Determination (LCD): Surgical Dressing (L38381)
- A54563 - Surgical Dressing Policy Article
- A55426 - Standard Documentation Requirements for All Claims Submitted to the DME MACs
- Medicare Program Integrity Manual (PIM) or Internet Only Manual (IOM) (Most specifically, but not limited to, Chapters 3 and 5)
- DME MAC Supplier Manuals

Wound Care Common Errors
Error: The prescribing physician/practitioner’s medical record conflicts with the Standard Written Order

- One conflict or missing requirement can invalidate a claim for surgical dressings, resulting in potential negative financial impacts for both the patient and supplier
- Many suppliers request extra assurances prior to providing products
  - Qualifying Wound, Stage/Grade/Wound Status, and Primary/Secondary Dressing information
- The standard written order must match and be justified by the medical record
  - Note: A properly written order will NEVER supersede justifying the prescribed products in the medical record.

### Prescription:  

<table>
<thead>
<tr>
<th>Detail Number</th>
<th>Product Description</th>
<th>Quantity / Frequency</th>
<th>Problem Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>MIPLEX BORDER - 4x4</td>
<td>12</td>
<td>Ulcer - L.Lower Leg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3x/week</td>
<td>Exudate: moderate</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Measurements: 1.0 x 0.6 x 0.1 (l x w x d)</td>
</tr>
</tbody>
</table>

Exudate and frequency of change are conflicting.

### Medical Records:

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Error: Order details are not in the medical record

Documentation does not contain all necessary information to support the order.

- An order is not considered part of the medical record. All information on an order must be corroborated by the medical record.

- Commonly, the medical records do not include certain elements
  - Wound thickness/stage/grade
  - Exudate level in the medical record contradicts what is written on the order
  - Measurements of the wound are missing or does not justify the size of dressing used
    - Lack of periwound characteristics documented to prove need of specific size of dressing
  - Instructions for patients in home dressing regimen:
    - Description of item(s)
    - Which is Primary/Secondary
    - Frequency of Change (FOC)
Other Common Errors

- Same diagnosis listed on several patients’ claims
- The product ordered and provided does not align with the HCPCS code billed
- Proof of Delivery (POD) not on file
- Beneficiary Refill elements not documented prior to dispensing

Questions & Panel Discussion

- [List names of presenter(s)]
- [List way(s) to contact for more info]
For information about woundcare initiatives and the AAHomecare Medical Supplies Council, please contact Ashley Plauché with AAHomecare (ashleyp@aahomecare.org).