## Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Face-to-Face Rule</td>
<td>4-7</td>
</tr>
<tr>
<td>Beds (Hospital)</td>
<td>8-11</td>
</tr>
<tr>
<td>Group 2 Mattress</td>
<td>12-13</td>
</tr>
<tr>
<td>Nebulizers</td>
<td>14-17</td>
</tr>
<tr>
<td>NPWT</td>
<td>18-21</td>
</tr>
<tr>
<td>Oxygen</td>
<td>22-27</td>
</tr>
<tr>
<td>PAP</td>
<td>28-33</td>
</tr>
<tr>
<td>TENS</td>
<td>34-39</td>
</tr>
<tr>
<td>Wheelchairs</td>
<td>40-43</td>
</tr>
<tr>
<td>Accessories</td>
<td>44-45</td>
</tr>
<tr>
<td>Insurance</td>
<td>46</td>
</tr>
<tr>
<td>Summary</td>
<td>47</td>
</tr>
</tbody>
</table>
Effective July 1, 2013:

• The Patient’s medical record must contain sufficient documentation of the patient’s medical condition to substantiate the necessity for the type and quantity of items ordered.

• A Physician, Physician’s Assistant (PA), Nurse Practitioner (NP), or Clinical Nurse Specialist (CNS) must have a Face-to-Face (F2F) evaluation with the beneficiary prior to the written DME order and document the Face-to-Face evaluation in the patient’s medical records.

• Every item subject to Face-to-Face requirement will also be subject to mandatory detailed written orders prior to delivery. This means NO MORE VERBAL ORDERS can be accepted on these products.

• Medicare beneficiaries discharged from a hospital do not need to receive a separate Face-to-Face evaluation. If a physician needs to order a Specified Covered Item for a beneficiary after an inpatient stay, the physician may use a Face-to-Face evaluation (done by a hospitalist or in-house physician), if the evaluation occurred within the 6 months prior to prescribing the equipment.

• The Face-to-Face evaluation must occur during the six months prior to the written order for each item. Exception: Oxygen, where F2F must be within 30 days of dispensing.

NOTE: Regarding all the Face-to-Face guidelines contained within the following pages of this booklet: These are Medicare’s current guidelines, and as such are subject to change without notice.
A detailed written order for the item must be received before the delivery of the item can take place and must include minimally the following information:

1. Physician’s Name
2. Prescriber’s NPI
3. Beneficiary name
4. Start date of order (if different from the date of the order)
5. DME item ordered
6. Signature of prescriber
7. Date of prescriber’s Signature. If hand signed, must be hand dated

Additional requirements, if applicable:
- Dosage or concentration
- Route of administration
- Frequency of use
- Duration of infusion
- Quantity to be dispensed
- Number of refills
Durable Medical Equipment
Face-to-Face Rule

Important Facts:

CMS expects that the patient’s medical records will reflect the need for the item ordered. The patient’s medical records include:

- Physician’s office records
- Hospital records
- Nursing home records
- Home health agency records
- Records from other healthcare professionals
- Test results

Each time a new prescription is ordered for a specified item, a new Face-to-Face exam is required. Medicare requires new prescriptions:

- If the claim is for a purchase or initial rental
- If there is a change in accessory, supply, drug, etc.
- If the LCD (local coverage determination) requires renewal
- If an item is replaced
- If the supplier is changed
- If required by state law

Other Stipulations of the Rule Include:

- A prescription is not considered a part of the medical record.
- Supplier-produced records (even if signed by the ordering Physician) and attestation letters are not considered by Medicare as part of the medical record.
Durable Medical Equipment

Face-to-Face Rule

Other Stipulations of the Rule Include:

- Templates and forms, including CMNs, are subject to corroboration with information documented in the patient’s medical record.

- While typically PTs, OTs, and Speech Language Pathologists (SLPs) participate in the assessment and evaluation of Medicare beneficiaries, for the purpose of ordering DME items, they cannot independently document the Face-to-Face visit.

- Signature stamps and date stamps are not allowed.

- Multiple items can be supported by a single Face-to-Face evaluation, so long as each item’s medical necessity is documented in the patient’s medical record.

Physician Compensation

- CMS has established a G-Code (G0454) to compensate Physicians who document that a PA, NP, or CNS performed the Face-to-Face evaluation.

- The G-Codes may only be used when Physician documents a Face-to-Face evaluation that is performed by a PA, NP, or CNS.

- If the physician performed the Face-to-Face evaluation him/herself, the G-Code does not apply when the Physician bills an evaluation and management code.

- If multiple orders for covered items originate from one Face-to-Face evaluation, the Physician is only eligible for the G-Code payment once.
Hospital Beds
Face-to-Face Rule

Effective July 1, 2013:

• The Patient’s medical record must contain sufficient documentation of the patient’s medical condition to substantiate the necessity for the type and quantity of items ordered.

• A Physician, Physician’s Assistant (PA), Nurse Practitioner (NP), or Clinical Nurse Specialist (CNS) must have a Face-to-Face evaluation with the beneficiary prior to the written DME order and document the Face-to-Face evaluation in the patient’s medical records.

• The Face-to-Face evaluation must occur during the six months prior to the written order for each item.

✓ Bed, mattress and rails all need to be listed on order.

✓ If patient has a lifetime condition, list LIFETIME on script versus 12 months, due to Medicare’s 13-month capped rental program.
A detailed written order for the item must be received before the delivery of the item can take place and must include minimally the following information:
(See Face-to-Face quick reference guide)

1. Prescriber’s NPI
2. Beneficiary name
3. Date of order
4. DME item ordered
5. Signature of prescriber
6. Date of prescriber’s Signature. If hand signed, must be hand dated

If patient qualifies for a bed, they may qualify for a Group 1 Pressure Reducing Mattress if they have limited mobility or a pressure ulcer on the trunk or pelvis and ONE of the following conditions:

- Impaired nutritional status
- Fecal or urinary incontinence
- Altered sensory perception
- Compromised circulatory status
Hospital Bed
Face-to-Face Rule

HCPCS code(s) affected:

E0260: Hospital bed semi-electric (head and foot adjustment) with side rails and mattress
E0261: Hospital bed semi-electric (head and foot adjustment) with side rails without mattress
E0301 - E0304: Heavy duty hospital bed
E0255-E0256: Variable height hospital bed

Coverage Criteria:

A standard fixed height hospital bed is covered if one or more of the following criteria are met and documented in the patient’s medical record:

- The patient has a medical condition which requires positioning of the body in ways not feasible with an ordinary bed, **OR**
- The patient requires positioning of the body in ways not feasible with an ordinary bed in order to alleviate pain, **OR**
- The patient requires the head of the bed to be elevated more than 30 degrees most of the time due to heart failure, chronic pulmonary disease, or problems with aspiration, **OR**
- The patient requires traction equipment, which can only be attached to a hospital bed.

Other types of hospital beds are covered if one or more of the previous criteria are met and documented in the patient’s medical record, **AND**:

- Variable height - The patient requires a bed height different than a fixed height bed to permit transfers to a chair, wheelchair, or standing position.
— Semi-electric - The patient requires frequent changes in body position and/or has an immediate need for a change in body position.

— Heavy-duty extra-wide - The patient’s weight is more than 350 pounds but less than 600 pounds. Patients weighing more than 600 pounds would qualify for an extra-heavy-duty bed.

Note: Total electric hospital beds are NOT covered.

**Accessories:**

Certain accessories are often needed as part of the patient’s treatment plan. The need for each additional item must be addressed in the Face-to-Face evaluation and documented in the patient’s medical record. The coverage criteria for the most commonly ordered accessories are:

— Trapeze equipment - The patient needs this device to sit up because of a respiratory condition, to change body position for other medical reasons, or to get in or out of bed.

— Heavy-duty trapeze equipment - The patient meets the criteria for a regular trapeze but weighs more than 250 pounds.

— Bed cradle - The patient requires this item to prevent contact with the bed coverage.

— Side rails - The patient’s condition requires this item and they are an integral part of, or an accessory to, a covered hospital bed.
Group 2 Support Services
Coverage Requirements

HCPCS code(s) affected:

E0277: Powered pressure-reducing air mattress

Coverage Criteria:

A Group 2 Support Surface is covered if the beneficiary meets at least ONE of the following criteria (1, 2 or 3):

1. The beneficiary has multiple Stage II pressure ulcers located on the trunk or pelvis which have failed to improve over the past month, during which time the beneficiary has been on a comprehensive ulcer treatment program, including each of the following:
   - Use of an appropriate Group 1 Support Surface (mattress, pressure pad, mattress overlay (foam, air, water, gel)), AND
   - Regular assessment by a nurse, physician, or other licensed healthcare practitioner, AND
   - Appropriate turning and positioning, AND
   - Appropriate wound care, AND
   - Appropriate management of moisture/incontinence, AND
   - Nutritional assessment and intervention consistent with the overall plan of care

2. The beneficiary has large or multiple Stage III or IV pressure ulcer(s) on the trunk or pelvis.

3. The beneficiary had a myocutaneous flap or skin graft for a pressure ulcer on the trunk or pelvis within the past 60 days and has been on a Group 2 or 3 Support Surface immediately prior to discharge from a hospital or nursing facility within the past 30 days.
If the beneficiary is on a Group 2 Surface, there should be a care plan established by the physician or home care nurse, which includes the elements on the previous page.

Continued use of a Group 2 Support Surface is covered until the ulcer is healed, OR, if healing does not continue, there is documentation in the medical record to show that:

1. Other aspects of the care plan are being modified to promote healing, OR

2. The use of Group 2 Support Surface is reasonable and necessary for wound management.

For continued coverage of Group 2 Support Surfaces, HME must receive monthly documentation from a nurse or doctor of patient’s ulcer condition and treatment.
Nebulizer

Face-to-Face Rule

Effective July 1, 2013:

- The Patient’s medical record must contain sufficient documentation of the patient’s medical condition to substantiate the necessity for the type and quantity of items ordered.

- A Physician, Physician’s Assistant (PA), Nurse Practitioner (NP), or Clinical Nurse Specialist (CNS) must have a Face-to-Face evaluation with the beneficiary prior to the written DME order and document the Face-to-Face evaluation in the patient’s medical records.

- The Face-to-Face evaluation must occur during the six months prior to the written order for each item.
A detailed written order for the item must be received before the delivery of the item can take place and must include minimally the following information:
(See Face-to-Face quick reference guide)

1. Prescriber’s NPI
2. Beneficiary name
3. Date of order
4. DME item ordered
5. Signature of prescriber
6. Date of prescriber’s Signature. If hand signed, must be hand dated

Helpful Hint

- Prescriptions should be written for nebulizer AND nebulizer SUPPLIES.
- Office notes and script need to be in hand PRIOR to dispensing equipment.
Nebulizers
Face-to-Face Rule

**HCPCS code(s) affected:**

E0570: Nebulizer with compressor

**Nebulizers E0570:**

- **Face-to-Face Examination (F2F)**
  - Date stamp indicating supplier’s date of receipt of F2F on or before date of delivery
- **Written Order Prior to Delivery (WOPD)**
  - Date stamp indicating supplier’s date of receipt of WOPD on or before date of delivery
Medical Records:
Small volume nebulizer kits (A7003, A7005), Related Compressor (E0570) and FDA-Approved Inhalation Drugs

- Medical records support the medical necessity to administer one (1) of the following inhalation drugs for one (1) of the listed conditions:

<table>
<thead>
<tr>
<th>Drug</th>
<th>HCPCs Code</th>
<th>Covered Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albuterol</td>
<td>J7611, J7613</td>
<td>Obstructive pulmonary disease</td>
</tr>
<tr>
<td>Arformoterol</td>
<td>J7605</td>
<td></td>
</tr>
<tr>
<td>Budesonide</td>
<td>J7626</td>
<td></td>
</tr>
<tr>
<td>Cromolyn</td>
<td>J7631</td>
<td></td>
</tr>
<tr>
<td>Formoterol</td>
<td>J7606</td>
<td></td>
</tr>
<tr>
<td>Ipratropium</td>
<td>J7644</td>
<td></td>
</tr>
<tr>
<td>Levalbuterol</td>
<td>J7612, J7614</td>
<td></td>
</tr>
<tr>
<td>Metaproterenol</td>
<td>J7669</td>
<td></td>
</tr>
<tr>
<td>Dornase Alpha</td>
<td>J7639</td>
<td>Cystic fibrosis</td>
</tr>
<tr>
<td>Tobramycin</td>
<td>J7682</td>
<td>Cystic fibrosis or Bronchiectasis</td>
</tr>
<tr>
<td>Pentamidine</td>
<td>J2545</td>
<td>Human Immuno-deficiency Virus (HIV), Pneumocystosis, or Complications of organ transplant</td>
</tr>
<tr>
<td>Acetylcysteine</td>
<td>J7608</td>
<td>Persistent thick or tenacious pulmonary secretions</td>
</tr>
</tbody>
</table>
Effective October 1, 2015:

Negative Pressure Wound Therapy (NPWT) is defined as the application of sub-atmospheric pressure to wounds to remove exudate and debris from wounds. NPWT is delivered through an integrated system of a suction pump, separate exudate collection chamber, and dressing sets to a qualified wound.

Coverage Criteria:

A Negative Pressure Wound Therapy pump (E2402) and supplies (A6550, A7000) are covered when either Criterion A or B is met:

A. Ulcers and Wounds in the Home Setting:

The beneficiary has a chronic Stage III or IV pressure ulcer, neuropathic ulcer, venous or arterial insufficiency ulcer, or a chronic (being present for at least 30 days) ulcer of mixed etiology. A complete wound therapy program described by Criterion 1 and Criteria 2, 3, or 4, as applicable depending on the type of wound, must have been tried or considered and ruled out prior to application of NPWT.

1. For all ulcers or wounds, the following components of a wound therapy program must include a minimum of all the following general measures, which should either be addressed, applied, or considered and ruled out prior to application of NPWT:

   a) Documentation in the beneficiary’s medical record of evaluation, care, and wound measurements by a licensed medical professional, **AND**

   b) Application of dressings to maintain a moist wound environment, **AND**

   c) Debridement of necrotic tissue if present, **AND**

   d) Evaluation of and provision for adequate nutritional status
2. For Stage III or IV pressure ulcers:
   a) Beneficiary has been appropriately turned and positioned, **AND**
   b) Beneficiary has used a Group 2 or 3 Support Surface for pressure ulcers on the posterior trunk or pelvis, **AND**
   c) Beneficiary’s moisture & incontinence have been managed

3. For neuropathic (for example, diabetic) ulcers:
   a) Beneficiary has been on a comprehensive diabetic management program, **AND**
   b) Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities

4. For venous insufficiency ulcers:
   a) Compression bandages and/or garments have been consistently applied, **AND**
   b) Leg elevation and ambulation have been encouraged

B. Ulcers and Wounds Encountered in an Inpatient Setting:

1. An ulcer or wound is encountered in the inpatient setting and, after wound treatments described under A-1 through A-4 have been tried or considered and ruled out, NPWT is initiated because it is considered, in the judgment of the treating physician, the best available treatment option.

2. Beneficiary has complications of a surgically created wound or a traumatic wound where there is documentation of the medical necessity for accelerated formation of granulation tissue which cannot be achieved by other available topical wound treatments (for example, other conditions of the beneficiary that will not allow for healing times achievable with other topical wound treatments).

In either situation (B-1 or B-2), NPWT will be covered when treatment is ordered to continue beyond discharge to the home setting.
Negative Pressure Wound Therapy Checklist

Medical History:

- Is the patient’s nutritional status compromised?
  - If yes, what is Albumin level?
  - What steps have been taken to improve nutrition? (Protein supplement, Enteral/NG feeding, TPN, Vitamin therapy, special diet)
  - What previous treatment modalities were utilized on this wound? (Saline gauze, Hydrogel, Alginate, Hydrocolloid, Absorptive, None, Other)
  - If patient is diabetic, is patient on a comprehensive diabetic management program?

Wound Information:

- **ACUTE**
  - Surgical wound (date of surgery)
  - Traumatic wound
  - Graft/Flap

- **CHRONIC** (present at least 30 days)
  - Pressure ulcer: Stage III or IV. Is patient being turned/positioned? Has patient been on support surface for Group 2/3? Is moisture/incontinence being managed?
  - Venous ulcer: Are compression bandages and/or garments being consistently applied? Is leg elevation/ambulation being encouraged?
  - Neuropathic ulcer (i.e., diabetic): Has pressure on the foot ulcer been reduced with appropriate modalities (must be total contact casting or custom orthotic boot)? Has patient been on comprehensive diabetic management program?
  - Arterial ulcer/Arterial insufficiency: Is pressure over the wound being relieved?
Wound Assessment:
- Date of wound assessment
- Wound location
- Wound length, width, depth
- Is there undermining? Tunneling/sinus?
- Exudate type/amount

Order:
- Length of need: # of months, # of weeks
- Settings to be placed at 80mmHG, 120mmHG, Other
- Continuous or intermittent
- Goal of NPWT to “assist granulation tissue formation”

Continued Coverage:
- Medicare: On a monthly basis, changes in the ulcer’s dimensions and characteristics must be documented.
- Medicaid: Patients need weekly documented changes to ulcer’s dimensions and characteristics.

Special Medicare/Medicaid Notes:

Medicaid Only:
- Wound must be 30 days old

Both Medicare & Medicaid:
- Other wound care treatments must have been trialed or considered and ruled out prior to considering a wound vac. Failed treatments and reasons for non-use must be documented.
- Documentation must state, “Wound vac needed to accelerate granulated tissue formation”
- Any patient condition that will inhibit normal granulation tissue formation necessitating use of NPWT must be documented (i.e., diabetes).
- Medical record must include a statement from treating physician describing the initial condition of the wound, including measurements.
Oxygen Concentrators, Portable $O^2$ Systems and Homefill Systems
Face-to-Face Rule

- Certain HCPCS codes for oxygen products ARE NOT included in the Face-to-Face rules implemented under the Affordable Care Act (ACA). These items can be dispensed based on a dispensing or verbal order. However, before the DME can bill for these products, a detailed written order must be received.

- The patient’s medical record must contain sufficient documentation of the patient’s medical condition to substantiate the necessity for the type and quantity of items ordered.

- Specific to ordering oxygen, since it is considered a drug, the dose and duration (i.e., nocturnal only) must be included on all orders to allow the dispensing to occur.
The dispensing order must minimally contain:

1. Prescriber’s NPI
2. Beneficiary name
3. Date of order
4. DME item ordered
5. Signature of prescriber
6. Date of prescriber’s signature. If handwritten, must be hand dated

Helpful Hint

- PRN (as needed) cannot be used on prescription. Prescription should read “continuous.”
Oxygen Concentrators, Portable O2 Systems and Homefill Systems
Face-to-Face Rule

**HCPCS code(s) affected:**
E1390: Oxygen Concentrator
E0431: Portable Gaseous O\textsuperscript{2}
K0738: Portable gaseous oxygen system, rental

**Coverage Criteria:**
Oxygen and Oxygen equipment are reasonable and necessary only if all the following conditions are met:

- Treating physician has determined the patient has a severe lung disease or hypoxia-related symptoms expected to improve with oxygen therapy; **AND**
- Patient's blood gas study* (BGS) meets required criteria, **AND**
- Qualifying BGS was performed by a Physician or a qualified provider or supplier of laboratory services; **AND**
- Qualifying BGS was obtained under the following conditions:
  - If performed during an inpatient hospital stay, the reported test must be the one obtained closest to, but no earlier than, 2 days prior to the hospital discharge date; **OR**
  - If not performed during an inpatient hospital stay, the reported test must be performed while the patient is in a chronic stable state; **AND**
- Alternative treatment measures have been tried or considered an deemed clinically ineffective.
**Group 1 Criteria:**
Arterial blood gas (ABG) at or below 55 Hg or arterial blood saturation at or below 88%
- At rest; OR
- During exercise (3 tests); OR
- During sleep (at least 5 minutes); OR
- During sleep (signs of hypoxemia)
  - Decrease in ABG more than 10 mm Hg or a decrease in arterial blood saturation more than 5% from baseline for at least 5 minutes taken during sleep
- Initial coverage limited to 12 months

**Group 2 Criteria:**
- Arterial blood gas (ABG) 56 - 59 mm Hg or arterial blood saturation at 89%
  - Same testing requirements as Group 1; AND
- Beneficiary has one of the following conditions:
  - Dependent edema, suggesting congestive heart failure; OR
  - Pulmonary hypertension or cor pulmonale; OR
  - Erythrocythemia with a hematocrit greater than 56%
Initial coverage limited to 3 months

**Cluster Headaches:**
No coverage for this condition.

**Portable O₂ Systems:**
- Medical records support the patient is mobile within the home; AND
- BGS performed at rest (awake) or during exercise

**High Liter Flow - Greater than 4 LPM:**
- Group I or II BGS performed while on 4 or more LPM

*“Blood Gas Study” shall refer to both Arterial Blood Gas (ABG) studies and pulse oximetry.*
Specific Documentation Requirements:

Documentation for initial coverage requires information in the medical record showing:

- Evidence of **qualifying test results done within 30 days** before the initial date of service.

- Evidence of an **in-person visit with a treating Physician/prescriber done within 30 days** before the initial date of service.

- Consider including in the medical record the verbiage: “I have evaluated patient’s oxygen needs.”

"Blood Gas Study" shall refer to both Arterial Blood Gas (ABG) studies and pulse oximetry.
Oxygen Gaseous Prescription:

A detailed written order for the item must be received before the delivery of the item can take place minimally and must include the following information:
(See Face-to-Face quick reference guide)

1. Prescriber’s NPI
2. Beneficiary name
3. Date of order
4. DME item ordered
5. Signature of prescriber
6. Date of prescriber’s Signature. If hand signed, must be hand dated

[Prescription form image]

Refills: 
Signature Date: 07/01/2013
Name (Printed): John Doe, M.D.
PAP Face-to-Face Rule

Effective July 1, 2013:

- The Patient’s medical record must contain sufficient documentation of the patient’s medical condition to substantiate the necessity for the type and quantity of items ordered.

- A Physician, Physician’s Assistant (PA), Nurse Practitioner (NP), or Clinical Nurse Specialist (CNS) must have a Face-to-Face evaluation with the beneficiary prior to the written DME order and document the Face-to-Face evaluation in the patient’s medical records.

- The Face-to-Face evaluation must occur during the six months prior to the written order for each item.

- For CPAP, the evaluation **must** occur prior to the sleep study.

- When CPAP/APAP/BiPAP is ordered, order must also include heated humidifier.
A detailed written order for the item must be received before the delivery of the item can take place and must include minimally the following information:
(See Face-to-Face quick reference guide)

1. Prescriber’s NPI
2. Beneficiary name
3. Date of order
4. DME item ordered
5. Signature of prescriber
6. Date of prescriber’s Signature. If hand signed, must be hand dated

Helpful Hint
For continued coverage beyond the first three months of therapy, physician must conduct a clinical re-evaluation and document that the patient is BENEFITING from PAP therapy.
PAP Face-to-Face Rule

HCPCS code(s) affected:

E0470 Respiratory Assist Device, Bi-Level, Without Backup
E0471 Respiratory Assist Device, Bi-Level With Backup
E0601 Continuous Airway Pressure Device

Documentation Checklist:

PAP Devices E0470, E0471, E0601
- Face-to-Face examination (F2F)
- Written Order Prior to Delivery (WOPD)

All PAP Accessories & Supplies
- Dispensing order, if applicable
- Detailed Written Order (DWO)
- Refill requirements

All PAP Devices, Accessories, and Supplies
- Beneficiary authorization
- Proof of Delivery (POD)
  - Method 1: Direct delivery to the beneficiary by the supplier. Date the beneficiary/designee signs for the supplies is to be the date of service of the claim.
  - Method 2: Delivery via shipping or delivery service. Shipping date is to be the date of service of the claim.
- Continued need
- Continued use
Medical Records:
Initial Coverage (First 3 Months)
Positive Airway Pressure Device - E0601

- Medical records document:
  - F2F prior to the sleep test to assess the patient for obstructive sleep apnea (OSA); AND
  - Medicare-covered sleep test that meets either:
    - Apnea-Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) ≥ 15 events per hour with a minimum of 30 events; OR
    - AHI or RDI ≥ 5 and ≤ 14 events per hour with minimum 10 events and documentation of:
      - Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; OR
      - Hypertension, ischemic heart disease, or history of stroke, AND
      - Documentation the beneficiary and/or their caregiver has received instruction from the supplier of the PAP device in the proper use and care of the equipment.

Documentation for Beneficiaries Who Fail the Initial 12-Week Trial

- F2F re-evaluation to determine the etiology of the failure to respond to PAP therapy; AND
- Repeat sleep test in a facility-based setting (Type 1 study).
Bi-level Respiratory Assist Device (RAD) Without Backup Rate (E0470)

- Medical records document:
  - Beneficiary meets all the criteria listed above for a positive airway pressure device (E0601); AND
  - An E0601 PAP device has been tried and proven ineffective based on a therapeutic trial conducted in either a facility or home setting.
- Documented failure to meet therapeutic goals using an E0601 during the titration portion of a facility-based study or during home use despite optimal therapy
- A new initial F2F if E0601 has been used for more than 3 months and the beneficiary switched to E0470 (a new sleep test is not required)

PAP - Continued Coverage (Beyond the First 3 Months of Therapy)

- Documentation the beneficiary is benefiting from PAP therapy as demonstrated by:
  - F2F re-evaluation by the treating physician between the 31st and 91st day after initiating therapy documenting that the symptoms of OSA are improved; AND
  - Objective evidence of adherence to use of the PAP device reviewed by treating physician.
- Adherence is defined as use of the PAP device $\geq 4$ hours per night on 70% of nights during a consecutive 30-day period anytime during the first 3 months of initial use
Beneficiaries Entering Medicare

- Sleep test - Documentation the beneficiary had a sleep test, prior to FFS Medicare enrollment, that meets Medicare AHI/RDI coverage criteria in effect at the time the beneficiary seeks replacement PAP device and/or accessories; **AND**

- Clinical evaluation - Following enrollment in FFS Medicare, the beneficiary must have a F2F which documents:
  - Diagnosis of OSA; **AND**
  - The beneficiary continues to use the PAP device.

Replacement (E0601, E0470)

- Replacement following the 5-year reasonable useful life (RUL) requires a F2F that documents the beneficiary continues to use and benefit from the PAP device

Non-heated or Heated Humidifier (E0561, E0562)

- Beneficiary meets PAP coverage criteria
- Detailed written order includes the type of humidification
TENS Units
Face-to-Face Rule

Effective July 1, 2013:

- The Patient’s medical record must contain sufficient documentation of the patient’s medical condition to substantiate the necessity for the type and quantity of items ordered.

- A Physician, Physician’s Assistant (PA), Nurse Practitioner (NP), or Clinical Nurse Specialist (CNS) must have a Face-to-Face evaluation with the beneficiary prior to the written DME order and document the Face-to-Face evaluation in the patient’s medical records.

- The Face-to-Face evaluation must occur during the six months prior to the written order for each item.
A detailed written order for the item must be received before the delivery of the item can take place and must include minimally the following information:
(See Face-to-Face quick reference guide)

1. Prescriber’s NPI
2. Beneficiary name
3. Date of order
4. DME item ordered
5. Signature of prescriber
6. Date of prescriber’s Signature. If hand signed, must be hand dated

Helpful Hint

- Medicare policies are very specific and detailed for TENS therapy. Please use diagnosis codes consistent with policy.
TENS Units

Face-to-Face Rule

HCPCS code(s) affected:
E0720: TENS Two-Lead
E0730: TENS Four-Lead

Coverage Criteria:
All TENS (E0720, E0730)
  • Face-Face Examination (F2F)
    - Date stamp indicating supplier’s date of receipt of F2F on or before date of delivery
  • Written Order Prior to Delivery (WOPD)
    - Date stamp indicating supplier’s date of receipt of WOPD on or before date of delivery
Medical Records:

**TENS Unit (E0720, E0730)**

- Physician ordering TENS unit & supplies must be the treating physician for the disease or condition justifying the need for the TENS unit.

- TENS is covered for the treatment of beneficiaries with chronic, intractable pain, or acute post-operative pain when one of the following coverage criteria are met:
  - Acute post-operative pain
    - Limited to 30 days from the day of surgery
    - Payment made only as a rental
    - Documentation must include:
      - Date of surgery
      - Nature of surgery
      - Location and severity of the pain; **OR**
  - Chronic pain other than low back pain
    - Presumed etiology of the pain must be a type that is accepted as responding to TENS therapy; **AND**
    - Pain must have been present for at least three (3) months; **AND**
    - Other appropriate treatment modalities must have been tried and failed.
    - Information in the medical record must describe:
      - Location of pain
      - Severity of pain
      - Duration of time the beneficiary has had pain (pain must be present for at least 3 months)
– Presumed etiology of pain
– Prior treatment and results of that treatment
– Re-evaluation of the beneficiary at the end of the trial period indicating:
  • How often the beneficiary used TENS unit
  • Typical duration of use each time
  • Results (effectiveness of therapy); OR
– Chronic low back pain (CLBP)
  • Beneficiary has one of the diagnoses listed on the next page; AND
  • Beneficiary is enrolled in an approved clinical study.
• General requirements for chronic pain
  – Must be used on a trial basis for a minimum 30 days, but not to exceed two (2) months
  • Trial period will be paid as a rental; AND
  • Trial period must be monitored by the physician to determine the effectiveness of the TENS unit in modulating the pain.
  – For coverage as a purchase, the physician must determine that the beneficiary is likely to derive significant therapeutic benefit from continuous use over a long period of time.
  – If ordered for use with 4 leads, the medical record must document why 2 leads are insufficient to meet the beneficiary’s needs.
• General requirements for CLBP
  – If ordered for use with 4 leads, medical record must document why 2 leads are insufficient to meet beneficiary’s needs.
Chronic Low Back Pain (CLBP) Diagnoses

The patient has one of the listed diagnoses AND is enrolled in an approved clinical study that meets all of the requirements set forth by Medicare:

✓ Lumbosacral root lesions, not elsewhere classified
✓ Sacroilitis, not elsewhere classified
✓ Lumbosacral spondylosis without myelopathy
✓ Thoracic or lumbar spondylosis with myelopathy-lumbar region
✓ Lumbar intervertebral disc without myelopathy
✓ Lumbosacral intervertebral disc
✓ Intervertebral disc disorder myelopathy - lumbar region
✓ Post laminectomy syndrome - lumbar region
✓ Other and unspecified disc disorders, lumbar region
✓ Spinal stenosis, lumbar region without neurogenic claudication
✓ Spinal stenosis, lumbar region with neurogenic claudication
✓ Lumbago
✓ Sciatica
✓ Thoracic or lumbosacral neuritis or radiculitis, unspecified, radicular syndrome or lower extremities
✓ Acquired spondylolysthesis
✓ Non-allopathetic lesions NEC (not elsewhere classified) - lumbar region
✓ Spondylosis, lumbosacral region
✓ Spondylolisthesis
✓ Fracture of vertebral column without mention of spiral cord injury, lumbar, closed
✓ Fracture of vertebral column with mention of spiral cord injury, lumbar, closed
✓ Sprains and strains of sacroiliac region - lumbosacral (joint) (ligament)
✓ Sprains and strains of sacroiliac ligament
✓ Sprains and strains of other and unspecified part of back, lumbar
✓ Injury to nerve roots and spinal plexus, lumbar root
Effective July 1, 2013:

- The Patient’s medical record must contain sufficient documentation of the patient’s medical condition to substantiate the necessity for the type and quantity of items ordered.

- A Physician, Physician’s Assistant (PA), Nurse Practitioner (NP), or Clinical Nurse Specialist (CNS) must have a Face-to-Face evaluation with the beneficiary prior to the written DME order and document the Face-to-Face evaluation in the patient’s medical records.

- The Face-to-Face evaluation must occur during the six months prior to the written order for each item.
A detailed written order for the item must be received before the delivery of the item can take place and must include minimally the following information:
(See Face-to-Face quick reference guide)

1. Prescriber’s NPI
2. Beneficiary name
3. Date of order
4. DME item ordered
5. Signature of prescriber
6. Date of prescriber’s Signature. If hand signed, must be hand dated

Helpful Hint

• If patient qualifies for a manual wheelchair, they also qualify for a general use seat cushion and back rest, provided it is written on doctor’s prescription.

• Documentation needs to state WHICH mobility-related activities of daily living (MRADLs) patient is unable to complete.
Manual Wheelchair
Face-to-Face Rule

HCPCS code(s) affected:
K0001: Standard manual wheelchair
K0002: Standard hemi-wheelchair
K0003: Lightweight wheelchair
K0004: High-strength lightweight wheelchair
K0006: Heavy-duty wheelchair
K0007: Extra-heavy-duty wheelchair

Coverage Criteria:
A manual wheelchair for use inside the home is covered if the following criteria are met and documented in the patient’s medical record:

- The patient has a mobility limitation that significantly impairs his/her ability to participate in one or more mobility-related activities of daily living (MRADL). A mobility limitation is one that:
  - Prevents the patient from accomplishing an MRADL entirely; **OR**
  - Places the patient at reasonably determined heightened risk of morbidity or mortality secondary to the attempts to perform an MRADL; **OR**
  - Prevents the patient from completing an MRADL within a reasonable time frame.

- The patient’s mobility limitation cannot be sufficiently resolved by the use of a cane or walker.

- The patient’s home provides adequate access between rooms, maneuvering space, and surfaces for the use of the manual wheelchair.

- Use of the manual wheelchair will significantly improve the patient’s ability to participate in MRADLs.

- The patient has not expressed an unwillingness to use the manual wheelchair.
In addition to the foregoing, one of the following criteria must be met and documented in the patient’s medical record:

- The patient has sufficient upper extremity function and other physical and mental capabilities needed to safely propel the manual wheelchair.
- The patient has a caregiver who is available, willing and able to provide assistance with the wheelchair.

**Criteria Checklist for Manual Wheelchairs**

Medicare will only cover payment of manual wheelchairs for use **INSIDE THE HOME** to complete MRADLs.

Your face-to-face encounter documentation **MUST ADDRESS ALL OF THE FOLLOWING:**

- What is the patient’s mobility limitation which requires the use of a wheelchair?
- What specific MRADL (toileting, feeding, bathing, dressing, grooming) is impaired secondary to this mobility limitation (i.e., patient is unable to ambulate to the toilet; patient unable to ambulate distance needed to reach the dining room, etc.)?
- How will the use of a wheelchair improve patient’s ability to complete this MRADL?
- Why is the patient not able to use a cane or walker to resolve their mobility limitation?
- Is patient’s upper extremity strength sufficient to self propel the wheelchair? If not, does the patient have a caregiver available 24/7 to manage wheelchair for them?
- Will patient use the wheelchair regularly in their home?

If above criteria is not met in its entirety, Medicare will **DENY COVERAGE** of this wheelchair.
Additional Coverage Criteria for Specific Manual Wheelchairs:

In addition to the general manual wheelchair criteria noted, one of the following criteria must be met and documented in the patient’s medical record:

- Standard hemi wheelchair - The patient requires a lower seat height because of short stature or to enable the patient to place his/her feet on the ground for propulsion.

- Lightweight wheelchair - The patient cannot self-propel a standard wheelchair in the home, but can and does propel in a lightweight wheelchair.

- High-strength lightweight wheelchair - The patient meets one of the following criteria:
  - The patient self-propels the wheelchair while engaging in frequent activities in the home that cannot be performed in a standard or lightweight wheelchair, OR
  - The patient requires a seat width, depth, or height that cannot be accommodated in a standard, lightweight or hemi wheelchair, and spends at least two hours per day in the wheelchair.
  - A high-strength lightweight wheelchair is rarely reasonable and necessary if the expected duration of the need is less than three months (e.g. postoperative recovery)

- Heavy-duty wheelchair - The patient weighs more than 250 pounds or the patient has severe spasticity.

- Extra-heavy-duty wheelchair - The patient weighs more than 300 pounds.

Wheelchair Accessories

Face-to-Face Rule

HCPCS code(s) affected:
E0973, K0017, K0018, K0020: Adjustable arm height option
E2209: Arm trough
E0990, K0046, K0047, K0053, K0195: Elevating leg rests
E2201 - E2204: Non-standard seat width and/or depth
Coverage Criteria:

Options and accessories for wheelchairs are covered if the patient has a wheelchair that meets Medicare coverage criteria and documentation in the patient’s medical record substantiates the medical necessity for the item.

- **Adjustable arm height option** - The patient requires an arm height that is different than that available using non-adjustable arms and the patient spends at least 2 hours per day in the wheelchair.

- **Arm trough** - The patient has quadriplegia, hemiplegia, or uncontrolled arm movements.

- **Elevating leg rests** - The beneficiary has a musculoskeletal condition or the presence of a cast or brace which prevents 90 degree flexion at the knee; **OR**
  The beneficiary has significant edema of the lower extremities that requires an elevating leg rest; **OR**
  The beneficiary meets the criteria for and has a reclining back on the wheelchair.

- **Non-standard seat width and/or depth** - The patient’s physical dimensions justify the need.

- **Anti-rollback device** - The patient self-propels and needs the device because of ramps.

- **Safety belt/pelvic strap** - The patient has weak upper body muscles, upper body instability or muscle spasticity which requires use of this item for proper positioning.

- **Manual fully reclining back** - The patient has one or more of the following conditions documented in the medical record:
  - At high risk for development of a pressure ulcer and is unable to perform a functional weight shift;
  - Utilizes intermittent catheterization for bladder management and is unable to independently transfer from the wheelchair to the bed.
**HME HOME MEDICAL INSURANCE CONTRACT LIST**

Partial list of contracted carriers, as of 10/9/2015. HME facilitates payments with hundreds of payors. This insurance list is subject to change.

**HME IS a provider for:**
- Aetna (only HealthEOS networks)
- Anthem Blue Cross Blue Shield
- Arise
- Auxiant
- Coalition America Network
- Common Ground (Trilogy Only)
- Cypress Benefit Administrators
- Dean Health Plan-Prevea360 Ntwk
- EBC-Employee Benefit Consultants
- Group Health Cooperative Eau Claire
- HealthEOS – Multiplan Network
- Homelink
- HPS – Health Payment Systems
- Meritain
- MSC Care Mgmt (One Call Care Mgmt)
- Network Health
- PBA-Professional Benefit Admin.
- PHCS Savility Network
- Prairie States
- Prevea Health Network
- Prevea360 (exclusive)
- SEHN (Sheb. Area Health Network)
- Tricare and ChampVA
- Trilogy Network
- UHC – United HealthCare
- UMR – incl. HealthEOS, Trilogy, UHC
- WEA
- WPS

**Medicare Advantage Plans**
- AARP Medicare Complete
- Advantage by Managed Health Sys.
- Aetna Medicare Open Plan
- Anthem BCBS Medicare Advantage
- Care Improvement Plus
- Health Net Medicare
- iCare Independent Care Health Plan
- UHC Dual Complete – Evercare
- United HealthCare Medicare

**Medicaid**
- Anthem BCBS-Community Connect
- Care Wisconsin First
- Children’s Community Health Plan
- ContinuUs
- Forward Health
- iCare
- Lakeland Care
- MHS Managed Health Plan
- UHC Community Plan

**HME is NOT a provider for:**
- Aetna HMO
- Aurora Ntwks (Common Ground/UMR)
- CIGNA (unless Multiplan Network PPO)
- Community Care Inc.
- GEHA
- HUMANA
- Michigan Medicaid
- Molina
- Security Health Plan - Northwoods
- UMR Aurora Groups
Documentation in Medical Records Required by CMS

Documentation Requirements:

☐ Duration of patient’s condition
☐ Clinical course
☐ Prognosis
☐ Nature & extent of functional limitations
☐ Other therapeutic interventions & results

Key Items to Address:

☐ Why does the patient require the item?
☐ Do the physical examination findings support the need for the item?
☐ Signs and symptoms that indicate the need for the item
☐ Diagnoses that are responsible for these signs and symptoms
☐ Other diagnoses that may relate to the need for the item