Expenses incurred by a beneficiary for the rental or purchases of durable medical equipment (DME) are reimbursable if the following three requirements are met:

- The equipment meets the definition of DME (§110.1);
- The equipment is necessary and reasonable for the treatment of the patient’s illness or injury or to improve the functioning of his or her malformed body member (§110.1); and
- The equipment is used in the patient’s home.

The purpose of this dossier is to demonstrate that MedClineMD device meets all requirements to be considered durable medical equipment.

Chapter 15, §110.1 of the Medicare Benefit Policy Manual defines durable medical equipment as equipment which:

- Can withstand repeated use;
- Is primarily and customarily used to serve a medical purpose;
- Generally is not useful to a person in the absence of an illness or injury; and
- Is appropriate for use in the home.

The following analysis further describes the underlying policies for determining whether an item meets the definition of DME and may be covered and how the MedClineMD device meets these requirements.

1. Can Withstand Repeated Use;

   A. Durability/Rentable

   An item is considered durable if it can withstand repeated use, i.e., the type of item that could normally be rented. Medical supplies of an expendable nature, such as incontinent pads, lambs wool pads, catheters, ace bandages, elastic stockings, surgical facemasks, irrigating kits, sheets, and bags are not considered “durable” within the meaning of the definition. There are other items that, although durable in nature, may fall into other coverage categories such as supplies, braces, prosthetic devices, artificial arms, legs, and eyes.

   The durability requirements state that an item must be rentable and meet a minimum lifetime requirement (See Section B. Minimum Lifetime Requirements) in order to be considered durable medical equipment. Figure 1 illustrates the MedCline rental cycle developed in 2015. Because of high patient compliance rates, overall satisfaction with using MedClineMD, the chronic nature of gastroesophageal reflux disease, and mostly one-time purchases by payers, this rental cycle has seldom been called into action. Regardless, the MedClineMD rental flow is well established and compliant with FDA and CDC guidelines for the cleaning, disinfecting, and redistribution of durable medical equipment.
Figure 1. MedClineMD Rental Cycle

76 Fed. Reg. 70286 (November 10, 2011) elaborates on the definition of “rentable” and states:

Items that are disposable cannot be rented and items that last for short periods of time are not likely to be items that would be rented.

This definition also references Ch. 15, §110.1 in underscoring that the durable criteria “excludes items that are of an expendable nature”. Examples given of expendable items are “incontinent pads, lambs wool pads, catheters, ace bandages, elastic stockings, surgical facemasks, irrigating kits, sheets, and bags.” Based on the definition of “rentable” §110.1 and elaboration in 76 Fed. Reg. 70286, MedClineMD is neither disposable nor expendable in nature. MedClineMD is also not an item that lasts for “short periods of time”, as will be discussed below. (See Section B.)

It should be further noted that DME definitions establish the criterion that an item “could be normally rented” (emphasis added). The criterion does not require that the item “is normally rented,” “is always rented,” or “is rented more than purchased”. Neither does the durability definition preclude items without rental history from being considered as DME, which is particularly important for new products. Prior marketing methods and direct-to-consumer purchases of any MedCline device should have no bearing on the ability of MedClineMD, or any other medical equipment, to be considered rentable. Rather, rentability is a function of durability of the item’s components and the ability of the item to be cleaned/disinfected and/or serviced at relatively low cost between patient use.

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2 US Food and Drug Administration. 2017. Covers for Hospital Bed Mattresses: Learn How to Keep Them Safe. [ONLINE] Available at: https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/HospitalBeds/ucm585737.htm
Based on the CMS definitions and policies, including examples of what constitutes a rentable item, we respectfully assert that MedClineMD is an item that currently meets the “could normally be rented” requirement.

B. Minimum Lifetime Requirement

76 Fed. Reg. 70291 establishes the requirement that an item must also meet a minimum lifetime requirement (MLR) of 3 years in order to be considered durable. MedClineMD meets these durability requirements.

When compared to hospital mattresses, MedClineMD is made from near-identical inner and outer materials. Figure 2 contains a description of the materials used in MedClineMD integral to meeting and exceeding the 3-Year MLR and 5-year RUL.

![Figure 2. MedClineMD materials](image)

(1) FOAM CORE ASSEMBLIES

The foam core assemblies of MedClineMD consist of multiple types of polyurethane foams bonded with permanent low VOC adhesives. These foams vary in density and stiffness measured by indentation force deflection (IFD). Foam types were selected to ensure proper long-term patient positioning for effectively treating nocturnal gastroesophageal reflux and ensure MedClineMD meets and exceeds product lifespan requirements. The various foams used in the Incline Base and Lateral Positioner are shown in Figure 3, with descriptions called out in Table 1.
The primary weight bearing components of MedCline MD are the high-resilience foam portions of the Incline Base (A, B) and the high density viscoelastic foams found in the Insert Pillow and the Lateral Positioner (C, D), which are important for maintaining proper torso elevation, head and neck support, and lateral positioning, collectively.

In addition to the 3-year product warranty of MedCline MD, 76 Fed. Reg. 70290 states that “standardized test results” are also an appropriate method of determining minimum life expectancy for DME. In the case of MedCline MD, all foams were cycle tested utilizing the constant force pounding standardized test: ASTM D3574 Test I₃ (American Society for Testing and Materials - Standard Test Methods for Flexible Cellular Materials—Slab, Bonded, and Molded Urethane Foams). Results for foams “A, B, E” and “C, D” are shown in Table 2.

Each cycle involves compressing the foam test block to 60% of its original height, which simulates the compression on the MedCline MD foam stack by the patient. This testing shows that both weight-bearing components of MedCline MD maintain excellent dimensional stability. As expected, fatigue curve results in Figure 4 show that after the initial “break-in period,” Indentation Force Deflection (IFD) values change quickly and approach near-steady state losses after approximately 10,000 cycles. For this reason, high resilience polyurethane foam is traditionally rated for a minimum life

### Table 1. Foam descriptions and specifications

<table>
<thead>
<tr>
<th>Fig. 2 Call Outs</th>
<th>Foam Description</th>
<th>Foam Density</th>
<th>IFD</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>High Resilience (HR) Polyurethane Foam</td>
<td>31 kg/m³</td>
<td>130N</td>
</tr>
<tr>
<td>B</td>
<td>High Resilience (HR) Polyurethane Foam</td>
<td>32 kg/m³</td>
<td>95N</td>
</tr>
<tr>
<td>C</td>
<td>Viscoelastic Polyurethane Foam</td>
<td>48 kg/m³</td>
<td>36N</td>
</tr>
<tr>
<td>D</td>
<td>50% Viscoelastic / 50% High Resilience Shredded Polyurethane Foam Mixture</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>E</td>
<td>High Resilience (HR) Polyurethane Foam</td>
<td>30 kg/m³</td>
<td>142N</td>
</tr>
</tbody>
</table>

### Table 2. Results of ASTM D3574 Test I₃ testing

<table>
<thead>
<tr>
<th>Foam Type (See Table 1)</th>
<th>Cycle Rate</th>
<th>Total Cycles</th>
<th>ΔIFD Min/Max</th>
<th>Thickness Loss</th>
</tr>
</thead>
<tbody>
<tr>
<td>A, B, E</td>
<td>70 cycles/min</td>
<td>80,000</td>
<td>18-22%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>C, D</td>
<td>10 cycles/min</td>
<td>12,000</td>
<td>15-19%</td>
<td>&lt;1%</td>
</tr>
</tbody>
</table>
expectancy of 10 to 20 years. Conservatively assuming that a MedClineMD user would cycle their foam 20 times per night (by repeated ingress and egress from the device), this would equate to 7,300 cycles per year, or 11 years, to reach 80,000 cycles for the high resilience polyurethane layers. Furthermore, following to CDC and FDA guidelines for hospital mattresses and pillows, all MedCline will be inspected between patients by a CMS accredited DME supplier for damage (e.g. cracks in impermeable covers, stains, etc.). Any worn or damaged components will be replaced (at no charge to MACs/CMS or beneficiaries per CR 7212) to ensure that beneficiaries receive like-new devices with each rental and throughout the rental period.

Figure 4. Fatigue curves for foam “A”.

(2) IMPERMEABLE UNDERCOVERS

All components of MedClineMD are encapsulated with durable hospital-grade undercovers. These covers are made from the same materials used to cover hospital mattresses and pillows. Features of the material used include:

- Waterproof and breathable for moisture projection and heat control
- Bi-elastic polyurethane coating (4-way stretch) to reduce skin friction and shear
- Polyester or nylon fabric backing for durability
- Anti-bacterial and anti-fungal
- Autoclavable
- Easy wipe cleanable and washable at 90°C
- Resistant to CDC-approved disinfectants

(3) WASHABLE OUTER COVERS

The final layer of protection ensuring that all MedClineMD components can withstand prolonged use is offered by the zippered, removable outer covers made of a commercial grade fabrics. The outer cover
made of Chief Value Cotton (CVC) Velour, which is an 80% cotton / 20% polyester blend with the side panels made of 100% polyester knitted mesh. CVC fabrics guarantee low shrinkage (less than 5%), high color-fastness, product durability, and the ability to withstand commercial wash cycles per CDC guidelines.

Outer covers are made removable by #8 nylon coil zippers rated for a minimum of 720 open and close cycles. Assuming users will wash the outer covers one time per week, the zippers will be subjected to only approximately 260 cycles over a 5-year period.

C. Multi-component devices

76 Fed. Reg. 70290 also provides guidance on multi-component devices; it states that a multi-component device may be considered durable so long as the “component that performs the medically necessary function of the device” is durable. Although we maintain that all of the components of MedClineMD easily exceed the 3-year MLR, the high-resilience polyurethane foam core of the base assembly is the primary weight bearing component of the system and thus subject to the most wear. However, as previously demonstrated in this document, that this component very reasonably exceeds both the 3-year MLR and 5-year RUL requirements.

D. MedClineMD Durability/Rentability Summary

Based on the analysis above, we respectfully assert that MedClineMD “can withstand repeated use” by meeting all durability and rentable requirements.

2. Is primarily and customarily used to serve a medical purpose;

The second and third requirements of the durable medical equipment definition determine whether or not a particular item should be considered to be medical equipment. Chapter 15, §110.1 of the Medicare Benefit Policy Manual defines medical equipment as follows:

A. Medical Equipment Definitions

Medical equipment is equipment primarily and customarily used for medical purposes and is not generally useful in the absence of illness or injury. In most instances, no development will be needed to determine whether a specific item of equipment is medical in nature. However, some cases will require development to determine whether the item constitutes medical equipment. This development would include the advice of local medical organizations (hospitals, medical schools, medical societies) and specialists in the field of physical medicine and rehabilitation. If the equipment is new on the market, it may be necessary, prior to seeking professional advice, to obtain information from the supplier or manufacturer explaining the design, purpose, effectiveness and method of using the equipment in the home as well as the results of any tests or clinical studies that have been conducted.

The Merriam-Webster dictionary defines “primarily” as: “for the most part; mainly”, and “customarily” as: “by or according to custom or established practice”. Expounding on the definition of medical equipment, an item must be mainly used for medical purposes and said purposes must be according to established medical practices. Items that are primarily and customarily used for
nonmedical purposes are presumptively nonmedical. §110.1 gives the example of air conditioners in the treatment of cardiac patients:

...in the case of a cardiac patient, an air conditioner might possibly be used to lower room temperature to reduce fluid loss in the patient and to restore an environment conducive to maintenance of the proper fluid balance. Nevertheless, because the primary and customary use of an air conditioner is a nonmedical one, the air conditioner cannot be deemed to be medical equipment for which payment can be made.

According to U.S. Energy Information Administration3, in 2009, 87% of US households were equipped with air conditioners, whereas only a small percentage of the population are afflicted with cardiac conditions that require environmental control to help maintain proper fluid balance. Air conditioners, therefore, are primarily used in the absence of illness and injury. Additionally, possession of an air conditioner serves only a remote medical purpose, as the therapeutic benefits are only tangentially related.

B. Regulated for primarily medical purposes only

MedClineMD is used and regulated for the medical purpose of treating nocturnal acid reflux. MedClineMD is recognized by the United States Food and Drug Administration, European Union, and the Therapeutic Goods Administration (Australian FDA) as a Class I medical device. As part of these regulatory approvals and auditing, the MedClineMD Instructions For Use (IFU) are reviewed and scrutinized by the respective reviewing bodies. The approved MedClineMD IFU references gastroesophageal reflux disease and laryngopharyngeal reflux (LPR) as the only two conditions MedCline is intended to treat. Patients are instructed to consult a physician for any uses other than gastroesophageal reflux disease and laryngopharyngeal reflux. Any deviation from these intended uses and medical claims would require additional approvals from the respective regulatory agencies. To further ensure alignment with the intended usage of MedClineMD, acquisition of the item would also require a prescription containing applicable GERD diagnosis codes.

C. Developed and marketed solely for medical purposes

Chapter 15, § 110.1 of the Medicare Benefit Policy Manual provides additional guidance to those reviewing items for potential consideration as durable medical equipment:

If the equipment is new on the market, it may be necessary, prior to seeking professional advice, to obtain information from the supplier or manufacturer explaining the design, purpose, effectiveness and method of using the equipment in the home as well as the results of any tests or clinical studies that have been conducted.

The manufacturer of MedClineMD, Amenity Health, Inc., has never and currently does not market the device for any nonmedical purpose. Furthermore, in both written and verbal communications with potential users, the manufacturer actively dissuades individuals from purchasing the device for any “nonmedical purpose”. Additionally, all prior commercial payer E1399 claims were submitted with diagnoses of either gastroesophageal reflux disease or laryngopharyngeal reflux. In developing whether MedClineMD constitutes medical equipment, we respectfully request that CMS and DME

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MACs appropriately consider these assertions by the manufacturer regarding design, purpose, effectiveness, and method of using the equipment in the home, per the above CMS policy.

D. Developed for GERD by a doctor with a precancerous condition

Many examples exist of items that were initially developed for nonmedical purposes, convenience, or solely for the comfort of the patient. After discovering an “item has some remote medically related use”, some manufacturers have sought for CMS reimbursement for these items. Appropriately, CMS has not granted coverage for these items. Most recent examples of this are the disposable La Petite and disposable Le Grand pillows (Save My Face, Inc., Valencia, CA). These pillows were first developed to help prevent facial wrinkles, which is a nonmedical purpose, and later found “some remote medically related” uses in facial surgery recovery and use with constant positive airway pleasure (CPAP) masks. In addition to not meeting durability criteria, these pillows also do not meet the criterion of “primarily and customarily used to serve a medical purpose”.

In contrast, MedClineMD was developed solely for the purpose of treating nocturnal gastroesophageal reflux disease. The device was initially conceived by Carl W. Melcher, MD, a 75 year old retired physician, collegiate professor of medicine and Medicare beneficiary. Dr. Melcher suffered with chronic nocturnal reflux on a nightly basis. Despite significant lifestyle changes, head of head of bed elevation, sleeping with many types of bed wedges, and even sleeping in a recliner, Dr. Melcher remained symptomatic. For decades, he also remained on a concomitant treatment of maximum proton pump inhibitor (PPI) medication therapy. However, despite the lifestyle changes and PPI therapy, Dr. Melcher remained symptomatic and developed Barrett’s esophagus, a precursor to esophageal adenocarcinoma. Indecently, esophageal cancer is one of the fastest growing cancers in the United States. From inception, MedClineMD has been solely focused on the medical purpose of treating nocturnal reflux and providing clinically proven relief to GERD sufferers.

E. MedClineMD clinical studies

To date, seven clinical trials have been completed using the MedCline device. However, the clinical efficacy of the positioning techniques, only accomplished with the MedCline device, are backed by decades of prior research and a library of peer-reviewed articles. Ultimately, in addition to weight loss, the only other lifestyle changes proven through controlled studies to reduce gastroesophageal reflux are:

- Head of bed elevation (i.e., elevating the full torso)
- Left-lateral decubitus positioning

The volumes of published literature related to head of bed elevation (HOB) and a separate body of literature examining left-lateral positioning for GERD were heavily leveraged throughout the development of MedClineMD. MedCline permitted the first ever studies to be conducted examining the therapeutic benefits of combining HOB with left-lateral positioning. Clinical study abstracts and manuscripts have been provided to CMS and DME MACs in previous correspondence. Table 3 compares the effectiveness of MedClineMD to PPI medications and surgical techniques at reducing esophageal acid exposure and improving the quality of life PPI refractory patients and patients with laryngopharyngeal reflux.

Table 3. MedClineMD Clinical Results Comparison
Clinical Citations for Table 3.


As shown in Table 3, MedClinemD has been shown to be as effective or more effective than medical and surgical treatments that are approximately 10x and 100x more costly, respectively. Of particular mention, with the exception of the first MedClinemD study, all other studies have been conducted free from financial interests of the manufacturer and funded internally by the research institutions who conducted the studies.
MedClineMD studies have shown that the device dramatically reduces nocturnal esophageal acid exposure. However, the majority of study outcomes have focused heavily on symptom reduction and improvement in health-related quality of life. This focus was chosen for two reasons. First, GERD symptoms are tightly correlated with the presence of acid in the esophagus and upper airway. Therefore, symptom control is directly correlated to a reduction in esophageal acid exposure. Second, uncontrolled symptoms directly correlated to increased healthcare utilization and costs. Also of particular mention is that the symptom reductions and quality of life improvements demonstrated in MedClineMD studies are compared to baseline data of patients on once daily or twice daily PPI dosages. Therefore, the dramatic reductions in symptoms and quality of life improvements shown in the clinical studies are in addition to any benefits already derived from the patients’ ongoing PPI therapy.

F. Professional Medical Advice

Chapter 15, §110.1 also provides guidance to those reviewing items for potential consideration as durable medical equipment with respect to seeking professional medical advice:

...some cases will require development to determine whether the item constitutes medical equipment. This development would include the advice of local medical organizations (hospitals, medical schools, medical societies) and specialists in the field of physical medicine and rehabilitation.

One need not look very far to see consistent examples of support for MedClineMD amongst medical organizations and specialists. First, positional therapy has been included for many years in clinical guidelines for the treatment of GERD published by the American College of Gastroenterology (ACG) and the American Gastroenterological Society (AGA). Second, MedCline has been incorporated into the “standard of care” for nocturnal GERD patients by one of the most respected hospitals in the U.S., the Cleveland Clinic. After recommending HOB and bed wedges for many years, many gastroenterologists have turned to MedCline to more effectively treat their patients with uncontrolled nocturnal reflux. One of these physicians is former AGA president Donald O. Castell, MD whose coverage recommendation is found in Appendix A.

3. Generally is not useful to a person in the absence of an illness or injury;

§110.1 provides guidance on the interpretation of this third requirement. It states:

Equipment which basically serves comfort or convenience functions or is primarily for the convenience of a person caring for the patient...[does] not constitute medical equipment.

Furthermore, §110.1 states that “in most instances, no development will be needed to determine whether a specific item of equipment” satisfies this requirement. The general intent of this requirement appears to be made even more clear through the examples given in this section, namely air conditioners, room heaters, humidifiers, dehumidifiers, and electric air cleaners. Each of these items is clearly useful to individuals in the absence of illness or injury, while serving only a remote medical purpose.
We acknowledge that one possibly could conjure up an obscure nonmedical use for which the MedClineMD device could be used. For example, one could suggest that the incline base of MedClineMD could be positioned vertically against a headboard or wall in one’s bed for sitting up to read or watch television. Anticipating this concern, the developers of MedClineMD engineered a permanently bonded foam arc into the incline base. This foam arc, which is rounded on the bottom creates a flimsy and nonplanar bottom surface if the incline based were to be positioned vertically, thus causing the incline base to become unstable and fall to one side or the other.

Figure 5. Incline Base integrated arc feature

Any attempt to demonstrate that MedClineMD is generally useful in the absence of illness or injury by conceiving some abstract use for the device would be inconsistent with the elaborated definitions and examples of items that do not meet this requirement. This is evidenced by the fact that there are scores of existing durable medical equipment items which have much more plausible nonmedical uses than MedClineMD. The following are just a few examples:

- Hospital beds (E0250, E0260) can be used by any person for general sleep.
- Dry pressure pads (E0199) can be used and sleeping pads while camping.
- Powered pressure-reducing air mattress (E0277) can be used as an inflatable guest bed.
- Bed safety enclosures (E0316) can be used by healthy individuals to prevent rolling from the bed.
- Water circulating heat pads (E0217) can be used to simply keep warm during cold weather.
- Oxygen concentrators (E1391) can be used by athletes for recovery after an anaerobic activity.

As with most medical equipment that interfaces directly with the human body, various design features commonly are incorporated into items to improve patient experience in order to increase patient compliance rates. Features exit on the MedClineMD device that, in addition to improving clinical effectiveness, secondarily also contribute to increased patient comfort. However, it has been the manufacturer’s experience that it is highly unlikely that any Medicare beneficiary would prefer to sleep with the MedClineMD device in the absence of an illness or injury as the angle of incline created is significant to ensure effective GERD relief but without this therapeutic benefit would not be a natural and preferred sleeping position. Additionally, the beneficiary acquisition process of MedClineMD would require a prescription with appropriate GERD diagnostic codes to ensure conformity with intended usage.
4. **Is appropriate for use in the home.**

Although it seems obvious that MedClineMD is appropriate for use in the home, it may be worth noting that the device has never been sold or marketed for use in hospitals or clinician offices. Additionally, all clinical studies conducted with MedCline have been conducted in the home setting.

**Summary**

Based on the above analysis, we respectfully request that CMS issue a determination indicating that MedClineMD falls within the durable medical equipment benefit category.