Challenges in Enteral Nutrition Access and Management: Safeguarding Life-Sustaining Nutrition

EXECUTIVE SUMMARY

Hundreds of thousands of children and adults who are malnourished or at risk of malnourishment in the United States require life sustaining enteral nutrition (EN) to receive necessary nutrition and hydration. Individuals requiring EN have a variety of medical conditions and may need EN on a temporary basis or have long term or life-long needs. EN refers to any method of feeding that uses the gastrointestinal tract to deliver the nutrition. EN is provided via tube feeding and/or oral nutrition supplements (ONS) and requires disposable supplies for administration.

Durable Medical Equipment (also known as Home Medical Equipment or HME) providers work closely with the prescribing clinician to provide the most clinically appropriate EN to an end user, monitoring for tolerance, proper utilization, ongoing product availability, and satisfaction. In addition to supplying the EN products, HME providers play a critical role in EN management and provide extensive, labor-intensive services in sourcing the most medically appropriate products in a rapidly changing EN market, educating end users on EN management, coordinating with prescribers on documentation, and submitting claims on behalf of the end user in compliance with payer requirements. Appendixes A and B detail the steps HME providers must complete when supplying EN.

Proper EN management by knowledgeable HME providers is critical to prevent malnourishment and negative health outcomes which can lead to avoidable payer expenses. Malnutrition can complicate conditions and lead to frailty, risk of falling, delayed wound healing, and healthcare-acquired pressure ulcers. Additionally, readmission rates, institutionalization, and ongoing healthcare services increase in end users suffering from malnutrition. Complications with feeding tubes are the third most common reason and account for 10% of hospitalizations in medically complex children.[1]

Current market conditions create significant headwinds to ensure end user access to EN. A 2023 nationwide study revealed that one in four HME providers of EN are considering or actively planning to stop providing EN/supplies due to cost pressures.[2] While other sectors can adjust their pricing to reflect current market realities, EN is constrained by set reimbursement rates that often fail to factor in the increased costs of providing EN products, supplies, support, and services. HME providers report significant increases in product, labor, and shipping costs, yet 88% have received no reimbursement increase from payers outside of the Medicare FFS CPI-U adjustment to offset the new market realities.[2] Billing and coding challenges present additional complications for HME providers due to the wide variety of products, dressing, and adapters within a single miscellaneous non-reimbursable billing code, affiliated costs of safety initiatives including change management and execution, as well as limitations on feeding kit reimbursement.

To ensure continued access to life-sustaining EN, payers should: 1) adjust reimbursement to assure appropriate end user access, 2) expedite Prior Authorization for EN formula, 3) provide regular review and expeditious product additions to approved product lists/formularies, and 4) decrease excessively burdensome documentation requirements.

OVERVIEW OF ENTERAL NUTRITION

Enteral Nutrition (EN) refers to any method of feeding that uses the gastrointestinal (GI) tract to deliver necessary nutrition and hydration to individuals of all ages in a variety of settings for various reasons. EN includes tube feeding and oral nutrition supplements (ONS); EN supplies are necessary components required for

the delivery of EN. EN is indicated when end users with functional GI tracts are unable to consume enough macronutrients, (carbohydrates, fat, protein, and water), and/or micronutrients (vitamins and minerals) to promote health or sustain life.[3, 4]

End User Population & Clinical Conditions

EN therapy is utilized by individuals of all ages, from infancy to old age, at every juncture along the healthcare continuum from inpatient hospital care to outpatient in-home care. As of 2017, an estimated 500,000 people per year in the United States require tube feeding as their main source of EN.[5] The number of people using ONS is harder to estimate due to a) the variance in prescriber recommendation and individual utilization, ranging from 1-2 containers per day as supplement to 6-8 containers per day as full meal replacements or sole source of nutrition and b) the variance in insurance coverage prompting some users to purchase out-of-pocket while others access through a health plan benefit.

Individuals requiring EN are malnourished or at risk of malnutrition. Common additional diagnoses from chronic illnesses include Crohn's disease, short bowel syndrome, neurological conditions, inflammatory bowel disease, cystic fibrosis, pediatric feeding disorders, and many cancers. Users may also suffer from acute illnesses, malnutrition, growth failure, and/or bowel obstruction.[4] Individuals that suffer from short- or long-term oral mechanical dysfunction, such as swallowing or chewing problems, may also require EN. Duration of EN is variable and is determined by an individual's medical team, and may be as brief as several weeks to lifelong dependence. Pediatric EN users are often medically complex with frequently changing care plans requiring adjustments in EN therapy, specialized formulas, ongoing supply/equipment education, and monitoring from highly trained homecare staff and clinicians.

Routes & Methods of EN Administration

Routes of Administration

EN can be consumed orally or through a feeding tube. A feeding tube can be inserted into existing orifices or openings in the body that lead into the GI tract, such as a person's nose or mouth, or surgically by a physician directly into the stomach or small intestine. The following briefly describes the indications for different types of feeding tubes provided in the home setting.

- Short-term feeding (up to 4-6 weeks):
    - Nasogastric (NG-Tube) – Tube is inserted through nose, past throat, and into the stomach
- Long-term feeding (more than 6 weeks):
    - Gastrostomy (G-Tube) – Surgical tube insertion into stomach
    - Jejunostomy (J-Tube) – Surgical tube insertion into middle section of small intestine, used to reduce risk for aspiration of gastric contents or bypass a dysfunctional stomach
    - Gastrojejunostomy (GJ-Tube) – Surgical opening through stomach with a dual port for simultaneous venting and feeding; the feeding tip is placed in jejunum
- Low profile G-Tube "button" – Skin-level tube surgical insertion through stomach, used to reduce incidence of dislodgement; G-Tube "buttons" can be replaced in a home-based setting by the end user or caregiver after the initial surgical insertion has healed.

Methods of Administration

Tube feedings are administered using one of the following methods:

- Syringe: Nutrients are injected or pushed into the feeding tube via a syringe.
- Gravity: Nutrients enter the feeding tube unassisted via gravity bag feeding system.
- Feeding Pump: Nutrients are administered at a controlled flow rate into the feeding tube as programmed by the pump setting. *See Appendix C glossary for details.*

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Equipment & Supplies to Administer EN:

The disposable supplies required for each method of administration are translated into one of three HCPCS codes for billing, commonly referred to as "feeding kits":

Code	Description
B4034	Enteral feeding supply kit: syringe fed, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape
B4035	Enteral feeding supply kit: pump fed bag, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape
B4036	Enteral feeding supply kit: gravity fed bag, per day, includes but not limited to feeding/flushing syringe, administration set tubing, dressings, tape

The feeding kits include supplies required for the administration of enteral feeding for one day. Administration supplies consistently include, but are not limited to, a catheter/tube anchoring device, feeding bag/container, flushing solution bag/container, administration set tubing, feeding/flushing syringes, gastrostomy tube holder, dressings (any type) used for gastrostomy tube site, tape (to secure tube or dressings), and various connectors and adapters. Feeding kits exclude the feeding tube and the administered nutrients. Gastric pressure relief valves, declogging devices, and extension sets unique to G-Tube "buttons" may or may not be included in the feeding kits, dependent on payer billing guidelines.

For many payers, the billing unit for the kit is a calendar day, similar to a per diem charge used in the home infusion industry. The use of individual items often differs between users and changes over the course of the user's EN therapy. The feeding kits are not pre-packaged or provided as the same components to all of a HME provider's EN users. Although the feeding kits are often user-specific, the component items must not be separately billed outside of the feeding kit code unless specifically authorized by the payer. Feeding pump backpacks that allow the end user to be mobile, may reduce fall risk, and increase quality of life are often provided although they are not separately reimbursable. It's important to note that the cost of the component parts within a single feeding kit code vary greatly, as do their costs, but are reimbursed at the same single flat per diem rate, even if the component costs exceed the reimbursed rate.

The feeding pump is not included in the billing or reimbursement of the B4035 "pump fed" supply kit. The device is billed separately, typically on a monthly rental basis and converts to purchase according to the payer's billing guidelines.

ENFit Supplies: New Modified EN Tubing Connection to Improve End User Safety - Global Initiative[6]

ENFit connectors are part of a patient safety initiative to decrease the avoidable, negative health outcomes caused by medical device misconnections. An ENFit transition adaptor is also required if the end user does not have an ENFit feeding tube. The ENFit transition adaptor enables legacy (non-ENFit) tubing that lacks these safety features to be compatible with the new ENFit feeding set, thus reducing the risk of being connected with an unrelated delivery system. The associated costs, both tangible and intangible, during the transition period costs are not covered by the significant majority of payers.

Types of EN Nutrients

Nutrients

Enteral formulas come in a variety of preparations to meet specific nutrition needs for different medical conditions, but are generally categorized as "oral" or "tube fed".

Oral Enteral Nutrients: Oral EN can include liquid, semi-solids, or powders. End users who drink EN formulas (i.e. ONS) can consume ONS as a sole source, in combination with regular food, and/or in combination with tube

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feeding to meet their nutritional needs which may fluctuate depending on one's medical condition. For example, a person experiencing a Crohn's Disease flare may require an exclusive EN liquid supplement diet taken orally for several months as an adjunct treatment until the flare resolves before transitioning back to a regular food diet.

Tube Fed Enteral Nutrients: EN delivered through a feeding tube is in the form of commercial manufactured standard formulas, manufactured specialized formulas, manufactured blenderized formulas (eligible for coverage by insurance), or home blenderized foods (not eligible for coverage by insurance). See Appendix C for descriptions of the different types of EN formulas.

The more a formula's macro- and micro-nutrients have been modified for specific medical conditions, the higher the cost for both manufacturer and HME providers.

HME PROVIDER PROCESSES & REQUIREMENTS

EN Services & Product Fulfillment

HME providers work closely with the prescribing clinician to provide the best clinically appropriate EN to an end user, monitoring for tolerance, proper utilization, ongoing product availability, and satisfaction. EN supply availability has been dramatically impacted by supply chain issues, and HME providers play an integral role in coordinating with the prescribing clinician to identify clinically appropriate alternate products to minimize disruption in care and avoid more costly interventions and complications.

HME providers are also responsible for collecting and providing required medical documentation for initial provision and the ongoing fulfillment of EN and supplies. At times, prescriber orders do not contain all the necessary detailed information necessary for billing, requiring HME providers to act as a liaison between the prescribing clinician and payer, gathering the required documentation to submit claims on behalf of end users. This process is cumbersome, time-consuming, and requires combined subject matter expertise in medical necessity, product knowledge, and payer guidelines to ensure the end user receives the product they need within the constraints of their insurance coverage.

Documentation supporting the medical necessity is labor-intensive, requiring prescribers to present comprehensive reasons to cover EN, including duration of treatment, and HME providers must confirm that the medical need details are included in medical records to justify coverage and reimbursement. For justification of a specialized formula, the documentation could include why a standard formula was considered but not used and depending on payer requirements, must document more than a diagnosis for specialized formula coverage.

The service component of HME providers is invaluable and cannot be understated. In their multi-faceted role, they are:

- Logistics coordinators to source products amidst a rapidly changing landscape;
- Billing experts to comply with a variety of payers' requirements;
- Clinical liaisons to educate prescribers on documentation requirements;
- Front line advocates for the end users educating on EN management in the home;
- Product experts who understand the range of options available to best meet one's needs; and
- Care coordinators who conduct ongoing assessments for renewal and change orders with the medical care team.

For additional information, see Appendix A and B.

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FACTORS THAT INCREASE COSTS OF PROVIDING ENTERAL NUTRITION

HME Provider Costs

Unlike other sectors that can adjust their pricing to reflect current market realities, fluctuations, and inflationary impacts, EN is constrained by set reimbursement rates that often fail to factor the increased costs of providing EN products, supplies, support, and services.

Coding Challenges Costs

When determining HME providers' cost of providing EN to end users, several variables must be considered:

- Acquisition cost variances
    - Wide variety of products with different end user indications captured under a single HCPCS code;
    - Higher cost of low-profile G-Tube "button" commonly reimbursed at the same reimbursement rate as a traditional gastrostomy tube in spite of having dramatically different acquisition costs; and
    - Higher cost of a dual (feed and flush) pump, which is reimbursed at the same rate as a feed-only pump.
- Additional costs with ENFit international safety initiative
    - The process of change has inherent costs, both tangible and intangible
- Limitations on feeding kit reimbursement
    - Breadth of essential supplies included in the "kit" definition that are not separately reimbursable, and
    - High-cost component items that are not sufficiently reimbursed in the "kit" rate.

External Contributing Factors Impacting Costs

EN products are significantly impacted by supply chain disruptions, jeopardizing end user access to life-sustaining nutrition; this was exacerbated by the pandemic and the infant formula crisis and remains past the end of the COVID-19 Public Health Emergency. Other ripple effects of the pandemic also increased the operational overhead required by HME providers, thus increasing EN costs:

- Additional time and resources required to source alternative EN products as needed with continued and ongoing supply chain interruption and rolling national backorders;
- Increased time securing updated prescription(s) from the prescribing clinician in order to dispense alternatives;
- Additional shipping and operational costs due to shipping partial orders and multiple orders due to product backorders;
- Additional staff time contacting end users/family caregivers to discuss product changes, backorders, and other updates; and
- Supply-chain shortages requiring product substitutions cost more than originally prescribed product, sometimes exceeding the allowable rates.

A 2023 nationwide survey of HME providers who provide EN found significantly increased product, shipping, and labor costs over the last 12 months. Over half reported EN backorder delays of 31-90 days with 23% exceeding 121 days; tubes/pumps/supplies faced similar challenges. The majority of the Industry ships the EN supplies to end users, of which 94% report increased shipping .[2] Backorder delays significantly increase costs due to multiple shipments required to fulfill the order.

In total, 89% of HME providers reported increased labor, and product costs increased for 89% of those providing EN (Table 1) and 95% of those providing tubes/pumps/supplies (Table 2). Relief is not in sight as 75% also

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reported that their manufacturers/distributors provided an advance notice of price increases or an expectation that prices will increase again in 2023. [2]

TABLE 1

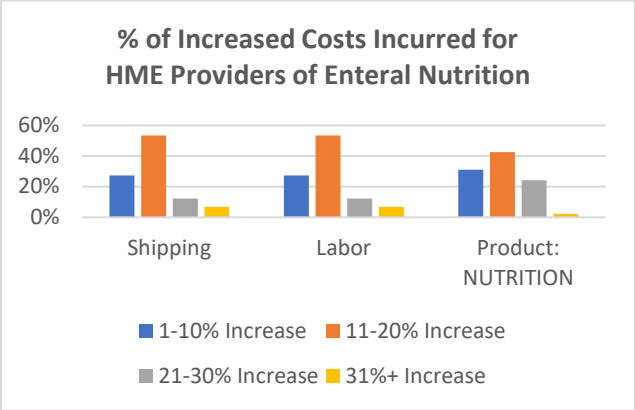
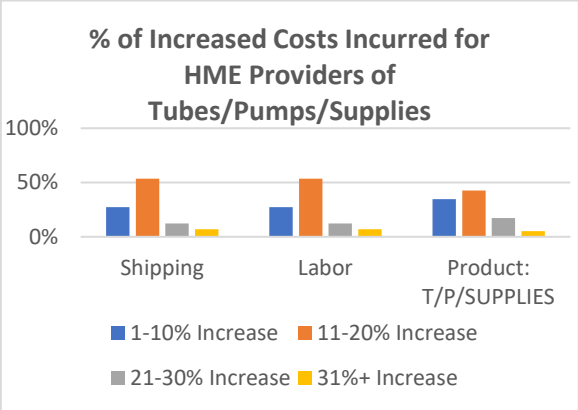


TABLE 2



The Bureau of Labor and Statistics and the Food Price Index have information on inflation of commodities utilized in EN. These commodities have dramatically increased under inflationary pressures. The cost of EN formula ingredients such as dairy, vegetable oils, and protein sources have been impacted by inflation, increasing +10-40%. [7] Increased transportation costs have also contributed to the increases in acquisition costs for HME providers.

See Appendix D for additional information.

Costs to the Payer

For those with or at risk of malnutrition, EN is life-sustaining. It is critical to ensure access to clinically appropriate and well-tolerated EN provided by knowledgeable HME providers to prevent malnourishment and negative health outcomes which can lead to avoidable payer expenses. "Disease-associated malnutrition in the USA has been estimated as more than $147 billion per year", but "improved nutrition care has been associated with fewer complications and faster recovery (shortened lengths of stay, lower readmission rates)."[8] In addition, complications with feeding tubes are the third most common reason and account for 10% of hospitalizations in medically complex children.[1]

"Malnutrition is linked to increased rates of mortality, increased incidence of healthcare-acquired pressure ulcers, immune suppression and increased infection rates, delayed wound healing, decreased respiratory and cardiac function, muscle wasting and functional loss increasing the risk of falls, longer length of hospital stay, higher readmission rates, and higher treatment costs."[9] Additionally, readmission rates, institutionalization, and ongoing healthcare services increase in end users suffering from malnutrition. In particular, disease-related malnutrition is a common reason for end users to be readmitted to hospitals.[10] A study published in *HCUP Statistical Briefs,* developed by the Agency for Healthcare Research and Quality (AHRQ), in 2013 found that "malnutrition in U.S. hospitalized patients is associated with a more than 50 percent higher rate of readmission within 30 days, compared to patient stays not associated with malnutrition."[11] "In 2021, a draft comparative effectiveness review on malnutrition in hospitalized adults, prepared for AHRQ by the Evidence-based Practice Center, found an association between malnutrition and prolonged hospital stays as well as increased mortality among malnourished patients" according to the Healthcare Nutrition Council.[12] "Hospitalized patients at risk of malnutrition are also more likely to be discharged to another facility or require ongoing healthcare services after being discharged from the hospital than patients who are not at risk."[12]

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Some other payers still require a tried-and-failed approach with negative outcomes before end users can receive coverage for their prescribed formula regimen. This increases the cost of care and creates avoidable adverse health outcomes for the end user.

PROPOSED SOLUTIONS

The changes in availability of EN formulas, combined with increased cost of goods, labor, and shipping continue to impact end user access to care in the home or residential care facility. Payer requirements for authorization when formulas are changed and restrictive formularies in some cases are no longer sustainable in today's market environment. The added delay in providing necessary products and expense of pursuing oftentimes redundant authorizations combined with other external market factors is contributing to widespread enteral formula access concerns. The current extensive prior auth process for EN formulas may reduce patient access, increase delays to patient care, and reduce patient satisfaction.

The following solutions could help ensure end user access to EN and supplies:

- **Adjust reimbursement to better assure appropriate patient access** – would maintain the safety net of HME providers available to care for end users;
- **Expedited & simplified process for Prior Authorization for EN formula** – would minimize disruption in access (which prevents end users from being fed) while waiting on administrative process, help prevent ED visits and/or adverse health outcomes of end users while using improper product waiting on prior authorization, and help expedite hospital discharges reducing strain on the hospital system;
- **Flexibilities to substitute medically appropriate alternative EN formulas without requiring new Prior Authorization** – preventing unnecessary delays in providing EN while waiting for a secondary prior authorization
- **Regular review and expeditious product additions to Approved Products Lists/Formularies** – would ensure that end users have access to current products on the market that are the most appropriate to meet their medical needs;
- **Decrease excessively burdensome documentation requirements by payers** – would minimize delays in providing needed EN to the end user

CONCLUSION

Enteral nutrition is utilized when medically necessary to sustain life and provide required nutrition for individuals with a variety of medical conditions. EN is an essential component of nutrition intervention to improve clinical outcomes for individuals with, or at risk for, malnutrition and to prevent complications that lead to avoidable ED and physician visits as well as hospital readmissions. The clinical community, HME Industry, advocacy groups, end users, and their caregivers are concerned about access to the most medically appropriate EN and related products/supplies. As provider networks continue narrowing their networks, it is difficult for EN end users to find HME providers that offer the particular EN and/or products they may need.

Insufficient reimbursement means that HME providers are likely to either stop providing EN and related products/supplies or only offer limited/lower-end nutrition/products. Over 30% of HME providers have closed or stopped taking Medicare since 2013 due to unsustainable rates and market pressures. Now, **over 1 in 4 HME providers are actively considering dropping EN, tubes, pumps, and supplies due to current market dynamics and increased operational expense.**[2]

The short-term savings for a health plan with limited reimbursement may result in negative health outcomes which have resulted in higher health care costs. **To ensure end users requiring EN and related**

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products/supplies receive the appropriate product to promote positive outcomes, payers must set rates at appropriate levels. At current EN rates, uninterrupted end user access for life sustaining EN is at risk.

Citations:

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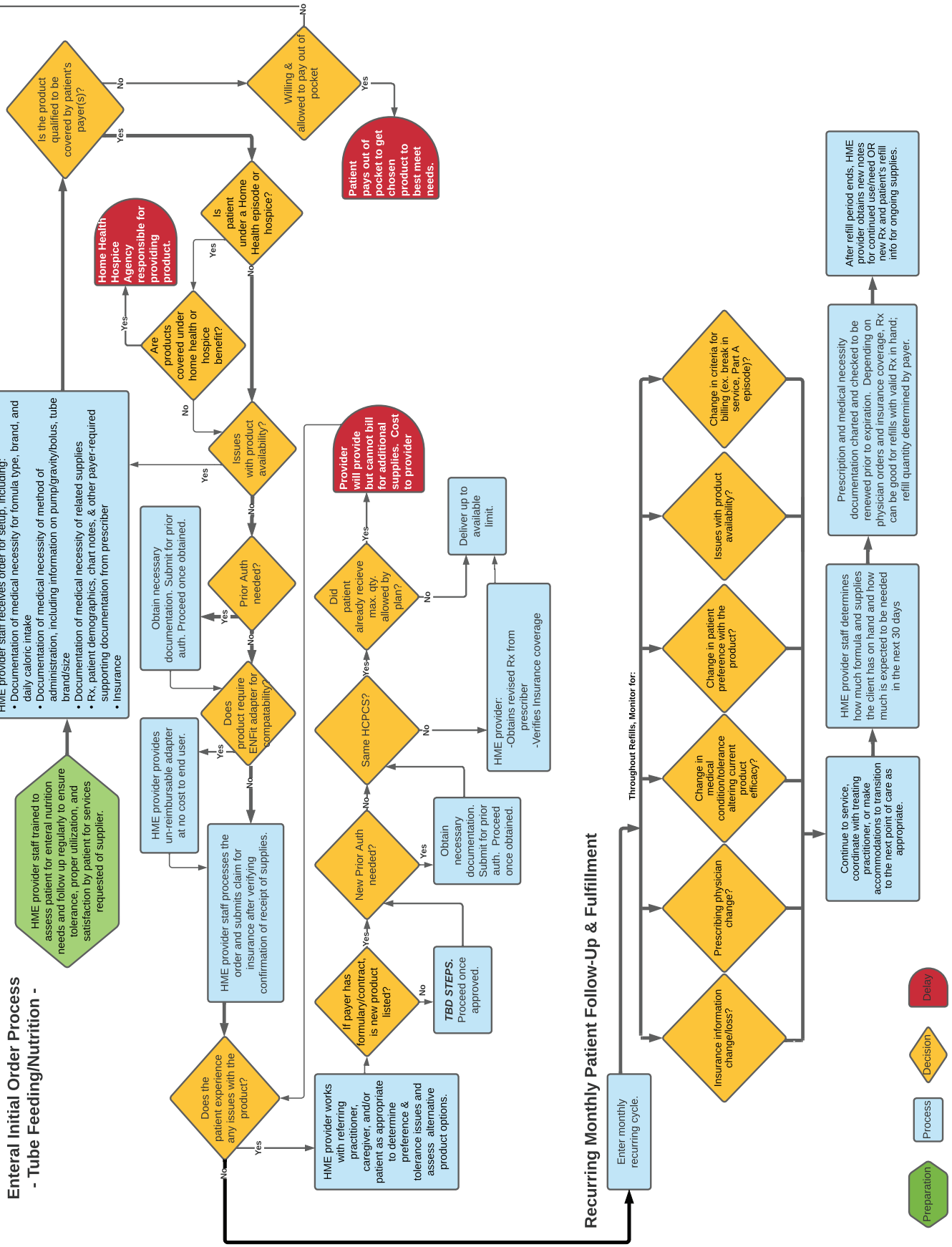
11. Fingar K, Weiss A, Barrett M, Elixhauser A, Steiner C, Guenter P, and Hise Brown M. All-Cause Readmissions Following Hospital Stays for Patients with Malnutrition, 2013. HCUP Statistical Brief #218. 2018. 1-18. https://hcup-us.ahrq.gov/reports/statbriefs/sb218-Malnutrition-Readmissions-2013.jsp
12. https://healthcarenutrition.org/wp-content/uploads/2022/07/HNC-Comments-to-CMS-FY2023-IPPS-Proposed-Rule-Final.pdf

Appendices A & B: Order Flowcharts



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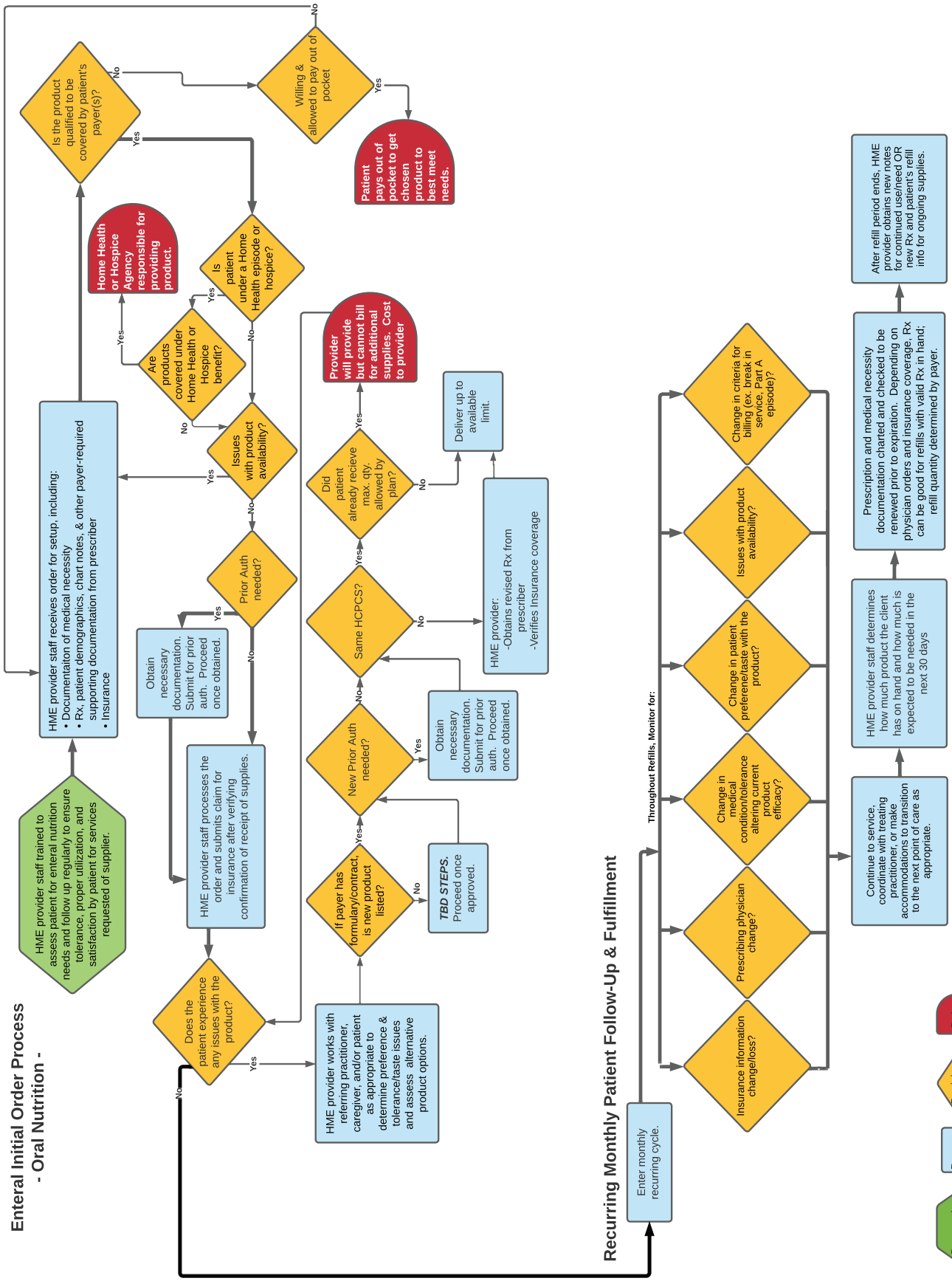

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Appendix C: Glossary and Supplemental Information

Feeding Pump:

- The pump can administer nutrients "continuously" over a specified amount of time (typically between 8-24 hours) or "intermittently" as a bolus feeding delivered in a larger volume of nutrition over a short amount of time (repeated several times throughout the day to mimic meals).
- A standard feeding pump is indicated for a) users at risk for feeding intolerances (nausea, vomiting, stomach distension or bloating) with uncontrolled or larger feeding volumes, b) users requiring faster or intermittent feeding rates or c) users requiring feedings into the small bowel.
- The functionality of a "feed-flush" pump is indicated for end users on feedings that require intermittent water flushes for hydration and tube patency. The feed-flush pump is becoming the preferred pump for adult feeding. All feeding pumps can be secured on an IV pole for use at bedside and minimal portability. Many pumps also provide additional portability features, placed in and worn as a backpack, so feedings can occur while the user is mobile.

Low Profile G-Tubes:

- To minimize the likelihood of complications, a low-profile gastrostomy tube is the standard of practice for pediatric end users who are expected to require tube feedings for an extended period. As compared to a traditional "long" gastrostomy tube, the low-profile device allows for increased mobility in a developing child to promote fine and gross motor skills, caregiver ease of use to maintain nutrition and medication regimens, and skin level proximity to avoid tube dislodgement and site breakdown.
- The low-profile device has its own HCPCS code (B4088) but is commonly reimbursed at the same rate as a traditional gastrostomy tube (B4087) despite having an exponentially higher acquisition cost. With proper care and training, the low-profile gastrostomy tube can be used for a period of 3 months before it is replaced, making the additional investment in the device a most cost-effective option to avoid more costly interventions associated with complications.

Type of Formulas:

- *Standard formulas* – Often comprised of semi-synthetic ingredients, using intact carbohydrates, protein and fat. Indicated for majority of EN users.
- *Specialized formulas* – Comprised of intact or hydrolyzed protein that is broken down to its individual components (peptides and amino acids) or specific macro- or micronutrient content is modified to address the needs of a medical condition. Indicated for users with medical conditions such as GI malabsorption conditions, inborn errors of metabolism, or any organ injury or dysfunction.
- *Blenderized feedings* – Commercially manufactured tube feeding formulas are covered by payers but conventional foods that are home blenderized are not covered by Medicare or other payers.

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Appendix D: Enteral Market Infographic

AAHOMECARE
American Association for Homecare

COST INCREASES AFFECTING ENTERAL NUTRITION & SUPPLIES

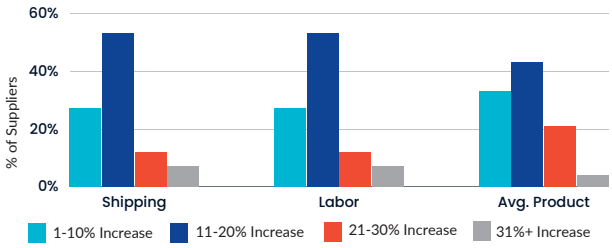
Current reimbursement rates for life sustaining enteral nutrition & related supplies* fail to factor the increased costs and *must be addressed to preserve access to care*

REPORTED IMPACT ON SUPPLIERS:

11-30%+ Increased cost of goods
11-20%+ Increased shipping costs
11-20%+ Increased labor costs

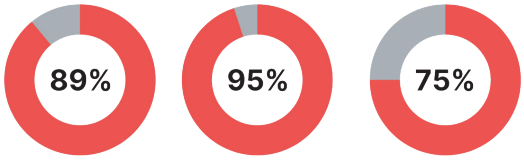
88% REPORT NO PAYER RATE INCREASES
Excluding Medicare CPI-U Adjustment

Percent of Increased Costs Incurred[1]



10-40% Increase in food commodities used in EN formula in the last year[2]

HME PROVIDERS' COST INCREASES FROM MANUFACTURER/DISTRIBUTOR[1]



Incurred increased **enteral nutrition costs** in the last 12 months

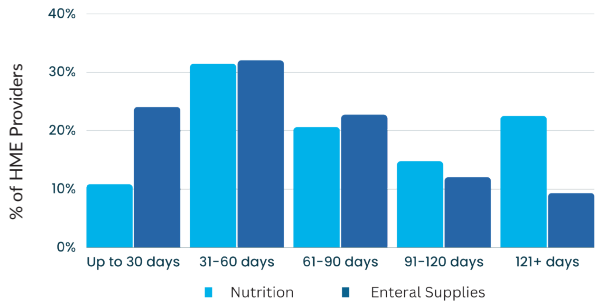
Incurred increased **enteral supplies costs** in the last 12 months

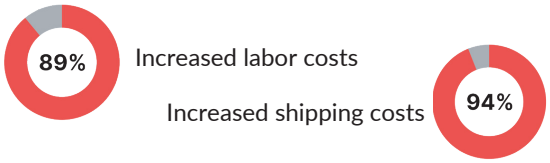
Received advance notice or expectation of **cost increase this year**

CONTINUED MARKET CHALLENGES WITH SUPPLY CHAIN DISRUPTION & INCREASE SHIPPING COSTS[1]

Respondents report supply chain, inflation, labor market, and challenges managing operational costs as issues negatively impacting their ability to provide disposable supplies

Supply Chain Interruption - Delayed TimeFrame for Order Fulfillment[1]





100% experienced **supply chain disruption** in the last 12 mo.

84% **ship enteral nutrition & supplies** at least 80% of the time to end users

6.9% **Minimum additional increase in shipping costs** by major carriers to take effect in 2023[4]

1 in 4 are considering or actively planning to **stop providing enteral nutrition/supplies** due to cost pressures[1]

37% **fewer HME Providers nationwide since 2013**[3]

UNSUSTAINABLE REIMBURSEMENT CAN JEOPARDIZE PATIENT ACCESS TO CARE

1) National AAH supplier survey on enteral nutrition and supplies, March-April '23.
2) www.bls.gov. 3) AAH analysis of Medicare DMEPOS supplier, July '23.
4) www.partnership.com/blog/post/fedex-ups-general-rate-increase

**Supplies includes tubes, pumps, & other supplies required for provision of enteral nutrition*
Note: Home Medical Equipment (HME) Providers are also referred to as suppliers

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