Clinical Policy Title: Nutritional support

Coverage policy

Select Health of South Carolina considers the use of nutritional support in specific situations to be clinically proven and, therefore, medically necessary when any of the following criteria are met:

<table>
<thead>
<tr>
<th>✓</th>
<th>Criteria for medical necessity (One of the following criteria must be met)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Location of care: Critically ill hospitalized patients (severe traumatic brain injury, major trauma/surgery, mechanical ventilation, patient anticipated to be Nothing per Orem (NPO) &gt; seven days, malnourishment anticipated for &gt; two days).</td>
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<td></td>
<td>Physiologic status: Patient must have permanently inoperative body organ or function or judgment of attending physician that impairment will be long or of indefinite duration.</td>
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<td>Type of nutritional support (at least one):</td>
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<td>• Enteral nutrition: Functioning gastrointestinal tract (GI) tract, pathology or</td>
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<tr>
<td>✓</td>
<td>Criteria for medical necessity</td>
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<td>(One of the following criteria must be met)</td>
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</table>

- non-function of structures normally permitting food to reach digestive tract, inability to maintain weight and strength commensurate with general condition.
- **Specialized infant formulas**: For inborn errors of metabolism or inherited metabolic diseases where such formulas are sole sources of nutrition.
- **Daily parenteral nutrition**: Severe pathology of alimentary tract precluding absorption of sufficient nutrients to maintain weight and strength commensurate with general condition.

**Limitations:**

All other uses of nutritional supplements or aids are not medically necessary, including, but not limited to, the following:

- Standardized or specialized infant formula except as above.
- Food thickeners.
- Dietary and food supplements.
- Lactose-free products or aids to lactose digestion.
- Gluten-free food products.
- Weight loss foods or aids.
- Normal grocery items.
- Low carbohydrate items.
- Baby food.
- Grocery items that can be blenderized and used for enteral feeds.
- Nutritional supplement puddings.
- High protein powders and mixes.
- Oral vitamins and minerals.

**Alternative covered services:**

- Physician assessment and nutritional counseling within the network.

**Background**

Ninawer (2001) reported a consensus that nutritional support should be provided to intensive care unit (ICU) patients, rationalizing that hospitalized patients with malnutrition (macro- and/or micro-nutrient deficiency) are at increased risk for infections, prolonged stays, and death. Even patients with adequate pre-hospital nutritional statuses are subject to stress, infection, and impaired organ function, all of which increase calorie needs during their stays.

Nutritional support interventions include enteral nutrition (“tube feeding”) administered via trans-oral, -nasal, or -gastric routes or by surgical jejunostomy (directly into the small intestine) and parenteral or total...
parenteral nutrition (TPN) used when enteral routes are unavailable or contraindicated. Calorie requirements for critically ill patients are estimated pragmatically as 25 kilocalories per kilogram of ideal body weight, administered in a fluid volume consistent with the patient’s needs and with protein sources comprising 15 to 20 percent of daily calorie requirements; glucose, 30 – 70 percent; and fats, 15 – 30 percent.

**Searches**

Select Health of South Carolina searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on August 12, 2016. The search term was “nutritional support.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines** based on systematic reviews.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

The medical literature contains many meta analyses and systematic reviews on efficacy of nutritional support for various patient populations. This policy reports only a relatively small number of these citations, with a focus on the most current and largest-scale reviews. A summary of research findings are as follows:

- As noted above, nutritional support in critically ill hospitalized patients is based largely on consensus.
- Reviews tabulated below do not substantively alter that picture. Many find insufficient evidence for nutritional intervention benefit in the specific groups of patients considered, or instead find substantial harms.
- More and higher-quality (design and reporting) research is needed.

Studies generally show that nutritional support improves body weight, protein intake, and caloric intake for patients. Improvements such as shorter hospital stays, fewer re-admissions, and cost benefits have frequently been documented. However, mortality typically is not lower for patients receiving nutritional support compared to controls, and there is a lack of strong, consistent evidence for other improvements in outcomes.

**Policy updates:**
September, 2016: We identified four new systematic reviews/meta analyses from 2016 for this policy update. Outcomes for patients given nutritional support vs. controls are addressed in several studies, including mortality, hospital readmissions, a cost-benefit analysis, and a comparison of enteral vs. total parenteral nutrition. The many other meta-analyses not included in this policy often address specific categories of patients that may or may not be generalizable to broader populations.

September, 2015: We identified three new systematic reviews for this policy update. Two addressed the efficacy of nutritional support in critically ill adults (Wan, 2015; Li, 2014), and one in critically ill children (Wong, 2014). The results of both studies of adult populations are consistent with the Academy of Nutrition and Dietetics guidelines (2012). Current evidence is insufficient to support recommendations for nutritional support in critically ill children. The new evidence does not change the findings of the original policy.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
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<tbody>
<tr>
<td>Parikh (2016)</td>
<td>Key points:</td>
</tr>
</tbody>
</table>
| Effect of calorie delivery on hospital mortality among ICU adults with enteral nutrition | - Meta-analysis of 16 studies, n=3473  
- Mortality was 26.0% and 26.5% in low- and high-calorie group |
| Bally (2016)      | Key points:                       |
| Effects of nutritional support on outcomes of medical inpatients with malnutrition | - Meta-analysis of 22 RCTs, n=3736, compared patients with and without nutritional support  
- Mortality not different between intervention and control groups (9.8% vs. 10.3%)  
- Hospital-acquired infections not significantly different (6.0% vs. 7.6%)  
- Non-elective re-admissions reduced for intervention group (20.5% vs. 29.6%)  
- No differences between groups for functional outcomes (Barthel), or hospital LOS |
| Muscaritoli (2016)| Key points:                       |
| Ability of nutritional treatment to predict morbidity, mortality, and hospital stay | - Cochrane systematic review of 15 observational studies  
- In six (6) studies, malnutrition predicted re-admissions  
- In 11 studies, nutritional therapy reduced re-admissions  
  All studies reported economic benefit and cost-effectiveness |
| Zhao (2016)       | Key points:                       |
| Benefits of enteral nutrition vs. total parenteral nutrition in patients with GI cancer who underwent major surgery | - Meta-analysis/systematic review of 18 studies, n=2540  
- 1268 received enteral nutrition (EN), 1272 received total parenteral nutrition (TPN)  
  EN patients had shorter length of hospital stay, shorter time to flatus, significantly greater increases in albumin levels post-operatively |
| Wan (2015)        | Key points:                       |
| Early parenteral nutrition (PN) alone vs. with enteral nutrition (EN) in critically ill patients | - Five randomized controlled trials (RCTs); variable quality.  
- Early PN within 24 – 48 hours did not improve clinical outcomes or mortality rates; some improvement in duration of mechanical ventilation, but increased total length of hospital stay.  
- Early EN did not improve the efficacy of early PN. |
<table>
<thead>
<tr>
<th>Study (Year)</th>
<th>Key points</th>
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|             | Key points: | 2. Early EN, but not total parenteral nutrition (TPN) or delayed EN, is associated with reduced risk of pancreatic infection, mortality, organ failure, hyperglycemia, and catheter-related septic complications.
|             |             | 3. Early EN within 24 hours of admission had significantly better mortality outcomes than early EN between 24 and 72 hours.
|             | Nutritional supplementation in patients with cancer. | 2. Single included review covered 13 RCTs or quasi.
|             | Key points: | 3. Oral supplementation may be effective for preserving body weight and some aspects of quality of life (QoL).
|             |             | 4. Patients should be assessed but nutritional support not warranted as routine for cancer patients in chemotherapy.
| Collins (2014) | Interventions to prevent and treat malnutrition in patients admitted for rehabilitation. | 1. 1,765 screened studies narrowed to 10 (oral nutritional supplements, food service interventions, clinical care processes tested).
|             | Key points: | 2. Compared to meals alone, oral supplements improved protein and energy intake, with some evidence for anthropometric and length of stay improvements.
|             |             | 3. Oral nutrition supplements and energy-dense meals may be effective strategies for malnutrition in rehabilitation.
|             | Key points: | 2. Meta-analysis possible only for two trials (301 subjects).
|             |             | 3. No conclusive benefits for nutritional, clinical, functional, or patient-centered outcomes.
|             | Key points: | 2. Statistical model for pressure ulcers avoided (2,896); bed-days released (€12,397); cost change (€2,869,526 saved).
|             |             | 3. Interventions: nutrition staff, supplements, otherwise not specified.
| Beck (2013)  | Oral nutritional support for medical and surgical patients > 65 after discharge. | 1. RCTs; methods otherwise incompletely reported.
|             | Key points: | 2. Six trials (N = 716).
|             |             | 3. No significant effects on mortality or readmissions.
|             | Key points: | 2. Seventeen studies: behavioral interventions (four); oral supplementation (six); enteral feeding (four); study designs not reported.
|             |             | 3. Enteral feeding associated with weight gain.
<table>
<thead>
<tr>
<th>Source</th>
<th>Key Points</th>
</tr>
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</table>
| Wang (2013)                                                          | **Key points:**  
| Metanx medical food for diabetic neuropathy                          | Nutritional support for patients sustaining traumatic brain injury  
|                                                                     | - RCTs, CCTs, prospective studies: effects, timing or formulas for feeding; – 2012.  
|                                                                     | - Thirteen RCTs; three other designs.  
|                                                                     | - Early feeding (vs. later) reduced mortality and infectious complications.  
|                                                                     | - Parenteral (vs. enteral): non-significant (NS) trends to reduced mortality and better outcome.  
|                                                                     | - Immune enhancing formula (vs. standard): reduced infections.  
|                                                                     | - Small bowel (vs. naso-gastric): decreased risk of pneumonia.  
| Wyers (2013)                                                        | **Key points:**  
| Cost-effectiveness of nutritional intervention in elderly people after hip fracture | - Multi-center RCT (Netherlands): intensive nutritional intervention consisting of dietetic counseling and oral supplementation for three months after hip replacement.  
|                                                                     | - 152 subjects: 73 intervention; 79 control (method of randomization, sample size calculation, blinding not reported, so study fails to meet Cochrane trial criteria).  
|                                                                     | - Mean costs of intervention, €613/patient; no significant differences between groups: cost-effective for weight but not for quality adjusted life years (QALYs).  
| Academy of Nutrition and Dietetics (2012)                           | **Key points:**  
|                                                                     | - If EN is not contraindicated (e.g., by hemodynamic instability, bowel obstruction, high output fistula, or severe ileus) then EN is recommended over PN for the critically ill adult patient.  
|                                                                     | - Research shows less septic morbidity, fewer infectious complications and significant cost savings in critically ill adult patients who received EN vs. PN.  
|                                                                     | - There is limited evidence that EN vs. PN affects hospital length of stay (LOS), but an impact on mortality has not been demonstrated.  
| Antar (2012)                                                        | **Key points:**  
| Nutritional supplementation for hospitalized patients with alcoholic hepatitis | - Seven RCTs (N = 262).  
|                                                                     | - No significant differences for special nutritional therapy vs. ordinary balanced diet for mortality or ascites.  
| Burden (2012) - Cochrane review                                     | **Key points:**  
| Preoperative nutrition for patients undergoing gastrointestinal surgery | - RCTs published through Feb 2012.  
|                                                                     | - Six of seven trials used in meta-analysis.  
|                                                                     | - Significant benefits for pre-op PN: reduced complications; trials of EN or oral inconclusive.  
| Carey (2012)                                                        | **Key points:**  
| Long-term nutritional support in gastrointestinal disease            | - Oral nutrition support > two months for people with gastrointestinal illness; 1980 – 2009.  
|                                                                     | - Six studies: variable, not significant interventions, diagnoses.  
|                                                                     | - Overall support to long-term support in gastrointestinal disease.  
|                                                                     | - As time frame increases, role for individualized advice vs. oral supplementation may also increase.  
| Collins (2012)                                                      | **Key points:**  
| Nutritional support in COPD                                          | - English-language RCTs (dietary advice or enteral) — Jan 2010.  
|                                                                     | - Thirteen RCTs (N = 439).  
|                                                                     | - Increase in total protein and energy intake; body weight and grip strength.  
| Li (2012)                                                           | **Key points**  

Cochrane review
Acute kidney injury
- RCTs through July 2012.
- Insufficient evidence.

Koretz (2012)
Cochrane review
Nutritional support for liver disease
Key points:
- RCTs through Jan 2012.
- Thirty-seven trials, only one of high quality.
- No compelling evidence for routine use of parenteral, enteral, or oral supplementation in patients with liver disease.

Wasiak (2006)
Cochrane review
Burns patients
Key points:
- Insufficient evidence.

Glossary

Efficacy vs. effectiveness — Efficacy is impact on clinical outcomes in a research setting; effectiveness is impact in the less-controlled “real world” setting of widespread clinical use. RCTs demonstrate the former but are designed to optimize internal validity rather than generalizability to other settings.

Enteral nutrition — “Tube feeding” administered via trans-oral, -nasal, or -gastric routes, or by surgical jejunostomy directly into the small intestine.

NPO — (Latin nil per os) Nothing by mouth.

Nutritional supplementation — Nutrition for patients who require supplementation of daily protein and calorie intake; given as medicine between meals.

Parenteral nutrition — Delivery of micro- and macro-nutrients through catheters in central or peripheral veins.

Special medical foods taken orally — Used for treatment of inborn errors of metabolism, including histidinemia, homocystinuria, maple syrup urine disease, phenylketonuria, and tryrosinemia, in which special oral formulae are required to restrict intake of one or more amino acids. This classification does not include oral infant formulae in the absence of conditions listed.

Total parenteral nutrition (TPN) — Feeding a person only intravenously (with liquid formulae containing glucose, amino acids, lipids, vitamins and minerals) with no significant nutrition supplied by mouth or other routes. TPN is used when the gastrointestinal tract is non-functional (blocked or leaking) or its absorption capacity is impaired.

References

Professional society guidelines/other:


Peer-reviewed references:


**Clinical trials:**

Searched ClinicalTrials.gov on August 12, 2016, using terms “nutritional support.” | Open Studies. 147
studies found.

**CMS National Coverage Determinations (NCDs):**


**Local Coverage Determinations (LCDs):**

No LCDs identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comment</th>
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<tbody>
<tr>
<td>43246</td>
<td>EGD, flexible, transoral; with directed placement of percutaneous gastrostomy tube.</td>
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<tr>
<td>43752</td>
<td>Naso- or oro-gastric tube placement (requiring physician skill and fluoroscopic guidance)</td>
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<tr>
<td>43831</td>
<td>Gastrostomy, open; neonatal, for feeding</td>
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<tr>
<td>43832</td>
<td>Gastrostomy, open; with construction of gastric tube (eg, Janeway procedure)</td>
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<tr>
<td>44372</td>
<td>Small intestinal endoscopy, enteroscopy beyond the second portion of the duodenum not including the ileum; with placement of percutaneous jejunostomy tube</td>
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<tr>
<td>49440</td>
<td>Insertion of gastrostomy tube, under fluoroscopic guidance</td>
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<tr>
<td>49441</td>
<td>Insertion of jejunostomy or duodenostomy tube, percutaneous with fluoroscopy</td>
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<tr>
<td>49446</td>
<td>Conversion of gastrostomy tube to gastro-jejunostomy tube, percutaneous, under fluoroscopic guidance including contrast injection(s), image documentation and report</td>
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<tr>
<td>49450</td>
<td>Replacement of gastrostomy or cecostomy (or other colonic) tube, percutaneous, under fluoroscopic guidance including contrast injection(s), image documentation and report</td>
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<tr>
<td>49451</td>
<td>Replacement of duodenostomy or jejunostomy tube, percutaneous, under fluoroscopic guidance including contrast injection(s), image documentation and report</td>
<td></td>
</tr>
<tr>
<td>49452</td>
<td>Replacement of gastro-jejunostomy tube, percutaneous, under fluoroscopic guidance including contrast injection(s), image documentation and report</td>
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<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
<th>Comment</th>
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<tbody>
<tr>
<td>E40</td>
<td>Kwashiorkor</td>
<td></td>
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<tr>
<td>E41</td>
<td>Nutritional marasmus</td>
<td></td>
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<tr>
<td>E42</td>
<td>Marasmic kwashiorkor</td>
<td></td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
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</tr>
<tr>
<td>E43</td>
<td>Unspecified severe protein-calorie malnutrition</td>
<td></td>
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<tr>
<td>E43</td>
<td>Unspecified severe protein-calorie malnutrition</td>
<td></td>
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<tr>
<td>E44.0</td>
<td>Moderate protein-calorie malnutrition</td>
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<tr>
<td>E44.1</td>
<td>Mild protein-calorie malnutrition</td>
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<tr>
<td>E45</td>
<td>Retarded development following protein-calorie malnutrition</td>
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<tr>
<td>E46</td>
<td>Unspecified protein-calorie malnutrition</td>
<td></td>
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<tr>
<td>E46.0</td>
<td>Sequeulae of protein-calorie malnutrition</td>
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<tr>
<td>E70.0</td>
<td>Classical phenylketonuria</td>
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<tr>
<td>E70.1</td>
<td>Other hyperphenylalaninemas</td>
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<tr>
<td>K91.2</td>
<td>Postsurgical malabsorption, not elsewhere classified</td>
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<tr>
<td>Z93.1</td>
<td>Gastrostomy status</td>
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<tr>
<td>Z93.4</td>
<td>Other artificial openings of gastrointestinal tract status</td>
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<thead>
<tr>
<th>HCPCS Level II</th>
<th>Description</th>
<th>Comment</th>
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<tbody>
<tr>
<td>B4087</td>
<td>Gastrostomy/jejunostomy tube, standard, any material, any type, each</td>
<td></td>
</tr>
<tr>
<td>B4088</td>
<td>Gastrostomy/jejunostomy tube, low-profile, any material, any type, each</td>
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<tr>
<td>B4102</td>
<td>Enteral formula, for adults, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit</td>
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<tr>
<td>B4103</td>
<td>Enteral formula, for pediatrics, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit</td>
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<tr>
<td>B4104</td>
<td>Additive for enteral formula (e.g., fiber)</td>
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<tr>
<td>B4149</td>
<td>Enteral formula, manufactured blenderized natural foods with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, many include fiber, administered through an enteral feeding tube, 100 calories = 1 unit</td>
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<tr>
<td>S9364</td>
<td>Home infusion therapy, total parenteral nutrition (TPN); administrative services, professional pharmacy services, care coordination and all supplies including standard TPN formula</td>
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<tr>
<td>S9365</td>
<td>Home infusion therapy, TPN; 1 liter per day</td>
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<tr>
<td>S9366</td>
<td>Home infusion therapy, TPN; more than 1 liter, but no more than 2 liters/day.</td>
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</tr>
<tr>
<td>S9367</td>
<td>Home infusion therapy, TPN; more than 2 liters, but no more than 3 liters/day.</td>
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</tr>
<tr>
<td>S9368</td>
<td>Home Infusion therapy, TPN; more than 3 liters per day</td>
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