Some payers require additional documentation to justify coverage of diabetes formulas because they are produced to meet unique nutrient needs for individual patients. Failure to substantiate the medical necessity of the diabetes formula may result in a claim being denied as not medically necessary. The sample documentation checklist below is provided as an educational tool to help providers capture information specific to the patient’s medical condition.

A trial was conducted on the standard formula _______________ and a change to ________________ specialty formula is required due to:

- During this trial period adjustment to antihyperglycemic medication was needed to manage blood glucose levels.
- During this trial period blood glucose level increased or were more difficult to manage.
- During this trial period, the patient experienced hypoglycemia.
- During this trial period, the patient had increased glycemic variability.

This patient is not appropriate for a trial and requires a specialty formula because ________________

Physician Signature_____________________________________________

Consider the following values:

<table>
<thead>
<tr>
<th>Blood glucose levels</th>
<th>Baseline</th>
<th>Day 3</th>
<th>Day 7</th>
<th>Day 10</th>
<th>Day 14</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average 24 hr glucose</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glycemic variability</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A1C</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Diabetes specific formulas are formulated to help manage glucose levels and have clinically established superiority to standard formulas in managing glucose response. A meta-analysis showed that diabetes specific formulas significantly lower postprandial rise in blood glucose, peak blood glucose concentrations, and glucose AUC in patients with diabetes as compared to standard formulas.1

Glucerna products are diabetes specific formulas with low glycemic index (compared to standard formulas) and slowly digesting carbohydrates and are based on a foundation of over 19 clinical studies showing efficacy over standard nutrition products in people with diabetes, including studies in long term care patients with type 2 diabetes.

Use products under medical supervision.

In addition to showing significant improvement in post prandial glucose response, diabetes specific formulas (Glucerna) has been shown to significantly increases plasma GLP-1 level in adults with type 2 diabetes compared to a standard product.2 (Glucagon-like peptide-1 (GLP-1) stimulates insulin secretion by the pancreatic b-cells and has been the target of pharmaceuticals currently used in the treatment of patients with type 2 DM. A study of long term care patients showed that Glucerna reduced mean blood glucose, glycemic variability and amount of short-acting insulin as compared to a standard formula.3 Mori et al reported similar result, that consuming Glucerna reduced glycemic variability and hyperglycemia as compared to a standard formula.4 Glycemic variability or acute fluctuations in blood glucose levels, has been reported as an important marker of glycemic control.


Note: Each health care provider is ultimately responsible for verifying codes, coverage and payment policies used to ensure that they are accurate for the services and items provided. Abbott Nutrition does not guarantee reimbursement by any third-party payer and will not reimburse physicians or providers for claims denied by third-party payers. This checklist does not take the place of documentation which may be required to support a claim submission. Providers should consult with the payer for complete and accurate details concerning documentation for claims.

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