2.01.43 Chronic Intermittent Intravenous Insulin Therapy

Summary

Chronic intermittent intravenous insulin therapy (CIIIT) is a technique for delivering variable-dosage insulin to diabetic patients with the goal of improved long-term glycemic control. Through an unknown mechanism, it is postulated to induce insulin-dependent hepatic enzymes to suppress glucose production.

FDA REGULATORY STATUS

Any insulin infusion pump can be used for the purposes of chronic intermittent intravenous insulin therapy. Infusion pumps have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. FDA determined that this device was substantially equivalent to existing devices for the delivery of intravenous medications. FDA product code: IzG.

POLICY STATEMENT

Chronic intermittent intravenous insulin therapy is considered not medically necessary.

POLICY GUIDELINES (IF NEEDED)

This policy does not apply to use of intravenous insulin infusions in the inpatient setting (ie, for the treatment of diabetic ketoacidosis or diabetic hyperosmolar coma).

BENEFIT APPLICATION

Insulin pumps are covered under the DME benefit.

RATIONALE

Summary of Evidence

The evidence for use of chronic intermittent intravenous insulin therapy (CIIIT) in individuals who have type 1 diabetes includes 2 randomized controlled trials (RCTs) and uncontrolled studies. Relevant outcomes are symptoms and change in disease status. A limited number of uncontrolled studies suggest that CIIIT may improve glycemic control. The 2 RCTs report that CIIIT may moderate the progression of nephropathy and/or retinopathy. However, the published studies are small and report benefits on intermediate outcomes only (ie, changes in laboratory values). The clinical significance of the differences reported in the studies is uncertain. Additionally, most published evidence appeared between 1993 and 2000 and as a result, does not account for more recent improvements in diabetes care. The evidence is insufficient to determine the effects of the technology on health outcomes.
2.01.43 Chronic Intermittent Intravenous Insulin Therapy

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Clinical practice guidelines from professional associations, including the American Diabetes Association and the American Association of Clinical Endocrinologists, do not include CIIT within each organization’s clinical practice guidelines for diabetes.6-8 The American College of Physicians published a clinical practice guideline in 2011 on use of intensive insulin therapy for the management of glycemic control in hospitalized patients9; the recommendations put forth in this guideline were based on earlier systematic review on this topic, which did not include CIIT.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

In 2009, the Centers for Medicare and Medicaid Services issued a decision memo on use of outpatient intravenous insulin therapy, which stated: “Effective for claims with dates of service on and after December 23, 2009, the Centers for Medicare and Medicaid Services (CMS) determines that the evidence is adequate to conclude that outpatient intravenous insulin therapy (OIVIT, ie, CIIT) does not improve health outcomes in Medicare beneficiaries. Therefore, CMS determines that OIVIT is not reasonable and necessary for any indication under section 1862(a)(1)(A) of the Social Security Act. Services comprising an Outpatient Intravenous Insulin Therapy regimen are nationally non covered under Medicare when furnished pursuant to an OIVIT regimen.”

REFERENCES

2.01.43 Chronic Intermittent Intravenous Insulin Therapy

## POLICY HISTORY

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2011</td>
<td>New Policy</td>
<td>Policy Statement changed to not medically necessary.</td>
</tr>
<tr>
<td>December 2013</td>
<td>Update Policy</td>
<td>Policy update</td>
</tr>
<tr>
<td>September 2014</td>
<td>Update Policy</td>
<td>Policy update</td>
</tr>
<tr>
<td>September 2015</td>
<td>Update Policy</td>
<td>Policy update</td>
</tr>
<tr>
<td>September 2016</td>
<td>Update Policy</td>
<td>Policy update Policy statement unchanged</td>
</tr>
</tbody>
</table>

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 16, 2016 and is effective October 15, 2016.

Signature on File

Deborah M. Smith, MD, MPH