Clinical Review Criteria
Islet Cell Transplantation for Type I Diabetes

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Criteria
For Medicare Members

<table>
<thead>
<tr>
<th>Source</th>
<th>Policy</th>
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<tbody>
<tr>
<td>CMS Coverage Manuals</td>
<td>None</td>
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<tr>
<td>National Coverage Determinations (NCD)</td>
<td>Islet Cell Transplantation in the Context of a Clinical Trial (260.3.1)</td>
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<tr>
<td>Local Coverage Determinations (LCD)</td>
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For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Some patients with Type I diabetes fail to obtain adequate glucose control despite insulin treatment. Pancreas allo-transplantation can restore metabolic control, but this procedure is limited by a shortage of donor organs and a complex surgical procedure with associated morbidity and mortality. Transplantation of pancreatic islet cells is a possible alternative treatment. The islet of Langerhans cells contains insulin-secreting β cells and make up only about 1% of the whole pancreas.

In the early 1970s, researchers found that islet cell transplantation could be used to treat diabetes in rats. Since that time, there have been attempts to apply this treatment to humans. Most of the applications of this procedure were unsuccessful; the Islet Transplant Registry estimated in 1996 that only 6 percent of islet transplantations done between 1990-1996 were successful (success defined as not needing insulin treatment for a year after transplantation).

Medical Technology Assessment Committee (MTAC)

Islet Cell Transplantation
10/11/2001: MTAC REVIEW

Evidence Conclusion: To date, there has been one report of some success with islet cell transplantation in 7 patients; only 3 of these were followed-up for at least a year. The effectiveness of islet cell transplantation for type 1 diabetes cannot be determined based on the current published scientific evidence. A randomized controlled trial, which will provide higher-quality data, was recently initiated by the Juvenile Diabetes Foundation and the National Institutes of Health to study the effectiveness of islet cell transplantation.

Articles: The searches yielded 60 articles. These were predominantly review articles and articles on technical aspects of the procedure. There were no randomized controlled trials or meta-analyses. There were 3 empirical articles with clinical outcomes; all were case series studies with sample sizes less than n=10. An evidence table was done for the case series that used the most up-to-date techniques: Shapiro AMJ, Lakey JRT, Ryan EA, Korbutt GS, Toth E, Warnock GL, Kneteman NM, Rajotte RV. Islet cell transplantation in seven patients with type 1 diabetes mellitus using a glucocorticoid-free immunosuppressive regimen. NEJM 2000; 343: 230-8. See Evidence Table.
The use of Islet Cell Transplantation in the treatment of diabetes does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

<table>
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<tr>
<th>Creation Date</th>
<th>Review Date</th>
<th>Date Last Revised</th>
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<td>11/17/2000</td>
<td>05/03/2011 MDCRPC, 08/02/2011 MDCRPC, 06/05/2012 MDCRPC, 04/02/2013 MDCRPC, 02/04/2014 MPC, 12/02/2014 MPC, 10/06/2015 MPC, 08/02/2016 MPC, 06/06/2017 MPC, 04/03/2018 MPC, 03/05/2019 MPC, 03/03/2020 MPC</td>
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MDCRPC: Medical Director Clinical Review and Policy Committee
MPC: Medical Policy Committee

**Codes**

CPT: G0341, G0342, G0343, S2102