



Clinical Review Criteria Islet Cell Transplantation for Type I Diabetes

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Islet Cell Transplantation in the Context of a Clinical Trial (260.3.1)
Local Coverage Determinations (LCD)	None

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.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information 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 *b* 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, Korbitt 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*.

Applicable Codes

Considered not medically necessary

CPT® Codes	Description
0584T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; percutaneous
0585T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; laparoscopic
0586T	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; open
HCPC Codes	Description
S2102	Islet cell tissue transplant from pancreas; allogeneic *S codes not covered by Medicare

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met

Non-Medicare - Considered not medically necessary

HCPC Codes	Description
G0341	Percutaneous islet cell transplant, includes portal vein catheterization and infusion
G0342	Laparoscopy for islet cell transplant, includes portal vein catheterization and infusion
G0343	Laparotomy for islet cell transplant, includes portal vein catheterization and infusion

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the [Pre-authorization Code Check](#).

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Creation Date	Review Date	Date Last Revised
11/17/2000	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} , 03/02/2021 ^{MPC} , 03/01/2022 ^{MPC} , 03/07/2023 ^{MPC}	06/23/2020

^{MDCRPC} Medical Director Clinical Review and Policy Committee

^{MPC} Medical Policy Committee

Revision History	Description
06/23/2020	Added CPT codes 0584T, 0585T and 0586T