

Islet Cell Transplantation

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.

The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual, but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

DESCRIPTION

Autologous islet transplantation is commonly conducted during pancreatectomy among patients with chronic pancreatitis. The procedure consists of isolating islet cells from the patient's resected pancreas using enzymes and injecting a suspension of the cells back into the portal vein of the patient's liver, where the cells function as a free graft.

For patients with type 1 diabetes, allogeneic islet cell transplantation may be performed as a stand-alone procedure. Islet cells that have been harvested from a deceased donor's pancreas are processed and injected into the recipient's portal vein.

It is proposed that the beta cells in the transplanted islets will begin to make and release insulin. Therefore, one of the desired patient outcomes is insulin independence.

MEDICARE ADVANTAGE POLICY CRITERIA

CMS Coverage Manuals*

None ^[1,2]

See the “Required Documentation” section below

National Coverage

Determinations (NCDs)*

Islet Cell Transplantation in the Context of a Clinical Trial
([260.3.1](#)) (See References^[1])

For more information regarding this service and Medicare Advantage beneficiaries, see *Medicare Claims Processing Manual, Chapter 32 - Billing Requirements for Special Services, §70.5 - Special Billing and Payment Requirements Medicare Advantage (MA) Beneficiaries.*^[3]

POLICY GUIDELINES

REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

- Medicare Explanation of Benefits (MEOB).^[3] CMS has issued statement that Medicare or the Medicare contractor will make payment on behalf of Medicare Advantage Organizations (MAOs) for MA enrollees for these services. MAOs may process claims as secondary.

CROSS REFERENCES

[Pancreas Transplants](#), Transplants, Policy No. M-06

REFERENCES

1. NCD for Pancreas Transplants (260.3) (*This reference can be found on the [Medicare Coverage Database](#) website*)
2. Medicare Claims Processing Manual, Chapter 32 - – Billing Requirements for Special Services, [§70.1 - Healthcare Common Procedure Coding System \(HCPCS\) Codes for Carriers](#)
3. Medicare Claims Processing Manual, Chapter 32 - Billing Requirements for Special Services, [§70.5 - Special Billing and Payment Requirements Medicare Advantage \(MA\) Beneficiaries](#)

CODING

NOTE: CPT code 48160 is a Medicare Status N code, and therefore, is non-covered by Medicare and Medicare Advantage.^[2] In addition, HCPCS S-codes are also not recognized for payment for Medicare or Medicare Advantage members.

Codes	Number	Description
CPT	48160	Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islets <i>(Not recognized by Medicare for payment)</i>
	48999	Unlisted procedure, pancreas
	0584T	Percutaneous islet cell transplant, includes portal vein catheterization and infusion
	0585T	Laparoscopy for islet cell transplant, includes portal vein catheterization and infusion
	0586T	Laparoscopy for islet cell transplant, open approach
HCPCS	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
	S2102	Islet cell tissue transplant from pancreas; allogeneic <i>(Not recognized by Medicare for payment)</i>

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.