Medlearn Matters
Information for Medicare Providers

Related Change Request (CR) #: 3385
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Implementation Date: October 4, 2004

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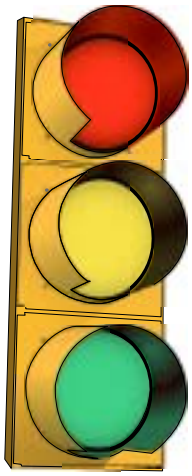
MMA-Billing Requirements for Islet Cell Transplantation for Beneficiaries in a National Institutes of Health (NIH) Clinical Trial

Provider Types Affected

All providers involved in an NIH sponsored clinical trial

Provider Action Needed



STOP – Impact to You

In the specific context of an NIH sponsored clinical trial:
For services performed on or after October 1, 2004, Medicare will cover islet cell transplantation for trial participants (patients) with Type I diabetes. The islet cell transplant may be done alone or in combination with a kidney transplant. Immunosuppressive therapy to prevent rejection of the transplanted islet cells and routine follow-up care will be necessary for each trial participant.

CAUTION – What You Need to Know

Partial pancreatic tissue transplantation or islet cell transplantation performed outside the context of a clinical trial continues to be non-covered.

GO – What You Need to Do

Please stay current on instructions pertaining to NIH sponsored clinical trials to ensure accurate claims processing.

Background

As a result of Section 733 of the Medicare Modernization Act (MMA), for services performed/discharged on or after October 1, 2004, Medicare will cover islet cell transplantation for patients with Type I diabetes who are participating in an NIH sponsored clinical trial.

For dates of service on and after October 1, 2004, for such beneficiaries, Medicare carriers will accept claims for islet cell transplantation with a type of service code of 2 and a HCPCS of G0341 (Percutaneous

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islet cell trans), G0342 (Laparoscopy islet cell trans), or G0343 (Laparotomy islet cell transp). Physicians should also use the QV modifier for islet cell transplantation and routine follow-up care related to this NIH trial.

Where beneficiaries are enrolled in a Medicare Advantage (MA) plan, Medicare carriers or intermediaries should make payment directly to providers of these islet cell transplants in accordance with Medicare payment rules, except that MA beneficiaries receiving the services are not responsible for the Part A and Part B deductibles. Such beneficiaries will be liable, however, for any applicable coinsurance amounts that the MA organization has in place for clinical trial benefits.

Providers billing Medicare intermediaries for these services should do so on an 11x type of bill. Such claims will be paid by the intermediary only for IPPS hospitals participating in the trial, and claims for beneficiaries in MA plans should also include condition code 30 so the deductible will not be applied.

For fee-for-service beneficiaries, deductibles and coinsurance will apply.

Additional Information

The official instruction issued to the intermediary regarding this change can be found online, referenced via CR 3385, at:

http://www.cms.hhs.gov/manuals/pm_trans/R261Cp.pdf

If you have questions regarding this issue, you may also contact your carrier or fiscal intermediary at their toll-free number, which may be found at:

http://www.cms.hhs.gov/medlearn/tollnums.asp

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