



Related MLN Matters Article #: MM3385

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

#### Key Words

MM3385, CR3385, R261CP, MMA, Prospective, Payment, Coverage, Islet, Cell, G0342, Laparoscopy, G0343, Laparotomy, QV, IPPS

#### Provider Types Affected

All providers involved in an NIH-sponsored clinical trial

#### Key Points

- The effective date of the instruction is October 1, 2004.
- The implementation date is October 4, 2004.
- Section 733 of the Medicare Modernization Act (MMA), indicates that 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 a NIH-sponsored clinical trial.
- Immunosuppressive therapy to prevent rejection of the transplanted islet cells and routine follow-up care will be necessary for each trial participant.
- The islet cell transplant may be done alone or in combination with a kidney transplant.
- Medicare carriers will accept claims for islet cell transplantation with a type of service code of 2 and a Healthcare Common Procedure Coding System code of G0341 (Percutaneous islet cell trans), G0342 (Laparoscopy islet cell trans), or G0343 (Laparotomy islet cell transp) for dates of service on and after October 1, 2004, for such beneficiaries.
- Physicians should also use the QV modifier for islet cell transplantation and routine follow-up care related to this NIH trial.

**Note:** Effective for services on or after May 1, 2006, the QR modifier (item or service provided in a Medicare-specified study) replaced the QV modifier for islet cell transplantation and routine follow-up services related to the islet cell transplantation done in conjunction with an NIH-sponsored clinical trial. This change was implemented by Change Request (CR) 5140

(<http://www.cms.hhs.gov/Transmittals/downloads/R986CP.pdf>). The related MLN Matters article may be found at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5140.pdf> on the CMS website.

- 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.
- MA beneficiaries will be liable 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 Inpatient Prospective Payment System hospitals participating in the trial. Claims for beneficiaries in MA plans should also include condition code 30 so the deductible will not be applied.
- Deductibles and coinsurance will apply for fee-for-service beneficiaries.

### Important Links

The related MLN Matters article can be found at

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM3385.pdf> on the CMS website.

The official instruction (CR3385) regarding this change may be viewed at

<http://www.cms.gov/Transmittals/downloads/R261CP.pdf> on the CMS website.

If providers have any questions, they may contact their carrier/fiscal intermediary at their toll-free number, which may be found at

<http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.