

**References: L33824, A52474**

## All Immunosuppressive Drugs

- Dispensing Order, if applicable
- Detailed Written Order (DWO)
- Beneficiary Authorization
- Refill Requirements
- Proof of Delivery (POD)
  - Method 1 - Direct Delivery to the Beneficiary by the Supplier  
**The date the beneficiary/designee signs for the supplies is to be the date of service of the claim.**
  - Method 2 - Delivery via Shipping or Delivery Service  
**The shipping date is to be the date of service of the claim.**
  - Method 3 - Delivery to Nursing Facility on Behalf of a Beneficiary
- Continued Need

Ongoing immunosuppressive medication need is assumed to be established by the performance of the transplant and the successful maintenance of its function. There is no requirement for further documentation of continued need for the life of the transplant.
- Continued Use

Continued use of immunosuppressive medication is demonstrated by meeting the Refill Documentation requirements.

## Medical Records

- Medical records support the following criteria are met:
  - Drug(s) is prescribed following a transplant (Refer to PA for ICD codes):
    - Kidney, heart, liver, bone marrow/stem cell, lung, heart/lung transplant; **or**
    - Whole organ pancreas transplant performed concurrent with or subsequent to a kidney transplant because of diabetic nephropathy (performed on or after 07/01/99); **or**
    - Intestinal transplant (performed on or after 04/01/01); **or**
    - Pancreatic islet cell transplant or partial pancreatic tissue transplantation (performed on or after 10/01/04), that is conducted as part of a National Institutes of Health-sponsored clinical trial; **or**
    - Pancreas transplants alone (performed on or after 04/26/06) that meet the 6 criteria listed in the PA; **and**

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- Transplant met Medicare coverage criteria in effect at the time; **and**
- Patient was enrolled in Medicare Part A at the time of the transplant; **and**
- Is enrolled in Medicare Part B at the time that the drug is dispensed; **and**
- Drug(s) is furnished on or after the date of discharge from the hospital following a covered organ transplant.

### **Azathioprine (J7501) or Methylprednisolone (J2920, J2930)**

- Medication cannot be tolerated or absorbed if taken orally; **and**
- Medication is self-administered by the patient.

### **Billing Reminders**

- ICD code(s) that justifies the need for the drug(s) must be included on the claim. See Immunosuppressive Drugs Policy Article for covered transplant ICD codes.
- KX modifier must be added to the claim line(s) for the immunosuppressive drug(s) **only** if:
  - Supplier obtains from the ordering physician the date of the organ transplant; **and**
  - Supplier is retaining this documentation of the transplant in its files; **and**
  - Beneficiary was enrolled in Part A at the time of the organ transplant (whether or not Medicare paid for the transplant); **and**
  - Transplant date precedes the date of service on the claim.
- GY modifier must be added to the claim line(s) for the immunosuppressive drug(s) if any of the coverage criteria noted in the Medical Records section above have not been met.
- If code J7599 is billed, the claim must list the name of the drug, the dosage strength, number dispensed and administration instructions.
- Quantity of immunosuppressive drugs dispensed is limited to a 30-day supply.
- Immunosuppressive drug coverage is limited to 36 months for beneficiaries whose Medicare entitlement is based solely on end-stage renal disease (ESRD).
- Supply fees
  - One unit of supply code Q0511 is covered for the first covered immunosuppressive drug that is dispensed in a 30-day period.
  - If covered drugs are dispensed by more than one pharmacy during a 30 day period, one unit of Q0511 is covered for each pharmacy.
  - One unit of supply fee code Q0512 is covered for each subsequent covered immunosuppressive drug that is dispensed in that 30-day period.
  - If two dosage strengths of the same drug are dispensed on the same day, one unit of service of the appropriate supply fee is payable for each one.
  - More than one unit of service of code Q0511 billed per 30 days by a single pharmacy will be denied as incorrect coding.
  - One unit of supply code Q0510 is payable in place of Q0511 or Q0512 for one drug on the **first claim** for immunosuppressive drugs following a transplant.
  - Q0510 is payable to only one supplier after each transplant.
  - Supply fee code(s) must be billed on the same claim as the drug(s). If it is not, the supply fee will be denied as incorrect billing.

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[Go Back to Front Page](#)