Required Documentation in Supplier’s File

Claims for All Immunosuppressive Drugs

- Documentation of a Dispensing Order (preliminary written or verbal order) that contains:
  - Description of the item
  - Name of the beneficiary
  - Name of the physician
  - Date of the order
  - Physician signature (for written order) or supplier signature (for verbal order)

**NOTE:** A dispensing order is only required if the items are dispensed prior to obtaining the detailed written order.

- Detailed Written Order (original, faxed, or copied) that contains:
  - Beneficiary’s name
  - Physician’s name
  - Physician’s signature (handwritten or electronic – no stamps)
  - Physician’s signature date (must be entered by physician)
  - Date of the order
  - List of every separately billable item
  - Dosage or concentration
  - Route of administration
  - Frequency of use
  - Quantity to be dispensed
  - Number of refills

- Physician’s signature on the written order meets **CMS Signature Requirements**

Written Order Reminders

- Suppliers should not submit claims to the DME MAC prior to obtaining a detailed written order.
- Items billed to the DME MAC before a signed and dated detailed written order has been received must be submitted with modifier EY.
- A new order is required if a new drug(s) is added to the beneficiary’s immunosuppressive regimen or if there is a change in dose or frequency of administration of an already allowed drug.
- **Suppliers cannot combine instructions from multiple physician orders and bill a total number of units equal to what is prescribed on these orders. Each order must stand alone in providing detailed instructions on the total dosage that is being prescribed.**
## Immunosuppressive Drugs

### REFILL REQUEST

**Items Were Obtained In Person at a Retail Store**

- Signed Delivery Slip
  - Beneficiary’s name
  - Date
  - List of items purchased
  - Quantity received
  - Signature of person receiving the items

**Written Refill Request Received from the Beneficiary**

- Name of beneficiary or authorized rep (indicate relationship)
- Statement that the beneficiary is requesting a refill
- Description of each item being requested
- Signature of requestor
- Date of request
- Quantity of each item beneficiary still has remaining
- Request was not received any sooner than 14 calendar days prior to the delivery/shipping date
- Shipment/delivery occurred no sooner than 10 calendar days prior to the end of usage for the current product

**Telephone Conversation Between Supplier and Beneficiary**

- Beneficiary’s name
- Name of person contacted (if someone other than the beneficiary include this person’s relationship to the beneficiary)
- Description of each item being requested
- Date of contact
- Quantity of each item beneficiary still has remaining
- Contact was not made any sooner than 14 calendar days prior to the delivery/shipping date
- Shipment/delivery occurred no sooner than 10 calendar days prior to the end of usage for the current product

*Reminder: Make sure the delivery information clearly shows that the items were purchased at the retail pharmacy and the pharmacy did NOT deliver the items to the beneficiary’s home.*

### DELIVERY DOCUMENTATION

#### Direct Delivery

- Beneficiary’s name
- Delivery address
- Quantity delivered
- Detailed description of item(s)
- Brand
- Serial number
- Signature of person accepting delivery
- Relationship to beneficiary
- Deliver date

#### Shipped/Mail Order Tracking Slip

- A common reference number (package ID #, PO #, etc.) links the invoice and tracking slip (may be handwritten on one or both forms by supplier)

#### Shipped/Mail Order Return Post-Paid Delivery Invoice

- A common reference number (package ID #, PO #, etc.) links the invoice and tracking slip (may be handwritten on one or both forms by supplier)

- Quantity shipped
  - Brand
  - Serial number

- Date shipped
  - Date delivered

- Shipping invoice

- Beneficiary’s name
- Delivery address
- Detailed description of item(s) shipped

- Tracking slip
  - References each individual package
  - Delivery address
  - Package I.D. number

- Date shipped
- Date delivered

- Signature of person accepting delivery
- Relationship to beneficiary
- Delivery date

### All of the Following Criteria Are Met:

- The beneficiary was enrolled in Medicare Part A at the time of the transplant.
- The beneficiary was enrolled in Medicare Part B at the time the drugs are dispensed.
- The drugs were furnished on or after the date of discharge from the hospital following a covered organ transplant.
- The transplant was performed at a Medicare-approved facility.
- The dosage, frequency and route of administration conform to generally accepted medical practice and is medically necessary to prevent or treat the rejection of an organ transplant.
- If the prescribed drug is parenteral azathioprine (J7501) or methylprednisolone (J2920, J2930), medical records confirm that the medication cannot be tolerated or absorbed if taken orally and is being self-administered by the beneficiary.

### Medical Records Document One of the Following Transplants

- Kidney – Limited to 36 months for beneficiaries whose Medicare entitlement is based solely on end-stage renal disease (ESRD)
- Heart
- Liver
- Bone Marrow
**Immunosuppressive Drugs**

- Stem Cell
- Lung
- Heart/Lung
- Whole Organ Pancreas
  - Performed concurrent with or subsequent to a kidney transplant because of diabetic nephropathy
  - Performed on or after July 1, 1999
- Intestinal
  - Performed on or after April 1, 2001
- Pancreatic Islet Cell or Partial Pancreatic Tissue
  - Performed on or after October 1, 2004
  - Conducted as part of a NIH clinical trial
- Pancreas
  - Performed on or after April 26, 2006
  - Performed in a facility that is Medicare-approved for kidney transplantation
  - Beneficiary has diagnosis of type 1 diabetes; and
    - Beta cell autoantibody positive; or
    - Demonstrates insulinopenia
  - History of labile insulin-dependent DM with life-threatening metabolic complications; and
  - Was under the care of an endocrinologist and receiving optimal/intensive management for at least 12 months prior to the transplant; and
  - Demonstrates emotional and mental understanding of surgical risks and is able to effectively manage lifelong need for immunosuppression; and
  - Is otherwise a suitable candidate for transplantation.
- The medical records verify that the immunosuppressive drug is part of the plan of care.

**Reminders**

- Immunosuppressive drugs are covered only for the specific labeled indications and approval for marketing by the FDA.
- The quantity of immunosuppressive drugs dispensed is limited to a 30-day supply. Quantities of immunosuppressive drugs dispensed in excess of a 30-day supply will be denied as not medically necessary.
- The KX modifier must be added to the claim line(s) for the immunosuppressive drug(s) only if all of the following four requirements are met:
  - The supplier has obtained from the ordering physician the specific date of the organ transplant, and
  - The supplier is retaining this documentation of the transplant in its files, and
  - The beneficiary was enrolled in Medicare Part A, at the time of the organ transplant (whether or not Medicare paid for the transplant), and
  - The transplant date precedes the date of service on the claim.
- If all coverage criteria are not met, the GY modifier must be added to the claim line(s).
- The diagnosis code(s) that justify the need for these items must be included on the claim.
- Code J7599 should be used for immunosuppressive drugs that do not have a specific J or K code. If code J7599 is billed, the claim must list the name of the drug, the dosage strength, number dispensed and administration instructions.
Immunosuppressive drugs are noncovered when used for the treatment of beneficiaries with non-transplant related diagnoses (e.g., rheumatoid arthritis, connective tissue diseases, vasculitis).

There is no coverage under the immunosuppressive drug benefit for supplies used in conjunction with the administration of parenteral immunosuppressive drugs.

One unit of service of supply fee code Q0511 is covered for the first covered immunosuppressive drug that is dispensed in a 30-day period. One unit of service of supply fee code Q0512 is covered for each subsequent covered immunosuppressive drug that is dispensed in that 30-day period. One unit of service for code Q0510 is payable in place of Q0511 or Q0512 for one drug on the first claim for immunosuppressive drugs following a transplant. See the Policy Article for detailed information regarding correct billing of supply fees.

For all immunosuppressive drugs, the number of units billed must accurately reflect the definition of one unit of service in each code narrative. For example, if fifty 10 mg prednisone tablets are dispensed, bill J7506, 100 units (1 unit of J7506 = 5 mg). If fifty 2.5 mg prednisone tablets are dispensed, bill J7506, 25 units.

Additional Information References on the Web

- Immunosuppressive Drugs LCD: [http://www.cms.gov/medicare-coverage-database/indexes/lcd-list.aspx?Cntnctr=140&ContrVer=2&CntrctrSelected=140*2&name=CGS+Administrators%2c+LLC+(18003%2c+DME+MAC)&LCntrctr=140*2&DocType=Active&bc=AgACAAAAAAA3d%3d%3d%3d#ResultsAnchor](http://www.cms.gov/medicare-coverage-database/indexes/lcd-list.aspx?Cntnctr=140&ContrVer=2&CntrctrSelected=140*2&name=CGS+Administrators%2c+LLC+(18003%2c+DME+MAC)&LCntrctr=140*2&DocType=Active&bc=AgACAAAAAAA3d%3d%3d%3d#ResultsAnchor)
- Immunosuppressive Drugs Policy Article: [http://www.cms.gov/medicare-coverage-database/indexes/article-list.aspx?Cntnctr=140&ContrVer=2&CntrctrSelected=140*2&name=CGS+Administrators%2c+LLC+(18003%2c+DME+MAC)&LCntrctr=140*2&bc=AgABAAAAAAA3d%3d#ResultsAnchor](http://www.cms.gov/medicare-coverage-database/indexes/article-list.aspx?Cntnctr=140&ContrVer=2&CntrctrSelected=140*2&name=CGS+Administrators%2c+LLC+(18003%2c+DME+MAC)&LCntrctr=140*2&bc=AgABAAAAAAA3d%3d#ResultsAnchor)

**NOTE**

It is expected that the beneficiary’s medical records will reflect the need for the care provided. These records are not routinely submitted to the DME MAC, but must be available upon request. Therefore, while it is not a requirement, it is a recommendation that suppliers obtain and review the appropriate medical records and maintain a copy in the beneficiary’s file.

**DISCLAIMER**

This document was prepared as an educational tool and is not intended to grant rights or impose obligations. This checklist may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either written law or regulations. Suppliers are encouraged to consult the DME MAC Jurisdiction C Supplier Manual and the Local Coverage Determination/Policy Article for full and accurate details concerning policies and regulations.