DOCUMENTATION CHECKLIST

JURISDICTIONS B & C

IMMUNOSUPPRESSIVE DRUGS

REQUIRED DOCUMENTATION

☐ **Standard Written Order (SWO)**
The SWO contains all of the following elements:

- ○ Beneficiary's name or Medicare Beneficiary Identifier (MBI)
- ○ Order Date
- ○ General description of the item
  - ☐ The description can be either a general description (e.g., wheelchair or hospital bed), a HCPCS code, a HCPCS code narrative, or a brand name/model number
  - ☐ For equipment - In addition to the description of the base item, the SWO may include all concurrently ordered options, accessories or additional features that are separately billed or require an upgraded code (List each separately).
  - ☐ For supplies – In addition to the description of the base item, the DMEPOS order/ prescription may include all concurrently ordered supplies that are separately billed (List each separately)
- ○ Quantity to be dispensed, if applicable
- ○ Treating Practitioner Name or NPI
- ○ Treating Practitioner's signature
- ○ The practitioner's signature on the standard written order meets **CMS Signature Requirements:** https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6698.pdf
- ○ Any changes or corrections have been initialed/signed and dated by the ordering practitioner.

☐ Additional documentation, that may support the medical necessity of the item billed include:

- ○ Dosage or concentration;
- ○ Frequency of use;
- ○ Number of refills.

WRITTEN ORDER REMINDERS

- Suppliers should not submit claims to the DME MAC prior to obtaining a standard written order.
- Items billed to the DME MAC before a completed standard 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 treating practitioner 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.**

☐ **Refill Request**

For dates of service prior to January 1, 2024

Items Were Obtained In Person at a Retail Store	Written Refill Request Received from the Beneficiary	Telephone Conversation Between Supplier and Beneficiary
☐ Signed Delivery Slip ○ Beneficiary's name ○ Date ○ List of items purchased ○ Quantity received ○ Signature of person receiving the items **OR** ☐ Itemized Sales Receipt ○ Beneficiary's name ○ Date ○ Detailed list of items purchased ○ Quantity received	☐ Name of beneficiary or authorized rep (indicate relationship) ☐ Description of each item being requested ☐ 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	☐ 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

For dates of service on and after January 1, 2024

Items Were Obtained In Person at a Retail Store	Delivered Refill Communications
☐ Signed delivery slip or copy of itemized sales receipt ☐ Delivery slip/receipt should indicate items were picked up at store front	☐ Beneficiary name and/or authorized representative (Suggested: if someone other than the beneficiary include this person's relationship to the beneficiary) ☐ Date of Request ☐ Description of each item requested ☐ Documentation of affirmative response indicating a need for the refill ☐ Contact must occur no sooner than 30 calendar days prior to the expected end of the current supply ☐ Shipment/delivery occur no sooner than 10 calendar days prior to expected end of current supply

☐ **Delivery Documentation**

Direct Delivery	Shipped/Mail Order Tracking Slip	Shipped/Mail Order Return Post-Paid Delivery Invoice
☐ Beneficiary's name ☐ Delivery address ☐ Quantity delivered ☐ A description of the item(s) being delivered. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number. ☐ Delivery date ☐ Signature of person accepting delivery ☐ Relationship to beneficiary	☐ Shipping invoice ○ Beneficiary's name ○ Delivery address ○ A description of the item(s) being delivered. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number. ○ Quantity shipped ☐ Tracking slip ○ References each individual package ○ Delivery address ○ Package I.D. #number ○ Date shipped ○ Date delivered ☐ A common reference number (package ID #, PO #, etc.) links the invoice and tracking slip (may be handwritten on one or both forms by the supplier)	☐ Shipping invoice ○ Beneficiary's name ○ Delivery address ○ A description of the item(s) being delivered. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number. ○ Quantity shipped ○ Date shipped ○ Signature of person accepting delivery ○ Relationship to beneficiary ○ Delivery date

NOTE: If a supplier utilizes a shipping service or mail order, suppliers have two options for the DOS to use on the claim:

1. Suppliers may use the shipping date as the DOS. The shipping date is defined as the date the delivery/shipping service label is created or the date the item is retrieved by the shipping service for delivery. However, such dates should not demonstrate significant variation.
2. Suppliers may use the date of delivery as the DOS on the claim.

☐ **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.

  Note: For DOS on or after April 3, 2019 mail-order deliveries of immunosuppressive drugs may be mailed one or two days prior to a beneficiary's anticipated date of discharge from an inpatient facility to a qualified place of service or alternate address, such as the inpatient hospital that performed the transplant or alternative location where the beneficiary is temporarily staying (such as temporary housing). The DOS on the claim must be the date of discharge.
- ○ 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
- ○ 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-sponsored 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 and intensive management for at least 12 months prior to the transplant, having received the most medically-recognized advanced insulin formulations and delivery systems; 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 treating practitioner's signature on the medical records meets **CMS Signature Requirements**: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6698.pdf

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:

  A. The supplier has obtained from the ordering treating practitioner the specific date of the organ transplant, and

  B. The supplier is retaining this documentation of the transplant in its files, and

  C. The beneficiary was enrolled in Medicare Part A, at the time of the organ transplant (whether or not Medicare paid for the transplant), and

  D. 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 non-covered 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 prednisolone tablets are dispensed, bill J7510, 100 units (1 unit of J7510 = 5 mg). If fifty 2.5 mg prednisolone tablets are dispensed, bill J7510, 25 units.

ONLINE RESOURCES

- **DME MAC Supplier Manual**
  - **JB:** https://www.cgsmedicare.com/jb/pubs/supman/index.html
  - **JC:** https://www.cgsmedicare.com/jc/pubs/supman/index.html
- **Immunosuppressive Drugs LCD and PA**
  - **JB:** https://www.cgsmedicare.com/jb/coverage/lcdinfo.html
  - **JC:** https://www.cgsmedicare.com/jc/coverage/lcdinfo.html

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 Supplier Manual* and the Local Coverage Determination/Policy Article for full and accurate details concerning policies and regulations.