

DOCUMENTATION CHECKLIST FOR IMMUNOSUPPRESSIVE DRUGS

Policy References:

- [Local Coverage Determination \(LCD\) \(L33824\)](#)
- [Policy Article \(A52474\)](#)

Documentation References:

- [Standard Documentation Requirements Policy Article \(A55426\)](#)

The supplier must be able to provide all these items upon request:

[Standard Written Order \(SWO\)](#)

- Beneficiary's name or Medicare Beneficiary Identifier (MBI)
- Order date
- General description of the item
- Quantity to be dispensed, if applicable
- Treating practitioner name or National Provider Identifier (NPI)
- Treating practitioner's signature

[Proof of Delivery \(POD\)](#)

Method 1—Direct Delivery	Method 2—Delivery via Shipping or Delivery Service	Method 3—Delivery to Nursing Facility
<ul style="list-style-type: none"> ■ Beneficiary's name ■ Delivery address ■ A description of the item(s) being delivered ■ Quantity delivered ■ Date delivered ■ Beneficiary (or designee) signature 	<ul style="list-style-type: none"> ■ Beneficiary's name ■ Delivery address ■ Delivery service's package identification number, supplier invoice number, or alternative method that links the supplier's delivery documents with the delivery service's records ■ A description of the item(s) being delivered ■ Quantity delivered ■ Date delivered ■ Evidence of delivery 	<ul style="list-style-type: none"> ■ Documentation demonstrating delivery of the item(s) to the facility by the supplier or delivery entity; and, ■ Documentation from the nursing facility demonstrating receipt and/or usage of the item(s) by the beneficiary. The quantities delivered and used by the beneficiary must justify the quantity billed.
Date of delivery equals date of service	Shipping date or delivery date equals date of service	Date of delivery equals date of service

[Request for Refill](#)

[Beneficiary Authorization](#)

[Continued Need](#)

[Continued Use](#)

Medical records from treating practitioner as noted below

Medical records should contain:

I. Drug(s) prescribed following a transplant (refer to Policy Article for diagnosis codes):

A. Kidney, heart, liver, bone marrow/stem cell, lung, heart/lung transplant; **or**

B. Whole organ pancreas transplant performed concurrent with or subsequent to a kidney transplant because of diabetic nephropathy (performed on or after July 1, 1999); **or**

C. Intestinal transplant (performed on or after April 1, 2001); **or**

D. Pancreatic islet cell transplant or partial pancreatic tissue transplantation (performed on or after October 1, 2004), that is conducted as part of a National Institutes of Health-sponsored clinical trial; **or**

E. Pancreas transplants alone (performed on or after April 26, 2006) must meet the six criteria listed in the Policy Article; **and**

Beneficiary has a diagnosis of type 1 diabetes with either beta cell positive antibody test or demonstrates insulinopenia

History of labile insulin dependent diabetes mellitus requiring hospitalization due to recurrent, severe, acutely life-threatening complications

12 months of endocrinologist care including optimal and intensive management including advanced insulin formulation and delivery

Documentation of emotional and mental state indicating comprehension of associated surgical risks and management of lifelong immunosuppression

Suitability of candidate for transplant

II. Transplant performed in Medicare approved facility and met Medicare coverage criteria in effect at the time; **and**

III. Beneficiary was enrolled in Medicare Part A at the time of the transplant; **and**

IV. Beneficiary is enrolled in Medicare Part B at the time that the drug is dispensed; **and**

V. Drug(s) furnished on or after the date of discharge from the hospital following a covered organ transplant.

NOTE: For immunosuppressive drugs covered under this policy, the dosage, frequency and route of administration must conform to generally accepted medical practice and must be medically necessary to prevent or treat the rejection of an organ transplant.

Azathioprine or Methylprednisolone

Medication cannot be tolerated or absorbed if taken orally; **and**

Medication is self-administered by the beneficiary.