

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 of these items on request:

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

[Beneficiary Authorization](#)

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

[Continued Need](#)

[Continued Use](#)

[Refill Request](#)

Medical records from treating practitioner as noted below

Medical records should contain:

Drug(s) prescribed following a transplant (refer to Policy Article for diagnosis 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 July 1, 1999); **or**

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

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**

Pancreas transplants alone (performed on or after April 26, 2006) that 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

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

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

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

Drug(s) 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 beneficiary.