

CLINICIAN CHECKLIST FOR IMMUNOSUPPRESSIVE DRUGS

Policy References:

- Local Coverage Determination (LCD) (L33824)
- Policy Article (A52458)

Documentation Reference:

Standard Documentation Requirements Policy Article (A55426)

The treating clinician must complete the following items:

Standard Written Order (SWO)

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

Medical Documentation

Only the immunosuppressive drugs listed in the LCD are covered (refer to the LCD link above). Drugs are covered if prescribed following a transplant (refer to Policy Article link above for covered ICD-10 diagnosis codes) and Criterion I., II., IV., and V. are met:

I. Immunosuppressive Drugs are covered if one of the Criteria A-E are met following an approved transplant for a beneficiary who is a suitable candidate for transplantation:

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 (NIH)-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 (link above); **and**

Beneficiary has a diagnosis of type 1 diabetes with either

Beta cell positive antibody test or

Insulinopenia demonstrated using fasting C-peptide testing

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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 met Medicare coverage criteria in effect at the time (approved Medicare facility, national and/or local medical necessity criteria etc.); **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. Drugs are 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.